MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

Promulgated, State Gazette No. 31/13.04.2007, effective 13.04.2007, amended, SG No. 19/22.02.2008; Constitutional Court Judgement No. 5/10.07.2008 - SG No. 65/22.07.2008; amended and supplemented, SG No. 71/12.08.2008, effective 12.08.2008, amended, SG No. 10/6.02.2009, effective 29.01.2009, amended and supplemented, SG No. 23/27.03.2009, effective 30.03.2009, SG No. 41/2.06.2009, effective 2.06.2009, supplemented, SG No. 88/6.11.2009, effective 6.11.2009, amended and suplemented, SG No. 102/22.12.2009, effective 22.12.2009, amended, SG No. 59/31.07.2010, effective 31.07.2010, SG No. 98/14.12.2010, effective 1.01.2011, SG No. 9/28.01.2011, amended and supplemented, SG No. 12/8.02.2011, effective 8.02.2011, SG No. 60/5.08.2011, effective 5.08.2011, amended, SG No. 61/9.08.2011, effective 10.11.2011, SG No. 38/18.05.2012, effective 1.07.2012, supplemented, SG No. 60/7.08.2012, effective 7.08.2012, amended and supplemented, SG No. 102/21.12.2012, effective 21.12.2012, amended, SG No. 15/15.02.2013, effective 1.01.2014, supplemented, SG No. 1/3.01.2014, effective 3.01.2014, amended and supplemented, SG No. 18/4.03.2014; Judgment No. 1/29.01.2015 of the Constitutional Court of the Republic of Bulgaria - SG No. 12/13.02.2015; amended and supplemented, SG No. 48/27.06.2015, amended, SG No. 43/7.06.2016, SG No. 85/24.10.2017, supplemented, SG No. 103/28.12.2017, effective 1.01.2018, amended and supplemented, SG No. 84/12.10.2018, effective 12.10.2018, supplemented, SG No. 91/2.11.2018, amended and supplemented, SG No. 102/11.12.2018, effective 1.01.2019, amended, SG No. 17/26.02.2019, amended and supplemented, SG No. 64/13.08.2019, amended, SG No. 17/25.02.2020, SG No. 52/9.06.2020, effective 9.06.2020, amended and supplemented, SG No. 67/28.07.2020, SG No. 103/4.12.2020, effective 1.01.2021, SG No. 105/11.12.2020, effective 11.12.2020

Text in Bulgarian: Закон за лекарствените продукти в хуманната медицина

Chapter One
GENERAL TERMS
Section I
General Provisions

Article 1. This Act shall specify the terms and procedure for:

1. Authorisation of the use or of the registration of medicinal products that have been manufactured industrially or using a method involving an industrial process, and which are destined for human medicine;
2. (Amended, SG No. 102/2012, effective 21.12.2012) Authorisation of the manufacturing and import of medicinal products;
2a. (New, SG No. 102/2012, effective 21.12.2012) Manufacturing, import of and wholesale in active substances;
3. Authorisation and conduct of clinical trials;
4. Wholesaling and retailing of medicinal products;
5. Parallel import of medicinal products;
5a. (New, SG No. 102/2012, effective 21.12.2012) Intermediation in the sphere of medicinal products;
5b. (New, SG No. 18/2014) Export of medicinal products under the terms and procedure set forth with Chapter Nine B of this Act;
6. Advertising of medicinal products;
7. Pharmacovigilance of medicinal products placed on the market;
8. Classification for prescription and supply of medicinal products;
9. Control of the manufacturing and import, of the wholesaling and retailing, of the conduct of clinical trials, of advertising and of the pharmacovigilance system for medicinal products placed on the market;
10. Pricing of medicinal products;
11. Drafting of a Positive Drug List;

12. (New, SG No. 67/2020) Follow up of the effect of the treatment with medicinal products.

Article 2. This Act shall have the purpose of making conditions available for placing medicinal products on the market in compliance with the quality, safety and efficacy requirements.

Article 3. (1) (Amended, SG No. 71/2008) A medicinal product in human medicine shall be:

1. any substance or combination of substances presented as possessing properties for the treatment or prevention of human disease, or
2. any substance or combination of substances that can be used or administered to humans for the purpose of:

a) restoring, correcting or changing human physiological functions through their pharmacological, metabolic or immunological action, or

b) for medical diagnostic purposes.

(2) A substance shall be any matter of which the origin may be:

1. Human (human blood, human blood products, etc.);
2. Animal (microorganisms, animal organs, extracts, secretions, toxins, blood products, etc.);
3. Vegetal (microorganisms, plants, plant parts, plant extracts, secretions, etc.);
4. Chemical (elements, natural chemical material, synthetic or semi-synthetic substances, etc.).

Article 4. Where a product simultaneously qualifies, based on its characteristics, as a medicinal product and as a product regulated in another Act, the requirements hereof shall apply.

Article 5. Medicinal products shall be classified in accordance with an Anatomical Therapeutic Chemical Classification system in compliance with the requirements of the World Health Organisation (WHO).

Article 6. This Act shall not apply to:

1. Hermetically closed radionuclides;
2. Blood, plasma or blood cells of human origin, except plasma obtained through a method involving an industrial process.

Article 7. (1) Manufacturing, import, wholesaling and retailing, advertising and treatment, prevention and diagnosis shall only be allowed with medicinal products that have been granted a marketing authorisation in compliance with:

1. This Act or
2. Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

(2) The import of, trade in, and the treatment, prevention and diagnosis using medicinal products whose shelf life has expired shall be prohibited.

(3) Holding authorisation or a certificate for the use, manufacturing or clinical trials of medicinal products, which have been issued in compliance with this Act, shall not serve as grounds for the exemption from liability under the legislation in force.

Article 8. No marketing authorisation in compliance with this Act shall be required for:

1. medicinal products prepared under a magisterial formula in a pharmacy;
2. medicinal products prepared under an official formula in a pharmacy;
3. intermediate products intended for industrial processing to be carried out by a person having obtained a manufacturing authorisation under this Act;
4. active substances and excipients;
5. medicinal products being developed and/or tested;
6. medicinal products intended for export;
7. (new, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 21.12.2012) medicinal products for a modern therapy, prepared for a concrete patient following individual physician's prescription in accordance with specific quality standards, and administered in a medical institution at the exceptional professional responsibility of the physician.

Article 8a. (New, SG No. 102/2012, effective 21.12.2012) The relevant provisions of Chapter Five shall be applicable to the manufacturing of medicinal products intended exclusively for export, of intermediate products, active substances and excipients.

Article 9. (1) The treatment of a specific patient may entail the administration of a medicinal product that has not been authorised under Chapter Three, following a special order of the in-patient care establishment under the terms and conditions set out in an Ordinance of the Minister of Health.
(2) The head of the medical establishment shall incur liability for the administration of treatment under Paragraph 1.
(3) (New, SG No. 84/2018, effective 12.10.2018) Any treatment involving a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No. 726/2004 of the European Parliament And Of The Council shall be administered under conditions and procedures laid down in the ordinance referred to in paragraph 1.

Article 10. (1) The Minister of Health, following a motivated proposal of the chief state health inspector, in coordination with the Executive Director of the Bulgarian Drugs Agency (BDA), may allow by an order for a specified period a treatment using a medicinal product which has not been authorised under Chapter Three, in the event that an epidemic has been declared in the country, caused by pathogenic microorganisms or toxins, or an alleged or confirmed spread of chemical agents or nuclear radiation exist and there is no suitable medicinal product allowed for use.
(2) In the cases under Paragraph 1, marketing authorisation holders, manufacturers and medical specialists shall incur no civil or penal administrative liability for the effects from the use of a non-authorised indication of a medicinal product or of a medicinal product which has not been authorised under Chapter Three.
(3) The provision of Paragraph 2 shall not exclude liability for faulty goods under the Consumer Protection Act.

Article 11. (1) The Minister of Health may, for reasons concerned with protecting the health of the population, give orders to the Bulgarian Drug Agency Executive Director to authorise the use of a medicinal product which has not been authorised on the territory of the Republic of Bulgaria and for which no licensing application has been submitted, but which is authorised in another Member State.
(2) In the cases under Paragraph 1, the Bulgarian Drug Agency Executive Director or an official authorised by him shall:
1. inform the marketing authorisation holder for the medicinal product about the launching of a procedure for authorising the use of the product;
2. register the person under item 1 as the holder of the issued authorisation;
3. obtain from the regulatory body of the Member State in which the marketing authorisation has been delivered a copy of the evaluation report and a copy of the marketing authorisation.
(3) (Supplemented, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall be obliged to ensure compliance of the label, patient brochure, classification, advertising and pharmacovigilance of the medicinal product placed on the market under Paragraph 1 with the requirements of this Act. It shall not be mandatory for the information on the packaging and on the leaflet of the medicinal product under Paragraph 1 to be in the Bulgarian language.
(4) The Bulgarian Drug Agency Executive Director shall inform the European Commission of the authorisations issued under Paragraph 1, of the name and address of the authorisation holder, as well as of the date of termination of their validity.

Article 12. (1) The official pharmacopoeia in the Republic of Bulgaria shall be the European Pharmacopoeia.
(2) The official pharmacopoeia may be supplemented with the requirements of the Bulgarian one.
(3) The Minister of Health shall specify by order the dates of entry into force of the up-to-date issue of the official pharmacopoeia and of the supplements thereto.
(4) The order under Paragraph 3 shall be promulgated in the State Gazette and posted on the Bulgarian Drug Agency website.

Article 13. (1) The European Pharmacopoeia monographs shall be mandatory for all substances, preparations and pharmaceutical forms contained therein. In case no European

Pharmacopoeia monographs exist, the requirements of up-to-date editions of pharmacopoeias of the Member States, the USA and Japan shall apply, provided they are in line with the general rules of the European Pharmacopoeia.
(2) Where the specification contained in a monograph of the European Pharmacopoeia or in another national pharmacopoeia is insufficient to ensure the quality of the substance or pharmaceutical form, the Bulgarian Drug Agency may require that the specification be supplemented by the applicant/marketing authorisation holder.

Chapter Two
MANAGEMENT AND FINANCE BODIES
Section I
Management Bodies

Article 14. (1) The medicinal policy shall be part of the state health policy of the Republic of Bulgaria and it shall be implemented by the Minister of Health.
(2) The Minister of Health shall:
1. be the national coordinator for any issues pertaining to medicinal products;
2. participate in international bodies and organisations carrying out operations in the area of medicinal products;
3. (repealed, SG No. 60/2011, effective 5.08.2011, new, SG No. 102/2012, effective 21.12.2012) organise the providing of public information to patient organisations and to consumer organisations concerning actions undertaken against the counterfeiting of medicinal products;
4. carry out other activities provided for under the law.
(3) (Repealed, SG No. 60/2011, effective 5.08.2011).

Article 15. (1) A Pharmacopoeia Committee shall be set up with the Minister of Health as an advisory body on any issues concerning the effective pharmacopoeia.
(2) The Minister of Health, based on a proposal by the Bulgarian Drug Agency Executive Director, shall specify by order the composition of the Pharmacopoeia Committee and of the expert groups attached to it, and he shall endorse their Rules of Operation.
(3) The operations of the Pharmacopoeia Committee shall be funded from the budget of the Ministry of Health.

Article 16. (1) (Supplemented, SG No. 91/2018, amended, SG No. 67/2020) A High Pharmacy Council shall be established with the Minister of Health, to be composed of five members designated by the Minister of Health, five representatives of the Bulgarian Pharmacy Union, one representative of the Bulgarian Association of Assistant Pharmacists, two representatives of the National Health Insurance Fund (NHIF) and one member designated by each Pharmacy Department of the Higher Schools. The Minister of Health shall be the Chairperson of the Council without voting rights.
(2) The High Pharmacy Council shall be an advisory body to discus and give opinion on:
1. the general directions and the main priorities in the area of pharmacy;
2. ethical issues in pharmacy;
3. draft legislation connected with pharmacy;
4. the research priorities in the area of pharmacy;
5. programmes for public education campaigns in the field of medicinal products.
(3) (Repealed, SG No. 60/2011, effective 5.08.2011).
(4) The organisation and the activities of the High Pharmacy Council shall be specified in Rules issued by the Minister of Health based on a proposal by the High Pharmacy Council.

Article 17. (1) The Bulgarian Drugs Agency shall be a specialised body of the Minister of Health that supervises the quality, safety and efficacy of drugs.
(2) (Amended, SG No. 15/2013, effective 1.01.2014) The Bulgarian Drug Agency shall be a public budget legal entity with a seat in Sofia, attached to the Minister of Health.
(3) The Bulgarian Drugs Agency shall be headed and represented by an Executive Director appointed under the Public Administration Act.

(4) The structure, functions and organisation of the work of the Bulgarian Drug Agency shall be specified in Rules adopted by the Council of Ministers.
(5) The Bulgarian Drugs Agency shall:
1. issue licenses for the manufacturing of medicinal products;
2. issue marketing authorisations and registration certificates for medicinal products;
3. (supplemented, SG No. 71/2008, effective 12.08.2008) issue licenses and certificates for wholesaling of medicinal products;
4. issue licenses for parallel import of medicinal products;
5. (amended, SG No. 60/2011, effective 5.08.2011) issue, refuse or terminate licences for medicinal product retail;
5a. (new, SG No. 102/2012, effective 21.12.2012) register the manufacturers, importers and wholesale traders in active substances;
5b. (new, SG No. 102/2012, effective 21.12.2012) keep a register of the persons engaged in mediation in the sphere of medicinal products;
6. issue licenses for conducting clinical trials of medicinal products;
7. carry out quality, efficacy and safety evaluations of medicinal products in relation to their marketing authorisation;
8. issue authorisations for the advertising of medicinal products;
9. exercise control on the manufacturing, import, storage, wholesaling and retailing, clinical trials, safety and advertising of medicinal products;
10. conduct laboratory analyses in case of suspected deviations in the quality, efficacy and safety of medicinal products, and take the measures provided for under the law;
10a. (new, SG No. 102/2012, effective 21.12.2012) discharge the functions of a competent pharmacovigilance body;
11. (amended, SG No. 102/2012, effective 21.12.2012) organise and maintain a pharmacovigilance system;
12. issue certificates in accordance with the WHO certification scheme;
12a. (new, SG No. 18/2014) issues certificates for Good Distrubutional Practice;
13. issue certificates of Good Manufacturing Practice;
14. (amended, SG No. 18/2014) provide consultations on construction development projects for new sites and/or for the reconstruction of existing sites related to the manufacturing of medicinal products in accordance with the rules of Good Manufacturing Practice;
13. issue certificates of Good Manufacturing Practice;
14. coordinate construction development projects for new sites and/or for the reconstruction of existing sites related to the manufacturing of medicinal products in accordance with the rules of Good Manufacturing Practice;
15. carry out the functions of a coordinator and of a consultative body on issues of quality, efficacy and safety of medicinal products;
16. carry out consultancy, scientific, information and publishing activities in the drugs sector;
17. coordinate and take part in activities connected with the European Pharmacopoeia and with the development of the Bulgarian pharmacopoeia;
18. take part in activities in the area of medicinal products, which concern the work of the European Medicines Agency, the European Directorate for the Quality of Medicines and Healthcare, of international bodies and organisations, as well as the enforcement of international treaties to which the Republic of Bulgaria is a party;
18a. (new, SG No. 102/2012, effective 21.12.2012) participate in the international harmonisation and standardisation of the technical measures related to monitoring drug safety under the coordination of the European Medicines Agency;
18b. (new, SG No. 102/2012, effective 21.12.2012) create and maintain a national internet portal for medicinal products;
19. carry out other activities provided for under the law.

(6) (Amended, SG No. 67/2020) The Bulgarian Drug Agency shall coordinate its operations in the area of medicinal products control jointly with the Regional Health Inspectorates (RHIs).
(7) (New, SG No. 102/2012, effective 21.12.2012) The measures stipulated under this Act, connected with preventing the introduction and spreading of counterfeit medicinal products, shall be implemented through cooperation between the Bulgarian Drug Agency and the customs authorities.
(8) (New, SG No. 84/2018, effective 12.10.2018) Drug agency can carry out joint inspections with the National Revenue Agency, Customs Agency, the national health insurance fund, the Ministry of health care and the National Council on pricing and reimbursement of medicinal products in the exercise of their functions in the field of control of medicinal products.

Article 17a. (New, SG No. 60/2011, effective 5.08.2011) Regional health inspectorates shall issue drugstore registration certificates.

Article 17b. (New, SG No. 18/2014) (1) (Amended and supplemented, SG No. 67/2020) An Expert Council on Retailing of Medicinal Products is established with the Bulgarian Drug Agency Executive Director, which shall include in its composition three representatives of the Bulgarian Pharmaceutical Union, one representative of the Bulgarian Association of Assistant Pharmacists, one representative each of the pharmaceutical faculties at the higher schools, and four representatives of the Bulgarian Drug Agency. The composition of the Council shall be determined by an order issued by the Bulgarian Drug Agency Executive Director in conjunction with the Minister of Health.
(2) The Council under Paragraph (1) above shall be a consultative body, which shall:
1. draft the opinions on applications and documents under Article 228(1) and (5) submitted to the Bulgarian Drug Agency, and present these opinions to the Executive Director of the Bulgarian Drug Agency;
2. submit, via the Executive Director of the Bulgarian Drug Agency, motivated proposals to the Minister of Health with regard to improving the accessibility of medicinal products for the population.
(3) The organising and the functioning of the Expert Council under Paragraph (1) above shall be governed by Rules, issued by the Bulgarian Drug Agency Executive Director based on a draft proposal by the Council.
(4) Expert Council members under Paragraph (1) above shall not be entitled to any payment for taking part in the sittings of the Council.
(5) The Expert Council under Paragraph (1) above shall submit to the Minsiter of Health an annual reprot on its activities.

Article 17c. (New, SG No. 18/2014) Persons not eligible to be members of the Expert Council under Article 17b (1), shall include:
1. owners, members of executive and control boards of trade companies, or sole traders operating in the manufacturing, import, whole sales or retailing of medicinal products;
2. partners or shareholders who posess more than 5 per cent of the equity of trade companies operating in the manufacturing, import, whole sales and retailing of medicinal products, or are employed based on a work contract in such companies.

Section II
Registries

Article 18. (Repealed, SG No. 60/2011, effective 5.08.2011).

Article 19. (1) The Bulgarian Drug Agency shall keep and maintain registries of:
1. (amended, SG No. 102/2012, effective 21.12.2012) the manufacturers and importers of medicinal products on the territory of the Republic of Bulgaria and of the individuals qualified under Article 148, item 2 and under Article 161, Paragraph 2, item 1;
2. (amended, SG No. 102/2012, effective 21.12.2012) the manufacturers, the importers and the wholesale traders in active substances;

3. (supplemented, SG No. 67/2020) medicinal products having market authorisation and registration in the territory of the Republic of Bulgaria and medicinal products authorised under a centralised procedure pursuant to Regulation No. 726/2004 of the European Parliament and of the Council;
4. wholesalers of medicinal products on the territory of the Republic of Bulgaria;
4a. (new, SG No. 102/2012, effective 21.12.2012) intermediaries in the sphere of medicinal products;
5. (amended, SG No. 60/2011, effective 5.08.2011) the issued authorisation for retail of medicinal products;
6. the authorised clinical trials;
7. the authorisations for parallel import issued;
8. (new, SG No. 18/2014, repealed, SG No. 84/2018, effective 12.10.2018).
(2) (Amended, SG No. 84/2018, effective 12.10.2018) Data on the registries under Paragraph 1, items 1 - 7 shall be posted within 14 days of issuance of the respective authorisation on the Bulgarian Drug Agency website.
(3) (New, SG No. 67/2020, repealed, SG No. 103/2020, effective 1.01.2021).
(4) (New, SG No. 67/2020, amended, SG No. 103/2020, effective 1.01.2021) The Bulgarian Drug Agency shall link the national identification number referred to in Article 259^{1}(1) with the product code within the meaning of Article 4(b)(i) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ, L 32/1 of 9.2.2016), hereinafter referred to as 'Delegated Regulation (EU) 2016/161', for medicinal products set out in Delegated Regulation (EU) 2016/161, that has been provided in accordance with Article 68(1)(11) and Article 217(6).
(5) (New, SG No. 67/2020, repealed, SG No. 103/2020, effective 1.01.2021).
(6) (New, SG No. 67/2020) The registers under paragraph 1 shall maintain interoperability and automated interface in machine-readable format, by means of which other information systems may be used.
(7) (Renumbered from Paragraph (3), SG No. 67/2020) The Bulgarian Drug Agency shall maintain systems for electronic exchange of data with the regulatory bodies of other Member States, the European Commission and the European Medicines Agency.

Article 19a. (New, SG No. 60/2011, effective 5.08.2011) (1) The relevant Regional Health Inspectorates shall keep and maintain public registers of the drugstore registration certificates they have issued.
(2) Within 7 days of issuing any drugstore registration certificate the relevant Regional Health Inspectorate shall submit information about it to the Ministry of Health.
(3) On its website the Ministry of Health shall keep and maintain a public national register of drugstore registration certificates issued.

Section III
Funding

Article 20. (1) The activities of the Bulgarian Drugs Agency shall be funded by the public budget and with revenues therefrom.
(2) (Amended, SG No. 15/2013, effective 1.01.2014) A state budget subsidy shall be provided from the budget of the Ministry of Health.

Article 21. (1) The Bulgarian Drugs Agency shall administer the revenues from its own activities generated from:
1. chemical and pharmaceutical expert assessments;
2. laboratory analyses and trials;
3. evaluations of documents and the issuance of licenses, certificates, attestations and other documentation specified herein;
4. evaluations upon the renewal, modification and deletion of marketing authorisations and registration certificates of medicinal products;

5. maintaining marketing authorisations and registration certificates of medicinal products;
6. fines and pecuniary sanctions imposed by penal decrees issued for violations of this Act;
7. consultancy, publishing and research activities in the drug sector;
8. coordination of construction development projects for new sites and/or for the reconstruction of existing sites related to the manufacturing of medicinal products;
9. inspections for evaluation of compliance of the manufacturing conditions with the requirements of Good Manufacturing Practice;
10. (new, SG No. 84/2018, effective 12.10.2018) carrying out inspections of authorised clinical trials;
11. (new, SG No. 84/2018, effective 12.10.2018) carrying out inspections related to the issuing of certificates of good manufacturing practice or certificates of good distribution practices, at the request of the person inspected;
12. (renumbered from item 10, SG No. 84/2018, effective 12.10.2018) other sources.
(2) (Amended, SG No. 84/2018, effective 12.10.2018) When conducting activities under Paragraph 1, items 1 - 5, and 7 - 11, the Bulgarian Drug Agency shall collect fees in the amounts specified in a Tariff adopted by the Council of Ministers.
(3) (New, SG No. 71/2008, effective 12.08.2008) The Tariff under Paragraph 2 shall provide for lower fees of different amounts for the procedures for licensing the use, production and import of medicinal products for small and medium-sized enterprises in the pharmaceutical sector under the Small and Medium-Sized Enterprises Act.

Article 22. (1) The financial resources under Article 21 shall be spent for:
1. control operations of the Bulgarian Drugs Agency;
2. payment for activities under Article 21, Paragraph 1, items 1 and 2, in cases these have been assigned by the Bulgarian Drug Agency to other persons under contract;
3. (repealed, SG No. 38/2012, effective 1.07.2012);
4. creation, maintenance and keeping of registries under Article 19, Paragraph 1;
5. maintenance of systems for the electronic exchange of data with the regulatory bodies of other Member States, the European Commission and the European Medicines Agency;
6. (supplemented, SG No. 102/2012, effective 21.12.2012) information and publishing activities pertaining to the quality, efficacy and safety of medicinal products, and drug safety monitoring;
7. (supplemented, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) providing support for the activities of specialised commissions under Article 47, Paragraphs 1 and 2, the Commission under Article 103, Paragraph 1 and of the Council under Article 251, Paragraph 3;
8. (repealed, SG No. 38/2012, effective 1.07.2012);
9. participation in international and national interlaboratory trials;
10. (amended, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 38/2012, effective 1.07.2012).
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended and supplemented, SG No. 12/2011, effective 8.02.2011, amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) The financial resources under Article 259, Paragraph 5 shall be spent for:
1. (repealed, SG No. 60/2011, effective 5.08.2011);
2. activities of the Pharmacopoeia Committee;
3. (amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) activities of the Commission for Transparency;
4. (repealed, SG No. 38/2012, effective 1.07.2012);
5. (supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 12/2011, effective 8.02.2011, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 38/2012, effective 1.07.2012).

Chapter Three
MARKET PLACEMENT OF MEDICINAL PRODUCTS
Section I
General Terms

Article 23. (1) (Amended, SG No. 71/2008, effective 12.08.2008) An industrially manufactured medicinal product or a medicinal product obtained through a method involving an industrial process may only be placed on the market after obtaining a marketing authorisation or certificate of registration, issued under this Act or in compliance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and in full compliance with the requirements of Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, and for amendments to Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, referred to below as "Regulation (EC) No. 1901/2006", and of Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on medicinal products for modern therapy and for amendments to Directive 2001/83/EC and to Regulation (EC) No. 726/2004 (OJ, L 324/121 of 10 December 2007

(2) A marketing authorisation under Paragraph 1 shall also be required for a radionuclide generator, a radionuclide precursor and for a kit.

(3) The types of procedures under Paragraph 1 shall be:

1. centralised;
2. procedure of mutual recognition/decentralised;
3. national.

(4) (New, SG No. 71/2008, effective 12.08.2008) Only medicinal products whose holder of marketing authorisation/certificate of registration is established on the territory of a Member State may be released on the territory of the Republic of Bulgaria.

Article 24. (1) (Amended, SG No. 71/2008, effective 12.08.2008) No marketing authorisation shall be required for radio pharmaceuticals prepared immediately prior to their use in radionuclide generators, radionuclide precursors or kits authorised in compliance with the instructions of their manufacturer.

(2) Products under Paragraph 1 shall be prepared by qualified persons in laboratories or institutes authorised to conduct such operations in compliance with the Safe Use of Nuclear Energy Act.

(3) The preparation, use and administration of products under Paragraph 1 shall be carried out in accordance with the medical standard in nuclear medicine.

Article 25. (1) The criteria for the qualification of medicinal products intended for the treatment, prevention or diagnosis of rare diseases shall be provided for in Regulation (EC) No. 141/2000 of the European Parliament and of the Council.

(2) The terms and conditions for issuance of licenses for the use of medicinal products under Paragraph 1 shall be provided for in Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

Article 26. (1) (Amended, SG No. 71/2008, effective 12.08.2008) A marketing authorisation of a medicinal product, a certificate of the registration of a homeopathic medicinal product under Article 35 or a certificate of the registration of a traditional herbal medicinal product under Article 37 on the territory of the Republic of Bulgaria shall be issued by the Bulgarian Drugs Agency Executive Director to a natural or legal person established on the territory of a Member State.

(2) Where the person under Paragraph 1 is not established on the territory of the Republic of Bulgaria, he shall designate au authorised representative.

(3) The marketing authorisation holder shall incur liability for medicinal products placed on the market. Designating a person under Paragraph 2 shall not exempt the marketing authorisation holder from liability in accordance with the effective legislation in the Republic of Bulgaria.

Section II
Requirements to the documentation for the issuance of licenses for use

Article 27. (1) (Amended and supplemented, SG No. 71/2008, effective 12.08.2008) A person under Article 26, Paragraph 1 shall file a model-based application for the issuance of a marketing authorisation with the Bulgarian Drugs Agency to be accompanied by a dossier in the format of an Electronic General Technical Document, which shall contain:

1. the name and business/permanent address of the applicant and of the representative under Article 26, Paragraph 2; where the applicant is a person other than the manufacturer or manufacturers - the address of the production sites;
2. the name of the medicinal product;
3. data about the quantitative and qualitative composition of the medicinal product, stating the international nonproprietary name recommended by WHO, if available, or the respective chemical name;
4. therapeutic indications, contraindications and adverse reactions;
5. (amended, SG No. 71/2008, effective 12.08.2008) the dosage, pharmaceutical forms, mode and route of administration, and proposed shelf life;
6. precautionary and safety measures for the storage of the product, for its administration to patients and for the destruction of product waste accompanied by instructions about the potential environmental hazards of the medicinal product;
7. a description of the manufacturing process;
8. a description of the control methods used by the manufacturer;

8a. (new, SG No. 102/2012, effective 2.01.2013) a declaration that the results of the audit under Article 160, Paragraph 2, conducted by the manufacturer of the medicinal product, confirm that the active substance has been produced in accordance with the Good Manufacturing Practice principles and guidelines; the declaration shall indicate the date on which the audit was conducted;

9. an evaluation of the potential environmental hazard of the medicinal product in each specific case and measures foreseen for its limitation;
10. the results from:

a) pharmaceutical (physical and chemical, biological or microbiological) trials;
b) preclinical (toxicological and pharmacological) trials;
c) clinical trials;

11. a declaration to the effect that during clinical trials performed outside the territory of Member States, the ethical principles of Good Clinical Practice have been complied with;
12. (amended, SG No. 102/2012, effective 21.12.2012) a summary of the system for monitoring drug safety, which shall comprise the following elements:

(a) name of the qualified person under Article 191, CV - education, acquired professional experience in the sphere of drug safety monitoring, and qualification for discharging his obligations in compliance with the provisions of Chapter Eight;
(b) each Member State in which the qualified person discharges his obligations;
(c) address, telephone number, fax and e-mail address of the person under (a) above;
(d) address where the principal document of the system for monitoring drug safety is kept;

12a. (new, SG No. 102/2012, effective 21.12.2012) declaration by the applicant that he possesses the necessary means for discharging his obligations under Chapter Eight;

13. (amended, SG No. 102/2012, effective 21.12.2012) risk management plan with description of the risk management system that the applicant intends to introduce for the respective medicinal product, together with a summary of the plan;
14. a product summary in accordance with Article 34;
15. a model of the immediate and outer packaging of the product and a proposal for a brochure in compliance with the requirements under Chapter Six;
16. a copy of the manufacturing authorisation issued by the regulatory body of the state in which the manufacturing takes place, accompanied by a certificate of Good Manufacturing Practice or a certificate to the effect that the manufacturing of the medicinal product and of the active substances

in its composition is carried out in compliance with standards that are at least equivalent to those for Good Manufacturing Practice;
17. a copy of a document, whereby the medicinal product has been designated for the treatment, prevention or diagnosis of rare diseases, accompanied by a copy of the opinion of the European Medicines Agency;
18. a copy of all licenses for use, issued in another Member State or in a third country, for the medicinal product for which a marketing authorisation is requested;
18a. (new, SG No. 102/2012, effective 21.12.2012) a copy of a summary of the safety data, including the data contained in the periodic updated safety reports, as well as notifications of suspected adverse reactions, if any;
19. a list of the Member States in which an application has been filed for the issuance of a marketing authorisation of a medicinal product;
20. (amended, SG No. 71/2008, effective 12.08.2008) a copy of the summary of product characteristics proposed by the person under Article 26, Paragraph 1, or a copy of the Summary of Product Characteristics approved by a regulatory body of a Member State(s) which has already issued a marketing authorisation;
21. a copy of the refusal to grant a marketing authorisation in a Member State or in a third country accompanied by reasons; information about any provisional suspension or about the termination of the effect of a marketing authorisation;
22. a copy of the proposed patient information leaflet accompanied by a summary of the results from the evaluation of brochure content understanding by a target group of patients selected by the applicant or a copy of the brochure approved by a regulatory body of a Member State which has already delivered a marketing authorisation;
23. a document evidencing the payment of a fee in the amount set out in the Tariff under Article 21, Paragraph 2;
24. (New, SG No. 71/2008, effective 26.07.2008) the documents under Article 7 of Regulation (EC) 1901/2006.
(2) (Supplemented, SG No. 18/2014) The documents under Paragraph 1, item 18 and item 18a with regard to Member States, respectively under item 19, shall only be filed in procedures under Section VII.
(3) The following documents shall be submitted in respect to radionuclide generators, in addition to data under Paragraph 1:
1. a description of the system together with a detailed description of its components which could influence the composition or quality of daughter radionuclides;
2. qualitative and quantitative characteristics of the eluate or sublimate.
(4) Documents and data from pharmaceutical, preclinical and clinical trials shall be accompanied by summary reports prepared by experts with the required level of technical and professional qualifications. A CV for the experts who have drafted the report shall be attached to them.
(5) The dossier of the medicinal product shall be provided in the Bulgarian and/or the English language.
(6) (New, SG No. 102/2012, effective 21.12.2012) The risk management system under Paragraph 1, item 13 shall be proportional to the identified and potential risks posed by the medicinal product and to the need of gathering safety data from post-marketing studies.
(7) (New, SG No. 102/2012, effective 21.12.2012) The holder of the marketing authorisation shall update the data in the dossier under Paragraph 1. Any change in the dossier shall be subject to Chapter Three, Section VI, where applicable.

Article 28. (1) (Amended, SG No. 71/2008, effective 12.08.2008) The person under Article 26, Paragraph 1, insofar as such person does not infringe upon any industrial or commercial property rights, shall not submit data under Article 27, Paragraph 1, item 10, b) and c) to the Bulgarian Drugs Agency, where it may prove that a medicinal product listed in the application is the generic product of a reference medicinal product which is or was authorised in a Member State no less than 8 years previously.

(2) The holder of the marketing authorisation for the generic product under Paragraph 1 may not place it on the market before 10 years have elapsed from the date of the initial marketing authorisation of the reference medicinal product.
(3) The person under Article 26, Paragraph 1, subject to the terms of Paragraphs 1 and 2, may also file an application with the Bulgarian Drugs Agency for a marketing authorisation of the generic product of a reference medicinal product, where the latter has not had any marketing authorisation issued on the territory of the Republic of Bulgaria.
(4) In cases under Paragraph 3, the person under Article 26, Paragraph 1 shall indicate in the application under Article 27, Paragraph 1 the Member State in which the reference product is or was authorised for use.
(5) In cases under Paragraph 3, the Bulgarian Drugs Agency shall obtain from the regulatory body of the Member State specified in the application under Article 27, Paragraph 1 a confirmation of the information under Paragraph 4, the quantitative and qualitative composition of the reference product and, if necessary, additional documentation.
(6) The Bulgarian Drugs Agency shall provide, upon request from a regulatory body of a Member State in which an application for the generic product of a reference medicinal product has been filed, the latter being or having been authorised on the territory of the Republic of Bulgaria, the necessary information under Paragraph 5 within one month of the date of request.
(7) The ten-year period under Paragraph 2 may be extended by no more than one year upon request by the holder of the marketing authorisation of the reference medicinal product where within the first 8 years following the issuance of the marketing authorisation of the reference medicinal product its holder obtains, in respect to the same product, an authorisation for a new therapeutic indication whose significant clinical advantages compared to existent treatment courses have been scientifically substantiated.
(8) (New, SG No. 12/2011, effective 8.02.2011) When an initial marketing authorisation has been issued for a medicinal product pursuant to Article 23, a marketing authorisation shall also be issued, in compliance with the requirements of this Act, in respect of any change to: the quantity of the active substance; the quantity in the package unit; the route of administration of the medicinal product; all other modifications to the marketing authorisation or any expansion of its scope. Alternatively, the initial marketing authorisation shall be amended accordingly. For the purposes of implementing this article, all such authorisations shall be considered as belonging to one global marketing authorisation for the relevant medicinal product.

Article 29. (1) The person under Article 26, Paragraph 1 shall submit to the Bulgarian Drugs Agency the results from the required preclinical and/or clinical trials in cases where a medicinal product listed in the application:
1. may not be defined as generic, or
2. the trials for bioavailability do not prove bioequivalence, or
3. (supplemented, SG No. 71/2008, effective 12.08.2008) A change has occurred in the active substance or substances, in the quantity of the active substance or substances in the dose unit, in the therapeutic indications, in the pharmaceutical form and in the route of administration compared to the reference medicinal product;
4. (repealed, SG No. 71/2008, effective 12.08.2008).
(2) Where a biological medicinal product listed in the application, similar to the reference biological medicinal product, does not meet the requirements for qualification as a generic medicinal product, due to a difference in the manufacturing process or to different starting materials compared to the reference product, or due to any other reasons, the applicant shall submit to the Bulgarian Drugs Agency the results from the required preclinical and/or clinical trials associated with those requirements.
(3) In the cases under Paragraphs 1 and 2, the documentation specified by the Ordinance under Article 42 shall also be submitted.

Article 30. (1) The person under Article 26, Paragraph 1, insofar as that person does not violate industrial and commercial property rights, shall not submit to the Bulgarian Drugs Agency

the data under Article 27, Paragraph 1, item 10, b) and c) where he can prove, subject to the conditions specified in the Ordinance under Article 42, that the active substance in the composition of the medicinal product proposed to be authorised has an established use in medical practice, a recognised efficacy and an acceptable level of safety. In such cases the results from trials and the trials may be replaced by the respective scientific publications.
(2) The person under Paragraph 1 shall submit the results of the required preclinical and clinical trials in the case of a medicinal product containing active substances with a well-established use, which have not been used in the proposed combination for therapeutic purposes. In this case no documentation with regard to each and every separate active substance shall be submitted.
(3) Where the active substance under Paragraph 1 has a new therapeutic indication proven on the basis of significant preclinical and clinical data associated with the new indication, no subsequent applicant may refer to data about the new indication of the active substance for a one-off period of one year.

Article 31. In case where a medicinal product contains active substances used in the composition of medicinal products authorised but which are not used in the proposed combination for therapeutic purposes, the person under Article 26, Paragraph 1 shall submit the results of the preclinical and of the clinical trials associated with this combination. In this case the applicant shall not submit any documentation with regard to the safety and efficacy of each and every active substance.

Article 32. The holder of a marketing authorisation of a medicinal product may authorise the use of the pharmaceutical, preclinical and clinical documentation, contained in the dossier of the medicinal product, in the evaluation of subsequent applications for medicinal products with the same qualitative and quantitative composition, with regard to the active substances, and in the same pharmaceutical form.

Article 33. Carrying out the required research and trials with the aim of preparing the documentation for a marketing authorisation and in order to comply with any subsequent practical requirements in relation to authorising the medicinal products under Articles 28 and 29 shall not be a violation of the patent or of the certificate for additional protection of a medicinal product.

Article 34. (1) The summary of the product shall specify the following information:
1. the name of the medicinal product, the quantity of the active substance per dosing unit and the pharmaceutical form;
2. the qualitative and quantitative composition, in terms of active substances, and of those of the excipients, the information about which is of significance for the regular administration of the product; the common name or the chemical description shall be used;
3. the pharmaceutical form;
4. clinical data:
a) therapeutic indications;
b) dosage and route of administration for adults and for children;
c) contraindications;
d) special warnings and precautions for use; for immunological medicinal products - precautions for persons who will handle and administer them to patients, as well as any precautionary measures to be taken by the patient;
e) interaction with other medicinal products or other forms of interaction;
f) use during pregnancy or breast-feeding;
g) effects on the ability to drive and to use machines;
h) adverse reactions;
i) overdose (symptoms, antidotes, emergency procedures);
5. pharmacological data:
a) pharmacodynamic properties;
b) pharmacokinetic properties;
c) preclinical safety data;
6. Pharmaceutical data:

a) a list of excipients;
b) main incompatibilities;
c) shelf life; shelf life after dissolving the medicinal product (where necessary) or after opening the immediate packaging for the first time;
d) special instructions for storage;
e) type and composition of packaging;
f) special instructions for disposing of the remaining medicinal product or of the waste material from it;
7. the marketing authorisation holder;
8. the registration number;
9. the date of the first marketing authorisation or of the renewal of the marketing authorisation;
10. the date on which a modification of the summary content for the product is made;
11. for radiopharmaceuticals - exhaustive information about the internal radiation dosimetry;
12. for radiopharmaceuticals - detailed instructions for their extemporaneous preparation and for the quality control thereof and, where appropriate, the maximum storage time during which any intermediate product, such as an eluate or the ready-to-use pharmaceutical, will conform to its specifications.
(2) The summary of medicinal products under Articles 28 - 33 may not include those parts of the summary of the reference medicinal product, which refer to the indications and pharmaceutical forms, having been the object of patent protection when the generic product was on the market.
(3) The requirements to the form and content of the product summary shall be specified in the Ordinance under Article 42.
(4) (New, SG No. 102/2012, effective 21.12.2012) The summary of medicinal products included in the list under Article 23 of Regulation (EC) No. 726/2004 of the European Parliament and Council shall contain information with the following text: "This medicinal product shall be subject to additional monitoring." A sign in black shall be placed before the text under Article 23, Paragraph 5 of Regulation (EC) No. 726/2004 of the European Parliament and Council, accompanied by an explanatory note.
(5) (New, SG No. 102/2012, effective 21.12.2012) The summary of medicinal products shall contain a standard text that encourages medical specialists to report any suspected adverse reaction in compliance with the models under Article 185, Paragraph 2, item 4.

Section III
Specific requirements applicable to homeopathic medicinal products

Article 35. (1) A certificate of registration for a homeopathic medicinal product shall be issued in compliance with a simplified procedure where the product meets the following conditions:
1. It is administered orally or externally;
2. No specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto;
3. There is sufficient dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part of the mother tincture per 10,000 or more than 1/100th of the smallest dose used in allopathy, as regards active substances whose presence in an allopathic medicinal product results in mandatory medical prescription.
(2) In order to obtain a certificate of registration for a homeopathic medicinal product, the person under Article 26, Paragraph 1 shall file a model-based application with the Bulgarian Drugs Agency, which could specify a series of medicinal products obtained from the same homeopathic stock or from the same stocks.
(3) The following documentation shall be attached to the application under Paragraph 2 in order to prove the pharmaceutical quality and the batch-to-batch homogeneity of the medicinal product concerned:

1. (amended, SG No. 71/2008, effective 12.08.2008) the scientific name or other name of the homeopathic stock or stocks given in a pharmacopoeia, together with a statement of the various routes of administration, the pharmaceutical forms and degree of dilution;
2. the dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic use, on the basis of an adequate bibliography;
3. a dossier of the manufacturing and control methods for each pharmaceutical form and a description of the methods of dilution and potentiation;
4. a manufacturing authorisation accompanied by a certificate of Good Manufacturing Practice or a certificate testifying that the product has been manufactured under conditions equivalent to the requirements of Good Manufacturing Practice;
5. copies of any registrations or licenses obtained for the same medicinal product in other Member States;
6. a mock-up of the immediate and/or outer packaging of the product;
7. data concerning the stability of the product.
(4) The requirements to the data under Paragraph 3 shall be specified in the Ordinance under Article 42.

Article 36. (1) The provisions of Articles 27 - 32 shall apply to homeopathic medicinal products other than those listed in Article 35, Paragraph 1.
(2) The person under Article 26, Paragraph 1 shall submit no results from preclinical and clinical trials for homeopathic medicinal products under Paragraph 1, where such person may prove, using bibliographic data from scientific literature, the established safe homeopathic use of the medicinal product concerned or of the homeopathic stocks within its composition.
(3) In the cases under Paragraph 2, bibliographic data must establish:
1. the homeopathic nature of the raw materials and their traditional administration, in the presence of the indication applied for;
2. the non-harmful nature of the homeopathic medicinal product, in terms of the level of dilution of each of its ingredients.

Section IV
Specific requirements applicable to traditional herbal medicinal products

Article 37. (1) A certificate of registration for a traditional herbal medicinal product shall be issued in compliance with a simplified procedure where the product meets the following conditions:
1. it has therapeutic indications inherent to the use of traditional herbal medicinal products and, bearing in mind its composition and intended use, is not subject to medical prescription and supervision;
2. it is only administered as a set quantity of the medicinal substance per dosing unit, at a set dose;
3. it is administered orally, through inhalation or is intended for external use;
4. the period of traditional use under Article 38, Paragraph 1, item 5 has expired;
5. data about the traditional use of the medicinal product prove that it is not harmful under the specified conditions for use and the pharmacological effect or efficacy of the medicinal product has been established through its long-term use and the experience accumulated.
(2) The Bulgarian Drugs Agency may apply the procedure under Paragraph 1 to a herbal medicinal product containing vitamins or minerals whose safety has been proven in a document form and whose action in respect to herbal medicinal substances in the product, as regards the latter's specific indications, is auxiliary.

Article 38. (1) In order to obtain a certificate of registration for a traditional herbal medicinal product, the person under Article 26, Paragraph 1 shall submit an application to the Bulgarian Drugs Agency accompanied by the following documents:
1. the data specified in Article 27, Paragraph 1, items 1 - 9 and item 10, a);
2. (amended, SG No. 71/2008, effective 12.08.2008) A product summary, with the exception of data under Article 34, Paragraph 1, item 5;

3. in the case of an herbal medicinal product under Article 37, Paragraph 2, or of a combined medicinal product - the information under Article 37, Paragraph 1, item 5, as regards the combination; where the active substances of the combined product are not sufficiently known, if taken separately, data about the traditional use of each shall be submitted;
4. a copy of the marketing authorisation or of the certificate of registration for the herbal medicinal product issued by a Member State or a third country, and/or a copy of a refusal accompanied by the reasoning of the decision concerned;
5. (amended, SG No. 71/2008, effective 12.08.2008) bibliographic data or expert opinions proving that the herbal medicinal product, for which an application for registration has been filed, or that a corresponding product has been in use, until the date on which the application for registration was filed, for more than 30 years in world medical practice, of which at least 15 years on the territory of a Member State;
6. bibliographic data about the safety of the product accompanied by a report of experts;
7. a copy of the manufacturing authorisation accompanied by a certificate of Good Manufacturing Practice or by a certificate proving that the product is manufactured under conditions that are equivalent to the requirements of Good Manufacturing Practice.
(2) The Bulgarian Drugs Agency may require from the applicant additional information in order to evaluate the safety of medicinal products under Paragraph 1.
(3) The Bulgarian Drugs Agency may request the opinion of the Committee on Herbal Medicinal Products with the European Medicines Agency as regards the truthfulness of data under Paragraph 1, item 5, providing it with the necessary parts of the medicinal product dossier.
(4) Data submitted under Paragraph 1, item 5 shall also be valid in cases where, in the 30-year period of use in medical practice:
1. the medicinal product corresponding to the one for which an application for registration is submitted has been on the market without authorisation or registration for use, or
2. where the number of ingredients in the medicinal product, for which an application for registration is filed, is reduced or their quantity per dosing unit is reduced.

Article 39. (1) Where the herbal medicinal product has been on the Community market for less than 15 years, but it meets the conditions of Article 37, Paragraph 1, the Bulgarian Drugs Agency shall submit the documentation under Article 38, Paragraph 1 to the Committee on Herbal Medicinal Products with the European Medicines Agency, in order to obtain its opinion.
(2) The Bulgarian Drugs Agency shall make a final decision after publication of the monograph of the Committee under Paragraph 1 with regard to the compliance of the product with registration criteria for traditional use.
(3) In the cases under Paragraph 1, the period under Article 44 shall be suspended.

Article 40. The Bulgarian Drugs Agency may require the applicant, in case of an herbal medicinal product, to file the documentation under Articles 27 - 32 or under Article 35.

Article 41. (1) (Amended, SG No. 71/2008, effective 12.08.2008) The Bulgarian Drugs Agency shall post on its website a list, to be prepared by the Committee on Herbal Medicinal Products with the European Medicines Agency, of the herbal substances, preparations or combinations thereof used in traditional herbal medicinal products. For each herbal substance the list shall specify its therapeutic indications, the active ingredient content per dosing unit, the route of administration and other information required for the safe use of the herbal substance as a traditional medicinal product.
(2) Where the product, as proposed in the traditional use application for registration, contains an herbal substance, preparation or a combination thereof, as per the list under Paragraph 1, the applicant shall not submit data specified in Article 38, Paragraph 1, items 4 - 6.
(3) Where the herbal substance, preparation or the combination thereof is excluded from the list under Paragraph 1, the holder of a certificate for registration of the herbal medicinal product must submit to the Bulgarian Drugs Agency the full documentation set under Article 38 within a period of three months after any such change.

(4) In case the holder of a certificate of registration for an herbal medicinal product fails to perform the duty under Paragraph 3, the Bulgarian Drugs Agency shall terminate the certificate of registration for the product.

Section V
Procedure for issuance of a marketing authorisation of medicinal products and for registration of homeopathic and traditional herbal products

Article 42. The requirements to data and documents in the dossiers under Articles 27 - 32, Article 35, Paragraph 3, Article 36, Paragraph 2 and under Article 38 shall be specified in an Ordinance of the Minister of Health.

Article 43. (1) (Amended, SG No. 67/2020) Within a period of 15 days from the date of submission of the documentation under Articles 27 - 32, Article 35, Paragraph 3 or under Article 38, the Bulgarian Drug Agency shall examine the various sections of the dossier for completeness and their compliance with the requirements for issuance of the marketing authorisation or of the certificate of registration under this Act.

(2) Where no incompleteness or discrepancies are found in the documentation submitted, the Bulgarian Drugs Agency shall notify the applicant in writing, within the period under Paragraph 1, that the documentation is valid. The notification shall specify the date from which the period under Article 44 is to start running.

(3) Where incompleteness and/or discrepancies are found in the documentation under Paragraph 1, the Bulgarian Drugs Agency shall notify the applicant in writing to submit additional information and/or a verbal or written explanation of the incompleteness and discrepancies found, within a period of 14 days of the date of the notification.

(4) Where the requirements under Paragraph 3 are not met within the specified period, the Bulgarian Drug Agency shall notify the applicant in writing that the application is not valid. In that case, the Bulgarian Drug Agency shall return within 14 days the documentation submitted and shall reimburse 75 per cent of the fee paid by the applicant.

(5) Where the requirements under Paragraph 3 are met within the specified period, the Bulgarian Drugs Agency shall notify the applicant in writing that the documentation is valid, the notification specifying the date from which the period under Article 44 is to start running.

Article 44. The procedure for issuance of a marketing authorisation or of a registration of a medicinal product shall start on the date specified in the notification under Article 43, Paragraph 2 or under Article 43, Paragraph 5, correspondingly, and shall terminate within a period of 210 days.

Article 45. (1) Where an application has been filed with the Bulgarian Drugs Agency for a marketing authorisation or for the registration of a medicinal product, for which information is available from data under Article 27, Paragraph 1, item 18 that a marketing authorisation of the same medicinal product has been issued in a Member State, the Bulgarian Drugs Agency shall notify the applicant in writing of the application of the procedure under Article 74.

(2) Where an application with the Bulgarian Drugs Agency has been filed for a marketing authorisation or for the registration of a medicinal product, for which information is available from data under Article 27, Paragraph 1, item 19, that the dossier of the same medicinal product in the Member State is under evaluation, the Bulgarian Drugs Agency shall not examine the documentation under Articles 27 - 32 or under Article 35, Paragraph 3, or under Article 38, and shall notify the applicant in writing of the application of the procedure under Article 75.

(3) For the purposes of applying the provisions of Paragraphs 1 and 2, a medicinal product authorised in another Member State shall be considered as being the same or as a product for which the file is under evaluation in another Member State, where two medicinal products:

1. are of identical quantitative and qualitative composition, in terms of the active substance(s) and are offered as the same pharmaceutical form, variation being allowed with regard to the excipients, provided this has no impact on safety and efficacy, and where

2. they belong to the same company or an application for the medicinal products is filed by persons belonging to the same company or group of companies, or an application is filed for the medicinal

products by persons who have entered a licensing or another agreement or who take joint actions relating to the marketing of the respective medicinal product in the different Member States.

Article 46. (1) When evaluating the documentation, the Bulgarian Drugs Agency shall:

1. be able to test the end product, the intermediate product or the starting materials for the medicinal product concerned, as well as to send them for testing to a laboratory within the system of official medicine control laboratories in a Member State, in order to establish whether the control methods of analysis used by the manufacturer and described in the dossier meet the relevant requirements;
2. following an on-site or document-based inspection, confirm whether manufacturers of medicinal products from third countries carry out manufacturing in accordance with data described in Article 27, Paragraph 1, item 7 and/or exercise control in accordance with the methods described in Article 27, Paragraph 1, item 8;
3. inspect the manufactured object specified in the application where the manufacturer(s) of medicinal products from third countries have, by way of exception, outsourced certain stages of the manufacturing or control of the medicinal product concerned to another manufacturer.

(2) Where the Bulgarian Drugs Agency conducts an on-site inspection of a manufacturing site, the period under Article 44 shall be suspended until the report containing the outcomes of the inspection comes out.

(3) In the cases under Paragraph 1, items 2 and 3, manufacturers shall pay a fee in the amount specified in the Tariff under Article 21, Paragraph 2.

Article 47. (1) The following specialised commissions shall be set up as consultative bodies with the Executive Director of the Bulgarian Drugs Agency:

1. Commission for Medicinal Products;
2. Commission for Immunological Medicinal Products;
3. Commission for Homeopathic Medicinal Products;
4. Commission for Herbal Medicinal Products;
5. Commission for Radiopharmaceuticals;
6. (new, SG No. 71/2008, effective 12.08.2008) Commission for Medicinal Products for Paediatric Use;
7. (New, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 21.12.2012) Commission for Medicinal Products for Modern Therapies;
8. (New, SG No. 102/2012, effective 21.12.2012) Commission for Risk Assessment in Drug Safety Monitoring.

(2) Where necessary, the Bulgarian Drug Agency Executive Director may also set up other specialised commissions outside those specified in Paragraph 1.

(3) The specialised commissions shall be composed of specialists with scientific achievements and practical experience in the respective fields of application of the medicinal products.

(4) External experts with scientific knowledge and practical experience in the area of the specific class of drugs could also be used in addition to the permanent composition of the commissions.

(5) The Bulgarian Drug Agency Executive Director shall specify, by order, the composition of commissions for a period of three years, the amount of their remuneration and shall endorse Rules on the terms and conditions of their work.

(6) No later than 30 January of each year, the Bulgarian Drug Agency Executive Director shall endorse lists of experts outside the composition of the commissions under Paragraph 1, subject to approval by the Minister of Health.

(7) The Bulgarian Drug Agency Executive Director may relieve prematurely a member of a specialised commission from office, upon his request, in case of failure to discharge his duties for a period of more than three months or in case of negligent performance of his functions.

(8) The composition of the commissions and the list of experts under Paragraph 6 shall be posted on the Bulgarian Drugs Agency website.

Article 48. (1) The members of specialised commissions under Article 47, Paragraph 1 and the experts under Article 47, Paragraph 4 shall sign a declaration, thereby taking the obligation not to:

1. disclose data and circumstances of which they have become aware while or on the occasion of carrying out their operations;
2. take part in operations associated with the manufacturing or wholesaling and retailing of medicinal products.
(2) In case individuals under Paragraph 1 have taken part in any of the stages in the preparation of documentation required for the authorisation of the use of the medicinal product concerned, they may not take part in the sessions of the respective specialised commission under Article 47.
(3) Individuals under Paragraph 1 shall not vote when decisions are made on matters in which they or members of their families have commercial, financial or other interests.

Article 49. (1) (Amended, SG No. 102/2012, effective 21.12.2012) Within a period of up to 200 days from the date of receiving valid documentation, the Bulgarian Drug Agency, together with the respective commission under Article 47, Paragraph 1 shall evaluate the quality, safety and efficacy of the medicinal product concerned and shall prepare an evaluation report with comments on the results of the pharmaceutical and preclinical tests, the clinical trials, the risk management system and the system for monitoring the safety of the respective medicinal product. The evaluation report shall be submitted to the Bulgarian Drug Agency Executive Director.
(2) (New, SG No. 102/2012, effective 21.12.2012) The report under Paragraph 1 shall be updated upon availability of new information that is important for assessing the quality, safety and efficacy of the medicinal product.
(3) (Renumbered from Paragraph (2), SG No. 102/2012, effective 21.12.2012) Where the medicinal product contains genetically modified organisms, the Bulgarian Drug Agency shall provide the Ministry of Environment and Waters with the necessary documentation from the medicinal product's dossier and shall obtain an opinion, within a period of 60 days, on the potential risk to the environment. The 60-day period shall be within the period under Paragraph 1.
(4) (Renumbered from Paragraph (3), SG No. 102/2012, effective 21.12.2012) In the case of radiopharmaceuticals, the Bulgarian Drug Agency shall provide the necessary documentation from the medicinal product's dossier and shall obtain an opinion within a period of 60 days from the Nuclear Regulation Agency with regard to the quality and safety of the product. The 60-day period shall be within the period under Paragraph 1.
(5) (Renumbered from Paragraph (4) and amended, SG No. 102/2012, effective 21.12.2012) Where the Ministry of Environment and Waters and the Nuclear Regulation Agency fail to rule within the periods set under Paragraphs 3 and 4, it shall be considered that their opinion is positive.

Article 50. (1) Where the Bulgarian Drugs Agency finds lack of compliance in the dossier with the requirements for issuance of a marketing authorisation or of a certificate of registration under this Act, it shall notify the applicant in writing to submit additional information relating to the documentation under Articles 27 - 32 or under Article 35, Paragraph 3, or under Article 38, and/or to submit a verbal or written explanation with regard to the incompleteness and discrepancies found, within a period of 180 days from the date of notification.
(2) In the cases under Paragraph 1, the period under Article 44 shall be suspended from the date of notification until submission of the requested information.
(3) The Bulgarian Drugs Agency Executive Director shall terminate the procedure for issuance of a marketing authorisation or of a certificate of registration of a medicinal product, where:
1. the applicant fails to submit the information under Paragraph 1 within the specified period;
2. the persons under Article 26, Paragraph 1 request its termination in writing.

Article 51. Within a period of 10 days from preparing the evaluation report under Article 49, Paragraph 1, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation/certificate of registration of the medicinal product or issue a motivated refusal.

Article 52. (1) (Amended, SG No. 102/2012, effective 21.12.2012) Within 5 days from the issuance date of the marketing authorisation/certificate of registration, the following data concerning the authorisation/certificate shall be entered in the register under Article 19, Paragraph 1, item 3:
1. a registration number;

2. a number and date of the marketing authorisation/certificate of registration of the medicinal product;
3. the name of the medicinal product;
4. the international non-patent name of each active substance;
5. the name and address of the holder of the marketing authorisation/certificate of registration;
5a. (new, SG No. 102/2012, effective 21.12.2012) the conditions under Articles 55a, 56 and 56a specified in the marketing authorisation/certificate of registration;
6. the date of the change introduced in the marketing authorisation/certificate of registration;
7. the date of termination of the marketing authorisation/certificate of registration;
8. other data.
(2) The marketing authorisation/certificate of registration of the medicinal product shall be served on the person under Article 26, Paragraph 1, and shall enter into force on the date of entry into the register under Article 19, Paragraph 1, item 3.

Article 53. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drug Agency shall post on its website the data under Article 52, Paragraph 1, the approved summary of the product and the data from the leaflet within a period of 14 days following the issuance of the marketing authorisation/certificate of registration.
(2) The Bulgarian Drug Agency shall post on its website the evaluation report under Article 49, Paragraph 1, including the reasoning for the decision made, deleting the data constituting commercial secrecy.
(3) The report under Paragraph 2 shall be accompanied by a summary in a language understandable to the general public. The summary shall contain a section on the conditions for use of the medicinal product.

Article 54. (1) (Amended, SG No. 12/2011) The holder of the marketing authorisation/certificate of registration for a medicinal product shall notify the Bulgarian Drug Agency in writing of the date on which the medicinal product has been actually placed on the market in the Republic of Bulgaria.
(2) (Amended, SG No. 18/2014) The holder of the marketing authorisation/certificate of registration of a medicinal product shall notify the Bulgarian Drug Agency in writing at least two months in advance of stopping the sales of any medicinal product, whether temporarily or on a permanent basis.
(3) (Amended, SG No. 18/2014) The Marketing Authroisation/Certificate of Registration Holder for any medicinal product shall indicate the reasons for the stop of sales in accordance with the Article 68, Paragraph (1), Item 6 and shall state whether the measures implemented on his/her behalf under Paragraph (2) are associated with any of the grounds specified under Article 276, or Article 277.
(4) (Amended, SG No. 18/2014) In case the sales of the medicinal product have been stopped as a result of unforeseeable circumstances, the holder of the marketing authorisation/certificate of registration of the medicinal product shall notify the Bulgarian Drug Agency in writing within a period of 7 days from establishing the circumstances.

Article 54a. (New, SG No. 60/2011, effective 5.08.2011) (1) (Amended, SG No. 18/2014) Within 30 days of receipt of information about stopped medicinal product sales, the Bulgarian Drug Agency shall conduct a check, except for the cases falling under Article 54, Paragraphs 2 and 4.
(2) While conducting the check provided for in Paragraph 1 the Bulgarian Drug Agency may ask the marketing authorisation holder and/or the person referred to in Article 26, Paragraph 2 to provide information regarding the stopping of the medicinal product sales, as well as ask wholesalers about the available stocks of the product concerned.
(3) The Bulgarian Drug Agency shall publish the results from the check on its website.

Article 55. (1) The marketing authorisation/certificate of registration of the medicinal product shall be issued by the Bulgarian Drug Agency Executive Director for a period of 5 years.
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008) Following the expiry of the term under Paragraph 1, the marketing authorisation/certificate of registration of the medicinal product may be

renewed by the Bulgarian Drugs Agency, based on an evaluation of the benefit/risk ratio under Article 59a.
(3) (Amended, SG No. 71/2008, effective 12.08.2008) The marketing authorisation/certificate of registration may also be terminated before the term under Paragraph 1 expires, if its holder demands that in writing from the Bulgarian Drug Agency Executive Director, citing the reasons for the request.
(4) (Supplemented, SG No. 71/2008, effective 12.08.2008) The marketing authorisation/certificate of registration shall become unlimited in time following its renewal, except in the cases under Paragraph 5.
(5) (Amended, SG No. 71/2008, effective 12.08.2008, SG No. 102/2012, effective 21.12.2012) If valid reasons exist concerning the monitoring of the drug safety, including as a result of exposure of the medicinal product on an insufficient number of patients, the Bulgarian Drug Agency may require from the holder of the marketing authorisation/certificate of registration to submit an application for its renewal under Article 59a for 5 more years.
(6) (Amended, SG No. 71/2008, effective 12.08.2008) Upon expiry of the term of the marketing authorisation/certificate of registration, or upon their termination, the medicinal product may be sold until the quantities available in the country are depleted, but for not more than one year after the date of expiry or termination, with the exception of the cases when the reasons for the termination are connected with the safety of the medicinal product.
(7) The Bulgarian Drug Agency Executive Director shall by order withdraw the marketing authorisation/certificate of registration of a medicinal product, where:
1. its holder has not placed the medicinal product on the market within up to three years from the date of issuance of the marketing authorisation, or
2. the sales of the medicinal product have been suspended for a period of up to three successive years after its release on the market.
(8) The order under Paragraph 7 shall be subject to appeal under the Administrative Procedure Code.
(9) By way of exception and in the interest of public health, the provision of Paragraph 7 may not be applied if the marketing authorisation holder for the medicinal product provides valid reasons. In such cases the Bulgarian Drug Agency Executive Director shall provide reasoning for his decision.
(10) The marketing authorisation holder shall pay an annual fee in the amount set in the Tariff under Article 21, Paragraph 2 for maintaining the marketing authorisation issued.

Article 55a. (New, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drug Agency Executive Director may issue a marketing authorisation/certificate of registration of a medicinal product that may comprise one or more of the following requirements:
1. to undertake certain measures for guaranteeing the safe use of the medicinal product, which shall be included in the risk management system;
2. to conduct post-marketing safety studies;
3. to comply with stricter obligations than the ones stipulated in Chapter Eight for registering or reporting adverse reactions;
4. to comply with all other conditions or restrictions with a view to the safe and efficient use of the medicinal product;
5. to ensure an adequate system for drug safety monitoring;
6. to conduct post-marketing efficiency studies in the event of apprehensions connected with the efficiency of the medicinal product, which may be authorised only after the medicinal product is released on the market.
(2) The marketing authorisation/certificate of registration of a medicinal product shall indicate the deadlines for complying with the conditions under Paragraph 1, where applicable.
(3) The grounds for imposing the condition under Paragraph 1, item 6 shall be determined with a delegated act under Article 22b of Directive 2001/83/EC, taking into account the scientific guidance developed in the manual under Article 194a.

(4) The requirements for conducting post-marketing efficacy studies shall be specified in a manual published by the European Medicines Agency

Article 56. (Amended, SG No. 102/2012, effective 21.12.2012) (1) By way of exception, following consultations with the applicant, the Bulgarian Drug Agency Executive Director, may issue a provisional marketing authorisation/certificate of registration, if the applicant is able to prove that he had failed to submit exhaustive data on the efficacy and safety of the medicinal product under normal conditions of use due to one of the following reasons.

1. the indications for the use of the medicinal product are with such rare occurrence than the applicant is unable to present complete proof, or
2. the state of scientific knowledge at the moment is such that it is impossible to present comprehensive data, or
3. the gathering of such data contravenes the universally accepted principles of medical ethics.

(2) The marketing authorisation/certificate of registration under Paragraph 1 shall be issued in compliance with one of the following conditions:

1. the applicant/holder shall implement a programme of tests under Paragraph 3, whereby the results of these tests shall be used for reassessment of the benefit/risk ratio;
2. the medicinal product shall be dispensed exclusively with a prescription by a physician, whereby in certain cases it may be administered only under strict medical supervision in a hospital, and in the event of a radiopharmaceutical product - only under the control of an authorised person;
3. the leaflet, as well as all other medical information accompanying the medicinal product, shall contain a text drawing the attention of medical specialists to the fact that some of the available data on the medicinal product are subject to further research.

(3) The marketing authorisation/certificate of registration under Paragraph 1 shall be issued for a period of one year and may be extended for each subsequent year on the basis of an evaluation of the compliance with the conditions under Paragraph 2.

Article 56a. (New, SG No. 102/2012, effective 21.12.2012) (1) Following the issuance of the marketing authorisation/certificate of registration, the Bulgarian Drug Agency may compel the holder of the authorisation/certificate to conduct:

1. a post-marketing safety study in the event of apprehensions concerning identified or potential risks, or lack of information connected with drug safety monitoring of the respective medicinal product; where the same risks are relevant to other medicinal products as well, following consultations with the Pharmacovigilance Risk Assessment Committee established under Article 56, Paragraph 1, item "aa" of Regulation (EC) No. 726/2004 of the European Parliament and European Council, the Bulgarian Drug Agency shall recommend to the respective marketing authorisation holder to conduct joint safety tests with the other marketing authorisation holders concerned;
2. a post-marketing efficacy test when the knowledge on the disease or on the clinical methodology used gives grounds for revising the efficacy evaluations on which conclusions were based at the time of issuance of the authorisation.

(2) The Bulgarian Drug Agency shall notify in writing the holder of the marketing authorisation/certificate of registration about his obligation under Paragraph 1, giving the reasons for and indicating the purpose of the study, as well as the period within which it is to be conducted.

(3) Within 30 days of receiving the notification under Paragraph 2, the holder of the marketing authorisation/certificate of registration may request the Bulgarian Drug Agency to provide an opportunity for presenting information on the obligations under Paragraph 1.

(4) Upon receiving the request under Paragraph 3, the Bulgarian Drug Agency shall set a deadline for the information to be submitted by the holder of the marketing authorisation/certificate of registration.

(5) Following analysis of the information under Paragraph 3, the Bulgarian Drug Agency may:

1. confirm the obligation under Paragraph 1, or
2. revoke it.

(6) The Bulgarian Drug Agency shall inform the holder of the decision reached under Paragraph 5.

(7) In the cases under Paragraph 5, item 1, the Bulgarian Drug Agency Executive Director shall officially modify the marketing authorisation/certificate of registration issued for the medicinal product by including as a condition in it the obligation under Paragraph 1.
(8) The grounds for imposing the obligations under Paragraph 1, item 2 shall be stipulated with a delegated act under Article 22b of Directive 2001/83/EC.

Article 56b. (New, SG No. 102/2012, effective 21.12.2012) (1) The holder of the marketing authorisation/certificate of registration shall include all conditions under Articles 55a, 56 and 56a in his risk management system.
(2) In the cases under Paragraph 1, the holder of the marketing authorisation/certificate of registration shall file a notification to the Bulgarian Drug Agency on the change in the risk management system.

Article 56c. (New, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall send information to the European Medicines Agency in the authorisations issued under Articles 55a, 56 and 56a.

Article 57. (1) The Bulgarian Drug Agency Executive Director shall refuse a marketing authorisation or a certificate of registration of a medicinal product where, after evaluation of the dossier under Articles 27 - 32, he finds that:
1. the benefit/risk ratio is unfavourable, or
2. the efficacy of the medicinal product is not convincingly defended by the applicant, or
3. the quantitative and qualitative composition of the medicinal product does not correspond to the one described in the dossier.
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008) The Bulgarian Drug Agency Executive Director shall refuse to issue a marketing authorisation or a certificate of registration of a medicinal product where some of the data in the dossier do not comply with the requirements of Articles 27 - 32 or with the Ordinance under Article 42.
(3) The Bulgarian Drug Agency Executive Director shall refuse the registration of a traditional herbal medicinal product when it is found, after evaluation of the documentation, that the product does not meet the conditions under Article 37, Paragraph 1, data in the dossier do not comply with Article 38, or:
1. the quantitative and qualitative composition does not comply with the description in the dossier;
2. the medicinal product may be harmful with correct use;
3. data about its traditional use are insufficient, especially if pharmacological properties or efficacy are not proven through long-term use based on the accumulated experience;
4. the pharmaceutical quality of the medicinal product has not been sufficiently justified.

Article 58. The marketing authorisation holder shall incur liability for the completeness and truthfulness of the data in the dossier.

Article 59. (1) The refusal by the Bulgarian Drug Agency Executive Director to issue a marketing authorisation/certificate of registration of a medicinal product may be appealed under the Administrative Procedure Code.
(2) A refusal by the Bulgarian Drug Agency Executive Director and the reasons for it shall be posted on the Agency website.

Article 59a. (New, SG No. 71/2008, effective 12.08.2008) (1) (Amended, SG No. 102/2012, effective 21.12.2012) In the cases under Article 55, Paragraphs 2 and 5, but not later than nine months prior to the expiry of the marketing authorisation/certificate of registration, its holder shall file an application for its renewal before the Bulgarian Drug Agency, accompanied by a summarised dossier concerning the quality, safety and efficacy of the medicinal product, which shall include also an assessment of the data contained in the reports on suspected adverse reactions and the periodic safety reports submitted in compliance with Chapter Eight, as well as all approved changes after the issuance of the marketing authorisation/certificate of registration.
(2) The requirements to the data and the documents in the dossier under Paragraph 1 shall be determined in the Ordinance under Article 42.

(3) Within 120 days after the filing of the application and of the documentation under Paragraph 1, the Bulgarian Drug Agency shall assess the safety, quality and efficacy of the medicinal product and shall draft an evaluation report, which shall be presented to the Bulgarian Drug Agency Executive Director.
(4) In the event that incompleteness or non-compliance is found in the documentation submitted under Paragraph 1, the Bulgarian Drug Agency shall inform in writing the holder of the marketing authorisation/certificate of registration and shall give instructions for their elimination. The holder of the marketing authorisation/certificate of registration shall eliminate the incompleteness and/or the non-compliance in the documentation within 30 days of receiving the notification.
(5) Within 10 days after receiving the evaluation report under Paragraph 3, the Bulgarian Drug Agency Executive Director shall issue the permission for the renewal of the marketing authorisation/certificate of registration of the medicinal product, or shall give a motivated refusal.

Article 59b. (New, SG No. 71/2008, effective 12.08.2008) (1) The Bulgarian Drug Agency Executive Director shall refuse to renew the marketing authorisation/certificate of registration of a medicinal product in the event that the assessment of the dossier under Article 59a, Paragraph 1, reveals that:
1. the medicinal product is harmful with correct usage, or
2. therapeutic efficacy is lacking, or
3. the benefit/risk ratio is unfavourable with correct usage, or
4. the qualitative and the quantitative composition of the medicinal product does not correspond to the composition described in the dossier, or 5. the data in the dossier under Article 59a, Paragraph 1, are untrue, or
6. no control has been performed on the medicinal product and/or on the components and intermediary stages of the production process, or some other requirement for the issuing of the permission for production has not been met, or
7. some data in the dossier do not meet the requirements under Article 59a, Paragraphs 1 and 2.
(2) The refusal by the Bulgarian Drug Agency Executive Director to renew a marketing authorisation/certificate of registration of a medicinal product may be appealed under the Administrative Procedure Code.
(3) The refusal by the Bulgarian Drug Agency Executive Director and the motives thereof shall be posted on the Bulgarian Drug Agency website.

Article 59c. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102.2012, effective 1.04.2013) Within 7 days of issuing the relevant act, the Bulgarian Drug Agency shall inform the National Council on Prices and Reimbursement of Medicinal Products about the terminated or withdrawn marketing authorisations, as well as about the refusals to renew any marketing authorisations issued.

Section VI
Variations to already issued marketing authorisations

Article 60. (1) (Amended, SG No. 12/2011) The marketing authorisation holder for a medicinal product shall be obliged to notify the Bulgarian Drugs Agency of each variation to the terms under which the authorisation was issued.
(2) (Amended, SG No. 12/2011, effective 8.02.2011) The variations may be: variations of type IA; variations of type IB; variations of type II; expansion of the scope of the marketing authorisation; urgent restrictive safety measures.
(3) (Amended, SG No. 12/2011, effective 8.02.2011) The conditions and criteria concerning the classification of variations shall be set out in the Ordinance under Article 42.
(4) (Amended, SG No. 12/2011, effective 8.02.2011) Any variation which does not represent a scope expansion and whose classification remains undetermined once the conditions and criteria of the Ordinance under Article 42 have been applied shall be considered a variation of type IB by default.

(5) (New, SG No. 12/2011, effective 8.02.2011) By way of exception to Paragraph 4, any variation which does not represent a scope expansion and whose classification remains undetermined once the conditions and criteria of the Ordinance under Article 42 have been applied shall be considered a variation of type II in the following cases:
1. upon the request of the marketing authorisation holder referred to in the variation application;
2. when the Bulgarian Drug Agency determines, upon assessing the validity of the notification under Article 63, that the variation concerned may have a significant impact on the quality, safety or efficacy of the medicinal product.

Article 61. (Amended, SG No. 12/2011, effective 8.02.2011) (1) In respect of any variation of type IA, type IB, type II or one concerning a scope expansion, the marketing authorisation holder for the relevant medicinal product shall submit a separate notification, or application, respectively, to the Bulgarian Drugs Agency.
(2) When a given variation results in a change to the data contained in the summary of the product characteristics, the package and/or the leaflet, such changes shall be considered part of the variation applied for, and no separate application shall be submitted for them.
(3) The marketing authorisation holder may group variations when:
1. the holder files a notification concurrently covering one and the same variations of type IA to the terms of one or more marketing authorisations;
2. the holder applies concurrently for several variations to the terms of marketing authorisations belonging to the global marketing authorisation under Article 28(8) for the medicinal product concerned, provided that the variations fall within one of the following scenarios:
a) one of the variations in the group is an extension of the scope of the marketing authorisation;
b) one of the variations in the group is a variation of type II, and all other variations in the group are variations which are consequential to this variation of type II;
c) one of the variations in the group is a variation of type IB, and all other variations in the group are variations which are consequential to this variation of type IB;
d) all variations in the group relate solely to changes of administrative nature to the summary of product characteristics, package leaflet/insert or the package;
e) all variations in the group are changes to an Active Substance Master File, Vaccine Antigen Master File or Plasma Master File;
f) all variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance(s);
g) all variations in the group are changes affecting the quality of a pandemic influenza vaccine;
h) all variations in the group are changes to the pharmacovigilance system referred to in Chapter Eight;
i) all variations in the group are consequential to a given urgent safety restriction and submitted in accordance with Article 66;
j) all variations in the group relate to including information about a given pharmaco-therapeutic class;
k) all variations in the group are consequential to the assessment of a given periodic safety update report;
l) all variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder;
m) all the variations in the group are consequential to a condition in the marketing authorisation carried out pursuant to Article 56;
3. the variations to the terms of one and the same marketing authorisation do not fall within the scenarios under Article 61(3)(2), provided that the Bulgarian Drug Agency agrees to apply one and the same procedure to the variations concerned.
(4) When grouping variations under Paragraph 3(2) and (3), the marketing authorisation holder shall submit the following documents to the Bulgarian Drug Agency:
1. a single notification when at least one of the variations is of type IB and all the other variations are of type IA or type IB;

2. a single notification when the main variation is of type II and none of the other variations is an extension of the scope of the marketing authorisation;
3. a single notification when the main variation is an extension of the scope of the marketing authorisation;
(5) Enclosed with the application or the notification under paragraph 1 or 4, respectively, the marketing authorisation holder shall also submit:
1. variation-related documentation specified in the Ordinance under Article 42;
2. a document attesting to the payment of the relevant fee in the amount specified in the tariff under Article 21(2).
(6) The executive director of the Bulgarian Drug Agency shall approve the template forms for the application, as well as for the notifications under Paragraphs 1 and 4. The template forms shall be disclosed on the Bulgarian Drug Agency website.

Article 62. (Amended, SG No. 12/2011, effective 8.02.2011) (1) The marketing authorisation holder may submit a notification for variation of type IA within 12 months after the variations were implemented, excluding those that require immediate notifying.
(2) Any variations of type IA which require immediate notifying shall be stipulated in the Ordinance referred to in Article 42.
(3) In the cases under Paragraph 2, the marketing authorisation holder shall submit a notification for the relevant variation of type IA immediately after the variation is implemented.
(4) Within 30 days from the date of receiving a notification under Paragraph 1 or 3, respectively, the Bulgarian Drug Agency shall notify the marketing authorisation holder whether:
1. the variation/s is/are accepted or not; if the variation/s are not accepted, the reasons thereof shall be disclosed, and
2. the variation results in a change to the data contained in the marketing authorisation issued; when a variation to the issued marketing authorisation is needed, Article 64a shall apply.
(5) Upon receiving a rejection notification under Paragraph 4(1), the marketing authorisation holder shall immediately cease to implement the relevant variation/s of type IA.

Article 63. (Amended, SG No. 12/2011, effective 8.02.2011) (1) When the notification for a variation of type IB complies with the requirements of Article 61, the Bulgarian Drug Agency shall inform the marketing authorisation holder that the notification is valid and shall also specify the date from which the period under Paragraph 2 starts to run.
(2) Within 30 days from the date of receiving a valid notification, the Bulgarian Drug Agency shall examine the documentation submitted and shall notify the marketing authorisation holder whether:
1. the Bulgarian Drug Agency approves the variation or not; if not, the reasons thereof shall be disclosed, and
2. the variation results in a change to the data contained in the marketing authorisation issued; when a variation to the issued marketing authorisation is needed, Article 64a shall apply.
(3) When finding-within the period under Paragraph 2-that the documentation submitted does not comply with the requirements of this Act and the Ordinance under Article 42, the Bulgarian Drug Agency shall notify the marketing authorisation holder accordingly.
(4) Within 30 days from the date of receiving the notification under Paragraph 3, the marketing authorisation holder may amend or supplement the documentation.
(5) When the marketing authorisation holder concerned fails to submit the amended or supplemented documentation within the period under Paragraph 4, the Bulgarian Drug Agency shall terminate the procedure and shall notify the marketing authorisation holder accordingly.
(6) Within 30 days from the date of receiving the amended documentation under Paragraph 4, the Bulgarian Drug Agency shall examine the documentation submitted and shall notify the marketing authorisation holder whether:
1. the Bulgarian Drug Agency approves the variation or not; if not, the reasons thereof shall be disclosed, and
2. the variation results in a change to the data contained in the marketing authorisation issued; when a variation to the issued marketing authorisation is needed, Article 64a shall apply.

(7) The marketing authorisation holder shall implement the approved variation of type IB after receiving a variation approval notification under Paragraph 2(1) or Paragraph 6(1), respectively.

Article 64. (Amended, SG No. 12/2011, effective 8.02.2011) (1) When the notification for variation of type II complies with the requirements of Article 61, the Bulgarian Drug Agency shall inform the marketing authorisation holder that the notification is valid and shall also specify the date from which the period under Paragraph 2 starts to run.

(3) Within 60 days from the date of receiving a valid application, the Bulgarian Drug Agency shall deliver an assessment report on the variation.

(3) The period under Paragraph 2 may be:

1. reduced in urgent cases connected with the safe use of the medicinal product, or
2. extended to 90 days in the event of a change that amends or supplements a therapeutic indication.

(4) When finding that the documentation submitted does not comply with the requirements of this Act and the Ordinance under Article 42, the Bulgarian Drug Agency shall notify the marketing authorisation holder accordingly and shall determine a time limit for submission of additional information and documentation.

(5) In the cases under Paragraph 4, the time limit under Paragraph 2 shall be suspended until the submission of the additional information and documentation concerned.

(6) Within 15 days from the date of delivering the assessment report, the Bulgarian Drug Agency Executive Director shall:

1. approve the variation or issue a reasoned refusal and shall then notify the marketing authorisation holder accordingly;
2. notify the marketing authorisation holder whether the approved variation results in changes to the data contained in the issued marketing authorisation; when a variation to the issued marketing authorisation is needed, Article 64a shall apply.

(7) The marketing authorisation holder may implement the approved variation of type II only after the issuance of a variation approval under Article 64a.

Article 64a. (New, SG No. 12/2011, effective 8.02.2011) The Bulgarian Drug Agency Executive Director shall issue a marketing authorisation variation approval within:

1. thirty days from the issue date of the notification under Article 62, Paragraph 4, item 2, Article 63, Paragraph 2, item 2, Article 63, Paragraph 6, item 2 or Article 64, Paragraph 6, item 2, in cases when the variation concerned results in a 6-month extension of the duration referred to in Article 13, Paragraphs 1 and 2 of Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, while complying with Article 36 of Regulation (EC) No. 1901/2006;
2. sixty days from the issue date of the notification under Article 62, Paragraph 4, item 2, in the case of variations of type IA which do not require an immediate notification;
3. sixty days from the issue date of the notification under Article 64, Paragraph 6, item 2, in the case of variations of type II;
4. one hundred and eighty days, in all other cases.

Article 64b. (New, SG No. 12/2011, effective 8.02.2011) (1) In the case of variations concerning changes to the active substance for the purposes of the annual update of influenza vaccines, the marketing authorisation holder shall submit an application to the Bulgarian Drug Agency along with the documentation required by the Ordinance under Article 42. Within 7 days, the Bulgarian Drug Agency shall verify the completeness of the documentation submitted.

(2) When the application complies with the requirements of Paragraph 1, the Bulgarian Drug Agency shall inform the marketing authorisation holder that the application is valid and shall also specify the date from which the period under Paragraph 3 starts to run.

(3) Within 45 days from the date of receiving a valid application, the Bulgarian Drug Agency shall deliver an assessment report.

(4) The Bulgarian Drug Agency may request the marketing authorisation holder to provide the clinical data, as well as the data concerning the stability of the medicinal product. The marketing

authorisation holder shall submit the required data to the Bulgarian Drug Agency within 12 days following the end of the time limit laid down in Paragraph 3.
(5) The Bulgarian Drug Agency shall evaluate the documentation and give its final decision within 10 days from the date of receiving the data referred to in Paragraph 4 and shall then issue a variation approval or rejection.

Article 65. (1) Where the marketing authorisation holder finds a health hazard associated with the use of the medicinal product, he shall take urgent restrictive measures and shall immediately notify the Bulgarian Drug Agency in writing.
(2) The Bulgarian Drugs Agency shall rule on these measures within 24 hours of notification.
(3) Where the Bulgarian Drugs Agency fails to rule within the period under Paragraph 2, the measures shall be considered approved.
(4) Where the Bulgarian Drugs Agency finds that there is a risk to human health associated with the use of the medicinal product, it shall order the marketing authorisation holder to take immediate restrictive measures.
(5) In the cases under Paragraphs 1 and 4, the marketing authorisation holder for the medicinal product concerned shall agree with the Bulgarian Drug Agency the manner and terms for implementing the measures taken.
(6) The marketing authorisation holder for the medicinal product concerned shall file an application for change with the Bulgarian Drug Agency Executive Director under Article 64 no later than 15 days after the date on which the measures were taken.

Article 66. (1) (Amended, SG No. 71/2008, SG No. 12/2011, effective 8.02.2011) The marketing authorisation holder for the medicinal product concerned shall submit an application for extending the scope of the issued marketing authorisation in the case of:
1. changes to the active substance(s):
a) replacement of a chemical active substance by a different salt/ester complex/derivative, with the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different;
b) replacement by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (e.g. racemate by a single enantiomer), where the efficacy/safety characteristics are not significantly different;
c) replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different, with the exception of changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;
d) modification of the vector used to produce the antigen or the starting material, including a new master cell bank from a different source, where the efficacy/safety characteristics are not significantly different;
e) a new ligand or coupling mechanism for a radiopharmaceutical, where the efficacy/safety characteristics are not significantly different;
f) change to the extraction solvent or the ratio of herbal drug to herbal drug preparation where the efficacy/safety characteristics are not significantly different;
2. changes to the quantity of the active substance, the pharmaceutical form and the route of administration:
a) change to the bioavailability;
b) change of pharmacokinetics e.g. change in rate of release;
c) change or addition of a new quantity of the active substance/potency;
d) change or addition of a new pharmaceutical form;
e) change or addition of a new route of administration - for parenteral administration, it is necessary to distinguish between intra-arterial, intravenous, intramuscular, subcutaneous and other routes.
(2) The application under Paragraph 1 shall be filed together with the documentation under Article 27, Paragraph 1, item 10, concerning the changes under Paragraph 1.
(3) The requirements to the documentation under Paragraph 2 shall be specified in the Ordinance under Article 42.

(4) The name of the medicinal product shall not be changed in the authorisation issued expanding the scope of the initial marketing authorisation.
(5) The issuance of an authorisation expanding the scope of a marketing authorisation of a medicinal product already issued shall take place in compliance with the terms and conditions of Articles 49-51.

Article 67. (1) The marketing authorisation holder for the medicinal product shall submit an application for the issuance of a new marketing authorisation where:
1. one or more active substances, including antigen components for vaccines, have been added or removed;
2. the quality of the active substance has been changed as specified in the dossier, significantly changing the safety and efficacy characteristics of the medicinal product, the changed substance thereby being defined as new;
3. an indication for the treatment, prevention or diagnostics has been added in another therapeutic area, or has been changed.
(2) (New, SG No. 71/2008, effective 12.08.2008) The marketing authorisation holder of the medicinal product shall file an application for the issuance of a new marketing authorisation when the application for the renewal of the marketing authorisation had not been filed before the deadline specified in Article 59a, Paragraph 1.
(3) (Renumbered from Paragraph 2, SG No. 71/2008, effective 12.08.2008) The application shall be accompanied by the documentation specified in the Ordinance under Article 42.
(4) (Renumbered from Paragraph 3, supplemented, SG No. 71/2008, effective 12.08.2008) In the cases under Paragraphs 1 and 2 the procedure under Articles 49-51 shall apply.

Article 68. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The holder of a marketing authorisation/certificate of registration of a medicinal product shall be obliged to:
1. take into account the achievements of scientific and technological progress, and introduce all necessary changes in the documentation under Article 27, Paragraph 1, items 7 and 8, so that the medicinal product can be manufactured and controlled in compliance with the universally accepted research methods; modifications shall be made in compliance with Chapters Three and Five;
2. submit immediately to the Bulgarian Drug Agency any new information that may necessitate a change in the data and documents under Articles 27 - 32 and in the product summary;
3. inform the Bulgarian Drug Agency immediately about any prohibition or restriction imposed by regulatory bodies of other states in which the medicinal product is on sale and of the reasons on account of which such measures have been imposed, as well as provide any other information that may influence the assessment of the risks and benefits of the respective medicinal product; the information shall include both the positive and the negative results of the clinical trials or other studies of all indications and populations, irrespective of whether they are included in the marketing authorisation, as well as data on the use of the medicinal product, when that use is outside the conditions in the marketing authorisation;
4. keep and update the information about the medicinal product with current scientific knowledge, including the conclusions of the assessment and the recommendations posted on the European Internet portal for medicinal products, created in compliance with Article 26 of Regulation (EC) No. 726/2004 of the European Parliament and of Council;
5. distribute the medicinal product with the last approved product summary and patient leaflet;
6. (new, SG No. 18/2014) inform the Bulgarian Drug Agency of any action on his part, associated with the temporary discontinuation of the market availability of any given medicinal product, reclaiming of any given medicinal product, request for termination of the marketing authorisation, or statement of intent not to seek renewal of the marketing authorisation, as well as indicate the reasons for the said action; in such cases, the Marketing Authorisation Holder shall state whether the actions he had undertaken are associated with any of the grounds under Article 276, or Article 277;

7. (new, SG No. 18/2014) inform the Bulgarian Drug Agency, whether the actions under Item 6 above have been undertaken in a third country and whether they are associated with any of the grounds under Article 276, or Article 277;
8. (new, SG No. 18/2014) inform the European Medicines Agency, where the measures under Items 6 and 7 above have been implemented on the grounds of Article 276, and 277;
9. (new, SG No. 18/2014) provide sufficient supply of the medicinal product to meet the health care demands of the population of the Republic of Bulgaria;
10. (new, SG No. 84/2018, effective 12.10.2018) using the specialized electronic system referred to in Article 217b(1), inform the Bulgarian Drug Agency, every week or after a change of circumstances, about:
(a) the quantities delivered in the territory of the Republic of Bulgaria, indicated by medicinal products included on the Positive Drug List that are held by the marketing authorisation holder;
(b) the wholesalers to whom the quantities of medicinal products under paragraph (a) have been delivered;
(c) the date on which a delivery under paragraphs (a) and (b) has been made;
(d) the quantities available in stock, indicated by medicinal products included on the Positive Drug List that are held by the marketing authorisation holder.
11. (new, SG No. 103/2020, effective 1.01.2021) provide to the BDA, in respect of all medicinal products authorised for use in the territory of the country, including in case of change of circumstances, through the specialised electronic system referred to in Article 217b(1), information about the product code within the meaning of Article 4(b)(i) of Commission Delegated Regulation (EU) 2016/161 for medicinal products set out in the Regulation.
(2) The holder of the marketing authorisation/certificate of registration shall be obligated, upon request from the Bulgarian Drug Agency, to submit:
1. data in support of a favourable risk/benefit ratio with regard to the medicinal product;
2. (amended, SG No. 18/2014) data relating to the amount of sales of that medicinal product and any other information available to the Marketing Authorisation Holder, regarding the gross amount of this product used according to the medical prescriptions issued;
3. a copy of the principal documentation of the system for drug safety monitoring.
(3) The holder of the marketing authorisation shall submit the documentation under Paragraph 2, item 3 to the Bulgarian Drug Agency within seven days of receiving the request.

Article 68a. (New, SG No. 67/2020) The marketing authorisation holder shall ensure the introduction of the unique identifier under Article 168, paragraph 8, item 1 of each packaging in the system of registers pursuant to Delegated Regulation (EU) 2016/161.

Article 69. (1) (Amended, SG No. 67/2020) The holder of a marketing authorisation of a vaccine or an immunological medicinal product intended for immunisation shall be obligated, prior to releasing each batch of the product concerned on the market, to submit to the Bulgarian Drug Agency the following:
1. an application in a standard format approved by the BDA Executive Director;
2. samples of the finished product and/or samples of the bulk product and/or sample of the intermediate and starting product in quantities specified in the Manual for batch release of a medicinal product by an official control body issued by the European Directorate for the Quality of Medicines and Healthcare;
3. batch manufacturing and quality control records issued by the manufacturer, which shall conform as a minimum with the data indicated in the sample form of the administrative procedure of the European Directorate for the Quality of Medicines and HealthCare for batch release by an official control body.
(2) The marketing authorisation holder of new immunological medicinal products or of immunological medicinal products manufactured using new or changed technologies or using technologies that are new to a particular manufacturer, shall discharge the obligations under Paragraph 1 for the specific period stated in the marketing authorisation.

(3) (Supplemented, SG No. 67/2020) Within a period of 60 days from the date of submission of the full set of documents, the Bulgarian Drug Agency shall evaluate the manufacturing and quality control records for live vaccines, immunological and new immunological medicinal products, and for testing the samples provided in an accredited laboratory, or another official control laboratory in order to establish whether the medicinal products under paragraphs 1 and 2 have been manufactured in accordance with the approved specifications.
(4) (Amended, SG No. 67/2020) In case of a positive outcome of the assessment and testing under paragraph 3, the Bulgarian Drug Agency shall issue a batch release certificate.
(5) (Amended, SG No. 67/2020) A batch release certificate shall be issued by the Executive Director of the Bulgarian Drug Agency or by an official authorised thereby, and prior to release of the batch of the medicinal product in the markets of other countries – at the request of the medicinal product marketing authorization holder. Samples under paragraph 1, item 2 and batch manufacturing and quality control records, issued by the manufacturer, conforming as a minimum with the data indicated in the Guidelines of the World Health Organisation on batch release by national control authorities should be attached to the application.
(6) (Amended, SG No. 67/2020) Where the testing and evaluation under paragraph 3 for the respective batch of the medicinal products have been carried out by an official medicinal product control laboratory in another Member State before the release of the batch on the domestic market, the marketing authorisation holder shall submit to the BDA the batch release certificate issued by the regulatory authority of the Member State, as well as a sales information form in a standard format approved by the Executive Director of the Bulgarian Drug Agency.
(7) In the cases under Paragraph 6, the Bulgarian Drugs Agency shall carry out the operations under Paragraphs 3 and 4.

Article 70. (1) (Amended, SG No. 67/2020) Prior to release of each batch of medicinal product on the market, the holder of a marketing authorisation of a medicinal product obtained from human blood or plasma shall be obligated to submit to the Bulgarian Drug Agency the following:
1. an application in a standard format approved by the BDA Executive Director;
2. samples of the finished product and/or samples of the bulk product and/or samples of the intermediate and starting products in quantities specified in the Manual for batch release of medicinal products by an official control body issued by the European Directorate for the Quality of Medicines and Healthcare;
3. batch manufacturing and quality control records issued by the manufacturer, which shall conform as a minimum with the data indicated in the sample form of the administrative procedure of the European Directorate for the Quality of Medicines and Healthcare for batch release by an official control body.
(2) (Supplemented, SG No. 67/2020) Within a period of 60 days from the submission of the full set of documents, the Bulgarian Drug Agency shall evaluate the manufacturing and quality control records for the medicinal product obtained from human blood or plasma and from testing the samples provided in an accredited laboratory or another official control laboratory, in order to establish whether the medicinal product under paragraph 1 has been manufactured in compliance with the approved specifications.
(3) (Amended, SG No. 67/2020) In case of a positive outcome of the assessment and testing under paragraph 2, the Bulgarian Drug Agency shall issue a batch release certificate.
(4) (Repealed, SG No. 67/2020).
(5) (Amended, SG No. 67/2020) Where the testing and evaluation under paragraph 2 for the respective batch of medicinal products have been carried out by an official medicinal product control laboratory in another Member State before the release of the batch on the domestic market, the marketing authorisation holder shall submit the batch release certificate for the medicinal products, issued by the regulatory body of the Member State, as well as a sales information form in a standard format approved by the Executive Director of the Bulgarian Drug Agency.
(6) In the cases under Paragraph 5, the Bulgarian Drugs Agency shall not carry out the operations under Paragraphs 2 and 3.

Article 70a. (New, SG No. 67/2020) The Bulgarian Drug Agency may perform additional tests of samples of a medicinal product under Articles 69 and 70 in the following cases:
1. a significant change in the production process classified pursuant to the ordinance under Article 42;
2. change of the place of production;
3. adverse event under § 1, item 40 of the Additional Provisions;
4. significant deviations in the production process;
5. changes in the manufacturer's testing procedures;
6. unexpected variability in the results of quality control testing performed by the manufacturer or by the official control body;
7. critical report of an inspection performed by the manufacturer.

Article 70b. (New, SG No. 67/2020) (1) For issuance of a batch release certificate the marketing authorisation holder shall submit to the Bulgarian Drug Agency a document attesting payment of a fee in an amount as set in the tariff under Article 21, paragraph 2.
(2) Expenses for tests performed under Articles 69 and 70 as well as expenses for additional tests under Article 70 shall be on applicant's account.
(3) The batch release certificate shall be issued in Bulgarian language in the name of the medicinal product authorisation holder, and at their request – also in English.
(4) Where in the cases under Articles 69 and 70 any batch of medicinal product is not in compliance with the approved specifications, the Bulgarian Drug Agency Executive Director or an official authorised thereby shall issue a reasoned refusal to issue a batch release certificate.
(5) The Bulgarian Drug Agency shall send data of the refusal under paragraph 4 to the network of official medicines control laboratories of Member States and of the Swiss Confederation.
(6) A refusal under paragraph 4 shall be subject to appeal under the Administrative Procedure Code.

Article 71. (1) The marketing authorisation holder shall be obligated to maintain a system for the prohibition and market withdrawal of medicinal products falling short of the requirements for quality, safety and efficacy.
(2) The marketing authorisation holder shall be obligated to prohibit and withdraw from the market medicinal products that have demonstrated lack of compliance with the quality, efficacy and safety requirements in compliance with the Ordinance under Article 274, Paragraph 1.

Article 72. (Repealed, SG No. 102/2012, effective 21.12.2012).

Article 73. (1) The marketing authorisation holder may transfer the rights on the marketing authorisation for the medicinal product to another legal person or to groups having no legal personality, established on the territory of the Member States.
(2) The marketing authorisation holder shall submit to the Bulgarian Drug Agency an application to which the documentation specified in the Ordinance under Article 42 shall be attached, proposing a date for the transfer.
(3) Where incompleteness of the documentation under Paragraph 2 is found, the Bulgarian Drugs Agency shall notify the marketing authorisation holder in writing to submit the necessary additional information within a period of 30 days. The period under Paragraph 5 shall stop running from the date of notification until the requested information is provided.
(4) Where the marketing authorisation holder fails to supplement the documentation within the period under Paragraph 3, the procedure for transfer of the marketing authorisation for the medicinal product shall be terminated.
(5) Within a period of 30 days from the date of submission of the application under Paragraph 2, the Bulgarian Drug Agency Executive Director shall issue an authorisation for change, thereby approving the transfer. The authorisation for change shall also specify the date of transfer of the marketing authorisation.
(6) The new marketing authorisation holder shall fully assume the rights and obligations of the previous marketing authorisation holder.
(7) Where the marketing authorisation has been transferred in compliance with Paragraphs 1-6, its term of validity shall not be changed.

Section VII
Mutual recognition and decentralised procedures

Article 74. (1) Where the person under Article 26, Paragraph 1 holds a marketing authorisation issued in another Member State for the same medicinal product within the meaning of Article 45, Paragraph 3, for which an application for marketing authorisation has been submitted with the Bulgarian Drugs Agency, this person shall file a request with the regulatory body of a Member State it has designated in the application, hereinafter referred to as "reference Member State", to proceed with an evaluation report or to update the existent one.
(2) Together with the application, the person under Paragraph 1 shall also file with the Bulgarian Drug Agency a dossier identical to the one filed in the reference Member State and in the other Member States designated in the application, hereinafter referred to as "concerned states."
(3) The Bulgarian Drugs Agency and the applicant shall obtain through official channels the evaluation report, together with the approved product summary, packaging mock-up and patient brochure from the regulatory body of the reference state under Paragraph 1.
(4) The Bulgarian Drugs Agency shall examine the documents under Paragraph 3 and shall inform in writing the reference state of the decision made within 90 days of the date of their receipt.
(5) Within a period of 30 days from receiving the notification that the reference state has terminated the procedure, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation for the medicinal product on the territory of the Republic of Bulgaria with the approved product summary, packaging mock-up and patient brochure.

Article 75. (1) Where the person under Article 26, Paragraph 1 simultaneously submits with the Bulgarian Drugs Agency and in other Member States an application for authorisation to use a medicinal product for which no marketing authorisation has been issued on the territory of a Member State, that person shall indicate in the application the regulatory body of the Member State, hereinafter referred to as "reference Member State", which shall prepare a draft evaluation report, a draft product summary and a project for a mock-up packaging and a draft patient brochure.
(2) Together with the application, the person under Paragraph 1 shall submit a dossier with the Bulgarian Drugs Agency, identical to the one filed in all other Member States designated in the application, hereinafter referred to as "concerned states."
(3) The Bulgarian Drugs Agency and the applicant shall obtain through official channels the draft evaluation report, the draft product summary, the project for a packaging mock-up and the draft patient brochure from the regulatory body of the reference Member State.
(4) The Bulgarian Drugs Agency shall examine the documents under Paragraph 3 and shall inform the reference Member State in writing of the decision made within 90 days from the date of their receipt.
(5) Within a period of 30 days from receiving a notification that the reference Member State has terminated the procedure, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation for the medicinal product on the territory of the Republic of Bulgaria with the approved product summary, packaging mock-up and patient brochure.

Article 76. (1) Where the Republic of Bulgaria is a reference Member State under Article 74, the Bulgarian Drugs Agency shall:
1. within a period of 90 days from the date of submission of valid documentation, send the regulatory bodies of the concerned states and the applicant an evaluation report accompanied by the approved product summary, packaging mock-up and patient brochure.
2. close the procedure and notify the applicant and the concerned states, where all concerned states have approved thereof.
(2) Within a period of 30 days from closing the procedure under Paragraph 1, item 2, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation for the medicinal product on the territory of the Republic of Bulgaria with the approved product summary, packaging mock-up and patient brochure.
(3) Where the Republic of Bulgaria is a reference state under Article 75, the Bulgarian Drug Agency shall:

1. within a period of 120 days from the date of submission of valid documentation, send the regulatory bodies of the concerned states and the applicant the draft evaluation report, a draft product summary, a project for a packaging mock-up and a draft patient brochure.
2. close the procedure and notify the applicant and the concerned states, where all concerned states have approved thereof.
(4) Within a period of 30 days from closing the procedure under Paragraph 3, item 2, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation for the medicinal product on the territory of the Republic of Bulgaria with the approved product summary, packaging mock-up and patient brochure.

Article 77. (1) Where the Bulgarian Drugs Agency fails to approve the documentation submitted under Article 74, Paragraph 3 or under Article 75, Paragraph 3, due to potential serious risk to the health of the population, it shall prepare a detailed motivated report to the reference Member State, the other concerned states and to the applicant.
(2) The disputed issues under Paragraph 1 shall be examined by the Coordination Group of the Member States. The applicant may give a statement on the issues examined in writing or verbally.
(3) The Bulgarian Drugs Agency shall take part in the Coordination Group under Paragraph 2 until the reference state closes the procedure.
(4) Within 30 days from receiving a notification that the reference state is closing the procedure, the Bulgarian Drug Agency Executive Director shall issue a marketing authorisation for the medicinal product with the approved product summary, packaging mock-up and patient brochure.

Article 78. (1) Where the Member States fail to reach agreement within the procedure under Article 77, Paragraph 2, taking place before the Coordination Group, the disputed issues shall be examined by the Committee for Medicinal Products for Human Use with the European Medicines Agency in an arbitration procedure. A copy of the documentation shall be sent to the applicant.
(2) The applicant shall submit the dossier of the medicinal product and the product summary to the European Medicines Agency.
(3) In the cases under Paragraph 1, if the Bulgarian Drugs Agency has approved the evaluation report, the draft product summary, the project for a packaging mock-up and the draft patient brochure, provided by the reference state, the Bulgarian Drug Agency Executive Director, at the request of the applicant, may issue a marketing authorisation for the medicinal product prior to the completion of the arbitration procedure under Paragraph 1.
(4) Following completion of the arbitration procedure, the Bulgarian Drug Agency Executive Director shall bring the marketing authorisation issued under Paragraph 3 in line with the decision of the European Commission.

Article 79. (1) Where regulatory bodies of one or more Member States have adopted differing decisions with regard to the marketing authorisation of the same medicinal product or for its temporary suspension or withdrawal, the Bulgarian Drugs Agency shall bring the issue to the Committee for Medicinal Products for Human Use with the European Medicines Agency for the implementation of an arbitration procedure. The applicant or the marketing authorisation holder may, if they so deem appropriate, bring the issue to the Committee for Medicinal Products for Human Use with the European Medicines Agency for the implementation of an arbitration procedure.
(2) (Repealed, SG No. 102/2012, effective 21.12.2012).
(3) (Amended, SG No. 102/2012, effective 21.12.2012) In the cases under Paragraph 1, the Bulgarian Drug Agency or the applicant for or holder of the marketing authorisation.
(4) (Repealed, SG No. 60/2011, effective 5.08.2011).
(5) (Repealed, SG No. 60/2011, effective 5.08.2011).

Article 79a. (New, SG No. 60/2011, effective 5.08.2011) (1) Depending on the European Commission's decision upon completion of the arbitration procedure and within 30 days of receipt of the notification the Bulgarian Drug Agency shall:
1. issue, suspend or terminate the marketing authorisation; or

2. request changes to be made to the authorisation issued to achieve compliance with the European Commission's decision.
(2) The Bulgarian Drug Agency shall inform the European Commission and the European Medicines Agency about any acts issued under Paragraph 1.

Article 79b. (New, SG No. 102/2012, effective 21.12.2012) (1) Where the interests of the European Union are affected and prior to reaching a decision on issuing a market authorisation for a medicinal product, on its provisional suspension, termination or modification, the Bulgarian Drug Agency, the applicant or the holder of a marketing authorisation may refer the issue to the Committee under Article 79, Paragraph 1 for applying an arbitration procedure.
(2) In the cases under Paragraph 1, when the referral results from the evaluation of data connected with drug safety monitoring of a medicinal product with market authorisation, the issue shall be referred to the Committee under Article 56a, Paragraph 1, item 1, and the procedure under Article 194x or Article 194y shall apply.
(3) (Amended, SG No. 18/2014) Where any of the measures under Article 194s, Paragraphs 2 and 3 need to be implemented, The Bulgarian Drug Agency shall apply the procedure under Chapter Eight, Section V.
(4) (New, SG No. 18/2014) Regardless of the Paragraphs 1 to 3 above, where emergency measures for protecting public health are required during any stage of the arbitrary proceedings, The Bulgarian Drug Agency may suspend the Marketing Authorisation effect and prohibit the use of the respective medicinal product on the territory of the Republic of Bulgaria until the final judgement is concluded.
(5) (New, SG No. 18/2014) In each case under Paragraph 4 above, the Bulgarian Drug Agency shall inform the European Medicines Agency and the other Member States about the grounds its decision is based on no later than the next working day.

Article 80. (Amended, SG No. 12/2011, effective 8.02.2011) The terms and procedures for making changes to authorisations issued under this section shall be governed by Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334/7, 12.12.2008).

Chapter Four
CLINICAL TRIALS
Section I
General provisions

Article 81. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of REGULATION (EU) No. 536/2014) (1) Clinical trials in the territory of the Republic of Bulgaria can be conducted after an authorisation has been obtained pursuant to the conditions and procedures set out in REGULATION (EU) No. 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158/1, 27.5.2014), hereinafter referred to as Regulation (EU) No. 536/2014, and pursuant to the conditions and procedures set out in this Act.
(2) The Bulgarian Drug Agency performs the activities of a reporting Member State or a Member State concerned or an additional Member State concerned, as the case may be, within the meaning of Regulation (EC) No. 536/2014; the agency is also the national contact point under Article 83 of Regulation (EC) No. 536/2014.

Article 82. (Amended, SG No. 71 of 2008, effective 12.08.2008, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) (1) In order to obtain a clinical trial authorisation or an authorisation for substantial modification to an authorised clinical trial, the sponsor shall submit an application and application dossier under Chapter IV of Regulation (EC) No. 536/2014 through the European Union (EU) portal referred to in Article 80 of Regulation (EC) No. 536/2014.

(2) The sponsor shall pay a fee for the submission of applications under paragraph 1 and for the evaluation of documentation enclosed with an application; the amount of the fee is set out in the rate schedule under Article 21(2).

Article 83. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) The Commission referred to in Article 103(1) shall assess the ethical aspects of a clinical trial or the substantial modification of a clinical trial in compliance with the conditions and procedures laid down in Regulation (EC) No. 536/2014 and shall submit its reasoned opinion to the Bulgarian Drug Agency.

Article 84. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) (1) The Bulgarian Drug Agency shall issue authorisations of a clinical trial, authorisations of a clinical trial subject to conditions, authorisations of a substantial modification to a clinical trial, and authorisations of a substantial modification to a clinical trial subject to conditions - or refuse to issue an authorisation - pursuant to the conditions and procedures laid down in Regulation (EC) No. 536/2014.

(2) A refusal under Paragraph 1 shall be subject to appeal under the Administrative Procedure Code.

Article 85. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) In a regulation, the Minister of Health shall determine:

1. the conditions and procedures for the submission of data and information by the Bulgarian Drug Agency and the Ethics Committee on Clinical Trials to the EU portal referred to in Article 80 of Regulation (EC) No. 536/2014;
2. the access of the Bulgarian Drug Agency and the Ethics Committee on Clinical Trials to the EU database referred to in Article 81 of Regulation (EC) No. 536/2014;
3. the conditions and procedures for the submission of opinions under Article 83, as well as the procedures for interaction between the Bulgarian Drug Agency and the Ethics Committee on Clinical Trials;
4. the documents and data in Annex I and Annex II to Regulation (EC) No. 536/2014 which are evaluated by the Bulgarian Drug Agency and the Ethics Committee on Clinical Trials, as well as the language of use.

Article 86. (1) (Supplemented, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) All persons carrying out a clinical trial must have the relevant professional qualifications, training and experience to perform the trial-related tasks in accordance with good clinical practice under Regulation (EC) No. 536/2014.

(2) The clinical testing of a medicinal product shall take place under the guidance of a physician or a doctor of dental medicine with a recognised medical specialisation in the respective area, who shall be aware of the available preclinical and/or clinical data about the product and the study risks and procedures.

(3) A physician with suitable qualifications or a doctor of dental medicine shall be responsible for the medical care provided to test subjects during the clinical trial, and for making medical decisions.

Article 87. (1) (Amended, SG No. 59/2010, SG No. 60/2011, effective 5.08.2011; supplemented, SG No. 84/2018, effective 12.10.2018) Clinical trials may be conducted in inpatient care medical facilities, mental health centres, dermal and venereal centres, integrated cancer centres, dialysis centers, diagnostic and consultative centres, medical centres, dental centres, dental medical centres, as well as private or group practice for primary and specialised medical care granted an authorisation/registration certificate pursuant to the Medical-Treatment Facilities Act.

(2) (New, SG No. 84/2018, effective 12.10.2018) A clinical trial of medicinal products containing narcotic substances can be conducted only in inpatient care medical facilities, mental health centres, dermal and venereal centres, and integrated cancer centres with an in-house pharmacy granted a licence pursuant to Article 33(1) of the Narcotic Substances and Precursors Control Act; alternatively, these can be facilities that have entered into an agreement with another medical

treatment facility with an in-house pharmacy granted a licence pursuant to Article 33(1) of the Narcotic Substances and Precursors Control Act.
(3) (Renumbered from Paragraph (2), amended, SG No. 84/2018, effective 12.10.2018) Clinical trials may be conducted only in a medical facility which has a contact person appointed under Article 107a(1).
(4) (Renumbered from Paragraph (3), SG No. 84/2018, effective 12.10.2018) The head of the treatment establishment in which a medicinal product is to be tested shall give consent for the participation of the chief researcher and for the conducting of the trial.

Article 88. (1) Clinical testing on humans shall be carried out for:
1. medicinal products not authorised in the Republic of Bulgaria;
2. medicinal products that have been authorised in the Republic of Bulgaria when tested for an unauthorised indication, for a pharmaceutical form other than the authorised one, in a group of patients who have not been studied so far or for obtaining additional information.
(3) Medicinal products authorised in the Republic of Bulgaria, within the meaning of Paragraph 1, item 2, shall be those that have obtained marketing authorisation in compliance with this Act or Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

Article 89. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 90. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 91. The sponsor and the chief researcher shall make an insurance covering their liability for material and immaterial damage caused to subjects during or on the occasion of clinical testing.

Article 92. (1) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) The sponsor shall be held responsible for any damage to health or death caused during or in relation to a clinical trial, when the trial is conducted in accordance with the requirements and procedures of the approved protocol.
(2) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) The principal investigator shall be held responsible for any damage to health or death caused during or in relation to a clinical trial, when the requirements or procedures of the approved protocol have not been observed.

Article 93. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) (1) When a clinical trial is conducted only in the territory of the Republic of Bulgaria, or in the Republic of Bulgaria and in the territory of a third country, the sponsor shall designate a representative for the clinical trial concerned in the Republic of Bulgaria.
(2) The person referred to in paragraph 1 is the addressee of communications with the sponsor, as provided for in Regulation (EC) No. 536/2014.

Article 94. The sponsor shall ensure the tested medicinal product(s) and all articles required for its administration free of charge.

Article 95. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 96. (1) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) Clinical trials of medicinal products shall be allowed to only involve subjects who have given their written informed consent.
(2) (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
(3) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) Informed consent under Chapter V of Regulation (EC) No. 536/2014 can be only given by a person of full capacity who understands the

substance, meaning, scope and possible risks of the clinical trial. The informed consent for participation in a clinical trial may be withdrawn at any time.
(4) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) Informed consent under Chapter V of Regulation (EC) No. 536/2014 for an incapacitated adult shall be given by their legal representative. The consent given by the legal representative must represent the presumable will of the subject in the trial and may be withdrawn at any time with no negative consequences for the subject.
(5) In the cases under Article 162, Paragraph 3 of the Health Act, informed consent shall be given by a person appointed by the court.
(6) Incapacitated adults shall be provided with information about the trial, the possible risks and benefits, which shall correspond to their ability of understanding.
(7) The express wish of an incapacitated adult to refuse taking part or to withdraw at any time from the clinical trial must be taken into account by the researcher and, where necessary, by the chief researcher.

Article 97. (1) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) Clinical trials involving a minor under 14 years of age shall be conducted on the basis of written informed consent given by both parents or the guardians of the person concerned in compliance with Chapter V of Regulation (EC) No. 536/2014 and Article 96(3).
(2) The consent of the parents and legal guardians must represent the presumed will of the minor and may be withdrawn at any time without negative consequences for him.
(3) The express wish of the child to refuse taking part or to withdraw at any time from the clinical trial must be taken into account by the researcher and, where necessary, by the chief researcher.
(4) (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) Clinical trials involving a minor between 14 and 18 years of age shall be conducted on the basis of written informed consent given by the person concerned and both parents or the person's guardian in compliance with Chapter V of Regulation (EC) No. 536/2014 and Article 96(3). When one of the parents is unknown, deceased or deprived of parental rights, or do not have such rights in cases of divorce, written informed consent is given by the minor and the parent who has custody over the child.
(5) The consent of the minor, of the parents or of the custodian may be withdrawn at any time without negative consequences for the minor.
(6) The express wish of the minor to withdraw at any time from the clinical trial must be taken into account by the researcher and, if necessary, by the chief researcher.
(7) The child or minor shall be given information about the trial and about the possible risks and benefits in a way that will ensure understanding by a physician who has experience with children and minors.

Article 98. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 99. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section II
(Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014)
Clinical trials with vulnerable groups of patients

Article 100. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 101. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 102. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section III
Ethical Committee for clinical trials
(Title amended, SG No. 84/2018, effective 12.10.2018)

Article 103. (Amended, SG No. 60 of 2011, effective 5.08.2011, SG No. 84/2018, effective 12.10.2018) (1) An Ethics Committee on Clinical Trials shall be set up under the Minister of Health; the committee members, including standing and reserve members, shall be appointed in an order of the Minister of Health. Reserve members participate in the meetings of the committee and have the right to vote in the absence of standing members.

(2) The committee referred to in paragraph 1 consists of 7 to 12 standing members, including a chair and a vice-chair, who shall have qualifications and experience to review and assess the scientific, medical and ethical aspects of a proposed clinical trial. The requirements for the qualifications of the committee members under paragraph 1, as well as the conditions and procedures for nominating the committee members hall be set out in the rules of procedure under Article 106(1).

(3) The committee referred to in paragraph 1 includes at least two standing members, from both genders, with non-medical education.

(4) For work purposes, the committee referred to in paragraph 1 may employ external professionals.

(5) Only members of the committee referred to in paragraph 1 who are not in conflict of interest, are not involved in a particular trial and are independent (of the sponsor, the hospital where a clinical trial is being conducted and the principal investigator) may participate in assessments under of Article 83 and vote, as well as participate in the discussion.

(6) Persons who are not in conflict of interest, are not involved in a particular trial and are independent (of the sponsor, the hospital where a clinical trial is being conducted and the principal investigator) may be employed as external professionals under paragraph 4.

(7) The members of the committee referred to in paragraph 1 and external professionals under paragraph 4 may not have private interest or benefits that might affect their impartiality in assessments under Article 83.

(8) In order to attest to the circumstances referred to in paragraphs 5 - 7, the members of the committee referred to in paragraph 1 and external professionals under paragraph 4 shall sign a statement following the procedures and model form indicated in the Rules of Procedure referred to in Article 106(1).

Article 104. (Repealed, SG No. 84/2018, effective 12.10.2018).

Article 105. (1) (Amended, SG No. 84/2018, effective 12.10.2018) The term of office of the members of the commission under Article 103, Paragraph 1 shall be four years.

(2) (Amended, SG No. 84/2018, effective 12.10.2018) Every two years half of the ethics committees' composition under Article 103, Paragraph 1 shall be renewed.

(3) (Amended, SG No. 84/2018, effective 12.10.2018) No ethics committee member under Article 103, Paragraph 1 may be appointed to the same committee for more than two consecutive terms of office.

Article 106. (Amended, SG No. 84/2018, effective 12.10.2018) (1) The Minister of Health shall approve Rules of Procedure and Operation concerning the work of the committee referred to in Article 103(1).

(2) The committee referred to in Article 103(1) shall develop and adopt written standard operating procedures in accordance with the rules of good clinical practice.

(3) The committee referred to in Article 103(1) shall meet in camera.

Article 107. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 107a. (New, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) (1) The heads of medical facilities where clinical trials are conducted shall appoint a contact person or contact persons.

(2) The contact person or persons referred to in paragraph 1 shall have qualifications and experience to monitor ongoing clinical trials in the medical facility so as to ensure compliance with the rules of good clinical practice.
(3) The requirements concerning the qualifications of contact persons referred to in paragraph 1 shall be set out in the Rules of Procedure under Article 106(1).
(4) Upon ascertaining any deviation from the approved protocol and/or adverse effects having occurred during a clinical trial which have not been reported pursuant to Regulation (EC) No. 536/2014, the contact person referred to in paragraph 1 shall notify the Bulgarian Drug Agency and the committee referred to in Article 103(1).

Article 108. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section IV
Authorisation to conduct clinical trials

Article 109. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 110. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 111. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 112. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 113. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 114. (1) (Amended, SG No. 84/2018, effective 12.10.2018) In order to obtain an opinion under Article 83, the sponsor shall submit an application to the committee referred to in Article 103(1).
(2) (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
(3) (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82 (3) of Regulation (EC) No. 536/2014).
(4) (New, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82 (3) of Regulation (EC) No. 536/2014).

Article 115. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 116. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 117. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 118. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 119. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 120. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 121. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 122. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 123. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 124. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 125. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section V
(Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014)
Changes

Article 126. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 127. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 128. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 129. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 130. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 131. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section VI
(Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014)
Suspension of the clinical trial

Article 132. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 133. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 134. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section VII
(Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014)
Safety Follow-up

Article 135. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 136. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 137. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 138. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 139. (Amended, SG No. 71/2008, effective 12.08.2008, SG No. 102/2012, effective 21.12.2012, repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82 (3) of Regulation (EC) No. 536/2014).

Article 140. (Amended, SG No. 102/2012, effective 21.12.2012, repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82 (3) of Regulation (EC) No. 536/2014).

Article 141. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Section VIII
(Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014)
Notification of completion of the clinical trial

Article 142. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 143. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Article 144. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).

Chapter Four "a"
(Previous Section IX from Chapter Four, SG No. 12/2011, effective 8.02.2011)
Non-interventional studies
(Title amended, SG No. 12/2011, effective 8.02.2011)

Article 145. (1) (Supplemented, SG No. 12/2011, effective 8.02.2011) A non-interventional study shall be conducted with the use of medicinal products authorised in the Republic of Bulgaria when they are tested in order to obtain additional information about the product prescribed in the usual way, while complying with the terms specified in the marketing authorisation. No diagnostic or monitoring procedures that differ from the common practice shall be administered in respect of the participants in non-interventional studies. Epidemiological methods shall be used to analyse the data obtained.

(2) (Amended, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 102/2012, effective 21.12.2012).

(3) (Amended, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 102/2012, effective 21.12.2012).

(4) (New, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 102/2012, effective 21.12.2012).

(5) (New, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 102/2012, effective 21.12.2012).

(6) (New, SG No. 12/2011, effective 8.02.2011, repealed, SG No. 102/2012, effective 21.12.2012).

Article 145a. (New, SG No. 102/2012, effective 21.12.2012) (1) Non-interventional post-marketing safety studies shall be conducted on the initiative of the market authorisation holder or pursuant to the conditions under Articles 55a and 56a, and shall be connected with gathering of drug safety data from patients and medical specialists.

(2) (Amended, SG No. 17/2019) When gathering of data from patients is planned in the study, their prior consent shall be obtained. The patients' personal data shall be processed in compliance with the requirements for the protection of personal data.

(3) Medical specialists shall not receive financial or other incentives for participation in non-interventional safety studies, except for compensations for the time and means spent.

Article 145b. (New, SG No. 102/2012, effective 21.12.2012) (1) During the conducting of the study under Article 145c, Paragraph 1 and Article 145f, Paragraph 1, the marketing authorisation holder shall monitor the data obtained and shall record their effect on the benefit/risk ratio for the medicinal product.

(2) The marketing authorisation holder shall report to the Bulgarian Drug Agency any new information that might influence the benefit/risk ratio of the medicinal product.

(3) The obligation under Paragraph 2 shall not exempt the marketing authorisation holder of the requirement under Article 194h to submit the information under Paragraph 2 also with the periodic updated safety reports.

Article 145c. (New, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 84/2018, effective 12.10.2018) When a study is conducted only in the territory of the Republic of

Bulgaria in order to comply with an obligation under Article 56a, the holder of the marketing authorisation shall submit the draft protocol of the study to the Bulgarian Drug Agency. The draft protocol, along with a written consent under Article 145(2), shall be also be submitted to the committee referred to in Article 103(1).
(2) The Bulgarian Drug Agency Executive Director shall send to the marketing authorisation holder a notification on the approval of the study or shall make a motivated refusal within 60 days of receiving the documentation under Paragraph 1.
(3) The Bulgarian Drug Agency Executive Director shall refuse the conducting of the study with one or more of the motives under Article 145f, Paragraph 2, item 2.
(4) (Amended, SG No. 84/2018, effective 12.10.2018) No later than 60 days from the date of receiving the documentation under paragraph 1, the committee referred to in Article 103(1) shall send a positive or negative opinion to the marketing authorisation holder.
(5) (Amended, SG No. 84/2018, effective 12.10.2018) The conducting of the study may start after approval by the Bulgarian Dug Agency and positive opinion by the committee under Article 103, Paragraph 1 has been received.
(6) The Bulgarian Drug Agency shall collect a fee in an amount determined in the Tariff under Article 21, Paragraph 2 for the evaluation of the documentation under Paragraph 1.

Article 145d. (New, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 84/2018, effective 12.10.2018) The marketing authorisation holder shall apply planned substantial changes in the protocol in the cases under Article 145c, Paragraph 1, subject to their prior approval by the Bulgarian Drug Agency and by the committee under Article 103, Paragraph 1.
(2) (Amended, SG No. 84/2018, effective 12.10.2018) The marketing authorisation holder shall submit the documentation connected with the changes and the motives for them to the Bulgarian Drug Agency and to the committee under Article 103, Paragraph 1.
(3) Within 30 days of receiving the documentation under Paragraph 2, the Bulgarian Drug Agency Executive Director shall approve the modified protocol or shall issue a motivated refusal, notifying the marketing authorisation holder.
(4) (Amended, SG No. 84/2018, effective 12.10.2018) The committee under Article 103, Paragraph 1 shall send a positive or negative opinion to the marketing authorisation holder within 30 days after the date on which the documentation under Paragraph 2 was received.
(5) The Bulgarian Drug Agency Executive Director shall refuse the changes under Paragraph 1 citing one or more of the motives under Article 145f, Paragraph 2, item 2.
(6) (Amended, SG No. 84/2018, effective 12.10.2018) The marketing authorisation holder may apply the changes under Paragraph 1 subject to receiving approval by the Bulgarian Drug Agency and a positive opinion of the committee under Article 103, Paragraph 1.
(7) The Bulgarian Drug Agency shall collect a fee in an amount determined in the Tariff under Article 21, Paragraph 2 for the evaluation of the documentation under Paragraph 1.

Article 145e. (New, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall present the final report on the study to the Bulgarian Drug Agency within 12 months after completing the data gathering. The report shall also be accompanied by a summary of the results of the study.
(2) The marketing authorisation holder may file a motivated request to the Bulgarian Drug Agency for postponement of the deadline under Paragraph 1 no less than three months prior to the date on which the final report indicated in the protocol is to be submitted.
(3) The Bulgarian Drug Agency shall approve or shall give a motivated refusal of the request under Paragraph 2, and shall notify the marketing authorisation holder thereof.
(4) When the marketing authorisation holder decides on the grounds of the report under Paragraph 1 that a change in the marketing authorisation is needed, he shall file a request for change to the Bulgarian Drug Agency in compliance with Chapter Three, Section VI.
(5) The Bulgarian Drug Agency Executive Director shall suspend or terminate the marketing authorisation when the Bulgarian Drug Agency judges, based on the report under Paragraph 1 and

following consultations with the marketing authorisation holder, that a suspension or termination of the marketing authorisation is necessary.

Article 145f. (New, SG No. 102/2012, effective 21.12.2012) (1) When the study is conducted both on the territory of the Republic of Bulgaria and on the territory of other Member States, for medicinal products authorised in compliance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council or under Chapter Three, Section VII, discharging the obligations under Article 55a or under Article 56a, the marketing authorisation holder shall file the draft protocol to the committee under Article 56a, Paragraph 1, item 1.

(2) Within 60 days from the receipt date of the documentation under Paragraph 1, the committee under Article 56a, Paragraph 1, item 1 shall draft an opinion and shall send to the marketing authorisation holder:

1. notification of approval, or
2. motivated refusal when:

(a) he finds that the conducting of the study encourages the use of the medicinal product,, and/or

(b) he judges that the study design will not attain the goals set in the protocol, and/or

(c) the study has the character of a clinical trial.

(3) (Amended, SG No. 84/2018, effective 12.10.2018) In the cases under Paragraph 2, item 1, the marketing authorisation holder shall submit the notification to the Bulgarian Drug Agency.

(4) (Amended, SG No. 84/2018, effective 12.10.2018) The committee under Article 103, Paragraph 1 shall send a positive or negative opinion to the marketing authorisation holder within fifteen days of the date of receiving the notification under Paragraph 3.

(5) (Amended, SG No. 84/2018, effective 12.10.2018) The conducting of the study may start upon receiving a positive opinion of the committee under Article 103, Paragraph 1.

(6) The content and the format of the protocol under Paragraph 1 shall be determined with Implementing Regulation (EU) No. 520/2012 of the European Commission of 19 June 2012 concerning activities in the sphere of pharmacovigilance envisaged in Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and in Directive 2001/83/EC of the European Parliament and of the Council (OJ, L 159/5 of 20 June 2012), referred hereafter as "Implementing Regulation (EU) No. 520/2012."

Article 145g. (New, SG No. 102/2012, effective 21.12.2012) (1) In the cases under Article 145f, Paragraph 1, the marketing authorisation holder shall apply planned changes in the study protocol following their preliminary approval by the committee under Article 56a, Paragraph 1, item 1.

(2) The marketing authorisation holder shall submit to the committee under Article 56a, Paragraph 1, item 1 the documentation connected with the changes, and motives thereof.

(3) (Amended, SG No. 84/2018, effective 12.10.2018) When the committee under Article 56a, Paragraph 1, item 1 approves the changes in the protocol, the marketing authorisation holder shall notify the Bulgarian Drug Agency and the committee under Article 103, Paragraph 1.

(4) (Amended, SG No. 84/2018, effective 12.10.2018) The marketing authorisation holder may apply the changes under Paragraph 1 after receiving a positive opinion from the committee under Article 103, Paragraph 1.

Article 145h. (New, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall submit to the committee under Article 56a, Paragraph 1, item 1 the final report in electronic form, together with a summary of the results of the study within 12 month after the data gathering has been completed.

(2) The marketing authorisation holder may file a motivated request to the committee under Article 56a, Paragraph 1, item 1 for the deadline under Paragraph 1 to be extended no less than three months prior to the date for submitting the final report, indicated in the protocol.

(3) The committee under Article 56a, Paragraph 1, item 1 shall approve the request under Paragraph 2 or shall give a motivated refusal thereof, and shall notify the marketing authorisation holder accordingly.

(4)The content and the format of the report under Paragraph 1 shall be determined under the Implementing Regulation (EC) No. 520/2012.

Article 145i. (New, SG No. 102/2012, effective 21.12.2012) (1) On the basis of the report under under Article 145h, Paragraph 1, and following consultations with the marketing authorisation holder, the committee under Article 56a, Paragraph 1, item 1 shall issue a motivated recommendation concerning the marketing authorisation of the medicinal product and shall send it to:

1. The Committee for Medicinal Products for Human Use under Article 5 of Regulation (EC) No. 726/2004 of the European Parliament or of the Council, or
2. the Coordination Group under Article 77, Paragraph 2.

(2) In the cases under Paragraph 1, item 2, when the committee under Article 56a, Paragraph 1, item 1 has recommended change, suspension or termination of the marketing authorisation, the Coordination Group represented by the Member States in which the study has been conducted shall issue an opinion on the necessary actions to be undertaken with respect to the marketing authorisation, including a schedule for its implementation.

(3) When the Member States represented in the Coordination Group reach consensus on the opinion under Paragraph 2, it shall be posted on the European Internet portal for medicinal products under Article 68, Paragraph 1, item 4, and shall be sent to the marketing authorisation holder.

(4) In compliance with the opinion under Paragraph 2, the Bulgarian Drug Agency Executive Director shall suspend or terminate the marketing authorisation.

(5) Where changes in the marketing authorisation have been recommended in the opinion under Paragraph 2, the marketing authorisation holder shall file an application for modification under Chapter Three, Section VI to the Bulgarian Drug Agency, within the set schedule for implementation, which shall comprise an updated product summary and leaflet.

(6) In the event that no agreement can be reached within the Coordination Group, the position of the majority of Member States shall be submitted to the European Commission, which shall adopt a decision on the modification, suspension or termination of the marketing authorisation issued by the respective regulatory bodies of the Member States.

(7) The decision under Paragraph 6 shall be posted on the European Internet portal for medicinal products under Article 68, Paragraph 1, item 4 and shall be sent to the marketing authorisation holder.

(8) The Bulgarian Drug Agency shall apply the provisional and/or definitive measure under Paragraph 6 and shall inform the European Medicines Agency and the European Commission thereof.

(9) In the cases under Paragraph 1, item 1, the Committee for Medicinal Products for Human Use shall issue an opinion on the preservation, modification, suspension or termination of the marketing authorisation validity, including a schedule for the implementation of the opinion, in compliance with the recommendation of the committee under Article 56a, Paragraph 1, item 1. The opinion shall be posted on the European Internet portal for medicinal products under Article 68, Paragraph 1, item 4, and shall be sent to the marketing authorisation holder.

(10) When a position on undertaking regulatory actions with respect to the marketing authorisations is expressed in the opinion under Paragraph 9, the European Commission shall adopt a decision on modification, suspension or termination of the marketing authorisations issued under Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

Article 145j. (New, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 84/2018, effective 12.10.2018) Non-interventional studies on the territory of the Republic of Bulgaria shall be conducted in an ordinance issued by the Minister of health.

(2) When non-interventional studies under Paragraph 1 are conducted, the source of financing shall be indicated.

Chapter Five
MANUFACTURING AND IMPORT OF MEDICINAL PRODUCTS AND ACTIVE SUBSTANCES
(Title amended, SG No. 102/2012, effective 2.01.2013)
Section I
Manufacturing

Article 146. (1) (Amended, SG No. 102/2012, effective 2.01.2013) The manufacturing of all types of medicinal products within the meaning of this Act and of medicinal products intended for clinical trial may be carried out on the territory of the Republic of Bulgaria only by natural and legal persons registered as traders on the territory of Member States, who have obtained an authorisation for manufacturing, issued by the Bulgarian Drug Agency Director.
(2) A manufacturing authorisation shall also be required in cases where products under Paragraph 1 are only intended for export.
(3) (Amended, SG No. 71/2008, effective 12.08.2008) A manufacturing authorisation shall also be required for persons who simultaneously or separately carry out one of the following operations: complete or partial manufacturing, different processes of preparation for packaging, packaging, repackaging, labelling, quality control and releasing of batches of medicinal products and of medicinal products intended for clinical trials.
(4) (Repealed, SG No. 71/2008, effective 12.08.2008).
(5) No manufacturing authorisation shall be required where the process of preparation for packaging, mixing or packaging takes place in accordance with an official or magisterial formulation in a pharmacy.

Article 147. (Amended, SG No. 102/2012, effective 2.01.2013) The Bulgarian Drug Agency shall introduce information on the authorisations for manufacturing of medicinal products and on the Good Manufacturing Practice certificates issued into the EU database.

Article 148. In order to obtain a manufacturing authorisation, the person under Article 146 shall be obliged to have:
1. suitably qualified staff, depending on the specificity of the medicinal products and pharmaceutical forms manufactured;
2. at any point in time, at least one qualified individual meeting the conditions of Article 159;
3. premises for manufacturing, controlling and storing medicinal products having the required technical equipment and control laboratories.

Article 149. Heads of production and control over the quality of medicinal products at the manufacturing facilities shall be individuals:
1. with an educational and qualification degree of "master" in the specialised area of "pharmacy", "chemistry" or "biology" and at least two years of practical experience in pharmaceutical manufacturing;
2. meeting the requirements under item 1 and having a recognised additional specialisation in radiobiology or radiochemistry with regard to radiopharmaceuticals or medicinal products subjected to ionising radiation;
3. having a recognised specialisation in clinical haematology, medical microbiology, virology or immunology with regard to manufacturing immunological medicinal products, i.e., vaccines, toxins, serums, biotechnological products and medicinal products obtained from human plasma or human blood.

Article 150. (1) The person under Article 146 shall submit with the Bulgarian Drugs Agency an application based on a model approved by the Agency Director.
(2) The following shall also be submitted by the applicant together with the application under Paragraph 1:
1. (supplemented, SG No. 103/2017, effective 1.01.2018, amended, SG No. 67/2020) a higher education diploma, a document of acquired specialisation, a document evidencing record of service, and an employment contract for the persons under Article 148, item 2 and Article 149;

2. copies of contracts for entrusting the manufacturing and/or control of the products for whose manufacturing an application is made in the cases under Article 151;
3. (amended, SG No. 71/2008, effective 12.08.2008, SG No. 60/2011, effective 5.08.2011) details of the Unified ID code of the trader or cooperative from the Commercial Register and an up-to-date registration certificate under the respective national laws, issued by the relevant country's competent authority in the case of companies registered in Member States of the European Union or states signatories to the European Economic Area Agreement;
4. (amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 2.01.2013) a list of manufacturing activities and pharmaceutical forms to be manufactured;
5. drawings of manufacturing, control and storage premises, and a dossier for the production facility;
6. an environmental impact assessment when medicinal products are manufactured in cases provided for under the Environmental Protection Act;
7. an authorisation from the Nuclear Regulation Agency when the application concerns the manufacturing of radio pharmaceuticals or of medicinal products subjected to ionising radiation during manufacturing;
8. (repealed, SG No. 67/2020);
9. (repealed, SG No. 60/2011, effective 5.08.2011);
10. a document evidencing the payment of a fee at the amount specified in the Tariff under Article 21, Paragraph 2.
(3) The requirements of the Narcotic Substances and Precursors Control Act shall also be observed when narcotic substances and pharmaceutical forms containing these substances are manufactured.
(4) (New, SG No. 103/2017, effective 1.01.2018, amended, SG No. 67/2020) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the conviction status of the persons under Article 148, item 2 and of the persons under Article 149 where such persons are Bulgarian citizens. Persons who are not Bulgarian citizens shall submit together with the application a certificate of clean criminal record or an equivalent document, issued by a competent authority of the relevant country.
(5) (New, SG No. 67/2020) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the existence of a marketing authorisation or a certificate for commissioning into operation of the production, control an storage premises, issued pursuant to the Spatial Development Act, or another valid document within the meaning of the Spatial Development Act.

Article 151. When some stages of the manufacturing or control trials during the production process are carried out, by virtue of a contract, in another site on the territory of the Republic of Bulgaria or outside it, the persons under Article 146 shall be obligated to indicate the location of this site and to submit a copy of the contract, specifying the duties of each of the parties with regard to the compliance with the requirements of Good Manufacturing Practice in respect to medicinal products, as well as the obligations of the qualified person under Article 148, item 2.

Article 152. (Amended, SG No. 102/2012, effective 2.01.2013) (1) The principles and requirements for Good Manufacturing Practice for all types of medicinal products, for medicinal products for clinical trial and for active substances shall be stipulated with an Ordinance of the Minister of Health, and with acts and guidelines adopted by the European Commission.
(2) The principles and requirements for official risk assessment with a view to establishing Good Manufacturing Practice for excipients shall be stipulated with the Ordinance under Paragraph 1 and with guidelines adopted by the European Commission.

Article 153. (1) When an application under Article 150 is received, the Bulgarian Drugs Agency shall evaluate the documentation filed and shall conduct an on-site inspection of the manufacturing, control and storage sites, also including the cases under Article 151, in order to establish the level of compliance of the submitted documentation with the manufacturing, control and storage conditions applicable to starting materials used in manufacturing and the latter's conformity to the requirements of Good Manufacturing Practice.

(2) The costs of the on-site inspection under Paragraph 1 shall be borne by the applicant.
(3) In order to have an on-site inspection under Paragraph 1 carried out, the applicant shall pay a fee at the amount specified in the Tariff under Article 21, Paragraph 2.

Article 154. (1) When the Bulgarian Drug Agency finds incompleteness of the submitted documentation and/or non-compliance of the content of the submitted documentation with the state of affairs on site or with the requirements to the staff qualification, it shall notify the applicant in writing and shall issue written instructions.
(2) In the cases under Paragraph 1, the period under Article 155, Paragraph 1 shall be suspended until the site or the documentation is brought in line with the requirements.

Article 155. (1) (Amended, SG No. 84/2018, effective 12.10.2018) The Bulgarian Drug Agency Executive Director, within a period of 60 days of submission of the application under Article 150, shall:
1. issue a manufacturing authorisation, or
2. give a motivated refusal.
(2) (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 2.01.2013) A manufacturing authorisation shall only be issued in respect to the manufacturing activities and pharmaceutical forms, and medicinal products intended for clinical trials indicated in the application, and in respect to the premises in which manufacturing, control and storage is to take place.
(3) The acts under Paragraph 1 shall be served on the applicant.
(4) A manufacturing authorisation shall not be limited in time.
(5) A refusal under Paragraph 1, item 2 shall be subject to appeal under the Administrative Procedure Code.

Article 156. (1) The manufacturing authorisation holder shall file an application in case there is a change in:
1. the person under Article 148, item 2;
2. the persons under Article 149;
3. (repealed, SG No. 60/2011, effective 5.08.2011);
4. the location or restructuring of one of the manufacturing, control or storage sites;
5. (amended, SG No. 60/2011, effective 5.08.2011) manufacturing activities;
6. (amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 2.01.2013) the pharmaceutical forms manufactured;
7. (amended, SG No. 60/2011, effective 5.08.2011) the commercial registration.
(2) (Amended, SG No. 67/2020) The application under paragraph 1 shall be accompanied by documents relating to the change, as set out in Article 156a and a document in proof a paid fee in the amount as set out in the tariff referred to in Article 21, paragraph 2.
(3) (New, SG No. 60/2011, effective 5.08.2011) Within 14 days of any changes to the equipment the manufacturing authorisation holder shall inform the Bulgarian Drug Agency in writing.
(4) (New, SG No. 60/2011, effective 5.08.2011) In case the manufacturing authorisation holder starts manufacturing any new authorised medicinal product they shall submit a notification to the Bulgarian Drug Agency.
(5) (Renumbered from Paragraph 3, SG No. 60/2011, effective 5.08.2011) A manufacturing authorisation shall be terminated in case its holder terminates operation, of which he shall be obligated to notify the Bulgarian Drugs Agency.

Article 156a. (New, SG No. 67/2020) (1) In case of any change under Article 156, paragraph 1, items 1 and 2, the applicant shall submit:
1. a diploma for completed higher education;
2. an employment contract;
3. documents certifying additional qualification;
4. a document evidencing record of service.
(2) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the conviction status of the persons under Item 148 of Paragraph 2 where such persons are Bulgarian

citizens under Article 149. Persons who are not Bulgarian citizens shall submit together with the application a certificate of clean criminal record or an equivalent document, issued by a competent authority of the relevant country.
(3) In case of any change under Article 156, paragraph 1, item 4, the applicant shall submit the following documentation in relation to the relevant change:
1. a layout drawing of the construction or reconstruction of the production, control and storage premises;
2. an environmental impact assessment of the production of the medicinal products – in the cases provided for under the Environmental Protection Act;
3. a validation master plan including the premises change is applied for;
4. a copy of the contract, where some of the medicinal product manufacturing, control and storage activities are performed on another site in the territory of the Republic of Bulgaria or outside it.
(4) In case of any change under Article 156, paragraph 1, item 4, the Bulgarian Drug Agency shall establish by official channels the circumstances regarding the existence of a marketing authorisation or a certificate for commissioning into operation of the manufacturing, control and storage premises, issued pursuant to the Spatial Development Act, or another valid document within the meaning of the Spatial Development Act.
(5) In case of any change under Article 156, paragraph 1, item 5, the applicant shall submit the following documentation:
1. a list of the standard operational procedures for manufacturing, control and cleaning;
2. a validation master plan including the processes change is applied for that are subject to validation.
(6) In case of any change under Article 156, paragraph 1, item 6, the applicant shall submit the following documentation:
1. a list of International Nonproprietary Names and trade names of the medicinal products, their pharmaceutical form, strength of the medicinal product and the quantity in the final packaging;
2. a list of the manufacturing, control and storage procedures of the medicinal products.
(7) In case of any change under Article 156, paragraph 1, item 7, the Bulgarian Drug Agency shall establish by official channels the circumstances regarding the trade registration changes applied for.

Article 157. (1) (Amended, SG No. 67/2020) The provisions of Article 155 shall apply to the issuance of the authorisation, by which the change is permitted, and the term for its issuance shall be:
1. 14 days, in the cases under Article 156, Paragraph 1, items 1, 2, and 7;
2. (amended, SG No. 60/2011, effective 5.08.2011) 30 days, in the cases under Article 156, Paragraph 1, items 4 - 6.
(2) (Amended, SG No. 60/2011, effective 5.08.2011) Where the changes under Article 156, Paragraph 1, items 4 - 6 may not be evaluated on the basis of documents, the Bulgarian Drugs Agency shall conduct an on-site inspection. In these cases the period under Paragraph 1, item 2 shall be suspended until completion of the inspection.
(3) The on-site inspection costs under Paragraph 2 shall be borne by the applicant.
(4) In order to have an on-site inspection conducted under Paragraph 2, the applicant shall pay the fee stipulated in the Tariff under Article 21, Paragraph 2.

Article 158. (1) The Bulgarian Drugs Agency shall keep a register under Article 19, Paragraph 1, item 1of the manufacturing licenses issued, which shall contain:
1. the number and date of the manufacturing authorisation;
2. the name, seat and business address of the person who has obtained a manufacturing authorisation;
3. the address of the manufacturing, control and storage premises for the drugs;
4. (amended, SG No. 102/2012, effective 2.01.2013) the medicinal products and formulations for which authorisation is obtained;
5. the names of persons under Article 148, item 2;
6. the names of persons under Article 149;

7. the date of deletion from the register of the manufacturing authorisation and the grounds to do so.
(2) Data from the register of issued manufacturing licenses shall be posted on the Bulgarian Drugs Agency website.
(3) Upon request from the European Commission or a regulatory body of a Member State, the Bulgarian Drug Agency shall provide information about a manufacturing authorisation it has issued.

Article 159. (1) The manufacturing authorisation holder shall hire under labour contract at least one qualified person under Article 148, item 2, who shall be permanently available to him.
(2) The qualified person under Paragraph 1 must meet the following requirements:
1. have a master's degree in medicine, pharmacy, chemistry, biotechnology or biology;
2. have at least two years of practical experience in pharmaceutical production and/or in performing qualitative and quantitative analysis of medicinal products and active substances.
(3) When the holder of a manufacturing authorisation for a medicinal product meets the requirements of Paragraph 2, he may discharge the obligations of a qualified person.
(4) (New, SG No. 102/2012, effective 21.12.2012) The qualified person shall be responsible for the presence of the safety indicators under Article 168, Paragraph 8 on the packaging of the medicinal product.
(5) (Renumbered from Paragraph 4, SG No. 102/2012, effective 21.12.2012) The qualified person shall issue a certificate of release for each batch, certifying that the batch of medicinal products has been manufactured and controlled in compliance with the requirements of the marketing authorisation under this Act.
(6) (Renumbered from Paragraph 5, SG No. 102/2012, effective 21.12.2012, amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) The qualified person shall issue a certificate of batch release, for each batch, certifying that a batch of medicinal products intended for a clinical trial has been manufactured and controlled in compliance with the requirements of good manufacturing practice, the product manufacturing dossier and the documentation on the investigational medicinal product according to Regulation (EC) No. 536/2014.
(7) (Renumbered from Paragraph 6, SG No. 102/2012, effective 21.12.2012) The qualified person shall keep a register of the issued certificates of release for each batch of the medicinal product concerned.
(8) (Renumbered from Paragraph 7 and amended, SG No. 102/2012, effective 21.12.2012) Data on the register under Paragraph 7 shall be stored for at least 5 years after the last entry and shall be presented upon request to the control bodies.
(9) (Renumbered from Paragraph 8, SG No. 102/2012, effective 21.12.2012) When penal administrative proceedings are instituted on account of violations committed in the discharge of the qualified person's duties, the Bulgarian Drug Agency shall order the manufacturing authorisation holder to temporarily relieve from office the qualified person.
(10) (Renumbered from Paragraph 9, SG No. 102/2012, effective 21.12.2012) The criteria and requirements to the qualifications and education of persons under Article 148, item 2, shall be specified in the Ordinance under Article 152.

Article 160. (1) The manufacturing authorisation holder shall:
1. (amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) ensure that manufacturing operations are conducted in compliance with the requirements of good manufacturing practice and the information under Article 27, paragraph 1(7) and (8) approved by the Bulgarian Drug Agency; in cases of medicinal products intended for a clinical trial, the manufacturing operations must be conducted in compliance with the documentation on the investigational medicinal product according to Regulation (EC) No. 536/2014;
2. (amended, SG No. 102/2012, effective 2.01.2013) use only active substances manufactured in compliance with the Good Manufacturing Practice requirements;
2a. (new, SG No. 102/2012, effective 2.01.2013) ascertain that the excipients used in the medicinal products have been manufactured in compliance with the relevant Good Manufacturing Practices

for excipients, determined on the basis of official risk assessment in accordance with the applicable guidelines adopted by the European Commission;
3. ensure the permanent presence of qualified staff for manufacturing and control in accordance with the requirements of the Ordinance under Article 152;
4. (amended, SG No. 12/2011, effective 8.02.2011) only have available medicinal products with marketing authorisation, subject to complying with the requirements of this Act;
5. (repealed, SG No. 12/2011, effective 8.02.2011);
6. notify immediately the control bodies in case the qualified person under Article 148, item 2 has been replaced;
7. ensure at any time access by control bodies to the premises and documentation;
8. provide the necessary conditions to the qualified person under Article 148, item 2, in order to allow him to proceed with his duties;
9. (new, SG No. 102/2012, effective 2.01.2013) inform immediately the Bulgarian Drug Agency and the marketing authorisation holder if it receives information that the medicinal products within the scope of his authorisation are counterfeit, or if there exist suspicions of counterfeiting, irrespective of whether these medicinal products have been distributed within the legal supply chain or illegally, including by means of illegal trade using the services of the information community;
10. (new, SG No. 102/2012, effective 2.01.2013) check whether the manufacturers, importers or traders from whom he is receiving active substances have been registered by the competent body of the Member State in which they are established;
11. (new, SG No. 102/2012, effective 2.01.2013) check the authenticity and quality of the active substances and excipients.
(2) (New, SG No. 102/2012, effective 2.01.2013) The manufacturing authorisation holder shall conduct audits at the sites for manufacturing of and trade in active substances with respect to compliance with the Good Manufacturing Practice and the Good Distribution Practice. The manufacturing authorisation holder may sign a contract with a third person who is to conduct the audit on his behalf and at his expense.
(3) (New, SG No. 102/2012, effective 2.01.2013) The manufacturing authorisation holder shall support with documents the measures undertaken under Paragraph 1, items 2 and 2a.
(4) (Renumbered from Paragraph 2, SG No. 102/2012, effective 2.01.2013, amended, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) The manufacturing authorisation holder shall store samples and documentation concerning medicinal products and active ingredients manufactured by the holder pursuant to the conditions and procedures set out in the ordinance referred to in Article 152(1).
(5) (Renumbered from Paragraph 3, SG No. 102/2012, effective 2.01.2013, repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014).
(6) (Renumbered from Paragraph 4, SG No. 102/2012, effective 2.01.2013) The documentation concerning any concluded transaction shall be kept for 5 years and shall specify the date, the name of the medicinal product, the amount supplied, the name and address of the recipient, and the batch number.
(7) (Renumbered from Paragraph 5, SG No. 102/2012, effective 2.01.2013) The manufacturing authorisation holder shall ensure and maintain a system for blocking and withdrawal from the market of medicinal products that have demonstrated lack of compliance with quality requirements.
(8) (Renumbered from Paragraph 6, SG No. 102/2012, effective 2.01.2013) The manufacturing authorisation holder shall be obligated to block and withdraw from the market the medicinal products that have demonstrated lack of compliance with the quality, efficacy and safety requirements in compliance with the Ordinance under Article 274, Paragraph 1.
(9) (Renumbered from Paragraph 7, SG No. 102/2012, effective 2.01.2013) The manufacturing authorisation holder shall be obligated to update the manufacturing methods following the development of new technologies and the production of medicinal products for trial.

(10) (New, SG No. 12/2011, effective 8.02.2011, renumbered from Paragraph 8 and amended, SG No. 102/2012, effective 2.01.2013) Based on the manufacturing authorisation issued as per the procedures laid down in this section, its holder may import excipients needed for the manufacturing of the medicinal products specified in the manufacturing authorisation.
(11) (New, SG No. 67/2020) The manufacturing authorisation holder shall indicate the safety features under Article 168, paragraph 8 on the outer packaging, and in its absence – on the immediate packaging of the medicinal products, as laid down in Delegated Regulation (EU) 2016/161.

Article 160a. (New, SG No. 60/2011, effective 5.08.2011) (1) Where the conditions laid down in Article 148 and the Good Manufacturing Practice requirements laid down in Article 152 have not been met, the Bulgarian Drugs Agency Executive Director shall withdraw the issued manufacturing authorisation by means of an order.
(2) The Bulgarian Drugs Agency Executive Director shall terminate the manufacturing authorisation by means of an order:
1. at the written request of its holder;
2. in case of winding up the activities for which it has been issued;
3. where the trader's registration has been deleted;
4. in case of death of the sole trader who is a natural person.
(3) The order provided for in Paragraph 1 shall be subject to appeal under the Administrative Procedure Code. The appeal shall not suspend the enforcement.

Section II
Import of medicinal products
(Title amended, SG No. 102/2012, effective 2.01.2013)

Article 161. (1) (Amended, SG No. 102/2012, effective 2.01.2013) Only natural and legal persons registered as traders in accordance with the legislation of a Member State, who have obtained import authorisation issued by the Bulgarian Drug Agency Executive Director, can import into the territory of the Republic of Bulgaria from third countries all types of medicinal products and medicinal products intended for clinical trials.
(2) In order to obtain import authorisation, the person under Paragraph 1 must have:
1. (amended, SG No. 102/2012, effective 2.01.2013) at any time, at least one qualified person meeting the requirements of Article 159, Paragraphs 2 and 10;
2. (amended, SG No. 102/2012, effective 2.01.2013) a quality control laboratory in accordance with the requirements of the Ordinance under Article 152 and premises for the storage of medicinal products and of medicinal products for clinical trials, having the necessary technical equipment subject to the requirements of the Ordinance under Article 198.

Article 162. (1) In order to obtain import authorisation, the person under Article 161, Paragraph 1 shall file with the Bulgarian Drugs Agency an application based on a model approved by the Bulgarian Drugs Agency Director.
(2) The following shall be attached to the application under Paragraph 1:
1. (amended, SG No. 71/2008, effective 12.08.2008, SG No. 60/2011, effective 5.08.2011) details of the Unified ID code of the trader or cooperation from the Commercial Register, and an up-to-date registration certificate under the respective national laws issued by the relevant country's competent authority in the case of companies registered in European Union or European Economic Area Agreement member-states;
2. (amended, SG No. 102/2012, effective 2.01.2013, SG No. 67/2020) a list of International Nonproprietary Names and trade names of the medicinal products, their pharmaceutical form, strength of the medicinal product and the quantity in the final packaging;
3. (supplemented, SG No. 71/2008, effective 12.08.2008) a copy of the manufacturing authorisation issued by the regulatory body of the exporting state and a certificate verifying the compliance of the conditions for the manufacturing, control and storage with standards that are at least equivalent to the standards of Good Manufacturing Practice;

4. documents certifying the circumstances under Article 159, Paragraphs 1 and 2 with regard to the qualified person;
5. data about the address of the laboratory on the territory of the Republic of Bulgaria that will carry out a full quantitative and qualitative analysis at least of the active substances and of all other tests and inspections substantiating the quality of each imported batch of medicinal products, in compliance with the requirements of the marketing authorisation in pursuance hereof, as well as the address of the storage premises;
6. a contract specifying the duties of each party with regard to the observation of the principles of Good Manufacturing Practice, by the contractor, and the way in which the qualified person under Article 161, Paragraph 2, item 1 shall discharge his obligations, in cases where the person under Article 161, Paragraph 1 has no laboratory of his own;
7. a document evidencing the payment of a fee specified in the Tariff under Article 21, Paragraph 2.
(3) (New, SG No. 71/2008, effective 12.08.2008) When the application under Paragraph 1 is received, the Bulgarian Drugs Agency shall assess the documentation filed and shall perform an on-site inspection of the control laboratory and of the premises for storage of medicinal products and of medicinal products intended for clinical trials, with a view to determining whether they are in compliance with the requirements of the Good Manufacturing Practice and of the Good Distribution Practice.
(4) (Renumbered from Paragraph 3, SG No. 71/2008, effective 12.08.2008) Where manufacturing premises are located in a third country with which the European Community has concluded an agreement for the mutual recognition of certificates of Good Manufacturing Practice, the persons under Article 161, Paragraph 1 shall attach to their application the address of all premises for the manufacturing of medicinal products, active substances or medicinal products intended for clinical trials, the name, seat and business address of the person who has obtained a manufacturing authorisation, a certificate of the compliance of manufacturing, control and storage conditions with standards that are equivalent to those approved under the requirements of Good Manufacturing Practice, and the name of the qualified person.
(5) (Renumbered from Paragraph 4, amended, SG No. 71/2008, effective 12.08.2008) In cases other than those under Paragraph 4, the Bulgarian Drugs Agency, where necessary, shall conduct an on-site inspection to establish compliance of the documentation with the manufacturing, control and storage conditions for medicinal products in the exporting state. When compliance is established with Good Manufacturing Practice, the Bulgarian Drugs Agency shall issue a certificate.
(6) (Renumbered from Paragraph 5, amended, SG No. 71/2008, effective 12.08.2008) The costs of the on-site inspection under Paragraph 5 shall be borne by the importer.
(7) (Renumbered from Paragraph 6, amended, SG No. 71/2008, effective 12.08.2008) In order to have an on-site inspection conducted under Paragraph 3 or under Paragraph 5, the applicant shall pay a fee at the amount specified in the Tariff under Article 21, Paragraph 2.

Article 163. (1) The qualified person under Article 161, Paragraph 2, item 1 shall issue a certificate for the release of each batch, evidencing that the batch of a medicinal product imported from a third country, irrespective of whether the product was manufactured or not in another Member State, prior to being placed on the territory of the Republic of Bulgaria, has been subjected to a full qualitative and quantitative analysis, at least of the active substances, and that all necessary trials and inspection, in compliance with the requirements for issuing a marketing authorisation in pursuance hereof, have been carried out.
(2) Where the batch of a medicinal product imported from a third country has been subjected to the analyses under Paragraph 1 in another Member State and is accompanied by a certificate of release thereof signed by another qualified person, no control trials on the territory of the Republic of Bulgaria shall be required.
(3) Where the batch of a medicinal product is imported from a third country with which the European Community has signed an agreement for the mutual recognition of certificates of Good Manufacturing Practice, a qualified person shall issue a certificate for release of the batch on the

basis of the documentation that accompanies the said batch, without having to carry out control trials on the territory of the Republic of Bulgaria.
(4) (Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014).
(5) (Repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014).
(6) (Amended, SG No. 71/2008, effective 12.08.2008, repealed, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014).
(7) The qualified person under Paragraph 1 shall store the documentation in respect to every batch of a medicinal product for at least 5 years and shall, upon request, submit it to the control bodies.
(8) The import authorisation holder shall ensure and maintain a system for blocking and market withdrawal of medicinal products that have shown lack of compliance with quality requirements.
(9) The import authorisation holder must block and withdraw from the market medicinal products that have shown lack of compliance with the requirements to safety and efficacy as per the Ordinance under Article 274, Paragraph 1.
(10) (Amended, SG No. 12/2011, effective 8.02.2011) The provisions of Article 160, Paragraph 1, items 4 and 7 shall also apply with respect to the holders of an import authorisation.
(11) The import authorisation holder shall provide the qualified person under Article 161, Paragraph 2, item 1 with the necessary conditions for the discharge of his duties and shall immediately notify the control bodies when he is replaced.
(12) When penal administrative proceedings are instituted for violations committed while the qualified person is discharging his duties, the Bulgarian Drugs Agency shall order the import authorisation holder to temporarily relieve from office the qualified person.

Article 163a. (New, SG No. 12/2011, effective 8.02.2011) (1) When finding any incompleteness or deficiency in the submitted documentation, the Bulgarian Drugs Agency shall notify the applicant in writing and shall also give written instructions.
(2) In the cases under Paragraph 1, the period under Article 164(1) shall be suspended until the documentation is brought into compliance with the requirements.

Article 164. (1) The Bulgarian Drugs Agency Executive Director shall issue an import authorisation within a period of 30 days of the date of submission of the application under Article 162 or a motivated refusal.
(2) The refusal under Paragraph 1 shall be subject to appeal under the Administrative Procedure Code.
(3) The import authorisation shall only be issued in respect to medicinal products, the forms of their active substances and in respect to the medicinal products intended for clinical trials indicated in the application, as well as in respect to the premises in which control and storage is to take place.
(4) An import authorisation shall not be limited in time.

Article 164a. (New, SG No. 67/2020) The import authorisation holder shall ensure indication of the safety features under Article 168, paragraph 8 on the outer packaging, and in its absence – on the immediate packaging of the medicinal products, as laid down in Delegated Regulation (EU) 2016/161, and shall ensure the introduction of the unique identifier of each packaging in the system of registers pursuant to Delegated Regulation (EU) 2016/161.

Article 165. (Amended, SG No. 102/2012, effective 2.01.2013, SG No. 67/2020) (1) The holder of authorisation for import from a third country shall submit to the Bulgarian Drug Agency an application for change of:
1. the person under Article 161, Paragraph 2, item 1;
2. the list of International Nonproprietary Names and trade names of the medicinal products, their pharmaceutical form, strength of the medicinal product and the quantity in the final packaging;
3. the address of the laboratory under Article 161, Paragraph 2, item 2;
4. the commercial registration.

(2) The application under Paragraph 1 shall be accompanied by the documents relating to the change, as laid down in Article 165a, and a document for the payment of a fee in the amount set out in the tariff referred to in Article 21, paragraph 2.

Article 165a. (New, SG No. 67/2020) (1) In case of any change under Article 165, paragraph 1, item 1, the applicant shall submit the following documentation:
1. a diploma for completed higher education;
2. an employment contract;
3. documents certifying additional qualification;
4. a document evidencing record of service.
(2) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the conviction status of the person under Article 161, paragraph 2, item 1, where such person is a Bulgarian citizen. Persons who are not Bulgarian citizens shall submit together with the application a certificate of clean criminal record or an equivalent document, issued by a competent authority of the relevant country.
(3) In case of any change under Article 165, paragraph 1, item 2, the applicant shall submit the following documentation:
1. a list of International Nonproprietary Names and trade names of the medicinal products, their pharmaceutical form, strength of the medicinal product and the quantity in the final packaging;
2. a list of the manufacturing, control and storage procedures of the medicinal products.
(4) In case of any change under Article 165, paragraph 1, item 3, the applicant shall submit the data under Article 162, paragraph 2, item 6 and a copy of the contract under Article 162, paragraph 2, item 6.
(5) In case of any change under Article 165, paragraph 1, item 4, the Bulgarian Drug Agency shall establish by official channels the circumstances regarding the trade registration changes applied for.

Article 166. (1) The provisions of Article 164 shall apply to the issuance of the authorisation, the term for this being:
1. in cases under Article 165, Paragraph 1, items 1, 2, and 4 - up to 14 days;
2. in cases under Article 165, Paragraph 1, item 3 - up to 30 days.
(2) When the change under Article 165, Paragraph 1, item 3 may not be assessed on the basis of documents, the Bulgarian Drugs Agency shall conduct an on-site inspection. In such cases the term under Paragraph 1, item 2 shall stop running until the completion of the inspection.
(3) The costs of the on-site inspection under Paragraph 2 shall be borne by the applicant.
(4) In order to have an on-site inspection under Paragraph 2 carried out, the applicant shall pay a fee at the amount specified in the Tariff under Article 21, Paragraph 2.

Article 167. (1) The Bulgarian Drugs Agency shall keep a register under Article 19, Paragraph 1, item 2 of the authorisations for import issued, which shall contain:
1. the number and the date of the import authorisation;
2. the name, seat and business address of the person who has obtained an import authorisation;
3. the address of the control and storage premises for medicinal products;
4. (amended, SG No. 102/2012, effective 2.01.2013) the medicinal products and formulations for which authorisation has been obtained;
5. the name of the person under Article 161, Paragraph 2, item 1;
6. the date of deletion from the register of the date of the import authorisation and the grounds for this.
(2) Register data shall be posted on the Bulgarian Drugs Agency website.

Section III
(New, SG No. 102/2012)
Production, import and wholesaling of active substances

Article 167a. (New, SG No. 102/2012, effective 2.01.2013) Production, import or wholesaling of active substances may be effected only by natural or legal persons registered as traders under the legislation of a Member State and entered in the register under Article 167d.

Article 167b. (New, SG No. 102/2012, effective 2.01.2013) (1) The applicant shall file an application to be entered into the Register under Article 167d to the Bulgarian Drugs Agency, based on a model approved by the Bulgarian Drugs Agency Executive Director, which shall contain:
1. name, seat and business address of the person under Article 167a;
2. list of the active substances to be imported, manufactured or traded;
3. the activities to be conducted by the person under Article 167a;
4. address of the premises and data on the technical equipment needed for the activities of the persons under Article 167a.
(2) The application under Paragraph 1 shall be accompanied by:
1. data on the Unified ID Code of the trader, and for companies registered in a Member State - a document for current registration under the national legislation, issues by a competent body in the respective state;
2. document for paid fee under Article 21, Paragraph 2.
(3) Within 60 days of the filing of the application and of the documentation under Paragraphs 1 and 2, the Bulgarian Drugs Agency, based on risk assessment, shall:
1. enter the person under Article 167a in the Register under Article 167d, informing him thereof, or
2. notify about the date of the inspection for checking compliance of the conditions for conducting the activities under Article 167a with the requirements of the Good Manufacturing Practice under Article 152, Paragraph 1 and of the Good Distribution Practices for active substances under Article 198.
(4) When, as a result of the inspection under Paragraph 3, item 2, the Bulgarian Drugs Agency finds compliance with the requirements of the Good Manufacturing Practice under Article 152, Paragraph 1 and of the Good Distribution Practices for active substances under Article 198, it shall enter the applicant in the Register under Article 167d and shall notify him thereof.
(5) The costs for conducting the inspection under Paragraph 3, item 2 shall be covered by the applicant.
(6) The applicant shall pay a fee stipulated in the Tariff under Article 21, Paragraph 2 for the inspection under Paragraph 3, item 2.
(7) In the cases under Paragraph 3, item 1 and Paragraph 4, the applicant may start conducting his activities after being entered in the Register under Article 167d.

Article 167c. (New, SG No. 102/2012, effective 2.01.2013) When within the term specified in Article 167b, Paragraph 3, the Bulgarian Drugs Agency fails to notify that an inspection is to be effected, the applicant may start conducting his activities.

Article 167d. (New, SG No. 102/2012, effective 2.01.2013) (1) The Bulgarian Drugs Agency shall keep a public register of the importers, manufacturers and wholesale traders in active substances, which shall contain:
1. the name, seat and business address of the person under Article 167a;
2. list of the active substances that are imported, manufactured or traded;
3. the activities to be conducted by the person under Article 167a;
4. address of the premises in which the activities are to be conducted;
5. comments on the circumstances registered.
(2) The Bulgarian Drugs Agency shall enter information on the registered importers, manufacturers and wholesale traders in active substances in the database under Article 147.

Article 167e. (New, SG No. 102/2012, effective 2.01.2013) (1) The person under Article 167a shall file with the Bulgarian Drugs Agency every year before 31 January notification of any changes that have occurred in the information entered in the Register under Article 167d.
(2) In the event of changes that can affect the quality or the safety of the active substances that are manufactures, imported or distributed, the person under Article 167a shall notify immediately the Bulgarian Drugs Agency.

Article 167f. (New, SG No. 102/2012) (1) (Effective 2.01.2013 - SG No. 102/2012) The manufacturing, import and wholesale trade in active substances on the territory of the Republic of

Bulgaria, including of active substances intended for export, shall be done in compliance with the Good Manufacturing Practice and with the Good Distribution Practices for active substances.
(2) The importers may import active substances only provided the following conditions have been complied with:
1. (effective 2.01.2013 - SG No. 102/2012) the active substances have been manufactured in compliance with the Good Manufacturing Practice standards that are at least equivalent to those established in the European Union, and
2. (effective 2.07.2013 - SG No. 102/2012) the active substances are accompanied by confirmation in writing by the competent authority of the exporting state, testifying that:
a) the Good Manufacturing Practice standards applicable to the manufacturing site of the exported active substances are at least equivalent to the ones established in the European Union;
b) the respective manufacturing site is subject to regular control and that the Good Manufacturing Practice is effectively applied in it, which includes numerous and unexpected inspections aimed at guaranteeing public health protection, at least equivalent to that in the European Union, and
c) In the event of noticing non-compliance with the requirements, the exporting state shall notify immediately the Bulgarian Drugs Agency.
(3) (Effective 2.07.2013 - SG No. 102/2012) The requirement under Paragraph 2, item 2 shall not apply if the exporting state is included in the list under Article 111b of Directive 2001/83/EC.

Article 167g. (New, SG No. 102/2012, effective 2.07.2013) (1) Exceptionally, when it is necessary to secure availability of medicinal products, the importer may import the active substance without the confirmation in writing under Article 167f, Paragraph 2, item 2 for a period not longer than the validity of the Good Manufacturing Practice Certificate, when the manufacturing site for the active substance in the exporting state has been inspected by a regulatory body of a Member State and has been found to comply with the principles and guidelines of the Good Manufacturing Practice.
(2) In the cases under Paragraph 1, the Bulgarian Drugs Agency shall notify the European Commission.

Article 167h. (New, SG No. 102/2012, effective 2.01.2013) (1) Manufacturing authorisation holders, including those who conduct the activities under Article 168b, Paragraph 2, shall be considered to be manufacturers in the sense of § 13, item 3 of the additional provisions to the Consumer Protection Act and shall be responsible for damages caused by a defect in the commodities, provided for in it.

Chapter Six
PACKAGING AND BROCHURES OF MEDICINAL PRODUCTS

Article 168. (1) The packaging of a medicinal product shall consist of immediate and/or outer packaging and of a patient brochure.
(2) (Amended, SG No. 61/2011, effective 10.11.2011) The outer packaging of medicinal products containing the substances listed in the Schedules under Article 3, Paragraph 2, item 2 of the Narcotic Substances and Precursors Control Act shall be marked by two diagonal red bands and the outer packaging of medicinal products containing substances in the Schedules under Article 3, Paragraph 2, item 3 of the Narcotic Substances and Precursors Control Act - by two blue bands. The packaging shall mandatorily bear an indication that a medicinal product shall be dispensed only with special medical prescription.
(3) (Amended, SG No. 102/2012, effective 21.12.2012) The brochure for the medicinal products included in the list under Article 23 of Regulation (EC) No. 726/2004 of the European Parliament and of Council shall contain the following text: "This medicinal product shall be subject to additional observation." A symbol in black shall be placed before the text in compliance with Article 23, Paragraph 5 of Regulation (EC) No. 726/2004 of the European Parliament and of Council, accompanied by an explanatory note.
(4) (Amended, SG No. 102/2012, effective 21.12.2012) The brochure of medicinal products shall include a standard text inviting patients to report to medical specialists or directly to the Bulgarian

Drugs Agency any suspected adverse reaction in accordance with the models under Article 185, Paragraph 2, item 4.
(5) When a medicinal product is authorised on the territory of the Republic of Bulgaria, the outer packaging shall be marked for separate collection and recycling in accordance with the Waste Management Act and the instruments for its enforcement.
(6) When a medicinal product is allowed for use, its name on the outer packaging, the pharmaceutical form and the content of the active substance per dosing unit shall be printed in Braille as well.
(7) The requirements of Paragraph 6 shall not apply to vaccines and medicinal products in hospital packaging.
(8) (New, SG No. 102/2012, effective 21.12.2012) The outer packaging, and in its absence - the immediate packaging of the medicinal products, with the exception of radiopharmaceuticals, shall bear:
1. an individual identification marker of the safety indicators, which allows wholesale and retail traders:
a) to check the authenticity of the medicinal product;
b) to identify individual packagings.
2. a means with which to check whether the packaging of the medicinal product has been counterfeited.

Article 168a. (New, SG No. 102/2012, effective 21.12.2012) (1) Safety indicators under Article 168, Paragraph 8 shall be applied on the packaging of medicinal products dispensed with a medical prescription, with the exception of the cases when the medicinal product has been included in the list stipulated by the European Commission with a delegated act under Article 168b.
(2) Safety indicators under Article 168, Paragraph 8 shall not be applied on the packaging of medicinal products dispensed without medical prescription, with the exception of the cases when the medicinal product has been included in the list stipulated by the European Commission with a delegated act under Article 168b, after it has been estimated to be exposed to risk of counterfeiting.
(3) The Bulgarian Drugs Agency shall inform the European Commission:
1. about medicinal products dispensed without medical prescription, which have been found to be exposed to risk of counterfeiting;
2. about medicinal products which have not been found to be exposed to risk of counterfeiting, taking into account the following criteria:
a) price and sales volume of the medicinal product;
b) number and frequency of the cases of counterfeited medicinal products registered within the European Union and in third states, and change in the number and frequency of such cases in a historical perspective;
c) specific characteristics of the respective medicinal products;
d) severity of the diseases whose treatment is aimed at;
e) other potential risks to public health.

Article 168b. (New, SG No. 102/2012, effective 21.12.2012) (1) The rules related to the safety indicators under Article 168, Paragraph 8 shall be determined by the European Commission with delegated acts under Article 54a, Paragraph 2 of Directive 2001/83/EC.
(2) The safety indicators shall neither be removed, nor covered partially or entirely, except where the following conditions have been met:
1. the manufacturing authorisation holder, prior to removing or covering up completely or partially the safety indicators, shall check whether the respective medicinal product is authentic or whether it has been counterfeited;
2. the manufacturing authorisation holder may, while complying with the requirements under Article 169, Paragraph 8, replace the safety indicators with indicators equivalent to them in terms of the possibility to guarantee the authenticity, identification and securing evidence of the counterfeiting of the medicinal product.
(3) The safety indicators shall be considered to be equivalent if:

1. they comply with the requirements stipulated in the delegated acts under Article 54a, Paragraph 2 of Directive 2001/83/EC, and
2. they are equally effective, allowing inspection of the authenticity and identification of the medicinal products, as well as providing evidence of their counterfeiting.
(4) The replacing under Paragraph 2, item 2 shall be performed without opening the immediate packaging of the medicinal product and in compliance with the Good Manufacturing Practice for medicinal products.
(5) The Bulgarian Drugs Agency shall exercise supervision over the replacement of the safety indicators.

Article 169. (1) The information on packaging and in brochures for a medicinal product must be in full compliance with data on the product summary approved by the Bulgarian Drugs Agency upon issuance of the marketing authorisation, and must meet the requirements specified in the Ordinance under Article 170.
(2) The information on packaging and in the brochure may be in several languages, one mandatorily being Bulgarian. The content of the information in different languages must be identical.
(3) The name of the medicinal product shall be mandatorily written in the Bulgarian language and the international non-patent name of the medicinal substance shall be printed in accordance with the WHO Anatomical Therapeutic Chemical Classification System. The name and address of the marketing authorisation holder may be printed in Latin.
(4) The information on packaging and in brochures must be in a language that the patient understands, be easy to read and non-erasable.
(5) (New, SG No. 18/2014) The leaflet shall be made in such a way, as to be clear and easy to understand, thus allowing the patient to take appropriate actions, and where necessary, to be supported by medical specialists.

Article 170. (1) (Previous Article 170, SG No. 102/2012, effective 21.12.2012) The requirements to packaging and brochures of medicinal products shall be specified in an Ordinance of the Minister of Health.
(2) (New, SG No. 102/2012, effective 21.12.2012, supplemented, SG No. 18/2014) When a medicinal product with marketing authorisation under this Act is not intended to be directly dispensed to a patient, or is not available on the market of the Republic of Bulgaria, the Bulgarian Drug Agency may authorise its use when some of the data specified in the Ordinance under Paragraph 1 have not been applied on the packaging or in the brochure.
(3) (New, SG No. 102/2012, effective 21.12.2012) In the cases under Paragraph 2, the information on the packaging or in the brochure may not be presented in the Bulgarian language as well.
(4) (New, SG No. 102/2012, effective 21.12.2012) The conditions and the procedure for supplying the medicinal products under Paragraph 2 shall be determined with the Ordinance under Article 198.

Chapter Seven
CLASSIFICATION OF MEDICINAL PRODUCTS

Article 171. (1) Depending on the manner in which medicinal products are dispensed for use, they shall be classified as follows:
1. medicinal products dispensed with medical prescription;
2. medicinal products dispensed without medical prescription.
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008) The regime for the dispensation of medicinal products shall be determined by the Bulgarian Drugs Agency in the marketing authorisation/certificate of registration or by the authorisation for parallel import of the medicinal product on the territory of the republic of Bulgaria.
(3) The person under Article 26, Paragraph 1 shall specify the regime for dispensation of medicinal products in the application for marketing authorisation/certificate of registration, for changing a marketing authorisation or upon renewal thereof.

Article 172. Medicinal products under Article 171, Paragraph 1, item 1 shall fall in the following categories:
1. medicinal products subject to limited prescription intended for use only in some specialised areas;
2. medicinal products subject to special medical prescription;
3. medicinal products for one-off or multiple dispensation by a single prescription.

Article 173. Medicinal products meeting the following requirements shall be subject to medical prescription:
1. they may constitute a direct or indirect threat to human health, even if used correctly, if administered without medical supervision;
2. they are often widely administered incorrectly and, as a result, may constitute a threat to human health;
3. they contain substances whose activity and/or adverse reactions require subsequent additional study;
4. they are usually prescribed by a doctor for parenteral administration.

Article 174. Medicinal products shall be subject to special medical prescription when they meet any of the following conditions:
1. they contain narcotic substances, within the meaning of the Narcotic Substances and Precursors Control Act, in amounts admissible for use;
2. if used incorrectly, they may create considerable risk of abuse, resulting in drug dependence, or be used for illegal purposes;
3. they contain new medicinal substances whose characteristics are sufficiently well known and, for this reason, to a preventative purpose, they may be categorised as item 2 medicinal products.

Article 175. Medicinal products shall be subject to limited medical prescription if they meet any of the following conditions:
1. they are limited to use only in hospitals because of limited experience of use or in the interest of public health;
2. they are intended for the treatment of medical conditions that may only be diagnosed in treatment establishments, even though they may be administered and the course of treatment may be monitored in other medical establishments as well;
3. they are intended for outpatient treatment, but their use may cause serious adverse reactions requiring a prescription by a specialist and supervision during treatment.

Article 176. (1) The Bulgarian Drugs Agency may approve the regime of dispensation of a medicinal product requested by the applicant under Article 26, Paragraph 1, based on a judgement of:
1. the minimum single dose, the maximum daily dose, the amount of active substance per dosing unit, the pharmaceutical form, the specific type of immediate packaging of the product, and/or
2. other specific conditions for use.

(2) The Bulgarian Drugs Agency may indicate the exact category of the medicinal product under Article 172, but in accordance with the criteria under Article 174 and Article 175 it shall determine whether the medicinal product shall be classified as a product subject to medical prescription.

Article 177. Medicinal products that do not meet the requirements under Articles 173, 174 and 175 and the criteria specified in the Ordinance under Article 178, shall not be subject to medical prescription.

Article 178. The criteria for the classification of medicinal products and the requirements to the documentation for introducing a change in the classification shall be specified in an Ordinance of the Minister of Health.

Article 179. (1) The Bulgarian Drugs Agency shall prepare and post on its website a list of medicinal products subject to medical prescription on the territory of the Republic of Bulgaria.
(2) The list under Paragraph 1 shall be updated annually.

Article 180. In the presence of new data about a medicinal product, for which a marketing authorisation has been issued or a certificate of registration, the Bulgarian Drugs Agency

shall reconsider and, if necessary, amend the classification in accordance with the requirements of Article 173 and the criteria specified in the Ordinance under Article 178.

Article 181. In cases when a change in the classification of a medicinal product is allowed based on considerable preclinical and clinical trials, no subsequent applicant or marketing authorisation holder may refer, within a period of one year following the date of the authorisation for change issued by a regulatory body of a Member State, to the classification of the same substance when filing an application for change.

Article 182. The Bulgarian Drugs Agency shall notify the European Commission and the regulatory bodies of other Member States on an annual basis of the changes that have occurred in the list under Article 179.

Chapter Eight
MONITORING DRUG SAFETY
Section I
General provisions
(Title new, SG No. 102/2012, effective 21.12.2012)

Article 183. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall organise and maintain a system for drug safety monitoring with a view to fulfilling the obligations under this Chapter.

(2) The system under Paragraph 1 shall be used for gathering information about the risk of the medicinal products to the health of the patients and to public health. The information shall comprise notifications of adverse reactions after the use of a medicinal product in compliance with the approved product summary, as well as information about abuse and about use that is not in compliance with the approved product summary, including information on adverse reactions observed in the course of discharging professional obligations.

(3) The Bulgarian Drugs Agency shall validate, process and classify the information under Paragraph 2, it shall perform a scientific analysis of the data gathered with a view to reducing and preventing the risk, and it shall undertake the necessary actions with respect to the marketing authorisation of the medicinal product.

(4) The Bulgarian Drugs Agency shall conduct audits of the system under Paragraph 1 and shall send reports with the audit results to the European Commission once every two years.

(5) The Bulgarian Drugs Agency shall apply an adequate and effective quality system so as to ensure compliance of the system under Paragraph 1 with the requirements under this Act. The minimum requirements for the quality system shall be determined with Implementing Regulation (EC) No. 520/2012.

Article 184. (Amended, SG No. 102/2012, effective 21.12.2012) (1) Medical specialists shall be obliged to notify immediately the marketing authorisation holder or the Bulgarian Drugs Agency about any suspected serious adverse reaction and to provide, upon demand, additional information from the monitoring of the case.

(2) Patients may report adverse reactions at any time to the medical specialists or to the Bulgarian Drugs Agency.

(3) In the cases under Paragraphs 1 and 2, when the notification concerns a biological medicinal product that has been prescribed, distributed or sold on the territory of the Republic of Bulgaria, it shall mandatorily be clearly identified by the notifier with its trade name or batch number, or that information shall be presented during additional monitoring.

Article 185. (Amended, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drugs Agency shall maintain a national Internet portal for medicinal products, which shall be connected to the European Internet portal for medicinal products under Article 68, Paragraph 1, item 4.

(2) The Bulgarian Drugs Agency shall present through the portal under Paragraph 1 at least the following information:

1. the public evaluation reports under Article 53, Paragraph 2 and their summaries;
2. the product summaries and brochures;

3. summary of the plans for risk management for the medicinal products with marketing authorisation on the territory of the Republic of Bulgaria;
4. models of standardised forms for reporting suspected adverse reactions by medical specialists and patients, prepared in compliance with the requirements under Article 25 of Regulation (EC) No. 726/2004 of the European Parliament and of Council;
5. updated list of the medicinal products under Article 23 of Regulation (EC) No. 726/2004 of the European Parliament and of Council;
6. notifications providing information to the general public on apprehensions concerning the safety of the use of a certain medicinal product;
7. instructions on all ways and forms of reporting suspected adverse reactions by medical specialists and patients.

Article 186. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall conduct the following activities for the medicinal products released on the market of the Republic of Bulgaria:
1. monitoring of the result of the measures for reducing the risk of a medicinal product, contained in the risk management plan;
2. monitoring of the result of fulfilling the conditions specified in Articles 55a, 56 or 56a;
3. evaluation of the updating of the risk management system;
4. monitoring of the EudraVigilance database created under Article 24 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council for new risks and for changes in already identified risks, as well as for changes in the benefit/risk ratio.

Article 187. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall inform the European Medicines Agency and the marketing authorisation holder when signals of new risks or of a change in the identified risks have been identified, or in the event of a change in the benefit/risk ratio if a medicinal product.
(2) The Committee under Article 56a, Paragraph 1, item 1 shall analyse and prioritise the validated signals of new risks or of a change in the already identified risks, as well as of a change in the benefit/risk ratio.
(3) When the Committee under Article 56a, Paragraph 1, item 1 recommends follow-up actions, the Coordination Group under Article 77, Paragraph 2, or the Committee for Medicinal Products for Human Use accordingly, shall draft an opinion on regulatory actions with respect to the marketing authorisation within a schedule drafted in accordance with the seriousness and the degree of danger.
(4) The Bulgarian Drugs Agency shall implement the provisional and/or final measures recommended in the opinion of the Coordination Group under Article 77, Paragraph 2, or in the decision of the European Commission.

Article 188. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall inform the European Medicines Agency, the regulatory bodies of the other Member States and the European Commission not less than 24 hours prior to the public disclosure of the information on apprehensions connected with the safety monitoring of a medicinal product, except in the cases when public health protection requires immediate disclosure of the information.
(2) The Bulgarian Drugs Agency shall publish information connected with active substances contained in medicinal products with market authorisation in other Member States as well, using a harmonised draft of the communication and schedule for the publication, proposed by the European Medicines Agency.
(3) In the cases under Paragraphs 1 and 2, the information containing personal data or constituting commercial secret shall be deleted, unless the publishing of these data is necessary for public health protection.

Article 189. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency may delegate some of the rights and obligations under this Chapter to a regulatory body of another Member State by signing an agreement.
(2) In the cases under Paragraph 1, the Bulgarian Drugs Agency shall inform the European Commission, the European Medicines Agency and the regulatory bodies of the other Member States

about the delegating of powers and shall post an announcement on the Internet portal under Article 185, Paragraph 1, or on its website.

Article 190. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall be obliged to have a system for drug safety monitoring with a view to fulfilling his obligations under this Chapter.

(2) Using the system under Paragraph 1, the marketing authorisation holder shall make a scientific evaluation of the information gathered on the safety of the medicinal products, assess possibilities for minimising the risk or for risk prevention, and shall undertake the necessary measures.

(3) The marketing authorisation holder shall apply an adequate and effective quality assurance system with a view to ensuring compliance of the system under Paragraph 1 with the requirements under this Act. The minimum requirements for the quality system shall be determined with Implementing Regulation (EU) No. 520/2012.

(4) The marketing authorisation holder shall perform a regular audit of the system under Paragraph 1. Information on the principal findings of the audit shall be noted in the principal documentation of the system and shall serve for drafting a plan for applying appropriate corrective actions. This information may be deleted after comprehensive implementation of the correcting actions.

Article 191. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall appoint a qualified person with a suitable training to be responsible for drug safety monitoring.

(2) The person under Paragraph 1 shall be established on the territory of the Member State, and shall be permanently and without interruption at the disposal of the marketing authorisation holder.

(3) The marketing authorisation holder shall appoint a person established on the territory of the Republic of Bulgaria with a view to assisting the activities of the qualified person. The appointing of such a person shall not relieve the qualified person under Paragraph 1 of his responsibilities under this Chapter.

(4) The marketing authorisation holder shall submit to the Bulgarian Drug Agency the data under Article 27, Paragraph 1, item 12, a) - c) on the persons under Paragraphs 1 and 3.

(5) The marketing authorisation holder shall inform the Bulgarian Drug Agency in the event of any change in the data under Paragraph 4.

(6) The marketing authorisation holder shall submit data under Paragraph 4 on the qualified person to the European Medicines Agency.

Article 192. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall be obliged:

1. to maintain and submit, upon demand by the Bulgarian Drugs Agency, the principal document of the system for drug safety monitoring;
2. to apply a risk management system for each medicinal product;
3. to monitor the result of the measures contained in the risk management plan;
4. to monitor the result of the fulfilling of the conditions under Articles 55a, 56 or 56a;
5. to update the risk management system;
6. to monitor the data of the system under Article 190, Paragraph 1 with a view to identifying new risks or a change in the identified risks, as well as to determine whether changes have occurred in the benefit/risk ratio for the medicinal product monitored.

(2) The content and the procedure for keeping the principal documentation of the system for drug safety monitoring shall be determined with Implementing Regulation (EU) No. 520/2012.

Article 193. (Supplemented, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) The marketing authorisation holder shall inform the Bulgarian Drugs Agency and the European Medicines Agency in the event of signals of new risks or of changes in the identified risks, or in the event of change in the benefit/risk ratio of the medicinal product.

Article 194. (Amended, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall inform the Bulgarian Drugs Agency, the European Medicines Agency and the European Commission, simultaneously or prior to disclosing to the general public new

information on apprehensions connected with the drug safety monitoring of a certain medicinal product with marketing authorisation on the territory of the Republic of Bulgaria. (2) The information under Paragraph 1 shall be objective and not misleading.
(3) Prior to disseminating information connected with drug safety monitoring, the marketing authorisation holder shall coordinate that information in advance with the Bulgarian Drugs Agency, with the exception of the cases under Paragraph 1.
(4) A fee in an amount specified in the Tariff under Article 21, Paragraph 2 shall be paid for the evaluation of the information under Paragraph 3.

Article 194a. (New, SG No. 102/2012, effective 21.12.2012) (1) The principles and the requirements of the Good Practice for Drug Safety Monitoring shall be specified in a Manual issued by the European Medicines Agency.
(2) The marketing authorisation holder shall abide by the good practice under Paragraph 1 in conducting the activities for drug safety monitoring.

Section II
(New, SG No. 102/2012, effective 21.12.2012)
Gathering and disclosing information on suspected adverse reactions

Article 194b. (New, SG No. 102/2012, effective 21.12.2012) Implementing his obligations under Article 190, the marketing authorisation holder shall be obliged to document all communications on suspected adverse reactions observed on the territory of the European Union or in third countries, which have been reported to him spontaneously by medical specialists or by patients, or which have occurred in the course of post-marketing studies.

Article 194c. (New, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall submit electronically to the EudraVigilance database under Article 24 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council information about suspected serious adverse reactions occurring on the territory of the European Union and in third countries, within 15 days of the date on which the communication was received.
(2) The marketing authorisation holder shall file electronically to the EudraVigilance database information about all suspected adverse reactions, different from the ones under Paragraph 1, which have occurred on the territory of the European Union, within 90 days of the date on which the notification was received.
(3) The marketing authorisation holder shall follow the publications in the specialised medical literature and shall report to the EudraVigilance database every suspected adverse reactions described in it, with the exception of suspected adverse reactions of medicinal products containing active substances specified in the list under Article 27 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and described in literary sources monitored by the European Medicines Agency.
(4) The marketing authorisation holder shall create procedures for gathering accurate and authentic data permitting scientific evaluation of communications on suspected adverse reactions. The marketing authorisation holder shall gather subsequent information related to these communications and shall submit the updated data to the EudraVigilance database.
(5) The format and the content of the reports under Paragraphs 1-3 shall be determined with Implementing Regulation (EU) No. 520/2012.

Article 194d. (New, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall register in the system under Article 183 all communications on suspected adverse reactions that have occurred on the territory of the Republic of Bulgaria, from medical specialists and from patients, and shall require, wherever necessary, additional information from the monitoring of the case.
(2) When the communications on suspected adverse reactions occurring on the territory of the Republic of Bulgaria have been submitted by the marketing authorisation holder, he shall present additional information from the monitoring of the case upon demand by the Bulgarian Drugs Agency.

Article 194e. (New, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall submit electronically to the EudraVigilance database information about all suspected serious adverse reactions occurring on the territory of the Republic of Bulgaria within 15 days of the date of receiving that information.
(2) The Bulgarian Drugs Agency shall submit electronically to the EudraVigilance database information about all suspected adverse reactions occurring on the territory of the Republic of Bulgaria, different from the ones specified under Paragraph 1, within 90 days of the date of receiving that information.
(3) The Bulgarian Drugs Agency shall submit electronically to the EudraVigilance database reports on suspected adverse reactions occurring on the territory of the Republic of Bulgaria as a result of incorrect use of the medicinal product. The Bulgarian Drugs Agency shall inform thereof the Ministry of Health and the professional organisations of the medical specialists.
(4) Every institute or body to which information has been supplied about adverse reactions occurring on the territory of the Republic of Bulgaria shall inform the Bulgarian Drugs Agency thereof.
(5) The content and the format of the communications and reports under Paragraphs 1-3 shall be specified under Implementing Regulation (EU) No. 520/2012.

Article 194f. (New, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall receive the information submitted by the marketing authorisation holder about suspected serious adverse reactions occurring on the territory of the European Union or in a third country through the EudraVigilance database.
(2) The requirements for monitoring of the information in the EudraVigilance database shall be specified under Implementing Regulation (EU) No. 520/2012.

Article 194g. (New, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency, the marketing authorisation holders and the European Medicines Agency shall cooperate in the process of exchanging information with a view to detecting duplicated reports of suspected adverse reactions.

Section III
(New, SG No. 102/2012, effective 21.12.2012)
Periodic updated safety reports

Article 194h. (New, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation holder shall be obliged to submit electronically to the European Medicines Agency periodic updated safety reports, which shall contain:
1. summarised data on the benefit/risk ratio of the medicinal product, including the results of all studies, with a view to their potential impact on the marketing authorisation;
2. scientific evaluation of the benefit/risk ratio of the medicinal product; the evaluation is based on all available data, including data from clinical trials for unauthorised indications and for target groups that are not included in the product summary;
3 all data on the sales volume of the medicinal product and any other information available to the marketing authorisation holder regarding the volume of the prescriptions, including the approximate number of the persons who have used the medicinal product or have been exposed to its action for some other reason.
(2) The content and the format of the electronic periodic updated safety reports shall be specified under Implementing Regulation (EU) No. 520/2012.
(3) The information shall be gathered and stored in a register created under Article 25a of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and shall be accessible to the Bulgarian Drugs Agency.

Article 194i. (New, SG No. 102/2012, effective 21.12.2012) The holders of marketing authorisations/certificates of registration for medicinal products under Articles 28, 30, 35 and 37 shall file periodic updated safety reports only in the cases when:

1, the filing of a report is a condition under Article 55a or 56, written in the marketing authorisation/certificate of registration, or
2. the Bulgarian Drugs Agency or a regulatory body of another Member State requires this on the basis on considerations related to the safety of the medicinal product or due to absence of periodic updated safety reports for the active substance contained in the medicinal product for which a marketing authorisation/certificate of registration has been issued.

Article 194j. (New, SG No. 102/2012, effective 21.12.2012) (1) The marketing authorisation/certificate of registration shall specify the frequency of filing the periodic updated safety reports.
(2) The dates of filing the reports depending on the frequency under Paragraph 1 shall be calculated from the date of issuance of the marketing authorisation/certificate of registration.
(3) The periodic updated safety reports shall be filed at the following time intervals, with the exception of the cases when the frequency of filing the reports is a condition for issuing the marketing authorisation/certificate of registration, or has been specified under Articles 194k, 194l and 194m:
1. at every 6 months from the date of issuance of the marketing authorisation/certificate of registration of a medicinal product until the date of its release on the market;
2. at every 6 months during the first two years from the date of release of the medicinal product on the market;
3. once a year during the subsequent two years;
4. once in three years after the fourth year from the date of release of the medicinal product on the market.
(4) Apart from the cases under Paragraph 3, the periodic updated safety reports shall be filed immediately upon demand by the Bulgarian Drugs Agency or by a regulatory body of a Member State.
(5) Paragraphs 3 and 4 shall also be applicable to medicinal products with marketing authorisation only on the territory of the Republic of Bulgaria, which are not covered by the provisions of Article 194k.

Article 194k. (New, SG No. 102/2012, effective 21.12.2012) When medicinal products containing the same active substance or a combination of the same active substances have received separate marketing authorisations/certificates of registration, the frequency and the dates for filing the periodic updated safety reports may be changed and harmonised with a view to performing a unified evaluation of these reports.

Article 194l. (New, SG No. 102/2012, effective 21.12.2012) (1) The dates for filing the periodic updated safety reports for the medicinal products under Article 194k shall be calculated in accordance with the reference date of the European Union.
(2) The reference date of the European Union under Paragraph 1 shall be:
1. the date of the first marketing authorisation in the European Union for the medicinal product containing the respective active substance or combination of active substances;
2. the earliest known date of the marketing authorisations of the medicinal product containing the respective active substance or combination of active substances, if the date specified in Paragraph 1 cannot be established.

Article 194m. (New, SG No. 102/2012, effective 21.12.2012) (1) The holder of the marketing authorisation for medicinal products under Article 194k may file a modified application to the Committee for Medicinal Products for Human Use, or accordingly to the Coordination Group under Article 77, Paragraph 2, for determining the reference date of the European Union or for modifying the frequency of filing periodic updated safety reports on one of the following grounds:
1. for reasons connected to public health;
2. for avoiding duplicated evaluations;
3. for achieving international harmonisation.

(2) The Committee for Medicinal Products for Human Use, and accordingly the Coordination Group under Article 77, Paragraph 2, following consultations with the Committee under Article 56a, Paragraph 1, item 1, shall approve the application or shall give a motivated refusal.
(3) The filing frequency and the reference date of the European Union shall be determined after consultation with the Committee under Article 56a, Paragraph 1, item 1 by:
1. the Committee for Medicinal Products for Human Use - when at least one of the marketing authorisations for medicinal products containing the respective active substance has been submitted in compliance with the centralised procedure envisaged in Section II, Chapter One of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, or
2. the Coordination Group under Article 77, Paragraph 2 - for cases different from those specified in Paragraph 1.
(4) The list with the reference data of the European Union for medicinal products under Article 194k and the harmonised frequency for filing their periodic updated safety reports shall be posted on the European Internet portal under Article 68, Paragraph 1, item 4.
(5) Following the publication of the data under Paragraph 4, the marketing authorisation holder shall file an application to the Bulgarian Drug Agency for modification of the marketing authorisation of the respective medicinal product. Every change in the filing dates and in the filing frequency for the periodic updated safety reports shall become effective 6 months after the date of their publication.

Article 194n. (New, SG No. 102/2012, effective 21.12.2012) (1) The Bulgarian Drugs Agency shall evaluate the periodic updated safety reports for the medicinal products with a view to determine whether there exist new risks, or a change in the identified risks, or a change in the benefit/risk ratio.
(2) The Bulgarian Drugs Agency shall conduct a unified evaluation of the periodic updated safety reports for the medicinal products for which the Republic of Bulgaria has performed the functions of reference state under Article 76 and has been determined by the Coordination Group under Article 77, Paragraph 2.
(3) A rapporteur from the Republic of Bulgaria shall participate in the unified evaluation of the periodic updated safety reports for medicinal products when at least one of the products has received marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and has been determined as such by the Committee under Article 56a, Paragraph 1, item 1.

Article 194o. (New, SG No. 102/2012, effective 21.12.2012) (1) In the cases under Article 194n, Paragraphs 2 and 3, the Bulgarian Drugs Agency, or accordingly the rapporteur from the Republic of Bulgaria, shall draft an evaluation report within 60 days from the date of receiving the periodic updated safety report, and shall send it electronically to the European Medicines Agency and to the regulatory bodies of the Member States. The marketing authorisation holder shall receive the evaluation report from the European Medicines Agency.
(2) Within 30 days from receiving the report under Paragraph 1, the marketing authorisation holder or the regulatory bodies of the Member States may submit their comments to the European Medicines Agency and to the Bulgarian Drugs Agency.
(3) Within 15 days from the date on which the comments under Paragraph 2 were received, the Bulgarian Drugs Agency shall update the evaluation report, taking into account all objections submitted, and shall send it to the Committee Under Article 56a, Paragraph 1, item 1 for approval and recommendation.
(4) The European Medicines Agency shall include the approved evaluation report and the recommendation of the Committee under Article 56a, Paragraph 1, item 1, and shall send it to the marketing authorisation holder.

Article 194p. (New, SG No. 102/2012, effective 21.12.2012) When the Republic of Bulgaria is not rapporteur in the procedure under Article 194n, the Bulgarian Drugs Agency may submit comments within the period under Article 194o to the European Medicines Agency and to the regulatory body of the Member State, which had drafted the evaluation report.

Article 194q. (New, SG No. 102/2012, effective 21.12.2012) (1) In the cases of unified evaluation of periodic updated safety reports for medicinal products under Article 194k, and when none of the marketing authorisations of these products has been issued under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, the Coordination Group under Article 77, Paragraph 2 shall issue an opinion on the preservation, change, suspension or termination of the respective marketing authorisations, including a schedule for compliance with the opinion, within 30 days from the date of receiving the recommendation from the Committee under Article 56a, Paragraph 1, item 1.
(2) When the Member States represented in the Coordination Group under Article 77, Paragraph 2 reach agreement on the actions to be taken, the Bulgarian Drugs Agency shall implement the decision reached.
(3) When the opinion under Paragraph 1 refers to suspension or termination of the marketing authorisation, the Bulgarian Drugs Agency Executive Director shall issue an order to that effect.
(4) When the opinion under Paragraph 1 recommends changes in the marketing authorisation, the marketing authorisation holder shall file an application for modification to the Bulgarian Drugs Agency, which shall include product summary and brochure, within the schedule specified for the implementation.
(5) When no agreement can be reached within the Coordination Group under Article 77, Paragraph 2, the position of the majority of the Member States shall be presented to the European Commission, which shall decide on the modification, suspension or termination of the marketing authorisations issued by the respective regulatory authorities of the Member States.
(6) The Bulgarian Drugs Agency shall apply the provisional and/or final measures in the decision under Paragraph 5.

Article 194r. (New, SG No. 102/2012, effective 21.12.2012) (1) In the case of unified evaluation of periodic updated safety reports for medicinal products under Article 194k, and when at least one of the marketing authorisations has been issued under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, the Committee for Medicinal Products for Human Use shall, within 30 days of receiving the recommendation of the Committee under Article 56a, Paragraph 1, item 1, issue an opinion on the preservation, modification, suspension or termination of the validity of the respective marketing authorisations, including a schedule for implementing the opinion.
(2) When the opinion under Paragraph 1 contains a position on undertaking regulatory actions with respect to the marketing authorisations, the European Commission shall:
1. adopt a decision for modification, suspension or termination of the marketing authorisations issued under Regulation (EC) No. 726/2005 of the European Parliament and of the Council;
2. adopt a decision with recommendation for modification, suspension or termination of marketing authorisations issued by the respective regulatory authorities of the Member States.
(3) The Bulgarian Drugs Agency shall apply the provisional and/or final measures in the decision under Paragraph 2, item 2.

Section IV
(New, SG No. 102/2012, effective 21.12.2012)
Emergency procedure European Union level

Article 194s. (New, SG No. 102/2012, effective 21.12.2012) (1) An emergency procedure at European Union level may be initiated by the European Commission, by the European Medicines Agency, or by a Member State.
(2) (Amended, SG No. 18/2014) The Bulgarian Drug Agency shall initiate an emergency procedure under this Section by notifying the regulatory bodies of the other Member States, the European Medicines Agency and the European Commission when it deems, for considerations connected with drug safety monitoring, that for a certain medicinal product released on the bgn market it is necessary to undertake one of the following measures:
1. suspension or termination of the marketing authorisation;

2. ban on the distribution of a medicinal product;
3. issuing of a refusal for renewing the marketing authorisation.
(3) (Amended, SG No. 18/2014) The Bulgarian Drug Agency shall initiate the procedure specified under Paragraph 2 above in case it has been notified by the Marketing Authorisation Holder, that for reasons related to drug safety monitoring, the distribution of the medicinal product has been terminated, or that the Marketing Authorisation Holder has implemented, or intends to implement measures for product recall from the market, or will not be seeking renewal of the marketing authorisation issued.
(4) (Amended, SG No. 18/2014) The Bulgarian Drug Agency may initiate the procedure set forth under the Paragraph 2 above in cases, where on grounds of drug safety monitoring it has deemed necessary new contraindications to be added, or the recommended dose to be reduced, or the indications for use to be restricted for a certain medicinal product.
(5) (Amended, SG No. 18/2014) The Bulgarian Drug Agency shall provide to the The European Medicines Agency and the regulatory authorities of other Member States the complete scientific information it has available, as well as the data evaluation, and also the grounds for initiating any of the procedures under this Section
(6) (Amended, SG No. 18/2014) In the cases under Paragraphs 2 - 4 above, the European Medicines Agency shall inform the Bulgarian Drug Agency and shall initiate such a procedure, where safety concerns also hold to other medicinal products within the same pharmacotherapeutic group, or where the active substance they contain, is the same as that in the product, reported in the information under Paragraph 5, or where the said medicinal product has been granted Marketing authorisation in other Member State(s).
(7) (Amended, SG No. 18/2014) In the cases under Paragraph 4, where no emergency measures need to be implemented, The Bulgarian Drug Agency shall proceed by applying the procedure set forth under Articles 77 or 79b.
(8) (New, SG No. 18/2014) The Bulgarian Drug Agency shall inform the Marketing Authorisation Holder of any procedure started under the terms and conditions of this Section.

Article 194t. (New, SG No. 102/2012, effective 21.12.2012) (1) In the cases under Article 194s, Paragraph 2, the Bulgarian Drugs Agency may, whenever it deems necessary to undertake emergency measures for public health protection, suspend provisionally the marketing authorisation and ban the use of the medicinal product on the territory of the Republic of Bulgaria until the adoption of a final decision under Articles 194x and 194y.
(2) The Bulgarian Drugs Agency shall notify the European Medicines Agency and the regulatory bodies of the other Member States about the measures taken under Paragraph 1 within one working day after their enforcement, indicating the motives therefor.
(3) When the Bulgarian Drugs Agency participates in the procedure under this Section, upon demand by the European Medicines Agency the Bulgarian Drug Agency shall take the recommended provisional measures with respect to the marketing authorisation of the medicinal product, or when the medicinal product has marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council - with respect to the actual product, until the procedure is completed.

Article 194v. (New, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall post an announcement on the national Internet portal under Article 185, Paragraph 1 on the way in which interested parties can provide information to be posted on the European Internet portal under Article 68, Paragraph 1, item 4 for the medicinal product that is subject to the procedure under Article 194s, and on the possibility to take part in a public discussion, if such a discussion is announced.

Article 194w. (New, SG No. 102/2012, effective 21.12.2012) (1) The Committee under Article 56, Paragraph 1, item 1 shall draft a motivated recommendation within 60 days of the announcing of the procedure on the European Internet portal.
(2) The marketing authorisation holder may submit comments in writing within the time period specified in Paragraph 1.

(3) The recommendation under Paragraph 1 shall be posted on the European Internet portal under Article 68, Paragraph 1, item 4 and it shall contain one or more of the following conclusions:
1. no additional study or actions at community level are needed;
2. the marketing authorisation holder is obliged to conduct an additional study and analysis of the data;
3. the marketing authorisation holder is obliged to conduct a post-marketing safety study with subsequent evaluation of its results;
4. the Member State or the marketing authorisation holder needs to adopt measures for reducing the risk;
5. the marketing authorisation needs to be suspended, terminated, or a refusal of its renewing needs to be issued;
6. the marketing authorisation needs to be modified.
(4) The concrete measures under Paragraph 3, item 4, as well as the conditions and the restrictions that need to be included in the marketing authorisation, shall be specified in the recommendation.
(5) In the cases under Paragraph 3, item 6, when the changes are connected with modification or addition of information in the product summary, on the packaging or in the brochure of the medicinal product, the recommendation shall include the wording of the modified or added information, and the place where it is to appear.

Article 194x. (New, SG No. 102/2012, effective 21.12.2012) (1) When the scope of the procedure under Article 194s does not include a medicinal product with marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, the Coordination Group under Article 77, Paragraph 2, based on the recommendation under Article 194w, shall issue an opinion within 30 days of the date of receiving it, on the preservation, modifying, suspension, termination of the validity of the respective marketing authorisations or refusal to renew them, together with a schedule for implementing the opinion.
(2) When there is a recommendation in the opinion to undertake the measures under Article 194w, Paragraph 3, item 5, the Bulgarian Drugs Agency Executive Director shall issue an order to stop the validity or terminate the marketing authorisation, or refuse its renewing.
(3) When the opinion under Paragraph 1 contains recommendations of changes in the marketing authorisation issued, the marketing authorisation holder shall file an application for modification to the Bulgarian Drug Agency, which shall include updated product summary and brochure, within the specified schedule for implementation.
(4) When the opinion under Paragraph 1 contains recommendation to undertake measures under Article 194w, Paragraph 3, items 2-4, the marketing authorisation holder shall undertake the necessary actions and shall inform the Bulgarian Drugs Agency and the regulatory authorities of the other Member States.
(5) When no agreement can be reached within the Coordination Group under Article 77, Paragraph 2, the position of the majority of Member States shall be submitted to the European Commission, which shall adopt a decision with recommendation for modification, suspension or termination of the marketing authorisation issued by the respective regulatory bodies of the Member States.
(6) The Bulgarian Drugs Agency shall implement the provisional and/or final measures recommended in the decision under Paragraph 5.

Article 194y. (New, SG No. 102/2012, effective 21.12.2012) (1) When the scope of the procedure under Article 194s includes a medicinal product with marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, the Committee for Medicinal Products for Human Use, on the basis of the recommendation under Article 194w, Paragraph 3, shall issue within 30 days of its receipt an opinion on the preservation, modifying, suspension, termination of the validity of the respective marketing authorisations, or refusal of their renewal, together with a schedule for the implementation of the opinion.
(2) When the opinion under Paragraph 1 contains a position for undertaking regulatory actions with respect to the marketing authorisation, the European Commission shall:

1. adopt a decision for modifying, suspension or termination of the validity of the marketing authorisations issued under Regulation (EC) No. 725/2004 of the European Parliament and of the Council;
2. adopt a decision with recommendation for modifying, suspension or termination of the validity of the marketing authorisations issued by the respective regulatory bodies of the Member States.
(3) The Bulgarian Drugs Agency shall implement the provisional and/or final measures recommended in the decision under Paragraph 2, item 2.

Article 194z. (New, SG No. 102/2012, effective 21.12.2012) The recommendation under Article 194w, Paragraph 1, the opinion under Article 194y, Paragraph 1 and the decision of the European Commission under Article 194x, Paragraph 5 and Article 194y, Paragraph 2 shall be posted on the European Internet portal under Article 68, Paragraph 1, item 4.

Chapter Nine
WHOLESALING OF MEDICINAL PRODUCTS AND INTERMEDIATION IN THE SPHERE OF MEDICINAL PRODUCTS
(Title amended, SG No. 71/2008, effective 12.08.2008, SG No. 102/2012, effective 2.01.2013)

(Section I. Wholesaling of medicinal products)
(Title repealed, SG No. 71/2008, effective 12.08.2008)

Article 195. (1) Natural and legal persons holding an authorisation for this type of operations, issued by a regulatory body in the respective Member State, may wholesale medicinal products.
(2) Where the person under Paragraph 1 has warehouse facilities on the territory of the Republic of Bulgaria, he may wholesale medicinal products after obtaining an authorisation from the Bulgarian Drugs Agency Executive Director.

Article 195a. (New, SG No. 67/2020) A person having obtained an authorisation for wholesale trade in medicinal products may not be a holder of an authorisation for retail trade in medicinal products in a pharmacy, issued pursuant to this Act.

Article 196. (1) The manufacturer of medicinal products, within the meaning of this Act, may only wholesale the medicinal products for which he holds a manufacturing authorisation.
(2) The importer of medicinal products, within the meaning of this Act, may only wholesale the medicinal products for which he holds an import authorisation.

Article 197. Persons under Article 195 must have:
1. suitable premises, equipment and installations, and suitable transportation vehicles ensuring the right storage, distribution and transportation of medicinal products in compliance with the requirements of Good Distribution Practice;
2. qualified staff and a responsible master of pharmacy with at least two years of service record in the area of specialisation, whose duties shall be specified in the Ordinance under Article 198.

Article 198. (Amended, SG No. 102/2012, effective 2.01.2013) The principles and requirements of Good Distribution Practice for medicinal products and active substances shall be adopted with an Ordinance of the Minister of Health and with guidelines adopted by the European Commission.

Article 199. (1) The persons under Article 195, Paragraph 2 shall file with the Bulgarian Drugs Agency:
1. an application specifying the name, seat and business address of the trader; the address and a description of the premises and installations for the storage of medicinal products;
2. (amended, SG No. 60/2011, effective 5.08.2011) data on the Unified ID code of the trader or cooperation from the Commercial Register, and an up-to-date registration certificate under the respective national laws issued by the relevant country's competent authority in the case of companies registered in Member States of the European Union or European Economic Area Agreement;

3. (supplemented, SG No. 103/2017, effective 1.01.2018) the name, a certificate of criminal record or an analogous document concerning the person, if such person is not a Bulgarian citizen, a diploma of higher education and a document of service record of the responsible master of pharmacy under Article 197, item 2, and a copy of his labour contract;
4. (repealed, SG No. 60/2011, effective 5.08.2011);
5. (repealed, SG No. 60/2011, effective 5.08.2011);
6. a document certifying the legal grounds for the use of premises;
7. (repealed, SG No. 84/2018, effective 12.10.2018);
8. a document evidencing the payment of a fee at the amount set in the Tariff under Article 21, Paragraph 2.
(2) The persons under Article 195, Paragraph 1 shall file an application with the Bulgarian Drugs Agency together with:
1. a copy of the authorisation for wholesaling, issued by a regulatory body in a Member State;
2. the name and address of the contact person on the territory of the Republic of Bulgaria;
3. the address of storage premises for medicinal products on the territory of the Member States.
(3) In the case of wholesaling of narcotic substances and in pharmaceutical forms containing these, the requirements of the Narcotic Substances and Precursors Control Act shall also apply.
(4) (Repealed, SG No. 17/2020).
(5) (New, SG No. 103/2017, effective 1.01.2018) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the conviction status of the person under Item 3 of Paragraph 1 where such person is a Bulgarian citizen.
(6) (New, SG No. 67/2020) On the day of receipt of the application under paragraph 1 or 2, the Bulgarian Drug Agency shall, through the relevant official channels, send to the Management Board of the Bulgarian Pharmaceutical Union a request for issuance of a certificate of registration in the National Electronic Register of members of the Bulgarian Pharmaceutical Union regarding the master of pharmacy under Article 197, item 2, and for provision of information on any penalties imposed in accordance with the procedure provided for in the Professional Organisation of Masters of Pharmacy Act and the Health Act.
(7) (New, SG No. 67/2020) The Managing Board shall provide the documents under paragraph 6 within five working days of the receipt of the request.

Article 200. The Bulgarian Drugs Agency shall evaluate the documentation and conduct an on-site inspection of the sites specified in the application with a view to establishing their compliance with the requirements of Good Distribution Practice.

Article 201. (1) The Bulgarian Drugs Agency shall notify the applicant in writing where it finds incompleteness of the submitted documentation.
(2) In the cases under Paragraph 1 the period under Article 202, Paragraph 1 shall be suspended.

Article 202. (1) (Amended, SG No. 84/2018, effective 12.10.2018) Within a period of 60 days of the date of submission of the application under Article 199, Paragraph 1, the Bulgarian Drug Agency Executive Director shall issue an authorisation for wholesaling or a motivated refusal.
(2) A refusal under Paragraph 1 shall be subject to appeal under the Administrative Procedure Code.

Article 203. Within a period of 15 days of the date of submission of the documentation under Article 199, Paragraph 2, the Bulgarian Drugs Agency Executive Director shall issue a certificate of registration for wholesaling on the territory of the Republic of Bulgaria to the person under Article 195, Paragraph 1.

Article 204. (1) An authorisation for wholesaling of medicinal products shall not be limited in time.
(2) An authorisation under Article 202 or a certificate under Article 203 shall terminate where its holder so requests in writing from the Bulgarian Drugs Agency Executive Director.
(3) The person under Article 195 shall be obligated to notify the Bulgarian Drugs Agency in writing within 7 days of terminating its operations for wholesaling of medicinal products. In these cases the Bulgarian Drug Agency Executive Director shall terminate the authorisations/certificates or wholesaling of medicinal products that have been issued.

Article 205. (1) The Bulgarian Drugs Agency shall keep a register of the authorisations issued under Article 202, Paragraph 1 for wholesaling of medicinal products, which shall contain the following:
1. the number and date of the authorisation;
2. the name, seat and business address of the person who has obtained the authorisation;
3. the address of the premises for storage of medicinal products;
4. data on the responsible master of pharmacy under Article 197, item 2;
5. a list of the drugs containing narcotic substances, of radiopharmaceuticals, immunological medicinal products and medicinal products obtained from human plasma and human blood;
6. the date of deletion of the authorisation from the register and the grounds thereof;
7. comments on any of the recorded circumstances.
(2) The Bulgarian Drugs Agency shall keep a register of the certificates issued under Article 203 for wholesaling of medicinal products, which shall contain:
1. the number and date of the certificate;
2. the number of the authorisation for wholesaling of medicinal products and the issuing body;
3. the name, seat and business address of the person who has obtained the certificate;
4. data on the person under Article 199, Paragraph 2, item 2;
5. the date of deletion of the certificate from the register and the grounds thereof;
6. any comments on the recorded circumstances.
(3) Data from the register shall be posted on the Bulgarian Drugs Agency website.
(4) (New, SG No. 102/2012, effective 2.01.2013) The Bulgarian Drugs Agency shall introduce information on the authorisations for wholesaling of medicinal products issued in the database under Article 147.
(5) (New, SG No. 102/2012, effective 2.01.2013) Upon request by the European Commission or by a Member State, the Bulgarian Drugs Agency shall submit information on authorisations for wholesaling of medicinal products issued.

Article 206. (1) When circumstances pertaining to the issued authorisation for wholesaling have changed, the holder thereof shall file an application with the Bulgarian Drugs Agency in compliance with Article 199, attaching thereto documentation relating to such changes.
(2) An authorisation for change shall be issued under the terms and conditions of Articles 200 - 202. Where storage premises have been changed, the period under Article 202 shall apply, the period in all other cases being 14 days.

Article 207. (1) The holder of an authorisation for wholesaling carrying out his operations on the territory of the Republic of Bulgaria shall be obligated to:
1. provide access at any time by the control bodies to the storage premises for medicinal products;
2. trade only in medicinal products allowed under the present Act;
3. trade in medicinal products whose packaging and brochures are in compliance with the marketing authorisation issued, under the terms and conditions of the present Act, the shelf life of which has not expired;
4. supply medicinal products only from manufacturers, importers or wholesalers who have obtained licenses for these operations under the present Act;
4a. (new, SG No. 102/2012, effective 2.01.2013, amended, SG No. 67/2020) check if the medicinal products received from the persons under paragraph 4 are not counterfeit, and check the authenticity of the medicinal products, as laid down in Delegated Regulation (EU) 2016/161, using the safety features under Article 168, paragraph 8 in the cases laid down in Delegated Regulation (EU) 2016/161;
4b. (new, SG No. 67/2020) check the safety features and deactivate the unique identifier of a medicinal product before supplying this medicinal product in the cases set out in the ordinance under Article 198;
5. supply medicinal products to other wholesale authorisation holders, pharmacies and drugstores opened under the present Act;

5a. (new, SG No. 71/2008, effective 12.08.2008, amended, SG No. 84/2018, effective 12.10.2018) supply medicinal products for the needs of:
(a) medical treatment facilities;
(b) higher education institutions carrying out medical activities under Article 2a of the Medical-Treatment Facilities Act;
(c) institutions referred to in Article 26, paragraphs 1(1) and 3 of the Health Act, in particular for healthcare offices established in these institutions;
(d) shipowners, for the purpose of providing medicinal products on board vessels in accordance with the Merchant Shipping Code;
6. supply medicinal products to physicians and doctors of dental medicines when there is no pharmacy in the respective populated area, under the terms and conditions specified in an Ordinance of the Minister of Health;
6a. (new, SG No. 102/2012, effective 2.01.2013, supplemented, SG No. 84/2018, effective 12.10.2018) record (in shipping documentation) the batch numbers of delivered medicinal products, as well as the address of delivery of medicinal products;
6b. (new, SG No. 102/2012, effective 2.01.2013) have an emergency action plan that contains effective measures for withdrawal of a medicinal product from the market on the instruction of the Bulgarian Drugs Agency or on the initiative of the manufacturer or of the marketing authorisation holder for the respective medicinal product;
6c. (new, SG No. 18/2014) ensure the supply of sufficient amounts of medicinal products to meet the healthcare demands of the population within the territory of the Republic of Bulgaria;
7. (amended, SG No. 102/2012, effective 2.01.2013) keep data for each transaction with medicinal products received, expedited or marketed with intermediation in the form of invoices for purchase and sale, or in electronic form, or in some other form, as follows:
a) the date of receipt and submission;
b) the name of the medicinal product;
c) quantities received, expedited or marketed with intermediation;
d) the name and address of the person from whom the medicinal product has been received or to whom it has been supplied;
e) the batch number and the number of the certificate for release of the batch, issued by the qualified person under Article 148, item 2 or by the qualified person under Article 161, Paragraph 2, item 1, and the number of the certificate for release of the batch, issued by the Bulgarian Drugs Agency in cases under Articles 69 and 70;
8. (supplemented, SG No. 67/2020) keep the documentation of the purchases and/or sales of all medicinal products, including the purchase/sale invoices, which shall state the International Nonproprietary Name, the trade name of the medicinal product, the pharmaceutical form, the strength of the medicinal product and the packaging;
9. observe the requirements of Good Distribution Practice specified in the Ordinance under Article 198;
10. (new, SG No. 102/2012, effective 2.01.2013) maintain a quality system determining the responsibilities, the processes and the risk management measures connected with his activities;
11. (new, SG No. 102/2012, effective 2.01.2013) inform the Bulgarian Drug Agency and the marketing authorisation holder when he has established or suspects that the medicinal product received or offered to him has been counterfeited;
12. (new, SG No. 102/2012, effective 2.01.2013) check whether the wholesale trader from whom he has received the medicinal product complies with the principles and guidelines for Good Distribution Practices under Article 198, as well as whether he possesses wholesaling authorisation;
13. (new, SG No. 102/2012, effective 2.01.2013) check whether the manufacturer or the importer from whom he has received the medicinal product possesses a manufacturing/import authorisation;
14. (new, SG No. 102/2012, effective 2.01.2013) check whether the intermediary through whom he has received the medicinal product complies with the requirements under this Chapter;

15. (new, SG No. 84/2018, effective 12.10.2018) provide daily information to the Bulgarian Drug Agency through the system under Article 217 b(1) concerning:
(a) the quantities delivered to natural and legal persons under paragraphs 5, 5a and 6, indicated by medicinal products included on the Positive Drug List;
(b) natural and legal persons under paragraphs 5, 5a and 6 who have received supplies of medicinal products referred to in paragraph (a);
(c) the quantities available in stock in their warehouses, indicated by medicinal products included on the Positive Drug List;
(d) the quantities indicated by medicinal products included on the Positive Drug List which are subject to planned exports, as well as the countries of planned export destination;
(e) the quantities indicated by medicinal products included on the Positive Drug List which have been exported, as well as the country of export destination.
(2) The documentation under Paragraph 1, items 7 and 8 shall be kept for at least 5 years and shall be provided, upon request, to the control bodies.

Article 208. (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 2.01.2013, SG No. 84/2018, effective 12.10.2018) The provisions of Article 207, Paragraph 1, items 2 - 15, and Paragraph 2 and Article 209a, shall also apply to wholesalers under Article 203, as well as to importers and manufacturers who trade in medicinal products manufactured by them.

Article 209. The special requirements of other laws shall also apply to the wholesaling of medicinal products containing narcotic substances or obtained from blood, in immunological products and in radiopharmaceuticals.

Article 209a. (New, SG No. 71/2008, effective 12.08.2008) (1) Wholesalers of medicinal products may supply medicinal products to:
1. other wholesalers of medicinal products;
2. pharmacies and drugstores;
3. the Ministry of Defence and the Ministry of Interior for their own needs, with the exception of their institutional treatment establishments, as well as to the State Reserve and Wartime Reserves State Agency;
4. the Ministry of Health, notably:
a) vaccines, toxins and sera needed for the implementation of the Immunisation Calendar of the Republic of Bulgaria, as well as for emergency epidemic situations;
b) medicinal products intended for the treatment of diseases, which are paid for under the Health Act, as well as for securing the implementation of national programmes in the health care sphere;
5. (new, SG No. 60/2012, effective 7.08.2012) outpatient treatment establishments, having entered into contract with the National Health Insurance Fund, with medicinal products trequired for performing the health care activities under Article 82(2) Item 3 of the Health Act.
(2) Physicians and doctors of dental medicine in populated areas where there is no pharmacy may obtain supplies of medicinal products from wholesalers in compliance with the provisions of the Ordinance under Article 207, Paragraph 1, item 6.

Article 209b. (New, SG No. 102/2012, effective 2.01.2013) (1) The requirements under Article 207, Paragraph 1, items 2, 5 and 6, as well as the requirements under Chapter Nine "a", shall not be complied with for wholesaling of medicinal products in third countries.
(2) (Amended, SG No. 67/2020) The requirements under Article 207, paragraph 4, items 4, 4a and 4b shall not apply when a medicinal product is received directly from a third country, but has not been imported into the territory of the Republic of Bulgaria.
(3) (New, SG No. 18/2014) In cases under Paragraph 1 above, the wholesaler shall evidence by submitting in proof relevant documents, that the medicinal products have been obtained from persons who have been licenced or authorised to deliver medicinal products in conformity with the applicable third party national regulations.
(4) (New, SG No. 18/2014) When the wholesaler operates in supplying medicinal products to persons resident in third countries, he shall provide relevant documents as evidence in proof that the

supplies are intended for persons, who have been licensed or authorised to receive medicinal products, intended for wholesales, or to dispense such to the general public in conformity to the third country's applicable national regulations.
(5) (Renumbered from Paragraph 3, SG No. 18/2014) The wholesaler who supplies medicinal products to persons in third countries, who have the right under the national legislation to supply medicinal products to the consumers, shall issue a document testifying:
1. the date of supply;
2. name and form of the medicinal product;
3. quantity supplied;
4. name and address of the person to whom the medicinal product has been supplied;
5. batch number.

Article 210. (Amended, SG No. 60/2011, effective 5.08.2011) (1) The marketing authorisation holder and/or the person referred to in Article 26, Paragraph 2 may provide samples of authorised medicinal products to:
1. physicians and doctors of dental medicine;
2. higher medical schools and medical colleges;
(2) In the cases under Paragraph, 1 the packaging of the medicinal products shall bear the inscription "sample."
(3) No more than two samples of the same pharmaceutical form in the smallest existent packaging may be provided in one calendar year to persons under Paragraph 1, item 1, and to higher medical schools and medical colleges - only the amounts required for training purposes.
(4) The marketing authorisation holder and/or the person referred to in Article 26, Paragraph 2, shall keep a record of all persons to whom they have provided samples, of the type, amount and time of supplies and, upon request, shall submit these data to the control bodies.

Article 211. (1) Wholesalers must have a system for blocking and withdrawing medicinal products from the market, which have demonstrated non-compliance with quality, safety and efficacy requirements.
(2) The holder of a wholesaling authorisation shall be obligated to block and withdraw from the market medicinal products that have demonstrated lack of compliance with quality, safety and efficacy requirements, in compliance with the procedure specified in the Ordinance under Article 274, Paragraph 1.

Article 212. (1) The Bulgarian Drugs Agency Executive Director shall notify the European Commission, the regulatory bodies of other Member States and the European Medicines Agency of the wholesaling authorisations issued, of the authorisations suspended provisionally or withdrawn and of the reasons for this.
(2) (Amended, SG No. 102/2012, effective 2.01.2013) When the Bulgarian Drug Agency Executive Director finds that a person under Article 195, Paragraph 1 does not discharge his duties under Article 207, Paragraph 1, items 2 - 14, he shall notify the regulatory body of the Member State that had issued the wholesaling authorisation and the European Commission.
(3) When the regulatory body under Paragraph 2 suspends provisionally or withdraws the wholesaling authorisation of a person under Article 195, Paragraph 1, it shall notify the Bulgarian Drugs Agency Executive Director and the European Commission.

Article 212a. (New, SG No. 102/2012, effective 2.01.2013) (1) (Amended, SG No. 18/2014) Intermediation in the sphere of medicinal products may be performed by natural and legal persons registered as business intermediaries under the Commerce Act of the Republic of Bulgaria, who have been registered for these activities by the Bulgarian Drug Agency.
(2) The persons under Paragraph 1 who wish to be registered as intermediaries shall file a notification to the Bulgarian Drugs Agency following a model approved by the Bulgarian Drugs Agency Executive Director, which shall contain:
1. name, seat and business address;
2. contact data.
(3) The notification under Paragraph 2 shall be accompanied by:

1. data on the unified ID code;
2. document for paid fee in an amount specified in the Tariff under Article 21, Paragraph 2.
(4) The Bulgarian Drugs Agency shall enter in a public register the persons engaged in intermediation in the sphere of medicinal products.
(5) The persons under Paragraph 1 may engage in intermediation in the sphere of medicinal products after filing the notification under Paragraph 2 to the Bulgarian Drugs Agency.
(6) The persons under Paragraph 1 shall notify the Bulgarian Drugs Agency within 7 days from the occurrence of change in any of the circumstances under Paragraph 2.

Article 212b. (New, SG No. 102/2012, effective 2.01.2013) (1) The persons under Article 212a, Paragraph 1, shall be obligated:
1. to conduct their activities only with medicinal products having market authorisation;
2. to have an action plan for emergency situations, which shall contain effective measures for recalling a medicinal product from the market on the order of the Bulgarian Drugs Agency or on the initiative of the manufacturer or marketing authorisation holder for the respective medicinal product;
3. to keep data comprising the following information on every transaction with medicinal products marketed though intermediation:
a) date of the transaction;
b) name of the medicinal product;
c) quantity marketed through intermediation;
d) na me and address of the persons receiving and expediting the medicinal product;
e) batch number;
4. to comply with the requirements of the Good Distribution Practice adopted with the Ordinance under Article 198;
5. to maintain a quality system specifying the responsibilities, processes and measures of risk management connected with their activities;
6. to inform immediately the Bulgarian Drugs Agency and the marketing authorisation holder when it has been established or suspected that the medicinal product subject to intermediation has been counterfeited;
7. to check whether the trader possesses authorisation for wholesale trade in medicinal products;
8. to check whether the manufacturer or the importer possess manufacturing/import authorisation;
9. to store the data under Paragraph 3 for a period not less than 5 years and to submit them to the control bodies on demand.
(2) The requirements to the intermediation activities in the sphere of medicinal products shall be specified with the Ordinance under Article 198 and in guidelines of the European Commission.

Chapter Nine "a"
(Title amended, SG No. 71/2008, effective 12.08.2008)
PARALLEL IMPORT OF MEDICINAL PRODUCTS

Article 213. (Amended, SG No. 71/2008, effective 12.08.2008) A natural or legal person registered under the Commerce Act, under the legislation of a Member State, after obtaining authorisation for parallel import, issued by the Bulgarian Drugs Agency Executive Director, may carry out parallel import of medicinal products on the territory of the Republic of Bulgaria.

Article 214. (1) A medicinal product authorised in another Member State may be imported in parallel on the territory of the Republic of Bulgaria when it is identical or similar to a medicinal product authorised in the Republic of Bulgaria in pursuance hereof.
(2) (Amended, SG No. 71/2008, effective 12.08.2008, SG No. 12/2011, effective 8.02.2011) For the purposes of Paragraph 1, a medicinal product shall be identical or similar if it has identical quantitative and qualitative composition with respect to the active substance(s), is offered in the same pharmaceutical form and in the same primary packaging, with a similar graphic design of the packaging.

Article 215. (1) (Amended, SG No. 71/2008, effective 12.08.2008) In order to obtain an authorisation for parallel import of a medicinal product on the territory of the Republic of Bulgaria, the person under Article 213 shall file an application with the Bulgarian Drugs Agency Executive Director, indicating the Member State from which parallel import is to be made.
(2) The following data and documents shall be attached to the application:
1. the name, pharmaceutical form and amount of active substance per dosing unit of the medicinal product authorised in the Republic of Bulgaria;
2. the name, pharmaceutical form and amount of active substance per dosing unit of the medicinal product intended for parallel import;
3. (supplemented, SG No. 12/2011, effective 8.02.2011) the name of the marketing authorisation holder and of the manufacturer, if other than the marketing authorisation holder for the medicinal product intended for parallel import;
4. the number of the marketing authorisation for the medicinal product in the Republic of Bulgaria and the number of the marketing authorisation for the medicinal product in the Member State from which parallel import is to be effected;
5. a declaration establishing the circumstances under Article 217, item 1;
6. a copy of the patient brochure and a sample of the medicinal product as it is sold in the Member State from which parallel import is to be effected, a translation of the brochure content into Bulgarian, accompanied by a declaration that the translation corresponds to the original brochure;
7. a proposed patient brochure for the medicinal product subject to parallel import, accompanied by a declaration that the brochure content is identical with the brochure content of the medicinal product authorised in the Republic of Bulgaria, with the exception of the following data:
a) the name and business address of the person carrying out parallel import;
b) the name of the manufacturer, where different for the two products;
c) period of stability when different for the two products;
d) excipients when different for the two products;
8. in case of repackaging:
a) (amended, SG No. 71/2008, effective 12.08.2008, SG No. 67/2020) a mock-up of the product in the form in which it is to be released on the market in Bulgaria;
b) a copy of the contract between the person carrying out parallel import and the persons carrying out partial manufacturing operations, i.e., packaging, labelling, etc.;
c) a certificate of Good Manufacturing Practice when the processes of repackaging are carried out outside the territory of the Republic of Bulgaria;
d) if carried out by the person under Article 213, a copy of the manufacturing authorisation issued by the regulatory body of the Member State in which repackaging takes place;
9. a document evidencing the payment of a fee at the amount specified in the Tariff under Article 21, Paragraph 2.
(3) (Amended, SG No. 71/2008, effective 12.08.2008) Where differences exist between the medicinal product for parallel import and the product authorised on the territory of the Republic of Bulgaria (in terms of the composition of excipients or others), the person under Paragraph 1 shall submit evidence that these do not have any impact on the therapeutic qualities of the medicinal product for parallel import.
(4) In the cases under Paragraph 3, the person under Paragraph 1 shall indicate the differences on the packaging and in the patient brochure of the medicinal product subject to parallel import.
(5) Where the person under Article 213 performs repackaging and/or labelling of the medicinal product in Bulgarian on the territory of the Republic of Bulgaria, he must hold a manufacturing authorisation issued by the Bulgarian Drugs Agency Executive Director.
(6) The product subject to parallel import shall be used under the terms of the issued marketing authorisation for the medicinal product on the territory of the Republic of Bulgaria.

Article 216. (1) An authorisation for parallel import on the territory of the Republic of Bulgaria shall be issued within 45 days of the date of submission of the documentation to the Bulgarian Drugs Agency.

(2) When the Bulgarian Drugs Agency requires additional documentation from the applicant, the period under Paragraph 1 shall be suspended until receipt of the requested documentation.
(3) When the Bulgarian Drugs Agency requires from the regulatory body of the Member State from which parallel import is carried out information relating to the issuance of the marketing authorisation of the imported medicinal product, the period under Paragraph 1 shall be extended by 45 days.
(4) In the event that the Bulgarian Drugs Agency does not receive the requested documentation in the period under Paragraph 3, the procedure for issuance of an authorisation for parallel import on the territory of the Republic of Bulgaria shall be terminated.
(5) Authorisations issued for parallel import on the territory of the Republic of Bulgaria shall be posted on the Bulgarian Drugs Agency website.
(6) The authorisation for parallel import shall be valid for 5 years. A new authorisation shall be issued in compliance with Article 215.
(7) The authorisation for parallel import shall not terminate automatically when the holder of the authorisation for the use of the medicinal product placed on the market on the territory of the Republic of Bulgaria withdraws it for reasons unrelated to a threat to the health of the population.

Article 216a. (New, SG No. 105/2020, effective 11.12.2020) (1) In the event a state of emergency has been declared due to epidemiological spread of infectious diseases under Article 61 (1) or (3) of the Health Act or in the event that an emergency epidemiological situation has been declared due to epidemiological spread of an infectious disease under Article 61(1) of the Health Act, the authorisation for parallel import shall be issued within 14 days from the date of submission of the documentation under Article 215 to the BDA.
(2) When the Bulgarian Drug Agency requires additional documentation from the applicant, the period under Paragraph 1 shall be suspended until receipt of the requested documentation.
(3) When the Bulgarian Drug Agency requires from the regulatory body of the Member State from which parallel import is carried out information relating to the issuance of the marketing authorisation of the imported medicinal product, the period under Paragraph 1 shall be extended by 14 days.
(4) When the Bulgarian Drug Agency does not receive the requested documentation in the period under Paragraph 3, the procedure for issuance of an authorisation for parallel import on the territory of the Republic of Bulgaria shall be terminated.
(5) Authorisations issued for parallel import under Paragraph 1 shall be posted on the Bulgarian Drug Agency website.
(6) The term of the authorisation for parallel import under Paragraph 1 shall expire on the date of the lifting of the state of emergency or the emergency epidemic situation under Paragraph 1.
(7) The authorisation for parallel import shall be automatically terminated as of the date of the lifting of the state of emergency or the emergency epidemic situation under Paragraph 1.
(8) Upon termination of the authorisation for parallel import under Paragraph 7, the medicinal product may be sold until the quantities available in the country are depleted, but for not more than 6 months after the date of termination.
(9) In the cases referred to in Paragraph 1 the National Council on Prices and Reimbursement of Medicinal Products shall rule within 14 days for approval/registration of the price of medicinal products for which authorisation for parallel import has been obtained as of the date of submission of an application according to the procedure laid down in the ordinance under Article 261a(5).

Article 217. The holder of an authorisation for parallel import shall be obligated to:
1. notify the marketing authorisation holder for the medicinal product placed on the market on the territory of the Republic of Bulgaria of his intentions to carry out parallel import and, upon request, to provide a sample of the medicinal product subject to parallel import;
2. store for a period of 5 years the following documentation: the name and address of the person to whom the medicinal product subject to parallel import has been supplied, the date of submission, the amount supplied and the batch number;
3. submit to the Bulgarian Drugs Agency:

a) an updated patient brochure of the product subject to parallel import in compliance with the changes made in the issued marketing authorisation for the medicinal product authorised in the Republic of Bulgaria;
b) (amended, SG No. 71/2008, effective 12.08.2008) A declaration that the content of the brochure under a) is identical to the content of the product brochure authorised in the Republic of Bulgaria with the exception of data under Article 215, Paragraph 2, item 7, a) - d);
4. record and report to the marketing authorisation holder and to the Bulgarian Drugs Agency all notifications of suspected adverse reactions to the imported medicinal product;
5. (new, SG No. 84/2018, effective 12.10.2018) using the specialized electronic system referred to in Article 217b(1), inform the Bulgarian Drug Agency, every week or after a change of circumstances, about:
(a) the quantities subject to parallel imports into the Republic of Bulgaria, indicated by medicinal products included on the Positive Drug List that are held by the parallel import authorisation holder;
(b) the quantities delivered to natural and legal persons under Article 207, paragraphs 1(5), 5a and 6, indicated by medicinal products included in the Positive Drug List;
(c) the natural and legal persons under Article 207, paragraphs 1(5), 5a and 6 who have received the supplies of medicinal products referred to in paragraph (a);
(d) date on which the import/delivery under paragraphs (a) and (b) has been made;
(e) the quantities available in stock, indicated by medicinal products included on the Positive Drug List that are held by the parallel import authorisation holder;
6. (new, SG No. 103/2020, effective 1.01.2021) provide to the BDA, in respect of all medicinal products authorised for parallel import in the territory of the country, including in case of change of circumstances, through the specialised electronic system referred to in Article 217b(1), information about the product code within the meaning of Article 4(b)(i) of Commission Delegated Regulation (EU) 2016/161 for medicinal products set out in the Regulation;
7. (new, SG No. 67/2020, renumbered from Item 6, SG No. 103/2020, effective 1.01.2021) ensure the replacement of the safety features on the outer packaging, and in its absence – on the immediate packaging of the medicinal products, as laid down in Delegated Regulation (EU) 2016/161, with indicators equivalent to them within the meaning of Article 168b, paragraph 3 and ensure the introduction of the unique identifier of each packaging in the system of registers pursuant to Delegated Regulation (EU) 2016/161.

Chapter Nine "b"
(New, SG No. 18/2014)
EXPORT OF MEDICINAL PRODUCTS SPECIALIZED ELECTRONIC SYSTEM FOR TRACKING AND ANALYSIS OF MEDICINAL PRODUCTS
(Title amended, SG No. 84/2018, effective 12.10.2018)

Article 217a. (New, SG No. 18/2014) (1) The export of medicinal products from the territory of the Republic of Bulgaria may be performed by a natural person, or by a legal entity who is the license holder for the wholesales of medicinal products, or of the manufacturing authorisation holder.
(2) Only medicinal products, manufactured by the Manufacturing Authorisation Holder may be exported by the said manufacturing authorisation holder.
(3) For the purposes of this Chapter, export shall be also an intra-community delivery within the European Union.
(4) (Amended, SG No. 84/2018, effective 12.10.2018) Medicinal products included on the Positive Drug List in respect of which shortages have been established pursuant to Article 217b cannot be exported during the period for which they are on the list under Article 217c(1).

Article 217b. (New, SG No. 18/2014, amended, SG No. 84/2018, effective 12.10.2018) (1) A specialized electronic system for tracking and analysis of medicinal products included on the Positive Drug List shall be set up; the system shall be administered and maintained by the Bulgarian Drug Agency.

(2) The electronic system referred to in paragraph 1 shall be set up and maintained on the basis of the following principles:
1. guaranteeing that the data submitted and stored is up-to-date and accurate;
2. ensuring an adequate data exchange environment;
3. guaranteeing regulated and controlled access to the data in the electronic information system, subject to the statutory requirements of the law;
4. ensuring operational compatibility and information security.
(3) The specialized electronic system referred to in paragraph 1 contains:
1. (amended, SG No. 103/2020, effective 1.01.2021) information referred to in Articles 54, 54a, 68, Paragraph 1, Item 10 and 11, Article 207, Paragraph 1, Item 15, Article 217, Item 5 and 6 and Article 232a, provided by the persons concerned;
2. (amended, SG No. 67/2020) information provided by the National Health Insurance Fund concerning the quantities indicated per reported and paid medicinal products included on the Positive Drug List for the previous month;
3. information provided by the Ministry of Health concerning the quantities indicated in relation to paid medicinal products included on the Positive Drug List for the previous month.
(4) On the basis of the information referred to in paragraph 3, the specialized electronic system referred to in paragraph 1 shall be utilized to conduct an analysis intended to establish any shortage of medicinal products included on the Positive Drug List in the Republic of Bulgaria pursuant to the conditions and procedures set out in the ordinance referred to in paragraph 8.
(5) (Supplemented, SG No. 67/2020) The shortage referred to in paragraph 4 of medicinal products included on the Positive Drug List shall be established where the analysis under paragraph 4 has indicated that the quantities of a medicinal product in stock in the Republic of Bulgaria are below 65 percent of the quantities needed to meet the healthcare needs of the population over one month, calculated on the basis of the average monthly consumption of the medicinal product concerned in the preceding 6 months, starting from the day the analysis was made.
(6) The specialized electronic system referred to in paragraph 1 maintains an automated interface for providing information under paragraph 3 and for sending communications.
(7) The right of access to the specialized electronic system referred to in paragraph 1 shall be granted to the institutions and persons referred to in paragraph 3 only for the purpose of providing information, as laid down in this law; these institutions and persons shall be responsible for the accuracy of any information provided, as well as for its timely submission.
(8) (New, SG No. 67/2020) Outside the cases under paragraph 7, the right of access to the data in the specialized electronic system under paragraph 1shall be granted to the Ministry of Health, the National Health Insurance Fund and to the Council under Article 258, paragraph 1.
(9) (Renumbered from Paragraph (8), SG No. 67/2020) The conditions and procedures for the provision, storage and analysis of information under paragraph 3, and for the administration, maintenance and access to the specialized electronic system referred to in paragraph 1 shall be set out in an ordinance of the Minister of Health.
(10) (Renumbered from Paragraph (9), SG No. 67/2020) The Bulgarian Drug Agency is obligated to ensure the network and information security of the specialized electronic system referred to in paragraph 3, subject to the obligation to protect the secrecy of the information received under paragraph 3.

Article 217c. (New, SG No. 18/2014; declared unconstitutional with Judgment No. 1 of the Constitutional Court of the Republic of Bulgaria – SG No. 12/2015; amended, SG No. 84/2018, effective 12.10.2018) (1) The Bulgarian Drug Agency shall create, update and maintain a list of medicinal products included on the Positive Drug List in respect of which shortages have been established in the territory of the Republic of Bulgaria.
(2) The list referred to in paragraph 1 shall be created on the basis of the analysis under Article 217b(4) and published on the website of the Bulgarian Drug Agency.
(3) The list of medicinal products in respect of which shortages have been established under Article 217b(5) shall indicate the name of the medicinal product included on the Positive Drug List,

international non-proprietary name (INN), amount of the active ingredient, pharmaceutical form and quantity in the package.
(4) The list under paragraph 1 shall be updated:
1. weekly;
2. upon any change of circumstances related to the import and/or export of medicinal products included on the Positive Drug List.
(5) In the event of list updates pursuant to paragraph 4(1) or a change of circumstances under paragraph 4(2) on the basis of information provided under Article 68(1)(10), Article 207(1)(15) and Article 217(5), a notice on the updated list shall be sent – through the specialized electronic system referred to in Article 217b(1) – to the persons referred to in Article 68(1), Article 207(1), Article 217 and Article 232a. The list shall be published on the website of the Bulgarian Drug Agency without delay.
(6) In the cases under paragraph 4, the list referred to in paragraph 1 shall also be sent to the Customs Agency ex officio by the Bulgarian Drug Agency.
(7) Once medicinal products have been included on the list referred to in paragraph 1, they may not be exported during the period for which they are on the list.

Article 217d. (New, SG No. 18/2014, amended, SG No. 84/2018, effective 12.10.2018) The Bulgarian Drug Agency shall inspect the persons obligated to provide information in accordance with this chapter.

Article 217e. (New, SG No. 105/2020, effective 11.12.2020) During the period of a declared state of emergency due to epidemiological spread of infectious diseases under Article 61(1) or (3) of the Health Act or in the event that an emergency epidemiological situation has been declared due to epidemiological spread of an infectious disease under Article 61(1) of the Health Act and within three months following their lifting, the export of medicinal products from the territory of the Republic of Bulgaria for which a shortage has been established on the territory of the country to meet the health care demands of the population may be temporarily prohibited by an ordinance of the Minister of Health.

Chapter Ten
RETAILING OF MEDICINAL PRODUCTS NATIONAL PHARMACY MAP
(Title amended, SG No. 67/2020)

Article 218. Retailing of medicinal products shall only be carried out in pharmacies and drugstores in pursuance hereof, with the exception of the cases under Article 232, Paragraph 2.

Article 219. (1) (Amended, SG No. 71/2008, effective 12.08.2008, supplemented, SG No. 23/2009, effective 30.03.2009, SG No. 41/2009, effective 2.06.2009, amended, SG No. 60/2011, effective 5.08.2011, SG No. 67/2020) A pharmacy is a healthcare institution in which the following activities are carried out: storage, preparation, packaging, control, providing consultations, dispensing of prescription and non-prescription medicinal products authorised for marketing in the Republic of Bulgaria, medical devices, dietary foods for special medical purposes and dietary foods for infants for special medical purposes and follow-on formulae, as well as food supplements, cosmetic products, health and hygiene products and biocide products of main group 1 "Disinfectants", product types 1 and 2, and of main group 3 "Pest control", product types 18 and 19,according to Annex V of Regulation (EU) № 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ, L 167/1 of 27 June 2012).
(2) (Amended, SG No. 60/2011, effective 5.08.2011) The structure, work procedures and arrangements of pharmacies, the nomenclature of medicinal products, shall be specified in an Ordinance of the Minister of Health.
(3) (Amended, SG No. 71/2008, effective 12.08.2008, repealed, SG No. 23/2009, effective 30.03.2009, new, SG No. 67/2020) The holder of a retail trade authorisation shall check the authenticity of the medicinal products using the safety features under Article 168, paragraph 8, and shall deactivate the unique identifier in the system of registers.

(4) (New, SG No. 67/2020) The activities under paragraph 3 shall be carried out pursuant to Chapter VI of Delegated Regulation (EU) 2016/161.

Article 220. (1) The operations under Article 219, Paragraph 1 shall be carried out by a master of pharmacy.

(2) (Supplemented, SG No. 71/2008, effective 12.08.2008) A master of pharmacy shall be obligated to comply with a medical prescription by a doctor, also in respect to pharmaceutical forms prepared under magisterial and official formulations in compliance with the procedure specified in the Ordinance under Article 221, Paragraph 1.

(3) (Amended, SGNo 102/2012, effective 2.01.2013) An assistant pharmacist may carry out all operations under Article 219, Paragraph 1 under the control of a master of pharmacy, with the exception of: dispensation of a medicinal product under medical prescription, control and consultations connected with the medicinal products.

Article 221. (1) (Previous Article 221, SG No. 71/2008, effective 12.08.2008) The Minister of Health shall designate in an Ordinance medical specialists who may issue prescriptions, the procedure for prescribing medicinal products, the period of execution, the cases and the procedure when a master of pharmacy may refuse to execute a medical prescription.

(2) (New, SG No. 71/2008, effective 12.08.2008, amended, SG No. 9/2011) Bulgarian citizens and foreign nationals holding permits to reside in Bulgaria may, when travelling abroad, bring or export medicinal products needed for their treatment in compliance with the provisions of the Ordinance referred to in Paragraph 1.

(3) (New, SG No. 71/2008, effective 12.08.2008, amended, SG No. 9/2011) Foreigners holding a short-stay visa for the territory of the Republic of Bulgaria may possess medicinal products intended solely for their treatment in quantities stipulated in the Ordinance referred to in Paragraph 1.

(4) (New, SG No. 1/2014, effective 3.01.2014) The requirements to the medical prescriptions, which are issued on the request of a patient, who intends to use them in another member state, as well as the acknowledgement and the fulfilment of such prescriptions, issued in another member state, are to comply with the terms and conditions, set forth with the Ordinance referred to in Paragraph 1 above.

(5) (New, SG No. 1/2014, effective 3.01.2014) Reimbursement of medicinal products dispensed on prescription fulfilled in another member state shall be carried out in accordance with the terms and conditions set forth with the Ordinance referred to in Article 80e, Paragraph 4 under the Health Insurance Act.

Article 222. (1) (Declared unconstitutional by the Constitutional Court of the Republic of Bulgaria - SG No. 65/2008, amended, SG No. 71/2008, effective 26.07.2008) A natural or legal person registered as trader under the Bulgarian legislation or under the legislation of a Member State, who has signed a labour contract or a contract for management of a pharmacy with a master of pharmacy, and in the cases provided under the law - with an assistant pharmacist, shall be entitled to retail medicinal products, whereby one person may open not more than 4 pharmacies on the territory of the Republic of Bulgaria.

(2) (New, SG No. 71/2008, effective 27.07.2008) Where the person under Paragraph 1 is a master of pharmacy and is in charge of the pharmacy, he shall not be required to present a labour contract or a contract for management of the pharmacy.

(3) (Renumbered from Paragraph 2, amended, SG No. 71/2008, effective 27.07.2008) The master of pharmacy under Paragraph 1 shall be in charge of the pharmacy and shall mandatorily work in it.

(4) (Renumbered from Paragraph 3, SG No. 71/2008, effective 27.07.2008) The following shall have the right to open a pharmacy for their own needs:

1. treatment establishments, under Article 5 of the Treatment Establishments Act, which provide in-patient care;
2. treatment establishments for in-patient care;
3. (amended, SG No. 59/2010) mental health centres, dermal-venereal diseases centres and comprehensive cancer centres;

4. hospices with in-patient facilities under Article 10, item 5 of the Treatment Establishments Act.
(5) (New, SG No. 60/2011, effective 5.08.2011) In order to meet their own needs medical establishments referred to in Paragraph 4 with no pharmacy of their own may receive supplies from the pharmacy of a medical establishment which has obtained an authorisation for retailing of medicinal products under the terms and conditions laid down in the Ordinance provided for in Article 219, Paragraph 2.
(6) (Repealed, renumbered from Paragraph 4, SG No. 71/2008, effective 27.07.2008, renumbered from Paragraph 5, amended, SG No. 60/2011, effective 5.08.2011) Pharmacies of treatment establishments for outpatient care with the Ministry of Defence and the Ministry of Interior may be headed by an assistant pharmacist at the proposal of the respective institution, provided an authorisation to this effect has been issued by the Bulgarian Drugs Agency Executive Director.

Article 222a. (New, SG No. 67/2020) A person having obtained an authorisation for retail trade in medicinal products in a pharmacy may not be a holder of an authorisation for wholesale trade in medicinal products, issued pursuant to this Act.

Article 223. (1) A master of pharmacy or an assistant pharmacist may only head one pharmacy and he shall mandatorily work in it.
(2) (Amended, SG No. 12/2011, effective 8.02.2011) A master of pharmacy or an assistant pharmacist, who is the head of a pharmacy, may not be hired to work under a contract with a sole proprietor or commercial company whose objectives are the manufacturing, import, wholesaling or retailing of medicinal products.
(3) A person under Paragraph 1 who holds an authorisation for retailing of medicinal products may not be the owner or take part in commercial companies whose objectives are the manufacturing, import, wholesaling or retailing of medicinal products, including the cases of companies belonging to related parties within the meaning of the Commerce Act.

Article 224. The head of a pharmacy must:
1. be a master of pharmacy, or assistant pharmacist in the cases provided for by law;
2. not be deprived of the right to exercise the profession;
3. not be convicted for criminal offences associated with the practising of his profession or for criminal offences against property and the economy, or for intentional criminal offences against the person;
4. have at least one year of experience as a master of pharmacy.

Article 225. (Amended, SG No. 71/2008, effective 27.07.2008) (1) A person under Article 222, Paragraph 1, who has signed a labour contract or a contract for management of a pharmacy with an assistant pharmacist or a master of pharmacy with less than one year's experience, shall be entitled to retail medicinal products in a populated area on the territory.
(2) An assistant-pharmacist who has obtained an authorisation for retailing of medicinal products under Paragraph 1, shall be in charge of the pharmacy and shall mandatorily work in it.
(3) (New, SG No. 60/2011, effective 5.08.2011) The assistant-pharmacist in charge of the pharmacy referred to in Paragraph 1 may conduct the following activities: storage and dispensing without medical prescription of medicinal product authorised in the Republic of Bulgaria, of medical devices, of dietetic foods for special medical purposes and of infant formulae and follow-on formulae, as well as of food supplements, cosmetic and sanitary products.

Article 226. (1) Pharmacies for the sale of medicinal products to the citizens may be opened on the territory of outpatient treatment establishments.
(2) No pharmacies for the sale of medicinal products to the citizens may be opened on the territory of medical establishments under Article 21, Paragraph 2 of the Health Act, of in-patient care establishments and of treatment establishments under Article 10 of the Treatment Establishments Act.

Article 227. (1) (Previous Article 227, SG No. 102/2009, effective 22.12.2009) The requirements to the locations and to the premises of pharmacies shall be specified in the Ordinance under Article 219, Paragraph 2.

(2) (New, SG No. 102/2009, effective 22.12.2009, amended, SG No. 60/2011) The requirements to the structure and premises of pharmacies under Article 228, Paragraph 5 shall be specified in the Ordinance referred to in Paragraph 1.

Article 227a. (New, SG No. 67/2020) (1) The population's needs of access to medicinal products dispensed in pharmacies shall be determined on territoriality principle through the National Pharmacy Map.

(2) The National Pharmacy Map shall not include pharmacies opened pursuant to Article 222, paragraph 4.

(3) The National Pharmacy Map shall determine the regions, municipalities and populated areas with shortage of available pharmacies by making an analysis of the population's access to pharmacies, which carry out activities of:

1. dispensation of medicinal products for home treatment fully or partially paid by NHIF under the conditions and according to the procedure of Article 45, paragraph 17 of the Health Insurance Act;
2. preparation of medicinal products;
3. dispensation of medicinal products containing narcotic substances within the meaning of the Narcotic Substances and Precursors Control Act;
4. dispensation of medicinal products to war veterans;
5. dispensation of medicinal products to war invalidated servicemen and war wounded servicemen;
6. dispensation of prescription medicinal products not paid by public funds;
7. dispensation of non-prescription medicinal products.

Article 227b. (New, SG No. 67/2020) (1) The National Pharmacy Map shall be created based on regional pharmacy maps.

For the purpose of creating the regional pharmacy map, the Minister of Health shall appoint a committee for each of the regions comprising: the regional governor; two representatives of the regional health inspectorate, two representatives of the regional health insurance fund; two representatives of the regional college of the Bulgarian Pharmaceutical Union, one representative of the regional college of the Bulgarian Association of Assistant Pharmacists, one representative of the patient rights protection representative associations acknowledged pursuant to Article 86c of the Health Act, and one representative per municipality from all the municipalities in the relevant region. The regional governor shall be the Chair of the committee.

(3) The municipal representatives under paragraph 2 shall be appointed pursuant to the Local Self-Government and Local Administration Act.

(4) The representative of the patient rights protection representative associations under paragraph 2 on each of the regional committees shall be elected and dismissed jointly by the representative organisations.

The regional pharmacy map shall be created by following an approved design and a procedure, set forth in the methodology approved by the Minister of Health.

(6) Each regional committee shall submit to the Minister of Health the regional pharmacy map it has prepared, along with the complete primary information used in the creation thereof.

Article 227c. (New, SG No. 67/2020) (1) The regional pharmacy map shall comprise:

1. data on the demographic structure and consumption of medicinal products for home treatment by the population on the territory of the region;
2. the number, types of activities and distribution of open pharmacies on the territory of the region;
3. the number of master pharmacists and assistant pharmacists working in the pharmacies opened on the territory of the region.

(2) A statement of opinion shall be attached to the regional pharmacy map referred to in paragraph 1, which shall be prepared according a procedure and criteria set out in the methodology referred to in Article 227b, paragraph 5, regarding the minimum number of pharmacies by type of activities under Article 227a, paragraph 3, and the minimum number of of master pharmacists and assistant pharmacists working in the pharmacies, which shall be determined according to the needs of the population of the relevant region.

Article 227d. (New, SG No. 67/2020) (1) The National Pharmacy Map shall be created by a national committee appointed by an order of the Minister of Health, who shall act as the committee's chair.

The composition of the committee shall include the Manager of the National Health Insurance Fund, the Chair of the National Council on Prices and Reimbursement of Medicinal Products, two representatives of the Bulgarian Drug Agency, of whom one will be the Executive Director of the Bulgarian Drug Agency, the director of the National Centre for Public Health and Analyses, the Chair of the National Association of Municipalities in the Republic of Bulgaria, two representatives of the Ministry of Health, three representatives of the Bulgarian Pharmaceutical Union, one representative of the Bulgarian Association of Assistant Pharmacists and one representative of the patient rights protection representative associations, acknowledged pursuant to Article 86c of the Health Act.

Article 227e. (New, SG No. 67/2020) (1) The National Pharmacy Map shall contain:

1. the regional pharmacy maps;
2. the population's specific minimum needs of access to medicinal products dispensed in pharmacies and to the types of activities under Article 227a, paragraph 3 by region, municipality and populated area;
3. the distribution by number of population of the opened pharmacies by region, municipality and populated area;
4. displaying graphically the opened pharmacies on the map of the country by the type of activities carried out pursuant to Article 227a, paragraph 3;
5. the population's specific minimum needs of access to medicinal products dispensed in pharmacies and to the types of activities under Article 227a, paragraph 3 by region, municipality and populated area;
6. determining the regions, municipalities and populated areas, where the analysis under item 5 identified a shortage of pharmacies by type of activities under Article 227a, paragraph 3.

(2) The analysis under paragraph 1, item 5 shall be made according a procedure and criteria set out in the methodology referred to in Article 227b, paragraph 5, and shall mandatorily include the population's specific minimum needs of access to medicinal products dispensed in pharmacies and to the types of activities under Article 227a, paragraph 3, as well as the distribution of opened pharmacies by number of population.

Article 227f. (New, SG No. 67/2020) (1) The National Pharmacy Map of the Republic of Bulgaria shall be approved by a decision of the Council of Ministers upon a proposal submitted by the Minister of Health.

(2) The National pharmacy map shall be updated when necessary in the cases stipulated in the methodology under Article 227b, paragraph 5.

Article 228. (Amended, SG No. 71/2008, effective 27.07.2008) (1) (Amended, SG No. 60/2011, effective 5.08.2011) An authorisation for retailing of medicinal products in a pharmacy shall be issued by the Bulgarian Drugs Agency Executive Director upon submission of a model-based application, to which the following shall be attached:

1. (amended, SG No. 60/2011, effective 5.08.2011) details of the Unified ID code of the trader or cooperation from the Commercial Register, and an up-to-date registration certificate of the persons referred to in Article 222, Paragraph 1, under the respective national laws issued by the relevant country's competent authority in the case of companies registered in Member States of the European Union or of the European Economic Area Agreement;
2. a labour contract or a contract for management of a pharmacy, signed with a master of pharmacy or with an assistant pharmacist;
3. a copy of the legal document on the constituting of the persons under Article 222, Paragraph 4;
4. documents certifying compliance with the requirements under Article 224;
5. (supplemented, SG No. 103/2017, effective 1.01.2018) criminal conviction record of the master of pharmacy or of the assistant-pharmacist designated as head of pharmacy, if they are not Bulgarian citizens;

6. a medical certificate for the master of pharmacy or the assistant-pharmacist designated as head of pharmacy;
7. (supplemented, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 48/2015);
7a. (new, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 67/2020);
8. a document for fee paid in an amount stipulated in the Tariff under Article 21, Paragraph 2.
(2) (New, SG No. 60/2011, effective 5.08.2011) When an authorisation for retailing of medicinal products is issued, a check shall be performed whether the degree certificate of the master of pharmacy/assistant pharmacist has been issued by the relevant competent institution.
(3) (Renumbered from Paragraph 2, amended, SG No. 60/2011, effective 5.08.2011) Pharmacies under Article 222, Paragraphs 4 and 6 shall be opened and closed down at the request of the person representing the treatment establishment.
(4) (Renumbered from Paragraph 3, SG No. 60/2011, effective 5.08.2011) The requirements of the Narcotic Substances and Precursors Control Act shall also apply to the opening of a pharmacy where medicinal products containing narcotic substances are to be dispensed and sold.
(5) (New, SG No. 102/2009, effective 22.12.2009, renumbered from Paragraph 4, SG No. 60/2011, effective 5.08.2011) An authorisation for retailing of medicinal products in a pharmacy to be opened in a populated area with population below 10,000 residents shall be issued on the basis of a request submitted as per a template form. The following shall be enclosed with the request:
1. (amended, SG No. 60/2011, effective 5.08.2011, SG No. 84/2018, effective 12.10.2018, SG No. 67/2020) the documents under paragraph 1, items 1 – 6;
2. (amended, SG No. 102/2012, effective 2.01.2013) a documents for the payment of a fee amounting to 50 per cent of the fee specified in the Tariff under Article 21, Paragraph 2 for issuing an authorisation for retailing of medicinal products under Article 222, Paragraph 1.
(6) (Renumbered from Paragraph 4, supplemented, SG No. 102/2009, effective 22.12.2009, renumbered from Paragraph 5, amended, SG No. 60/2011, effective 5.08.2011) The application and the documents under Paragraphs 1 and 5 shall be submitted to the Bulgarian Drugs Agency.
(7) (Renumbered from Paragraph 5, amended, SG No. 102/2009, effective 22.12.2009, renumbered from Paragraph 6, amended, SG No. 60/2011, effective 5.08.2011, SG No. 67/2020) On the date of receiving of the application under paragraph 1 or 5 the Bulgarian Drug Agency shall send ex officio a request to the respective Regional Health Inspectorate for issuing of a hygiene conclusion report. The Regional Health Inspectorate shall issue the hygiene conclusion report within 14 days from receipt of the request and shall forward it ex officio to the Bulgarian Drug Agency. The period referred to in Article 229, paragraph 2 shall be suspended until receipt of the hygiene conclusion report.
(8) (New, SG No. 48/2015, supplemented, SG No. 91/2018) On the date of receiving the application under paragraphs 1 and 5, the Bulgarian Drug Agency shall send requests, through the relevant official channels, for the issuance of a certificate of registration in the national electronic register of members of the Bulgarian Pharmaceutical Union; the request shall be sent to the Management Board of the Bulgarian Pharmaceutical Union (in respect of a pharmacist holding a Master of Pharmacy degree and managing a pharmacy) or to the Bulgarian Association of Assistant Pharmacists (in respect of an assistant pharmacist managing a pharmacy in the cases set out by law), whereby such requests can also seek information on any penalties imposed pursuant to the Professional Organisation of Masters of Pharmacy Act and the Health Act.
(9) (New, SG No. 48/2015) The Management Board shall provide the documents under Paragraph 8 within 5 working days of receiving the request.
(10) (New, SG No. 103/2017, effective 1.01.2018) The Bulgarian Drug Agency shall establish by official channels the circumstances regarding the conviction status of the persons under Item 5 of Paragraph 1 where such persons are Bulgarian citizens.

Article 229. (1) (Supplemented, SG No. 71/2008, effective 12.08.2008, repealed, SG No. 60/2011, effective 5.08.2011).
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2009, effective 22.12.2009, SG No. 60/2011, supplemented, SG No. 18/2014) Within one month of receiving the

documentation under Article 228, Paragraph 6, the Bulgarian Drug Agency Executive Director, subject to an opinion by the Expert Council on retailing of medicinal products shall issue an authorisation for retailing of medicinal products in a pharmacy or a motivated refusal to issue an authorisation. The authorisation or the refusal shall be served on the person who has filed an application.
(3) (Amended, SG No. 60/2011, effective 5.08.2011) Within 15 days of receipt of the documentation referred to in Article 228, Paragraph 6, the Bulgarian Drug Agency shall conduct a check on the documents submitted and inform the applicant in writing of any discrepancies or deficiencies. In these cases the period under Paragraph 2 shall be suspended from the date of notification until removal of the deficiencies.
(4) (New, SG No. 71/2008, effective 12.08.2008) In the event that within 60 days from the date of the notification under Paragraph 3 the applicant has failed to eliminate the identified non-compliances or incompleteness, the procedure of issuing an authorisation for retailing of medicinal products or of amending the authorisation issued shall be terminated.
(5) (Renumbered from Paragraph 4, SG No. 71/2008, effective 12.08.2008, amended, SG No. 60/2011, effective 5.08.2011) The refusal of the Bulgarian Drugs Agency Executive Director to issue an authorisation shall be subject to appeal under the Administrative Procedure Code.

Article 229a. (New, SG No. 23/2009, effective 30.03.2009, amended and supplemented, SG No. 41/2009, effective 2.06.2009) (1) (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 52/2020, effective 9.06.2020) The Bulgarian Drug Agency shall ex officio send to the Regional Health Inspectorate in charge of the relevant pharmacy that has been granted an authorisation for retailing of food supplements, dietetic foods for special medical purposes, infant formulae and follow-on formulae pursuant to Article 229, Paragraph 2 a copy of the authorisation for entry into the register provided for in Article 24, Paragraph 1 of the Foodstuffs Act.
(2) Any pharmacies retailing food supplements and dietetic foods for special medical purposes shall be subject to control under the procedure laid down in the Foodstuffs Act.

Article 230. (1) (Amended, SG No. 60/2011, effective 5.08.2011) The Bulgarian Drugs Agency shall keep a register of authorisations issued for retailing of medicinal products under Article 229, Paragraph 2, that shall contain:
1. the number and date of the authorisation;
2. (supplemented, SG No. 71/2008, effective 12.08.2008) the name, type of trader, seat and business address of the person that has been granted authorisation;
3. (amended, SG No. 12/2011, effective 8.02.2011) the name and personal identification number of the head of the pharmacy;
4. the address of the pharmacy;
5. the operations to be carried out in the pharmacy;
6. the date of termination of the authorisation and of deletion from the register and the grounds to do so;
7. comments with regard to any of the registered circumstances.
(2) (Amended, SG No. 60/2011, effective 5.08.2011) Register data shall be published on the website of the Bulgarian Drugs Agency.

Article 231. (1) In case circumstances entered in the register under Article 230, Paragraph 1, items 2-5 have changed, the person who has been granted authorisation for retailing of medicinal products shall file an application in compliance with Article 228, Paragraph 1, attaching thereto the documents pertaining to any such changes.
(2) (New, SG No. 60/2011, effective 5.08.2011) In case of simultaneous change of the name and type of trader, pharmacy address and head of pharmacy a new application shall be submitted under the procedure provided for in Article 228, Paragraph 1 and the fee for issuing of authorisation for retailing of medicinal products in a pharmacy, laid down in the tariff provided for in Article 21, Paragraph 2, shall be paid
(3) (New, SG No. 60/2011, effective 5.08.2011) Any person who has been granted authorisation for retailing of medicinal products under the procedure laid down in Article 228, Paragraph 5, may

introduce a change under Article 230, Paragraph 1, Item 4, only in a settlement of up to 10,000 population.
(4) (New, SG No. 60/2011, effective 5.08.2011) Where the person referred to in Paragraph 3 wishes to introduce a change under Article 230, Paragraph 1, Item 4, in a settlement of above 10,000 population, they shall pay the fee for issuing of an authorisation for retailing of medicinal products in a pharmacy, laid down in the tariff provided for in Article 21, Paragraph 2.
(5) (Renumbered from Paragraph 2, SG No. 60/2011, effective 5.08.2011) Upon issuance of the authorisation admitting the changes under Paragraph 1, the provisions of Article 229 shall apply.

Article 232. (1) Physicians and doctors of dental medicine may store medicinal products according to a list specified by the Minister of Health.
(2) Where there is no pharmacy in a populated area, the persons under Paragraph 1 may store and sell medicinal products only in the event that they have obtained an authorisation to this effect in compliance with a procedure specified in an Ordinance of the Minister of Health.

Article 232a. (New, SG No. 84/2018, effective 12.10.2018) Using the specialised electronic system referred to in Article 217b(1), the holders of authorisations for retail trade in medicinal products and the persons referred to in Article 207, paragraph 1(5a) and (6) shall inform the Bulgarian Drug Agency on a daily basis about:
1. the quantities delivered to them, indicated by medicinal products included on the Positive Drug List;
2. the quantities allocated/sold, indicated by medicinal products included on the Positive Drug List;
3. the quantities they have available, indicated by medicinal products included on the Positive Drug List.

Article 233. The head of pharmacy shall incur liability for the operations specified in Article 219, Paragraph 1.

Article 234. (1) The sale of medicinal products from automated machines shall be prohibited, except for medicinal products specified on a list included in the Ordinance under Article 219, Paragraph 2.
(2) Automated machines under Paragraph 1 may only be owned by persons under Article 222 and Article 238, Paragraph 2.
(3) The sale of second-hand medicinal products shall be prohibited.
(4) The sale on the Internet of medicinal products subject to medical prescription shall be prohibited.
(5) (New, SG No. 67/2020) Return of already purchased medicinal products shall be prohibited.
(6) (New, SG No. 60/2011, effective 5.08.2011, renumbered from Paragraph 5, SG No. 67/2020) Medicinal products not subject to medical prescription may be sold on the Internet only by a pharmacy or drugstore that has been granted authorisation under the terms and conditions of this Act and the Ordinance provided for in Article 219, Paragraph 2, or Article 243, respectively.
(7) (New, SG No. 102/2012, effective 2.01.2013, renumbered from Paragraph 6, amended, SG No. 67/2020) Pharmacies and drugstores under paragraph 6 shall publish a general logo recognisable throughout the European Union on the website through which they trade in medicinal products for which no medical prescription is required.
(8) (New, SG No. 102/2012, effective 2.01.2013, renumbered from Paragraph 7, amended, SG No. 67/2020) The requirements to the general logo under paragraph 7 shall be specified with a delegated act under Article 85c, Paragraph 3 of Directive 2001/83/EC.

Article 234a. (New, SG No. 102/2012, effective 2.01.2013) (1) The Bulgarian Drugs Agency shall post and maintain on its website:
1. information on the national legislation applicable to the supply of medicinal products for sale on the Internet, including information on the fact that differences may exist among the Member States with respect to the classification of the medicinal products and of the conditions for their delivery;
2. information on the purpose of the general logo;
3. list of the persons offering medicinal products to be sold on the Internet, as well as the addresses of their websites;

4. (amended, SG No. 67/2020) general information on the risks connected with medicinal products delivered to consumers through the Internet in violation of the Ordinance under Article 234, paragraph 6.
(2) The website of the Bulgarian Drugs Agency under Paragraph 1 shall be linked to the website of the European Medicines Agency.

Article 234b. (New, SG No. 102/2012, effective 2.01.2013) The Bulgarian Drug Agency shall participate in awareness campaigns on the danger of counterfeited medicinal products, organised by the European Commission and the European Medicines Agency.

Article 235. (1) An authorisation for retailing of medicinal products under Article 229, Paragraph 2 shall be terminated upon termination of the operations of persons under Articles 222 and 225.
(2) (Amended, SG No. 60/2011, effective 5.08.2011) The Bulgarian Drugs Agency Executive Director shall terminate an authorisation for retailing of medicinal products:
1. at the request of the person who has been granted a retailing authorisation
2. where it has been found that the head of a pharmacy does not meet the requirements specified in Articles 224 and 225.
(3) (Amended, SG No. 60/2011, effective 5.08.2011) Within 14 days of terminating the operations under Paragraph 1, the persons under Articles 222 and 225 shall notify in writing the Bulgarian Drugs Agency thereof.

Article 236. (1) A pharmacy may not be closed for more than 30 days in the same calendar year on account of the absence of its head.
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 12/2011, effective 8.02.2011, SG No. 60/2011, effective 5.08.2011) Where the head of a pharmacy is prevented from discharging his duties due to being on leave for temporary inability to work because of illness, pregnancy and childbirth or adoption, or due to being on parental leave as per the procedure laid down in the Labour Code, the pharmacy may operate for a term of not more than two years under the management of another master of pharmacy or assistant-pharmacist, correspondingly, in the cases under Article 225, who meets the requirements of Article 224. In these cases an authorisation shall be issued by the Bulgarian Drugs Agency Executive Director.
(3) The authorisation under Paragraph 2 shall be issued within 30 days.

Article 237. Upon termination of operations by the person who has been granted an authorisation to open a pharmacy, medicinal products may be sold to persons who have been granted an authorisation for wholesaling of medicinal products.

Article 238. (1) (Amended, SG No. 71/2008, effective 12.08.2008) Medicinal products not subject to medical prescription may be sold in a drugstore. Products and commodities of significance to human health, specified in the Ordinance under Article 243, and medical articles, may also be sold in a drugstore.
(2) (Amended, SG No. 71/2008, effective 12.08.2008) All natural and legal persons registered under the Commerce Act or under the legislation of a Member State shall have the right to retailing of medicinal products by opening a drugstore.
(3) (Amended, SG No. 71/2008, effective 12.08.2008) The head of a drugstore must be a medical specialist who:
1. has not been deprived of the right to practise his profession;
2. has not been convicted for crimes connected with the practising of his profession, for criminal offences against property and the economy, or for deliberate criminal offences against the person;
3. has at least one year of professional experience.

Article 239. (1) (Amended, SG No. 60/2011, effective 5.08.2011) Drugstores shall be opened following registration with the relevant Regional Health Inspectorate.
(2) (Amended, SG No. 60/2011, effective 5.08.2011) Persons under Article 238, Paragraph 2 shall file an application for registration with relevant Regional Health Inspectorate, to which the following documents shall be attached:

1. (amended, SG No. 60/2011, effective 5.08.2011) details details of the Unified ID code of the trader or cooperation from the Commercial Register, and an up-to-date registration certificate of the persons referred to in Article 238, Paragraph 1, under the respective national laws issued by the relevant country's competent authority in the case of companies registered in Member States of the European Union or of the European Economic Area Agreement;
2. (supplemented, SG No. 103/2017, effective 1.01.2018) a document evidencing education and a certificate of criminal record for the person designated as head of the drugstore if such person is not a Bulgarian citizen;
3. a medical certificate for the person under item 2;
4. (repealed, SG No. 60/2011, effective 5.08.2011);
5. (repealed, SG No. 60/2011, effective 5.08.2011);
6. a document evidencing the payment of a state fee at the amount specified in the Tariff under Article 21, Paragraph 2.
(3) (New, SG No. 60/2011, effective 5.08.2011) Within 14 days of receipt of the application referred to in Paragraph 2 the Regional Health Inspectorate shall conduct a check on the compliance with the requirements laid down in the Ordinance provided for in Article 243. Where it has been found that the requirements of the above Ordinance have not been met, within 7 days of the check the Regional Health Inspectorate shall give prescriptions and set a timeline for resolving the issues.
(4) (New, SG No. 60/2011, effective 5.08.2011) Within 14 days of receipt of the application and the documents referred to in Paragraph 2 the Regional Health Inspectorate Director shall inform in writing the person of any deficiencies found therein and shall set a timeline for the elimination thereof.
(5) (New, SG No. 60/2011, effective 5.08.2011) For submitting applications for drugstore registration or variation under Article 242, the relevant Regional Health Inspectorate shall collect fees in the amount laid down in the Tariff under Article 21, Paragraph 2.
(6) (New, SG No. 103/2017, effective 1.01.2018, amended, SG No. 67/2020) The Regional Health Inspectorate shall establish by official channels the circumstances regarding the conviction status of the person under paragraph 2, item 2 where such person is a Bulgarian citizen.

Article 240. (Amended, SG No. 60/2011, effective 5.08.2011) (1) Within 14-days of conducting the check provided for in Article 239, Paragraph 3, or of elimination of the deficiencies referred to in Article 239, Paragraph 4, the Regional Health Inspectorate Director shall issue a certificate of registration of the drugstore or a motivated refusal to do so.
(2) (New, SG No. 102/2012, effective 21.12.2012) The Regional Health Inspectorate Director shall refuse to issue a certificate of registration to the person under Article 238, Paragraph 2, when:
1. some of the documents under Article 239, Paragraph 2 have not been submitted;
2. the applicant has failed to remove the incompleteness noted within the period under Article 239, Paragraph 4.
(3) (New, SG No. 102/2012, effective 21.12.2012) When the Regional Health Inspectorate Director has failed to issue a certificate of registration of a drugstore or to give a motivated refusal within the period under Paragraph 1, the existence of tacit approval shall be assumed.
(4) (New, SG No. 102/2012, effective 21.12.2012) In the cases under Paragraph 3, the applicant may engage in the declared activities in compliance with Article 29 of the Act Restricting Administrative Regulation and Administrative Control over Economic Activity.
(5) (Renumbered from Paragraph 2, SG No. 102/2012, effective 21.12.2012) The refusal of the Regional Health Inspectorate Director under Paragraph 1 shall be subject to appeal under the Administrative Procedure Code.

Article 240a. (New, SG No. 102/2012, effective 21.12.2012) (1) The Director of the relevant Regional Health Inspectorate shall terminate with an order the registration of a drugstore:
1. upon request by the person who has obtained a certificate of registration for a drugstore;
2. upon termination of the activities of the person under Article 238, Paragraph 2, about which he shall notify the relevant Regional Health Inspectorate.

(2) Within 14 days of the termination of the activities under Paragraph 1, item 2, the person under Article 238, Paragraph 2 shall notify in writing the relevant Regional Health Inspectorate.

Article 241. (1) (Amended, SG No. 60/2011, effective 5.08.2011) The relevant Regional Health Inspectorate shall keep a register of drugstores that shall contain:
1. the number and date of the issued certificate;
2. the seat and business address of the person who has been granted a certificate of drugstore registration;
3. the name, personal data and address of the head of the drugstore;
4. the drugstore address;
5. the date of termination of the registration and the grounds for it;
6. comments about any of the registered circumstances.
(2) (Amended, SG No. 60/2011, effective 5.08.2011) Register data shall be posted on the relevant Regional Health Inspectorate's website.

Article 241a. (New, SG No. 60/2011, effective 5.08.2011) The national register of drugstore registration certificates issued under Article 19a, Paragraph 3, shall contain the following:
1.name of the relevant Regional Health Inspectorate which issued the registration certificate;
2. number and date of the certificate issued;
3. seat and business address of the person who was granted a drugstore registration certificate;
4. name of the person in charge of the drugstore;
5. drugstore's address;
6. date of registration termination and the grounds for that.

Article 242. In case the drugstore or head's address have changed, the person who has been granted the certificate of its opening shall file an application in compliance with Article 239, Paragraph 2 and documents pertaining to any such change.

Article 243. The terms and conditions of the drugstore work arrangements shall be specified in an Ordinance of the Minister of Health.

Chapter Eleven
ADVERTISEMENT OF MEDICINAL PRODUCTS

Article 244. (1) Any form of information, presentation, promotion or proposals with the aim of encouraging the prescription, sale or use of medicinal products shall be considered as advertising thereof, including the following:
1. advertisement intended for the population;
2. advertisement intended for medical specialists;
3. visits by medical trade representatives to medical specialists;
4. provision of sample medicinal products;
5. sponsorship of promotional meetings and scientific congresses attended by medical specialists, including the coverage of their travel and accommodation in the respective country in which the event takes place.
(2) The following shall not be considered advertising of medicinal products:
1. text appearing on the outer packaging approved during the licensing procedure for use;
2. correspondence concerning a specific issue or problems pertaining to a particular medicinal product;
3. information and instructions with regard to changes in packaging, warnings about adverse reactions as part of general measures for the safety of a medicinal product, trade catalogues and pricelists, provided they do not include data of advertising nature with regard to the medicinal product concerned;
4. statements concerning human health or diseases when they do not, directly or indirectly, suggest a course of treatment, the prevention or diagnosis involving the use of medicinal products;
5. campaigns conducted by the Ministry of Health for the vaccination of the population, if material associated with them contains no data about a particular medicinal product.

Article 245. (1) The marketing authorisation holder shall be obligated to set up a scientific unit for the distribution of information about the medicinal products for which he has been granted a marketing authorisation in pursuance hereof.
(2) The marketing authorisation holder shall be obligated to:
1. guarantee that the advertisement of a medicinal product has been presented to the population or to medical specialists in a manner compliant with the requirements of this Chapter and with the authorisation for advertising issued by the Bulgarian Drugs Agency;
2. have data and material available from all advertising campaigns undertaken as part of its operations, including information about the groups for which the advertisement is intended, about the manner of its implementation and about the date on which the advertising campaign is to be launched;
3. guarantee training for medical commercial representatives;
4. implement with accuracy and within the set timelines the instructions of officials controlling advertising.
(3) Medical commercial representatives must report to the scientific units under Paragraph 1 any information about the use of medicinal products they advertise, especially as regards information about adverse reactions notified to them by medical specialists.

Article 245a. (New, SG No. 71/2008, effective 12.08.2008) Advertising shall be allowed only for medicinal products for which a marketing authorisation has been issued under the present Act.

Article 246. (1) The content of the advertisement must correspond to data from the medicinal product summary approved in the course of the marketing authorisation and shall present only indications specified in the course of the marketing authorisation.
(2) The advertisement of a medicinal product must only suggest its correct use, objectively presenting its therapeutic indications, without exaggerating possibilities for treatment, prevention or diagnosis using the medicinal product concerned.
(3) The advertisement must not contain misleading information.
(4) (New, SG No. 71/2008, effective 12.08.2008) The advertisement may not contain an offer and/or promise of a gift and/or another material or nonmaterial benefit.
(5) (New, SG No. 71/2008, effective 12.08.2008) A medical specialist or a person claiming to be a medical specialist may not engage in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the Internet.

Article 247. Advertising of medicinal products among the general public shall be allowed only in respect of medicinal products not subject to medical prescription.

Article 248. (Supplemented, SG No. 71/2008, effective 12.08.2008) Apart from the cases under Article 247, vaccination advertising campaigns shall be admitted, carried out by marketing authorisation holders, subject to the requirements of Article 251 and following a procedure stipulated in the Ordinance under Article 249.

Article 248a. (New, SG No. 71/2008, effective 12.08.2008) Advertising on the Internet shall be prohibited for medicinal products subject to medical prescription, with the exception of vaccination advertising campaigns conducted in compliance with Article 248 and approved by the competent authorities.

Article 249. The requirements to the advertising of medicinal products shall be specified in an Ordinance of the Minister of Health.

Article 250. An application for authorisation of the advertisement of a medicinal product shall be filed by the holder of the marketing authorisation of the medicinal product concerned or by a person thereby authorised.

Article 251. (1) In order to be granted advertisement authorisation, the person under Article 250 shall file with the Bulgarian Drugs Agency an application based on a model approved by the Agency Executive Director to be accompanied by:
1. a project for the advertisement;

2. a notarised power of attorney from the marketing authorisation holder, where the application is filed by another person;
3. the literary sources of quotations, tables or other material used, if any;
4. a document evidencing the payment of a fee at the amount specified in the Tariff under Article 21, Paragraph 2.
(2) Advertisement projects under Paragraph 1, item 1 must be clear, with a text, if any, that is easy to understand and allow evaluating all of its elements: text and illustrations.
(3) An Advertisement Expert Council shall be set up with the Bulgarian Drugs Agency. Its composition shall include physicians and specialists with practical experience in the field of advertising. The Bulgarian Drugs Agency Executive Director shall by order determine the composition of the Council, including a representative of the Professional Ethics Committee of the Bulgarian Physicians' Union, of the Bulgarian Dentists' Union and of the Bulgarian Pharmacy Union, the amount of remuneration of its members and he shall approve Rules on the Terms and Conditions of its Work. Representatives of patient organisations may also be included in the composition of the Council.
(4) The Council under Paragraph 3 shall execute an expert assessment of the draft advertisement and come up with an opinion for the Bulgarian Drug Agency Executive Director.
(5) Where the advertisement is found to be incompliant with the requirements hereof, within 7 days of the date of submission of the application under Paragraph 1, the Bulgarian Drugs Agency shall give written instructions for the removal of incompliance within a month of the date of notification. The period for ruling shall start running on the day of notification until removal of incompliance.
(6) In case the applicant fails to act on the instructions within a month of the date of notification under Paragraph 5, the authorisation procedure shall be terminated.

Article 252. (1) Within a month of submission of the documentation under Article 251, Paragraph 1, based on the opinion under Article 251, Paragraph 4, the Bulgarian Drugs Agency Executive Director shall by order authorise the advertisement or issue a motivated refusal, of which the marketing authorisation holder shall be notified.
(2) (New, SG No. 60/2011, effective 5.08.2011) Failure on the part of the Bulgarian Drug Agency Executive Director to authorise the advertisement by means of an order or failure to provide a reasoned refusal within the timeline laid down in Paragraph 1 shall be deemed tacit approval of the draft advertisement under Article 251, Paragraph 1, Item 1, and it may be distributed.
(3) (Renumbered from Paragraph 2, SG No. 60/2011, effective 5.08.2011) The refusal of the Executive Director shall be subject to appeal under the Administrative Procedure Code.

Article 253. (1) The authorisation for advertisement issued under Article 252, Paragraph 1 shall refer to a specific medicinal product within the term of validity of its marketing authorisation.
(2) Where changes have been made in the marketing authorisation of a medicinal product, resulting in changes in an authorised advertisement for the product, the marketing authorisation holder shall file with the Bulgarian Drug Agency an application for change.

Article 254. In case the authorised advertisement has changed, the person under Article 250 shall file an application in compliance with Article 251.

Article 254a. (New, SG No. 60/2011, effective 5.08.2011) (1) Advertisements intended for healthcare professionals shall not be authorised under the procedure provided for in Articles 250-252.
(2) The advertisements referred to in Paragraph 1 shall be distributed following notification, with the draft advertisement attached, submitted to the Bulgarian Drugs Agency and in compliance with the requirements laid down in this Chapter and the Ordinance provided for in Article 249.

Article 255. (1) The distribution of sample medicinal products containing narcotic substances within the meaning of the Narcotic Substances and Precursors Control Act shall be prohibited.
(2) Direct provision of sample medicinal products by medical commercial representatives under Article 244, Paragraph 1, item 3 to the population shall be prohibited.

Article 256. Sample medicinal products shall be provided to medical specialists under the terms and conditions specified in the Ordinance under Article 249.

Article 257. (1) Medical commercial representatives under Article 244, Paragraph 1, item 3 must have been trained through arrangements made by the marketing authorisation holder who has appointed them, they must have scientific knowledge and be able to provide accurate maximally complete information about the medicinal product they present.

(2) At each visit medical commercial representatives must have available a product summary, data about the prices of the medicinal product, the terms of payment, and provide these upon request.

(3) When medicinal products are presented to medical specialists, the medical commercial representatives may not offer gifts or any other material or nonmaterial benefits.

Chapter Twelve
REGULATION OF THE PRICES OF MEDICINAL PRODUCTS
(Title amended, SG No. 102/2012, effective 21.12.2012)

Section I
(Title new, SG No. 102/2012, effective 21.12.2012)
National Council on Prices and Reimbursement of Medicinal Products

Article 258. (Amended and supplemented, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 43/2016) The National Council on Prices and Reimbursement of Medicinal Products, referred to hereafter as "Council", shall be established with the Minister of Health. The Council shall be a public budget legal entity, a secondary spender of budget. It shall have the status of a state commission with a seat in Sofia.

(2) The Council's activities shall be financed out of the state budget through the budget of the Ministry of Health.

(3) The Council shall be a collegiate body and shall consist of a Chairman and six members, three of whom shall be physicians or masters of pharmacy, two lawyers and two economists, all of whom with at least 5 years of experience. The Chairperson and the members of the Council shall be elected and relieved with a decision of the Council of Ministers subject to proposal by the Minister of Health. The Chairperson shall be in charge of the activities of the Council and shall represent it.

(4) The members of the Council may not hold posts or engage in activities under Article 19, Paragraph 6 of the Administration Act.

(5) The activities of the Council shall be assisted by an administration whose structure and organisation of work shall be stipulated by Rules adopted by the Council of Ministers.

Article 259. (Amended and supplemented, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) (1) The Council shall:

1. approve, refuse to approve, modify or delete the price of medicinal products under Article 261a, Paragraph 1;
2. approve, refuse to approve, modify or delete the price ceiling of medicinal products under Article 261a, Paragraph 2;
3. register, refuse to register, modify or delete prices of medicinal products dispensed without medical prescription under Article 261a, Paragraph 3;
4. (amended, SG No. 48/2015, SG No. 102/2018, effective 1.01.2019, amended and supplemented, SG No. 64/2019, SG No. 67/2020) approve, repeal or modify pharmaco-therapeutic manuals including criteria for assessing the effect of the therapy applied, as well as recommendations for algorithms for treatment with medicinal products, ascertained in a statement of opinion of the relevant expert council for the medical specialty, or the medical activities under Article 6a, paragraph 1, item 1 of the Health Act, and provided no statement of opinion is received within 30 days from the receipt of the request, the relevant expert council shall approve, repeal or modify the pharmaco-therapeutic manuals; the pharmaco-therapeutic manuals shall be adopted by ordinances and shall be published in the State Gazette;
5. include, modify or exclude medicinal products from the Positive Drug List;

6. (new, SG No. 102/2018, effective 1.01.2019) perform health technologies assessment of medicinal products;
7. (renumbered from item 6, SG No. 102/2018, effective 1.01.2019) maintain and update the Positive Drug List;
8. (new, SG No. 48/2015, renumbered from item 7, SG No. 102/2018, effective 1.01.2019) maintain the reimbursement status of medicinal products on a triennial basis after their inclusion in the Positive Drug List;
9. (new, SG No. 48/2015, renumbered from item 8, amended, SG No. 102/2018, effective 1.01.2019) assist in agreeing discounts in the cases referred to in Article 45, Paragraphs 10, 13 and 21 of the Health Insurance Act concerning medicinal products in respect whereof applications for inclusion in the Positive Drug List have been submitted;
10. (new, SG No. 102/2018, effective 1.01.2019) determine the medicinal products subject to surveillance of their therapeutic effect, the timelines, and also appoint the medical treatment facilities where these are performed, in compliance with the terms and the procedures set forth by the Ordinance under Article 261a, Paragraph 5;
11. (new, SG No. 102/2018, effective 1.01.2019) perform informational, publishing and scientific-research activities related to the pricing, reimbursement, and medicinal product policies;
12. (new, SG No. 103/2020, effective 1.01.2021) generate a unique national identification number for each medicinal product and shall enter it in the register referred to in Paragraph 2(4).
(2) The Council shall keep public registers of:
1. the approved prices of the medicinal products under Article 261, Paragraph 1;
2. the approved price ceilings of the medicinal products under Article 261, Paragraph 2;
3. the registered prices of the medicinal products under Article 261, Paragraph 3;
4. (new, SG No. 103/2020, effective 1.01.2021) register of national identification numbers for medicinal products.
(3) The Council shall exercise control over the sale of medicinal products with approved price, price ceiling and registered price.
(4) (Amended, SG No. 67/2020) The Council shall accept applications in writing for price approval or registration, or for inclusion in or deletion from, amendments to, maintenance of reimbursement status and health technologies assessment of medicinal products from the Positive Drug List under this Chapter, it shall conduct inspections and investigations related to them and shall issue reasoned decisions.
(5) The Council shall collect fees in amounts specified under Article 21, Paragraph 2 for filing applications for:
1. approval, registration or modifying of the approved or registered price of a medicinal product;
2. (amended, SG No. 48/2015) inclusion, modification or maintenance of the reimbursement status of medicinal products included on the list under Article 262, Paragraph 1;
3. (new, SG No. 102/2018, effective 1.01.2019) health technology assessment.

Article 259[1]. (New, SG No. 103/2020, effective 1.01.2021) (1) The national identification number of any medicinal product referred to in Article 259(1)(12) shall:
1. ensure unambiguous identification of each medicinal product and interoperability of health care information systems;
2. be used by all persons, in all registers and other databases, as well as in the medical documentation related with medicinal products.
(2) A national identification number for each medicinal product shall be generated and entered in the register referred to in Article 259(2)(4) according to a procedure laid down in the ordinance referred to in Article 261a(5).
(3) In accordance with the procedure laid down in Article 261a(5), the Bulgarian Drug Agency shall submit to the Council in an electronic format using a standard form approved by the Council information regarding the medicinal products authorised for use and registered on the territory of the Republic of Bulgaria and regarding the medicinal products authorised for use in accordance with a centralised procedure according to the procedure laid down in Regulation (EC) No. 726/2004

of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Article 259a. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) (1) The meetings of the Council shall be deemed regular if attended by more than half of all its members.

(2) The decisions of the Council shall be passed by a majority of more than half of all its members.

(3) (New, SG No. 102/2018, effective 1.01.2019) The sessions of the council, whenever the agenda covers health technologies assessments, shall be obligatory attended by a representative(s) of the NHIF, The Ministry of health and the BDA.

(4) (Renumbered from Paragraph 3, SG No. 102/2018, effective 1.01.2019) Interested parties may be invited to attend the meetings of the Council, and they shall be informed of the date and time of the meeting at which their application is to be examined.

Article 259b. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) (1) The Council shall announce its decisions within:

1. sixty days, when an application has been filed for approval of a price under Article 261a, Paragraph 1 and for inclusion of the medicinal product in the Positive Drug List;
2. thirty days, when an application has been filed for modifying or deletion of a medicinal product included in the Positive Drug List;
3, thirty days, when an application has been filed for approval, modifying or deletion of a price under Article 261a, Paragraph 2;
4. thirty days, when an application has been filed for registration, modifying or deletion of a price under Article 261a, Paragraph 3;
5. thirty days for approval/registration of the price of medicinal products for which authorisation for parallel import has been obtained;
6. (new, SG No. 48/2015, amended, SG No. 102/2018, effective 1.01.2019) one hundred and eight days, where the application filed is for the inclusion in The Positive Drugs List of a medicinal product subject to health technology assessment with a new International Nonproprietary Name;
7. (new, SG No. 48/2015) sixty days, when an application has been filed for maintenance of the reimbursement status of a medicinal product on the Positive Drug List;
8. (new, SG No. 102/2018, effective 1.01.2019, amended, SG No. 67/2020) ninety days, when an application has been filed for extending the indications of a medicinal product already on the Positive Drug List, for which no fee has been paid so far;
9. (new, SG No. 102/2018, effective 1.01.2019) ninety days, when an application has been filed for health technology assessment.

(2) The Council shall state its decision within thirty days for medicinal products under Article 262, Paragraph 5, when an application has been filed for price approval under Article 261, Paragraph 1 and for inclusion of the product in the Positive Drug List.

(3) The periods under Paragraphs 1 and 2 shall start running from the date of filing the application under Article 261a, Paragraph 5.

(4) (New, SG No. 67/2020) Where an application for initiation of the procedure under Article 259, paragraph 4 is filed for a medicinal product in hospital packaging, according to a marketing authorisation, the Council shall issue a decision within a term that is by half shorter than those set forth in paragraphs 1 and 2.

Article 259c. (New, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 102/2012, effective 21.12.2012).

Article 259d. (New, SG No. 60/2011, effective 5.08.2011, repealed, SG No. 102/2012, effective 21.12.2012).

Article 260. (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012) The state bodies, the officials and the applicants under this Chapter shall have the obligation to assist the Council and its staff in discharging their obligations.

Article 261. (Amended, SG No. 71/2008, effective 12.08.2008, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012) (1) The members of the Council and its staff shall be obliged not to disclose circumstances and facts that have become known to them during or in connection with their official duties under this Act, except subject to demand in writing by a public body, where this is regulated by law.
(2) In connection with their obligations under Paragraph 1, the persons shall sign a declaration based on a model approved by the Council's chairperson.

Section II
REGULATION OF THE PRICES OF MEDICINAL PRODUCTS. ALGORITHMS FOR TREATMENT WITH MEDICINAL PRODUCTS HEALTH TECHNOLOGY ASSESSMENT
(Title new, SG No. 102/2012, effective 21.12.2012, supplemented, SG No. 102/2018, effective 1.01.2019)

Article 261a. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) (1) The Council shall regulate the prices of the medicinal products included in the Positive Drug List under Article 262, Paragraph 1 and paid for with public funds, in accordance with the lowest reference prices in the Member States.
(2) The Council shall regulate the price ceilings of medicinal products dispensed subject to medical prescription, in addition to those under Paragraph 1, in accordance with the lowest reference prices in the Member States.
(3) The Council shall register maximum retail sale prices for the medicinal products dispensed without medical prescription.
(4) The price fixed under Paragraph 1 shall also be the price ceiling for the retailing of the medicinal products.
(5) The Council of Ministers, on a proposal submitted by the Minister of Health, shall stipulate with an Ordinance the conditions and the rules for regulating the prices of the medicinal products under Paragraph 1, for regulating the price ceilings of the medicinal products dispensed subject to medical prescription under Paragraph 2 when retailed, as well as the conditions and the rules for registering the prices of the medicinal products dispensed without medical prescription.
(6) (New, SG No. 67/2020) The National Health Insurance Fund and the Ministry of Health shall provide to the Council information of the medicinal products paid under Article 262, paragraph 6 according to a procedure laid down in the ordinance under paragraph 5.

Article 261b. (New, SG No. 67/2020) A medicinal product may be sold in the territory of the country only after the Council’s decision on approval of a price/price ceiling or registration of a price has come into force, with the exception of the medicinal products referred to in Articles 9 and 266a.

Article 261c. (New, SG No. 67/2020) (1) A medicinal product may be sold at a price not higher than the approved price under Article 261a, paragraph 1, the price ceiling under Article 261a, paragraph 2 or the registered price under Article 261a, paragraph 3.
(2) The retailer shall be obligated to indicate a sale price on the packaging of the medicinal product on the place marked by the manufacturer.
(3) Prices of medicinal products included in the value of the medical care provided in medical treatment establishments may not exceed the price at which the medical treatment establishment purchased the medicinal product from the wholesaler.
(4) Medicinal products may not be sold to medical treatment establishments under Article 5 of the Medical Treatment Facilities Act and to medical treatment establishments with state and/or municipal interest under Articles 9 and 10 of the Medical-Treatment Facilities Act at a price higher than the value set pursuant to the ordinance under Article 261a, paragraph 5.
(5) No mark-up shall be charged on retailers for dispensing in a pharmacy of medicinal products included in the Positive Drug List under Article 262, paragraph 6, item 1 with a 100 percent coverage.

Article 262. (Supplemented, SG No. 71/2008, effective 12.08.2008, SG No. 88/2009, effective 6.11.2009, amended, SG No. 98/2010, effective 1.01.2011, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 15/2013, effective 1.01.2014) The Positive Drug List shall be drafted and maintained by the Council, and it shall include medicinal products dispensed subject to medical prescription and paid from the National Health Insurance Fund budget, the state budget, outside the scope of mandatory health insurance, and from the budget of treatment establishments under Article 5 of the Medical-Treatment Facilities Act and from the budget of treatment establishments with state and/or municipal interest under Articles 9 and 10 of the Medical-Treatment Facilities Act.

(2) (Amended, SG No. 102/2018, effective 1.01.2019) The Positive Drug List shall include medicinal products classified as per pharmacological groups according to the Anatomical Therapeutic Chemical Classification Code, with their relevant International Nonproprietary Names and associated names, their relevant daily dose/therapeutic course defined, their price under Article 261a, Paragraph 1, their retail price ceiling, their daily dose/therapeutic course reference value, their package value based on the daily dose reference value/therapeutic course, the level of reimbursement, the therapeutic indications, and their International Classification of Diseases (ICD) code. For medicinal products, the reference value shall be determined on the basis of established daily dose or therapeutic course reference value, or concentration or volume.

(3) (Amended, SG No. 102/2018, effective 1.01.2019, SG No. 67/2020) The Positive Drug List shall include medicinal products, for which the International Nonproprietary Name to which the said medicinal product/combination (in cases of combined medicinal products, with the exception of generic medicinal products and medicinal products containing an active substance or active substances with well established use in medical practice) is paid for by a public health insurance fund and/or by public funds for the same therapeutic indications, in at least 5 countries, as stated in the Ordinance under Article 261a, paragraph 5. The International Nonproprietary Name to which the medicinal product intended for treatment of rare diseases belongs, is paid for by a public health insurance fund and/or by public funds for the same therapeutic indications in no less than 5 of all the Member States.

(4) (Supplemented, SG No. 48/2015, amended, SG No. 102/2018, effective 1.01.2019) The medicinal products on the Positive Drug List shall be selected according to the evidence-base for their efficacy, therapeutic effectiveness, safety and analysis of their pharmacoeconomic indicators, and in the case of medicinal products with a new International Nonproprietary Name, a health technology assessment shall also be performed. The health technology assessment shall be performed subject to conditions and in accordance with a procedure established in the Ordinance under Article 261a (5).

(5) (Amended, SG No. 102/2018, effective 1.01.2019) Where one or more medicinal products with the same International Nonproprietary Name, pharmaceutical form and concentration of the active substance, are already on the relevant part of the Positive Drug List, no assessment under Paragraph 4 shall be performed.

(6) (Amended, SG No. 67/2020) The Positive Drug List shall comprise four appendices and shall include:

1. medicinal products intended for the treatment of diseases paid in compliance with the Health Insurance Act;
2. medicinal products paid from the budget of the treatment establishments under Article 5 of the Medical Treatment Facilities Act and from the budget of treatment establishments with state and/or municipal interest under Articles 9 and 10 of the Medical Treatment Facilities Act;
3. (supplemented, SG No. 67/2020) medicinal products intended for the treatment of AIDS, communicable diseases, diseases outside the scope of the Health Insurance Act, paid in compliance with Article 82, paragraph 1, item 8 of the Health Act, as well as vaccines for mandatory immunisations and immunisation boosters, special indication and special circumstance vaccines, specific sera, immunoglobulins, as laid down in the ordinance under Article 58, paragraph 2 of the Health Act;

4. breakdown of the medicinal product price ceiling referred to in Article 261a, Paragraph 4;
(7) The Ministry of Health and the National Health Insurance Fund may make proposals to the Council under Article 258, Paragraph 1 for revision of medicinal products already on the Positive Drug List under the terms and conditions laid down in the Ordinance provided for in Article 261a, Paragraph 5.
(8) The National Health Insurance Fund shall pay for the medicinal products referred to in Paragraph 6, Item 1, under the terms and conditions laid down in the Ordinance provided for in Article 45, Paragraph 9 of the Health Insurance Act.
(9) (New, SG No. 18/2014, supplemented, SG No. 48/2015) The requirements, rules, and criteria for inclusion, changes and/or exclusion of medicinal products from the Positive Drug List and for maintenance of the reimbursement status of medicinal products shall be specified in the Ordinance issued under Article 261a, Paragraph 5.
(10) (New, SG No. 48/2015, amended, SG No. 102/2018, effective 1.01.2019) Medicinal products under Article 45, Paragraphs (10), (13) and (21) of the Health Insurance Act in respect whereof no discounts have been agreed shall not be included on the Positive Drug List. The discount agreements shall be provided to the Council in accordance with a procedure established by the Ordinance under Article 261a, Paragraph 5.
(11) (New, SG No. 48/2015, amended, SG No. 102/2018, effective 1.01.2019) Medicinal products in respect whereof the procedure under Article 259, Paragraph 1, Item 8 fails to prove a positive assessment upon their inclusion shall be excluded from the Positive Drug List.
(12) (New, SG No. 84/2018, effective 12.10.2018, amended, SG No. 102/2018, effective 1.01.2019) The Ministry of Health shall pay for the medicinal products under Paragraph 6, item 3 which have a new International Nonproprietary Name, if before their inclusion into the Positive Drug List a preliminary framework agreements has been already concluded between the Ministry of Health, and the Manufacturing Authorisation Holder/or a representative thereof, on the subject of the maximal value at which the said medicinal product may be supplied to The Ministry of Health in compliance with the Public Procurement Act. The agreement shall be binding to the parties involved in the arrangement; The agreements shall be submitted at the Council in accordance with a procedure established by the Ordinance under Article 261a, Paragraph 5.
(13) (New, SG No. 102/2018, effective 1.01.2019) The medicinal product under Paragraph 6, item 3, which have a new International Nonproprietary Name, and for which no preliminary framework agreement as per Paragraph 12 above has been concluded, shall not be entered into in the Positive Drug List.
(14) (New, SG No. 103/2020, effective 1.01.2021) For the medicinal products referred to in item 6 of Paragraph 3, for which the value paid from the budget of the Ministry of Health is calculated by grouping, in which medicinal products of other marketing authorisation holders do not participate, the Ministry of Health and the marketing authorisation holders or their authorised representatives shall conclude each year framework agreements on the maximum value at which the respective medicinal product may be supplied to the Ministry of Health in accordance with the procedure established by the Public Procurement Act. The terms and procedure for concluding the framework agreements shall be determined in the ordinance referred to in Article 82(1)(8) of the Health Act.
(15) (New, SG No. 103/2020, effective 1.01.2021) The provision of Paragraph 14 shall not apply to generic medicinal products and to vaccines for mandatory immunisation and re-immunisation, vaccines for specific indications and in emergency situations, specific serums, immunoglobulins and other bioproducts related to the prevention of infectious diseases, as defined on the ordinance referred to in Article 58(2) of the Health Act.
(16) (New, SG No. 103/2020, effective 1.01.2021) For the medicinal products referred to in Paragraph 12, the maximum value referred to in Paragraph 14 may not be higher than the value determined in the framework agreement referred to in Paragraph 12.
(17) (New, SG No. 103/2020, effective 1.01.2021) The Ministry of Health may not pay for the medicinal products referred to in Paragraph 14 of values higher than the maximum value of the respective medicinal product, determined in the framework agreement referred to in Paragraph 14.

(18) (New, SG No. 103/2020, effective 1.01.2021) Medicinal products referred to in Paragraph 14, for which a framework agreement in accordance with Paragraph 14 has not been concluded, shall not be paid by the Ministry of Health.

Article 262[1]. (New, SG No. 67/2020) (1) (Amended, SG No. 103/2020, effective 1.01.2021) The appendices to the Positive Drug List under Article 262, paragraph 6 shall specify: a code according to Anatomical Therapeutic Chemical Classification system, International Nonproprietary Name (INN), name of the medicinal product, the pharmaceutical form, the strength of the medicinal product, packaging, marketing authorisation holder, the set daily dose/course of treatment/concentration/volume, the price under Article 261a, paragraph 1, reference value, value per package calculated based on the reference value, level of reimbursement of the medicinal product, therapeutic indications, and diseases according to the International Classification of Diseases (ICD), manufacturer(s), information of the limitations to the dispensation for different indications, national identification number of the medicinal product under Article 259[1], paragraph 1, and additional information.

(2) The Positive Drug List shall contain information of the type of a medicinal product, as defined in the marketing authorization procedure. The information of the type of a medicinal product shall be provided by the Bulgarian Drug Agency within 7 days from receipt of the enquiry by the National Council on Prices and Reimbursement of Medicinal Products for every medicinal product.

Article 262[2]. (New, SG No. 67/2020) The Ministry of Health, National Health Insurance Fund and medical treatment establishments shall provide to the Council complete information of the medicinal products paid under Article 262, paragraph 6, items 1 – 3 according to a procedure laid down in the ordinance referred to in Article 261a, paragraph 5.

Article 262[3]. (New, SG No. 67/2020) (1) The marketing authorisation holder or an authorised representative thereof shall be obligated, within two business days from receipt of the Council's decision on a change of the price under Article 261a, paragraphs 1 – 3 of a medicinal product, to notify appropriately the Bulgarian Pharmaceutical Union and the wholesalers and they, on their part, are obligated to notify the retailers of medicinal products.

(2) The Council shall notify through the relevant official channels the Ministry of Health and the National Health Insurance Fund of the decisions, for which it has permitted earlier implementation.

Article 262a. (New, SG No. 60/2011, repealed, SG No. 102/2012, effective 21.12.2012, new, SG No. 102/2018, effective 1.01.2019) (1) The health technologies assessment under Article 262, Paragraph 4 shall not be undertaken for generic medicinal products, and for medicinal products containing active substance(s) of well established use in medical practice.

(2) Medicinal products included in the Positive Drug List shall undergo health technology assessment whenever an extension of their therapeutic indications was stated, and the product have not been paid for by public funds so far, in compliance with the terms and procedure set forth with the Ordinance under Article 261a, Paragraph 5.

(3) The Ministry of Health and the National Health Insurance Fund may require, by a motivated request a health technology assessment of medicinal products to be performed for agents on the Positive Drug List in compliance with the terms and procedures set forth with the Ordinance under Article 261a, Paragraph 5.

Article 262b. (New, SG No. 102/2018, effective 1.01.2019) (1) (Amended, SG No. 67/2020) The Positive Drug List shall include medicinal products belonging to a new International Nonproprietary Name, for which a health technology assessment is performed. The health technology assessment shall be part of the procedure for inclusion of the medicinal product in the Positive Drug List and it shall contain a clinical and pharmaco-economic assessment and shall include:

1. Health problem analysis;
2. comparative analysis of the therapeutic efficacy, effectiveness, and safety of a medicinal product;
3. analysis of pharmacoeconomic parameters;
4. budget impact analysis.

(2) The health technology assessment shall performed according to the following criteria:

1. availability of lack of availability of alternative treatment for the disease;
2. availability of lack of availability of medicinal alternative for the treatment of the disease;
3. efficacy and therapeutic effectiveness of treatment: evaluations of the therapeutic benefit, prolongation of life-expectancy, and improved quality of life, decrease in complications from the main disease;
4. estimated number of potential patients;
5. medicinal product safety: the frequency and the seriousness of adverse reactions, the need to administer add-on preventive or therapeutic measures for avoiding adverse reactions;
6. pharmacoeconomic parameters: the costs of treatment with the medicinal product, and comparison versus the cost of treatment with alternative medicinal products available, the cost-results ratio, economical evaluation of add on benefits;
7. health technology benefits, presented as life-year gained (LYG), quality adjusted life-year (QALY), or where no data on the final results are available, by presenting the interim results;
8. budget impact analysis based on estimated number of patients;
9. evaluation of public expenditures over a 5-year period;
10. health perspective analysis for the institution paying for the relevant treatment on the expense of public funds, or the societal perspective;
11. moral and ethic issues (for specific groups of diseases).
(3) (New, SG No. 67/2020) The respective appendix to the Positive Drug List shall include medicinal products belonging to a new International Nonproprietary Name, for which a health technology assessment has been performed pursuant to Article 1 and for which there is at least one positive health technology assessment by a state agency in Great Britain, France, Germany and Sweden.

Article 262c. (New, SG No. 102/2018, effective 1.01.2019) (1) (Supplemented, SG No. 67/2020) Follow up of the effect of treatment under Article 259, paragraph 1, item 10 shall be performed by the medical treatment establishments designated by the National Council on Prices and Reimbursement of Medicinal Products according to a procedure laid down in the ordinance under Article 261a, paragraph 5.
(2) (Amended, SG No. 67/2020) The National Council on Prices and Reimbursement of Medicinal Products shall analyse the information collected by medical treatment establishments per paragraph 1 under the conditions and according to the procedure laid down in the ordinance under Article 261a, paragraph 5.
(3) (New, SG No. 67/2020) The medical treatment establishments under paragraph 1 shall provide to the Council access to medical documentation kept by them in relation to the application of a specific medicinal product, for which the therapeutic effect is monitored.

Article 263. (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 15/2013, effective 1.01.2014) Medicinal products subject to medical prescription and not on the list provided for in Article 262, Paragraph 1 which are needed for the prevention and treatment of epidemic outbreaks, epidemics, pandemics, as well as where there is suspected or confirmed spreading of chemical or biological agents, or nuclear radiation may be covered by the state budget outside the scope of mandatory health insurance.

Article 264. (Amended, SG No. 60/2011, SG No. 102/2012, effective 21.12.2012) (1) (Supplemented, SG No. 18/2014) When the sales of a medicinal product on the Positive Drug List are terminated under Article 54, Paragraph 3 and when within the relevant International Nonproprietary Name there is no other medicinal product with market authorisation under the present Act, the marketing authorisation holder shall notify in writing the Ministry of Health and the National Council on Prices and Reimbursement of Medicinal Products
(2) (Supplemented, SG No. 18/2014) The marketing authorisation holder shall also notify the Ministry of Health and the National Council on Prices and Reimbursement of Medicinal Products in the cases of termination of the sale of a medicinal product whose price serves for determining the reference value within the relevant international nonproprietary name and pharmaceutical form.

(3) When the product under Paragraphs 1 and 2 is intended for treatment of diseases to be reimbursed under the Health Insurance Act, the marketing authorisation holder shall inform in writing the National Health Insurance Fund as well within the time periods specified in Paragraph 4.
(4) The marketing authorisation holder shall have the obligation to effect the notification under Paragraph 1 not later than 18 months prior to the date of discontinuation of the sales, and in the cases under Paragraph 2 - not later than three months prior to the date of discontinuation of the sales.
(5) (Supplemented, SG No. 18/2014) Prior to the discontinuation of the sales under Paragraphs 1 and 2, the marketing authorisation holder shall be obliged to secure sufficient quantities of the respective medicinal product for satisfying the health needs, except in cases where discontinuation is based on any of the grounds, specified under Article 276, or Article 277 of this Act.
(6) After the end of the time periods under Paragraph 4, the marketing authorisation holder shall file an application with the relevant document for deletion of the medicinal product from the Positive Drug List.
(7) When after the discontinuation of the sales of the medicinal product the marketing authorisation holder has failed to fulfil his obligation under Paragraph 6, the Council under Article 258, Paragraph 1 shall delete it ex officio from the Positive Drug List.

Article 265. (1) The Council of Ministers shall set up a Transparency Commission.
(2) (Supplemented, SG No. 60/2011, effective 5.08.2011) The composition of the Transparency Commission shall be determined by the Council of Ministers at the proposal of the Minister of Health. Representatives of the Ministry of Health, the Ministry of Labour and Social Policy, the Bulgarian Drug Agency, the National Health Insurance Fund, the Bulgarian Physicians' Union, the Bulgarian Dentists' Union, the Bulgarian Pharmacists' Union, and of patient and pharmaceutical industry organisations shall be mandatorily included in the Commission.
(3) (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012) A person who is member of the Transparency Commission may not be member of the National Council on Prices and Reimbursement of Medicinal Products.
(4) The Council of Ministers shall specify by Rules the terms and conditions of work of the Transparency Commission.

Article 266. (Amended, SG No. 60/2011, effective 5.08.2011, SG No. 102/2012, effective 21.12.2012, SG No. 67/2020) (1) The Transparency Commission shall be a body before which the decisions of the Council may be appealed against.
(2) Decisions of the Transparency Commission shall be made by a majority of two-thirds of its composition.
(3) Decisions of the Council may be appealed against in or out of court without availing to the full extent of the possibility of administrative appeal.

Article 266a. (New, SG No. 60/2011, effective 5.08.2011) (1) Where a disease treatment has no alternative in Bulgaria, medicinal products authorised in European Union Member States and under the terms and conditions laid down in this Act, but not marketed in Bulgaria, may be administered to individual patients.
(2) (Amended, SG No. 102/2018, effective 1.01.2019) Each year, acting upon proposal by in-patient care establishments and following the opinion of the relevant Expert Council in the specialist area of the disease, or the medical activity referred to in Article 6a, Paragraph 1, Item 1 of the Health Act, the Minister of Health shall approve the Drug List under Paragraph 1, which shall contain the following information:
1. Anatomical Therapeutic Chemical Classification Code;
2. International Nonproprietary Name to which the product belongs;
3. disease as per the International Classification of Diseases;
4. pharmaceutical form and strength;
5. further information.
(3) The list provided for in Paragraph 2 shall be published on the Ministry of Health website.

(4) The terms and conditions for inclusion, variation or deletion of medicinal products on the list provided for in Paragraph 2 shall be laid down in the Ordinance provided for in Article 9, Paragraph 1.
(5) The medicinal products referred to in Paragraph 1 shall be supplied by special order of in-patient care establishment under the terms and conditions laid down in the Ordinance provided for in Article 9, Paragraph 1.
(6) The head of the medical establishment referred to in Paragraph 5 shall be responsible for administering the treatment referred to in Paragraph 1.

Article 266b. (New, SG No. 67/2020) (1) By way of exception, in case of lack of any alternative for treatment of a specific patient and only in the interest of his/her health, a medicinal product authorised for marketing in this country may be applied beyond the terms and conditions of the marketing authorisation of the medicinal product, if there is scientific evidence of the safety and efficacy of that product.
(2) The medicinal product under paragraph 1 shall be prescribed by a panel of three physicians from a in-patient care establishment with recognised specialisation in the profile of the disease, who shall provide reasoning of its prescription on a patient-by-patient basis.
(3) The treatment under paragraph 1 shall take place in an in-patient care establishment after obtaining the patient's informed consent.
(4) Each phase of the patient's treatment shall be monitored and documented by the panel physicians under paragraph 2, who shall bear the responsibility for conducting treatment under paragraph 1.
(5) The panel under paragraph 2 shall notify the Medical Supervision Executive Agency and the Bulgarian Drug Agency about the conducted treatment under paragraph 1.
(6) The terms and conditions for obtaining the patient's informed consent under paragraph 3, monitoring and documenting of the treatment under paragraph 4 and of the safety and efficacy of the medicinal product shall be set forth in the ordinance under Article 9, paragraph 1.
(7) In the cases under paragraph 1 the medicinal product shall not be paid for by public funds.

Chapter Thirteen
STATE CONTROL OF MEDICINAL PRODUCTS

Article 267. (1) (Supplemented, SG No. 102/2012, effective 21.12.2012) The Ministry of Health shall head the state control of medicinal products. Immediate direction shall be provided by the Chief State Health Inspector, by the Chairperson of the Council under Article 258, Paragraph 1, by the Bulgarian Drugs Agency Executive Director and by Regional Health Inspectorate Directors, who shall be state inspectors controlling medicinal products.
(2) (Supplemented, SG No. 102/2012, effective 21.12.2012) The Council under Article 258, Paragraph 1, the Bulgarian Drugs Agency and the Regional Health Inspectorate shall be state control bodies for medicinal products.
(3) (New, SG No. 67/2020) Within their competences the regional health inspectorates shall cooperate with the Bulgarian Drug Agency in implementing the activities concerning control over the medicinal products.
(4) (Supplemented, SG No. 102/2012, effective 21.12.2012, renumbered from Paragraph 3, SG No. 67/2020) Immediate control shall be exercised by officials – inspectors and experts designated by orders of the Chairperson of the Council under Article 258, Paragraph 1, of the Bulgarian Drug Agency Director or of the Director of the respective Regional Health Inspectorate.
(5) (Renumbered from Paragraph 4, SG No. 67/2020) When discharging their control functions, the bodies under Paragraph 1 may request assistance from the bodies of the Ministry of Interior.

Article 267a. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012, SG No. 102/2018, effective 1.01.2019) (1) (Previous text of Article 267a, SG No. 67/2020) The Medical Supervision Executive Agency shall exercise control over the compliance with established pharmacotherapy guidelines and therapy effectiveness assessment in line with the criteria laid down in Article 259, paragraph 1, item 4.

(2) (New, SG No. 67/2020) The Medical Supervision Executive Agency may make inspections of pharmacies pursuant to Article 222, paragraph 4, which shall include an inspection of the conformity of the types and quantities of medicinal products prescribed and/or applied to patients with the types and quantities of medicinal products dispensed by the pharmacy, where such medicinal products are paid for by public funds.

Article 268. (1) The Bulgarian Drugs Agency shall exercise control over:

1. (supplemented, SG No. 102/2012, effective 2.01.2013) compliance of the premises, installations and conditions for the manufacturing, control of and trade in medicinal products and active substances, and for observing the requirements of Good Manufacturing Practice for medicinal products and of Good Distribution Practice;
2. (amended, SG No. 102/2012, effective 2.01.2013) the operations of the marketing authorisation holders, manufacturers, importers, wholesalers in medicinal products and active substances, of intermediaries in the sphere of medicinal products, of pharmacies and drugstores;
3. the quality, safety and efficacy of medicinal products;
4. the clinical trials of medicinal products and the compliance with the requirements of Good Clinical Practice;
5. the information about drugs in relation to their marketing authorisation and advertising;
6. (amended, SG No. 102/2012, effective 21.12.2012) the system for drug safety monitoring of the marketing authorisation holders and the compliance with the requirements of the Good Practice for Drug Safety Monitoring.

(2) (Amended, SG No. 102/2018, effective 1.01.2019) The Regional Health Inspectorates shall exercise control:

1. on the premises, the equipment, the storage conditions, and the trade in medicinal products;
2. over the operations of wholesalers, pharmacies and drugstores located on the territory of the respective region.
3. for the compliance with the approved price ceilings, registered prices of medicinal products for retail in pharmacies and drug stores, located on the territory of the respective region;
4. (new, SG No. 67/2020) on the activities for destruction of medicinal products.

(3) (New, SG No. 102/2018, effective 1.01.2019) The Council referred to in Article 258 (1) herein shall perform the surveillance for:

1. compliance with the approved price ceilings, and the registered prices in the sale of medicinal products by whole-traders dealing in medicinal products;
2. (supplemented, SG No. 67/2020) on the operations of the marketing authorisation holders and wholesalers of medicinal products to establish fulfilment of their responsibilities set forth in the ordinance under Article 261a, paragraph 5.

(4) (Renumbered from Paragraph (3), SG No. 102/2018, effective 1.01.2019) Development projects for the construction of new and/or the reconstruction of existent sites associated with the manufacturing of medicinal products shall be coordinated with the Bulgarian Drug Agency in accordance with the rules of Good Manufacturing Practice for medicinal products.

Article 268a. (New, SG No. 60/2011, effective 5.08.2011) (1) (Amended, SG No. 84/2018, effective 12.10.2018) Medicinal product donations by marketing authorisation holders, manufacturers, wholesalers and retailers, and the Bulgarian Red Cross may be made only after agreement with the Bulgarian Drug Agency through submission by the donor of an application as per model endorsed by the Minister of Health acting upon proposal by the Bulgarian Drug Agency Executive Director.

(2) The donations shall be made in compliance with the rules of Good Donorship Practice of the World Health Organisation.

(3) (Repealed, SG No. 84/2018, effective 12.10.2018).

(4) Medical establishments and the Bulgarian Red Cross shall inform the Bulgarian Drugs Agency of the medicinal product donations received within seven days of receipt thereof.

(5) At the end of each quarter the Bulgarian Drugs Agency shall submit to the Ministry of Health information about the donations under Paragraph 4.

(6) The donor shall inform the Bulgarian Drugs Agency within seven days of the donation where the latter concerned a medicinal product donated upon request by a medical establishment and intended for the treatment of an individual patient with life-threatening condition.
(7) The donations referred to in Paragraph 6 may not exceed the amount necessary for a single course of treatment.

Article 269. (1) Control under Article 267 shall be performed through inspections and laboratory tests.
(2) Inspections and laboratory tests under Paragraph 1 shall be performed:
1. in relation to the issuance of licenses for use, manufacturing, of authorisations for import and of certificates in compliance with this Act;
2. in relation to performing supervision of the market of medicinal products;
3. upon request of the European Commission, the European Medicines Agency or of a competent body in another Member State;
4. upon request of a manufacturer, importer or a marketing authorisation holder outside the cases under item 1.
(3) (Amended, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall perform inspections:
1. of manufacturers of medicinal products located on the territory of the Republic of Bulgaria, or a Member State or of third countries;
2. of importers and wholesalers of medicinal products;
3. of the premises of the manufacturers, importers and wholesalers of active substances located on the territory of the Republic of Bulgaria;
4. of the premises of manufacturers or wholesales of active substances, located in third countries, as well as of manufacturers or importers of excipients;
5. of the premises of the marketing authorisation holders for medicinal products and of the intermediaries in the sphere of medicinal products registered under Article 212a;
6. as part of the certification procedure in relation to the monographs of the European Pharmacopoeia;
7. of manufacturers of starting materials upon request in writing by the manufacturer.
(4) The Bulgarian Drugs Agency shall perform inspections of medicinal product manufacturers established in third countries in relation to an application they have filed to obtain a marketing authorisation or an import authorisation.
(5) (Amended, SG No. 102/2012, effective 21.12.2012) The inspections under Paragraphs 3 and 4 shall be performed in compliance with guidelines adopted by the European Commission.
(6) (Amended, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall participate, upon request by the European Commission, the European Medicines Agency or a Member State, in inspections under Paragraph 3 in the European Union or in third countries.
(7) (Amended, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall cooperate and exchange information with the European Medicines Agency in the planning and conducting of the inspections under Paragraph 3.
(8) (New, SG No. 102/2012, effective 21.12.2012) The Bulgarian Drug Agency shall cooperate with the European Medicines Agency in coordinating inspections in third countries.

Article 269a. (New, SG No. 102/2012, effective 21.12.2012) (1) (Amended, SG No. 67/2020) The officials under Article 267, paragraph 4 shall prepare a report for each inspection conducted under Article 269, paragraphs 3 and 4 on the compliance with the principles and guidelines of the Good Manufacturing Practices or of the Good Distribution Practices, or on the conformity with the requirements under Chapter Eight and the requirements under this Act.
(2) The report under Paragraph 1 shall be made available to the inspected person who may comment on it.
(3) Upon receiving a motivated request, the Bulgarian Drugs Agency shall send electronically the reports under Paragraph 1 to the competent body of another Member State or to the European Medicines Agency.

Article 269b. (New, SG No. 102/2012, effective 21.12.2012) (1) When an inspection under Article 269, Paragraph 3 ascertains compliance with the Good Manufacturing Practice or with the Good Distribution Practice, where applicable, the Bulgarian Drugs Agency shall issue to the manufacturer, importer or wholesaler a certificate for Good Manufacturing Practice, or accordingly a certificate for Good Distribution Practice, within 90 days of the inspection.
(2) When an inspection under Article 269, Paragraph 3 ascertains that the manufacturer, importer or wholesaler of medicinal products or of active substances has failed to observe the requirements of this Act and/or the principles and guidelines of Good Manufacturing Practice and/or of the Good Distribution Practice, the Bulgarian Drugs Agency shall issue an opinion on non-compliance.
(3) The Bulgarian Drugs Agency shall enter the certificates issued under Paragraph 1 and the information under Paragraph 2 in the database under Article 147.

Article 269c. (New, SG No. 102/2012, effective 21.12.2012) (1) When an inspection under Article 270, Paragraph 1, item 5 reveals that the marketing authorisation holder does not comply with the requirements under Chapter Eight, the Bulgarian Drugs Agency shall issue prescriptions for abolishing the non-compliance.
(2) In the cases under Paragraph 1, the Bulgarian Drugs Agency shall notify the Member States, the European Medicines Agency and the European Commission.

Article 270. (1) (Amended, SG No. 67/2020) The officials under Article 267, paragraph 4 shall have the right, within their competence:
1. (amended, SG No. 102/2012, effective 2.01.2013) to access all documents related to the object of the inspection, as well as documents directly or indirectly associated with a violation of this Act or of the legislation of Member States transposing the requirements of Directive 2001/83/EC, irrespective of the document format;
2. to order any person to provide information about the violation under item 1, which he is aware of;
2a. (new, SG No. 102/2012, effective 2.01.2013) to inspect the manufacturing and trading premises of the manufacturers of medicinal products, active substances or excipients, as well as the laboratories used by the holders of authorisations for manufacturing or import;
3. to inspect, at any time, the sites subject to control and to obtain, inspect and make copies of all documents pertaining to the overall operation of the controlled site;
4. to take samples of medicinal products, of active substances and excipients for laboratory testing;
5. (amended, SG No. 102/2012, effective 21.12.2012) to inspect the premises, records, documents and the principal documentation of the system for drug safety monitoring of the marketing authorisation holder or of persons to whom the marketing authorisation holder has entrusted operations under Chapter Eight;
6. (new, SG No. 102/2012, effective 21.12.2012) to inspect the compliance with the approved prices, price ceilings or registered prices in the sale of medicinal products;
7. (renumbered from Item 6, SG No. 102/2012, effective 21.12.2012) to draw up acts establishing the presence of administrative violations.
(2) (Repealed, SG No. 102/2012, effective 21.12.2012).
(3) The Bulgarian Drugs Agency Executive Director or the respective Regional Health Inspectorate Director, depending on the hierarchical system of the official who has found the violation, shall have the right to:
1. order in writing the offender to cease and desist the violation under Paragraph 1, item 1;
2. require the offender to declare that he would cease and desist the violation under Paragraph 1, item 1 and, if necessary, require him to publicly disclose the declaration;
3. order the termination or prohibition of any violation under Paragraph 1, item 1 and, where necessary, publicly disclose the order of termination or prohibition of the violation.
(4) (New, SG No. 102/2012, effective 21.12.2012) The Chairperson of the Council under Article 258, Paragraph 1 shall have the right to order in writing the offender to cease and desist the violation found during the inspection under Paragraph 1, item 6.

Article 270a. (New, SG No. 67/2020) (1) In exercising its control functions the Council under Article 258, paragraph 1 shall have the right to:

1. require information of:
(a) the quantities of medicinal products delivered on the territory of the Republic of Bulgaria and the prices of their acquisition;
(b) the wholesalers to whom the quantities of medicinal products under paragraph (a) have been delivered;
(c) the date on which a delivery under paragraphs (a) and (b) has been made;
(d) the quantities available in stock in their warehouses, indicated by medicinal products;
2. verify commercial or other records, documents and data carriers with a view to establishing compliance with the approved prices, price ceilings or registered prices of medicinal products;
3. require and collect original documents, data, information, records, fact sheets and other data carriers for establishing compliance with the approved prices, price ceilings or registered prices of medicinal products; require certified copies of documents in writing and certified data printouts of technical data carriers;
4. obtain from the inspected persons access to their automated information systems, products or archives, where collection, storage and processing of information is thus performed.
(2) In exercising its control functions, the Council shall have the right to require from the inspected persons to provide information and documents under paragraph 1 within a period set by the Council.
(3) In implementation of its functions under paragraph 1, the Council may enter into agreements for interaction with other control authorities.

Article 271. (1) The Regional Health Inspectorates shall have the right to:
1. stay construction operations and issue prescriptions when they find violations of hygiene standards and requirements in the process of construction; in case of illegal construction of sites and installations for the manufacturing, storage and sale of medicinal products, they shall notify the National Control of Construction Directorate or the municipal technical service;
2. prohibit putting into operation and suspend the operation of sites and installations when requirements and hygiene standards have been violated in the manufacturing, storage and sale of medicinal products until the violations have been removed;
3. (amended, SG No. 71/2008, effective 12.08.2008, SG No. 67/2020) prohibit medicinal products after receipt of a notification in writing by the Bulgarian Drug Agency of the existence of documented information about: non-compliance with the quality requirements; medicinal products imported or manufactured in violation of this Act; medicinal products offered in packaging with brochures that do not comply with the requirements of this Act, and send samples thereof to the Bulgarian Drug Agency;
4. give conclusions with regard to the compliance of controlled sites with statutory requirements;
5. issue orders, prescriptions and instructions within their competence that shall be binding on all persons on the territory of the respective region;
6. (new, SG No. 67/2020) exercise control over the compliance with the orders for withdrawal of medicinal products from sites located on the territory of the respective administrative region.
(2) (Supplemented, SG No. 67/2020) Compulsory administrative measures under paragraph 1 or under Article 270, paragraph 3 shall be imposed by an order of the RHI Director. A copy of the issued order shall be sent to the Bulgarian Drug Agency.
(3) Orders under Paragraph 2 shall be subject to appeal under the Administrative Procedure Code, whereby their appeal shall not stay their enforcement.
(4) (New, SG No. 67/2020) The Regional Health Inspectorates shall notify the Bulgarian Drug Agency if they find out that:
1. any pharmacy on the territory of the respective administrative region is not open for operation for a period longer than 30 days within one calendar year;
2. there is no pharmacy at the address for which authorisation of retailing of medicinal products has been issued.

Article 272. (1) The Bulgarian Drugs Agency shall:
1. (supplemented, SG No. 102/2012, effective 2.01.2013) prohibit putting into operation and suspend the operations of sites and installations when the rules of Good Manufacturing Practice of medicinal products and of active substances, as well as of Good Distribution Practices, are violated, until such violations have been removed;
2. prohibit the manufacturing, import, export and trade in medicinal products which directly or indirectly threaten the health of humans, and order their destruction, processing or use for other purposes;
2a. (new, SG No. 102/2012, effective 2.01.2013) delete from the register the persons engaging in intermediation activities with medicinal products when the obligations under Article 212b are not fulfilled;
3. provisionally suspend the operation of sites for wholesaling and retailing of medicinal products when the conditions under which the respective authorisation has been issued;
4. prohibit medicinal products in the presence of recorded information about: incompliance with quality, efficiency and safety requirements; medicinal products imported or manufactured in violation of this Act, as well as medicinal products offered in packaging with brochures that do not meet the requirements hereof; where necessary, order their withdrawal from pharmacies and drugstores, from wholesale trade warehouses, from manufacturers and treatment establishments, and notify the Ministry of Health thereof;
5. (amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) revoke an existing clinical trial authorisation, discontinue a clinical trial, or order that the sponsor submit an application for substantial modification to the clinical trial (in the case of violations of Regulation (EC) No. 536/2014) under the conditions and procedures laid down in said Regulation;
5a. (new, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 2.01.2013, supplemented, SG No. 67/2020) order prohibition, withdrawal and destruction of counterfeited medicinal products and of medicinal products of undetermined origin in the cases under Articles 24 and 30 of Delegated Regulation (EU) 2016/161;
5b. (new, SG No. 60/2011, effective 5.08.2011) conduct checks on the donations under Article 268a, Paragraph 1;
6. issue orders, prescriptions and instructions within its competence that shall be binding on all persons.
7. (new, SG No. 60/2011, effective 5.08.2011) restrict medicinal products and active substances in case of suspected quality deviation by placing certification marks at the relevant manufacturing sites.
(2) Compulsory administrative measures under Paragraph 1 and under Article 270, Paragraph 3 shall be imposed by order of the Bulgarian Drug Agency Director.
(3) The orders under Paragraph 2 shall be subject to appeal under the Administrative Procedure Code, whereby the appeal shall not stay their enforcement.

Article 272a. (New, SG No. 102/2012, effective 2.01.2013) (1) Delegated acts under Article 52b, Paragraph 2 of Directive 2001/83/EC shall specify the measures needed to prevent the circulation of medicinal products introduced into the European Union, but not intended for release on the market of the European Union, for which there exist sufficient grounds to suspect that they are counterfeited.
(2) The Bulgarian Drugs Agency shall undertake the necessary measures in accordance with the delegated acts under Paragraph 1 to prevent the circulation of medicinal products introduced into the European Union, but not intended for release on the market of the European Union, for which there exist sufficient grounds to suspect that they are counterfeited.
(3) The customs authorities shall notify the Bulgarian Drugs Agency about the introduction of new medicinal products under Paragraph 1 on the territory of the Republic of Bulgaria with a view to undertaking measures under Paragraph 2.

Article 272b. (New, SG No. 67/2020) (1) Manufacturing/import authorisation holders, marketing authorisation holders, parallel import authorization holders, holders of authorisation for wholesaling of medicinal products, holders of authorisation for retailing of medicinal products in a pharmacy and medical treatment establishments shall perform the activities laid down in Delegated Regulation (EU) 2016/161.
(2) The Bulgarian Medicine Verification Organisation shall establish and manage a National Register under Article 32, item 1, letter (b) of Delegated Regulation (EU) 2016/161 to serve the territory of the Republic of Bulgaria.
(3) The following national competent authorities shall be entitled to free of charge access to the register under paragraph 2 in accordance with Article 39 of Delegated Regulation 2016/161:
1. The Bulgarian Drug Agency – for the purposes of exercising supervision over the operation of the registers and investigation in cases of suspected counterfeiting, as well as for the purposes of pharmacovigilance or pharmacoepidemiology;
2. The Ministry of Health, the National Health Insurance Fund and the Council under Article 258, paragraph 1 – for the purposes of payment for medicinal products with public funds.

Article 273. (1) The terms and conditions for taking samples, conducting trials and tests and the payment for them shall be specified in an Ordinance of the Minister of Health.
(2) When the outcomes of laboratory tests are contested, these shall be repeated. Repeated tests shall be conducted upon written request by the interested party, submitted within 7 days of the date of receipt of the result of the initial test.
(3) Repeated tests under Paragraph 2 shall be conducted by experts designated by the Bulgarian Drugs Agency Executive Director, who have not been involved in the initial testing, in the presence of an authorised representative of the interested party.

Article 274. (1) The terms and conditions for blocking and withdrawing from the market of medicinal products that have demonstrated non-compliance with quality, safety and efficacy requirements shall be specified in an Ordinance of the Minister of Health.
(2) (Amended, SG No. 67/2020) The terms and conditions for destruction of medicinal products shall be laid down in an ordinance of the Minister of Health.

Article 275. (1) When exercising control, the Bulgarian Drugs Agency shall take all necessary measures in order to ensure the right validation of manufacturing and refinement of medicinal products obtained from human blood or human plasma, the sustainability of batch quality and in order to guarantee, within technological constraints, the absence of a specific virus contamination.
(2) The manufacturers shall notify the Bulgarian Drugs Agency of the method used to reduce or eliminate pathogenic viruses, which may be transmitted through medicinal products obtained from human blood or human plasma.
(3) The Bulgarian Drugs Agency shall test and send for testing to another official laboratory for control of medicinal products in the Republic of Bulgaria or in another Member State samples of bulk product/not poured into bottles and/or of a medicinal product intended for trial either in the course of evaluating the application for a marketing authorisation under Article 46, Paragraph 1, item 2, or after issuing a marketing authorisation.

Article 276. The Bulgarian Drugs Agency Executive Director shall temporarily suspend, withdraw, terminate or amend a marketing authorisation of a medicinal product/registration by order, where it is found that:
1. there is an inadmissible adverse reaction in case of correct use, or
2. there is no therapeutic efficacy (there shall be no therapeutic efficacy where it is found that the therapeutic results announced during its marketing authorisation cannot be obtained), or
3. the benefit/risk ratio is unfavourable with correct use, or
4. the quantitative and qualitative composition of the medicinal product do not correspond to those declared during licensing for use, or
5. the data from the dossier under Articles 27 - 32 are untrue, or

6. (amended, SG No. 71/2008, effective 12.08.2008) the data from the dossier under Articles 27 - 32 have not been completed or have not been changed in accordance with the requirements of Chapter Three, Section VI, or
6a. (new, SG No. 102/2012, effective 21.12.2012) the conditions under Articles 55a, 56 and 56a are not complied with, or
6b. (new, SG No. 102/2012, effective 21.12.2012) the manufacturing of the medicinal product has not been done according to the manufacturing method described under Article 27, Paragraph 1, item 7, or
7. (amended, SG No. 102/2012, effective 21.12.2012) no control trials have been conducted or they have not been conducted in accordance with the methods indicated in Article 27, Paragraph 1, item 8, or
8. the data on the packaging and/or in the brochure do not correspond to those approved when the marketing authorisation was issued;
9. (new, SG No. 71/2008, effective 12.08.2008) the marketing authorisation holder has not fulfilled his obligations under Article 45, Paragraph 1 of Regulation (EC) No. 1901/2006.

Article 277. (1) The Bulgarian Drugs Agency Executive Director, irrespective of the measures under Article 276, shall prohibit by order the supply of medicinal products concerned and shall order their prohibition and withdrawal from the market when:
1. (amended, SG No. 102/2012, effective 21.12.2012) there is an inadmissible adverse reaction, or
2. there is no therapeutic efficacy, or
3. (amended, SG No. 102/2012, effective 21.12.2012) the benefit/risk ratio is unfavourable, or
4. the quantitative and qualitative composition of the medicinal product concerned does not correspond to those declared during licensing for use, or
5. no control of the medicinal product and/or of the ingredients and at the intermediate stages of the manufacturing process has been exercised, or the requirements under which the manufacturing authorisation has been issued are not implemented.
(2) The Bulgarian Drugs Agency Executive Director may impose a prohibition under Paragraph 1 in respect only of specific batches of the medicinal product.

Article 278. (1) The Bulgarian Drugs Agency Executive Director shall, by order, temporarily suspend or withdraw the marketing authorisation of a class or of all medicinal products for which the requirements under which a manufacturing authorisation has been issued are not observed in respect to the place of manufacturing.
(2) By order, the Bulgarian Drugs Agency Executive Director may take, other than the measures under Article 276, a provisional suspension of import of a class or of all medicinal products from third countries, or withdraw the import authorisation of a class or of all medicinal products when they do not comply with the requirements of Chapter Five.
(3) By order, the Bulgarian Drugs Agency Executive Director may take, other than the measures under Article 276, a provisional suspension or the withdrawal of a manufacturing authorisation for a class or for all medicinal products that do not comply with the requirements of Chapter Five.

Article 279. (1) The orders under Articles 276, 277 or 278 shall be served on the marketing authorisation holder, the manufacturer or the importer.
(2) The orders under Paragraph 1 shall be subject to appeal under the Administrative Procedure Code, whereby their appeal shall not stay their enforcement.

Article 280. (1) When a violation of the provisions of Chapter Eleven has been found, or of the Ordinance under Article 249, the Bulgarian Drug Agency Executive Director shall order the suspension of advertisement distribution
(2) By virtue of the order under Paragraph 1, the Bulgarian Drugs Agency Director may obligate the advertiser to publish or distribute, in coordination with the Bulgarian Drugs Agency, a disclaimer of the allegations contained in the advertisement through the same means, in the same format and volume.
(3) The order under Paragraph 2 shall be subject to appeal under the Administrative Procedure Code.

Chapter Fourteen
PENAL ADMINISTRATIVE PROVISIONS

Article 281. (1) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 2.01.2013) Anyone manufacturing, importing, selling, storing or authorising in the Republic of Bulgaria medicinal products that have not been authorised for use, outside the cases under Articles 8, 9, and 10, unless subject to a more serious sanction, as well as medicinal products of undetermined origin, shall be sanctioned by a fine of BGN 25,000 to BGN 50,000.
(2) The same sanction shall be imposed on persons manufacturing, importing, selling or allowing the use, in the Republic of Bulgaria, of medicinal products that do not comply with the requirements of the effective pharmacopoeia and fail to meet the conditions stipulated during their licensing for use.
(3) When the violations under Paragraphs 1 and 2 relate to unauthorised medicinal products containing narcotic substances or when they have been committed for a second time, unless the acts constitute criminal offences, the authorisation issued in pursuance hereof shall be withdrawn.
(4) Medical specialists who manufacture, sell or allow the use of medicinal products that have not been authorised shall be barred from exercising the profession for a term of 6 months to 2 years.
(5) The sanction under Paragraph 4 shall be imposed by order of the Minister of Health at the proposal of the Bulgarian Drugs Agency Executive Director.

Article 282. (1) Anyone selling medicinal products in packaging or with patient brochures that do not comply with the requirements of this Act, shall be sanctioned by a fine of BGN 750 to BGN 1,500 and in case of repeating the same violation - by a fine of BGN 1,500 to BGN 3,000.
(2) Anyone selling medicinal products without patient brochures shall be sanctioned by a fine of BGN 750 to BGN 1,500, and in case of repeating the same violation - by a fine of BGN 1,500 to BGN 3,000.

Article 283. (1) Anyone importing, trading in or allowing the use of medicinal products whose shelf life has expired, shall be sanctioned by a fine of BGN 10,000 to BGN 20,000.
(2) Anyone breaking the immediate/outer packaging or selling/allowing the use of medicinal products whose immediate/outer packaging has been broken, shall be sanctioned by a fine of BGN 750 to BGN 1,500 and in case of repeating the same violation - by a fine of BGN 1,500 to BGN 3,000.

Article 284. (1) Anyone manufacturing, importing or conducting wholesaling of medicinal products or selling such products without the requisite authorisation shall be sanctioned by a fine of BGN 50,000.
(2) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 2.01.2013) Anyone manufacturing, importing or conducting wholesaling of medicinal products, or selling medicinal products in violation of the issued authorisation or authorisation, or selling, storing or providing medicinal products of undetermined origin, shall be sanctioned by a fine of BGN 25,000 to BGN 50,000.
(3) (Supplemented, SG No. 71/2008, effective 12.08.2008) In the cases under Paragraphs 1 and 2, the bodies of state control shall suspend by order the operation of the site concerned.
(4) The order under Paragraph 3 shall be subject to appeal under the Administrative Procedure Code, whereby the appeal shall not stay its enforcement.

Article 284a. (New, SG No. 102/2012, effective 2.01.2013) (1) (Previous text of Article 284a, SG No. 67/2020) Anyone manufacturing, importing, exporting, storing, selling or providing counterfeited medicinal products, or anyone acting as intermediary in the purchase or sale of counterfeited medicinal products, shall be sanctioned by a fine of BGN 25,000 to BGN 50,000.
(2) (New, SG No. 67/2020) Any manufacturing or import authorisation holder, marketing authorisation holder or parallel import authorization holder that fail to discharge their obligation relating to safety features of medicinal products, laid down in this Act or in Delegated Regulation

(EU) 2016/161, shall be penalized by a pecuniary sanction from BGN 5 000 to BGN 10 000 and in case of repeating the same violation – by a pecuniary sanction from BGN 25 000 to BGN 50 000.

Article 284b. (New, SG No. 102/2012, effective 2.01.2013) A manufacturing authorisation holder who fails to discharge his obligations under Article 160 shall be subject to a pecuniary sanction of BGN 5,000 to BGN 10,000, and in the event of repeating the same violation - a pecuniary sanction of BGN 10,000 to BGN 20,000.

Article 284c. (New, SG No. 102/2012, effective 2.01.2013) (1) (Previous text of Article 284c, supplemented, SG No. 84/2018, effective 12.10.2018) A wholesale authorisation holder for medicinal products who fails to discharge his obligations under Article 207, Paragraph 1, items 1 – 3, items 4a – 14 and paragraph 2 shall be subject to a pecuniary sanction of BGN 2,000 to BGN 5,000, and in the event of repeating the same violation – a pecuniary sanction of BGN 5,000 to BGN 10,000.

(2) (New, SG No. 84/2018, effective 12.10.2018) A wholesale authorisation holder for medicinal products who fails to discharge his obligations under Article 207, Paragraph 1, item 4 shall be subject to a pecuniary sanction of BGN 25,000 to BGN 50,000, and in the event of repeating the same violation – a pecuniary sanction of BGN 50,000 to BGN 100,000.

(3) (New, SG No. 67/2020) A wholesale authorisation holder for medicinal products who fails to discharge his obligation relating to safety features of medicinal products, laid down in this Act, in a statutory instrument of secondary legislation or in Delegated Regulation (EU) 2016/161, shall be subject to a pecuniary sanction from BGN 5,000 to BGN 10,000 and in case of repeating the same violation – by a pecuniary sanction from BGN 10 000 to BGN 20 000.

Article 284d. (New, SG No. 84/2018, effective 12.10.2018, amended, SG No. 103/2020, effective 1.01.2021) Anyone who does not fulfill their obligations under Article 68, paragraph 1(9) shall be sanctioned with a fine from BGN 50,000 to 100,000; in the case of a recurrent violation, the fine shall amount from BGN 100,000 to 150,000.

Article 284e. (New, SG No. 84/2018, effective 12.10.2018) Anyone who exports medicinal products included on the list referred to in Article 217c(1) shall be sanctioned with a fine from BGN 50,000 to 100,000; in the case of a recurrent violation, the fine shall amount from BGN 100,000 to 150,000.

Article 284f. (New, SG No. 84/2018, effective 12.10.2018, repealed, SG No. 67/2020q new, SG No. 103/2020, effective 1.01.2021) Anyone who does not fulfill their obligation to provide information under Article 217b(3)(1) or who fails to fulfill this obligation within the statutory time limit shall be sanctioned with a fine from BGN 5000 to 10,000; in the case of a recurrent violation, the fine shall amount from BGN 10,000 to 15,000.

Article 284g. (New, SG No. 84/2018, effective 12.10.2018, repealed, SG No. 67/2020, new, SG No. 103/2020, effective 1.01.2021) Anyone who provides information under Article 217b(3)(1) with incomplete and/or inaccurate content shall be sanctioned with a fine from BGN 3,000 to 5,000; in the case of a recurrent violation, the fine shall amount from BGN 5,000 to 10,000.

Article 284h. (New, SG No. 84/2018, effective 12.10.2018, amended, SG No. 67/2020) For failure to comply with the obligations under Article 217 b, paragraph 10 of the Executive Director of the BDA, according to an official of the FDA, having a fine of BGN 50,000 to BGN 100,000, and in case of repeating the same violation – by a fine of BGN 100,000 to BGN 150,000.

Article 284i. (New, SG No. 105/2020, effective 11.12.2020) Anyone who exports medicinal products included in the ordinance referred to in Article 217e shall be sanctioned with a fine from BGN 50,000 to 100,000; in the case of a recurrent violation, the fine shall amount from BGN 100,000 to 150,000.

Article 285. (1) Anyone trading in medicinal products without a certificate of batch release shall be sanctioned by a fine of BGN 5,000 to BGN 10,000, and in case of repeating the same violation - by a fine of BGN 10,000 to BGN 20,000.

(2) (Amended, SG No. 60/2011, effective 5.08.2011) A wholesaler supplying drugstores with medicinal products subject to medical prescription shall be sanctioned by a pecuniary sanction of

BGN 2,500 to BGN 5,000 and in case of repeating the same violation - by a fine of BGN 5,000 to BGN 10,000.
(3) A qualified person who has allowed the sale of batches of medicinal products without a certificate of release of each separate batch shall be sanctioned by a fine of BGN 2,500 to BGN 5,000.

Article 285a. (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012) Any marketing authorisation holder who fails to inform the Minister of Health of sale discontinuation referred to in Article 264 shall be subject to pecuniary sanction of BGN 25,000 to BGN 50,000.

Article 285b. (New, SG No. 102/2012, effective 21.12.2012) Anyone manufacturing, importing, exporting, selling or storing active substances in violation of this Act, shall be sanctioned by a fine of BGN 10,000 to BGN 20,000.

Article 285c. (New, SG No. 18/2014, amended, SG No. 84/2018, effective 12.10.2018) Anyone who exports medicinal products in quantities higher than those indicated in Article 207(1)(15)(d) shall be sanctioned with a fine from BGN 50,000 to 100,000; in the case of a recurrent violation, the fine shall amount from BGN 100,000 to 150,000.

Article 286. (1) (Supplemented, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) For clinical trials conducted in violation hereof or Regulation (EU) No. 536/2014, unless the act constitutes a criminal offence, the guilty persons who have allowed or committed this violation shall be imposed a fine of BGN 5,000 to BGN 10,000, and in case of allowing or committing the same violation for a second time – a fine of BGN 10,000 to BGN 20,000.
(2) Medical specialists who have allowed or committed violations under Paragraph 1 may also be imposed the sanction of "disbarment from exercising the profession" for a period of 6 months to two years.
(3) The measure under Paragraph 2 shall be imposed by the Minister of Health at the proposal of the Bulgarian Drugs Agency Executive Director.

Article 287. (1) (Supplemented, SG No. 71/2008, effective 12.08.2008, amended, SG No. 60/2011, effective 5.08.2011) Anyone retailing medicinal products without an authorisation/certificate for this or who works in violation of the authorisation/certificate issued to him shall be sanctioned by a fine of BGN 5,000 to BGN 10,000.
(2) (New, SG No. 84/2018, effective 12.10.2018) Any retailer who delivers medicinal products from the list referred to in Article 217c(1) to a wholesaler or other persons in violation of the requirements set out in this law or the regulations on its application shall be subject to a fine or pecuniary sanction from BGN 10,000 to 20,000; in the case of a recurrent violation, the fine/sanction shall amount from BGN 25,000 to 35,000.
(3) (Renumbered from Paragraph (2), SG No. 84/2018, effective 12.10.2018) The sanction under Paragraph 1 shall also be imposed on persons retailing in a pharmacy or drugstore after termination of the effects of the authorisation/permit.
(4) (Amended, SG No. 71/2008, effective 12.08.2008, supplemented, SG No. 60/2011, effective 5.08.2011, renumbered from Paragraph (3), SG No. 84/2018, effective 12.10.2018) Anyone selling or storing in a drugstore medicinal products subject to medical prescription or products of significance to human health, outside those stipulated in the Ordinance under Article 243, shall be sanctioned by the fine under Paragraph 1, and in case of repeating the same violation, the certificate of registration of the drugstore shall be withdrawn.
(5) (Renumbered from Paragraph (4), amended, SG No. 84/2018, effective 12.10.2018) In the cases under Paragraphs 1, 2 and 3 the state control bodies for medicinal products shall suspend by order the operation of the site concerned.
(6) (Repealed, SG No. 71/2008, effective 12.08.2008, renumbered from Paragraph (5), amended, SG No. 84/2018, effective 12.10.2018) The order under Paragraph 5 shall be subject to appeal under the Administrative Procedure Code, whereby the appeal shall not stay its enforcement.

Article 287a. (New, SG No. 71/2008, effective 12.08.2008) (1) A medical specialist working with persons retailing medicinal products, without having an authorisation/certificate for that, shall be sanctioned with a fine of BGN 2,500 to BGN 5,000.
(2) The sanction under Paragraph 1 shall also be imposed on persons under Paragraph 1 working in a pharmacy or drugstore after the termination of the validity of its authorisation/certificate.
(3) In the event that more than two violations under Paragraphs 1 and 2 have been found, the Minister of Health may deprive the medical specialist of the right to practice his profession for a period of up to two years.

Article 287b. (New, SG No. 102/2012, effective 2.01.2013, amended, SG No. 67/2020) Anyone trading in medicinal products online in violation of the requirements of this Act and of the ordinance under Article 234, paragraph 6, shall be penalised by a fine of BGN 5,000 to BGN 10,000.

Article 288. (1) A retailer of medicinal products who has allowed the operations under Article 219 to be carried out by an incompetent person shall be sanctioned by a pecuniary sanction of BGN 5,000 to BGN 10,000, and in the event of repeating the same violation, the authorisation for retailing shall be withdrawn.
(2) In the cases under Paragraph 1, the state control bodies shall suspend the operation of the site by order.

Article 288a. (New, SG No. 67/2020) A holder of authorisation for retailing of medicinal products in a pharmacy who fails to discharge his obligation relating to safety features of medicinal products, laid down in this Act, or in Delegated Regulation (EU) 2016/161, shall be penalized by a pecuniary sanction from BGN 1,000 to BGN 3,000, and in case of repeating the same violation – by a pecuniary sanction from BGN 5,000 to BGN 10,000.

Article 289. (1) (Previous text of Article 289, SG No. 60/2012, effective 7.08.2012, amended, SG No. 102/2018, effective 1.01.2019) Anyone selling medicinal products without the formation and registration of a price, or at prices other than those formed in pursuance hereof shall be sanctioned by fine of BGN 1500 to BGN 3000, and in the event of repeating the same violation, by a fine of BGN 2500 to BGN 4000.
(2) (New, SG No. 60/2012, effective 7.08.2012, amended, SG No. 102/2012, effective 21.12.2012, supplemented, SG No. 67/2020) Any marketing authorisation holder or a wholesaler of medicinal products, who fails to fulfil an obligation sin the ordinance under Article 261a, paragraph 5, shall be penalised by a pecuniary sanction of BGN 5,000 to BGN 10,000, and in case of repeating the same violation – by a pecuniary sanction of BGN 10,000 to BGN 20,000.
(3) (New, SG No. 102/2012, effective 21.12.2012, repealed, SG No. 102/2018, effective 1.01.2019, new, SG No. 67/2020) A retailer of medicinal products who sells medicinal products included in the Positive Drug List to a medical treatment establishment at a price higher than the value formed in pursuance with the ordinance under Article 261a, paragraph 5 shall be penalised by pecuniary sanction from BGN 3,000 to BGN 5,000 and in case of repeating the same violation – by a pecuniary sanction from BGN 6,000 to BGN 10,000.
(4) (New, SG No. 67/2020) A medical facility under Article 262, paragraph 6, item 2, which purchases medicinal products included in the Positive Drug List at a price higher than the value formed in pursuance with the ordinance under Article 261a, paragraph 5 shall be penalised by pecuniary sanction from BGN 3,000 to BGN 5,000 and in case of repeating the same violation – by pecuniary sanction from BGN 6,000 to BGN 10,000.
(5) (New, SG No. 67/2020) The violations under paragraphs 1 - 3 shall be established by acts drawn up by officials appointed by the Chairperson of the Council under Article 258, paragraph 1, and the penal decrees shall be issued by the Chairperson of the Council under Article 258, paragraph 1.
(6) (New, SG No. 67/2020) The violations referred to in paragraph 4 shall be established by acts drawn up by officials appointed by the Executive Director of the Medical Supervision Executive Agency, and penal decrees shall be issued by the Executive Director of the Medical Supervision Executive Agency.

Article 289a. (New, SG No. 60/2011, effective 5.08.2011) (1) (Amended, SG No. 102/2012, effective 21.12.2012, SG No. 102/2018, effective 1.01.2019) Anyone working in violation of the established pharmacotherapy guidelines or conducting assessment of the therapeutic results without complying to the criteria laid down in Article 259, Paragraph 1, Item 4, shall be sanctioned by a fine of BGN 1000 to BGN 2000. If they repeat the same violation, the fine shall be BGN 2000 to BGN 3000.
(2) (Amended, SG No. 102/2018, effective 1.01.2019) The presence of any violations referred to in Paragraph 1 shall be established by acts drafted by officials appointed by the Executive Director of the Medical Surveillance Executive Agency. Penal decrees shall be issued by the Executive Director of the Medical Surveillance Executive Agency.
(3) (New, SG No. 67/2020) If during the inspections under Article 267a, paragraph 2 any discrepancy is found between the types and quantities of medicinal products prescribed and/or applied to patients and the types and quantities of medicinal products dispensed by the pharmacy, the Medical Supervision Executive Agency shall notify the authority paying the relevant medicinal product with public funds, and if there are any data of a criminal offence, it shall apprise the competent authorities to take actions for its prosecution.

Article 289b. (New, SG No. 67/2020) (1) Anyone who conducts treatment in violation of the requirements of Article 266b shall be sanctioned by a fine of BGN 1,000 to BGN 3,000, and in case of repeating of the same violation – by a fine of BGN 2,000 to BGN 4,000.
(2) The violations referred to in paragraph 1 shall be established by acts drafted by officials appointed by the Executive Director of the Medical Supervision Executive Agency, and penal decrees shall be issued by the Executive Director of the Medical Supervision Executive Agency.

Article 290. (1) (Amended, SG No. 71/2008, effective 12.08.2008) Anyone advertising medicinal products not authorised in pursuance hereof shall be sanctioned by fine of BGN 10,000 to BGN 20,000.
(2) (New, SG No. 71/2008, effective 12.08.2008) Anyone advertising a product by ascribing to it and/or suggesting properties connected with the prevention, diagnosis or treatment of human diseases shall be sanctioned by fine of BGN 10,000 to BGN 20,000.
(3) (Renumbered from Paragraph 2, amended, SG No. 71/2008, effective 12.08.2008) Anyone advertising medicinal products in violation hereof shall be sanctioned by fine of BGN 10,000 to BGN 20,000.
(4) (Renumbered from Paragraph 3, amended, SG No. 71/2008, effective 12.08.2008) The sanctions under Paragraph 2 shall also be imposed on persons who have allowed the broadcasting, publication and distribution of advertisement.

Article 290a. (New, SG No. 71/2008, effective 12.08.2008) A medical specialist or a person claiming to be a medical specialist, who engages in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the Internet, shall be sanctioned with a fine of BGN 1,000 to BGN 5,000, and in the event of repeated offence - a fine of BGN 3,000 to BGN 10,000.

Article 290b. (New, SG No. 60/2011, effective 5.08.2011) Anyone who donates medicinal products in violation of Article 268a, Paragraph 1, shall be sanctioned by a fine of BGN 1,000 to BGN 3,000. If they repeat the same violation the fine shall be BGN 3,000 to BGN 5,000.

Article 290c. (New, SG No. 102/2012, effective 21.12.2012) A marketing authorisation holder who conducts non-interventional studies in violation of this Act shall be subject to a pecuniary sanction of BGN 5,000 to BGN 10,000, and if the same violation is repeated, the pecuniary sanction shall be BGN 10,000 to BGN 20,000.

Article 290d. (New, SG No. 102/2012, effective 21.12.2012) A marketing authorisation holder who fails to comply with the conditions laid in Articles 55a, 56 and 56a shall be subject to a pecuniary sanction of BGN 5,000 to BGN 10,000, and if the same violation is repeated, the pecuniary sanction shall be BGN 10,000 to BGN 20,000.

Article 290e. (New, SG No. 102/2012, effective 21.12.2012) A marketing authorisation holder who fails to fulfil his obligations under Articles 190 - 192, 194b, 194c, 194h and 194i shall

be subject to a pecuniary sanction of BGN 5,000 to BGN 10,000, and if the same violation is repeated, the pecuniary sanction shall be BGN 10,000 to BGN 20,000.

Article 290f. (New, SG No. 102/2012, effective 21.12.2012) A marketing authorisation holder who fails to fulfil his obligations under Articles 193 and 194 shall be subject to a pecuniary sanction of BGN 2,000 to BGN 5,000, and if the same violation is repeated, the pecuniary sanction shall be BGN 5,000 to BGN 10,000.

Article 291. (1) (Supplemented, SG No. 60/2011, effective 5.08.2011, SG No. 60/2012, effective 7.08.2012, amended, SG No. 102/2012, effective 21.12.2012, supplemented, SG No. 84/2018, effective 12.10.2018, SG No. 67/2020, amended, SG No. 105/2020, effective 11.12.2020) Where the violations under Articles 281 - 284a, paragraph 1, Articles 284d - 284i, 285, 285b, Article 286, paragraph 1, Articles 287 and 287b, Article 289, paragraph 1, Article 289a, Articles 290, Article 290b, Article 292 and Article 294 have been committed by legal persons or sole proprietors, pecuniary sanctions at an amount no lesser than triple the amount of the stipulated minimum amounts of the respective fines and not larger than the triple amount of the stipulated maximum amounts of the respective fines shall be imposed.

(2) (Supplemented, SG No. 60/2012, effective 7.08.2012) For violations under Article 289, Paragraph (1), the pecuniary sanction shall be nine times the amount of the sum taken in excess, where the latter exceeds the maximum amount of the sanction under Paragraph 1.

(3) The imposition of a pecuniary sanction shall not exclude the imposition of a fine to the delinquent officials.

(4) The imposition of pecuniary sanctions shall not exclude the imposition of measures envisaged with regard to the competency of medical specialists and qualified persons.

Article 292. (1) Anyone failing to implement an order, prescription or instruction of the state control bodies under this Act, outside the cases under Article 270, Paragraph 1, item 2 and Paragraph 3, shall be sanctioned by fine of BGN 1,500 to BGN 3,000.

(2) For failure to implement an order under Article 270, Paragraph 1, item 2 and Paragraph 3, the guilty persons shall be sanctioned by fine of BGN 500 to BGN 1,000.

Article 293. (1) (Amended, SG No. 102/2012, effective 2.01.2013, SG No. 84/2018, effective 12.10.2018) In the event of failure to fulfil the obligations under which the authorisations/certificates for manufacturing, import, parallel import, wholesaling and retailing of medicinal products in a pharmacy, as well as in the cases under Article 281, Paragraphs 1 - 3, Article 283, Paragraph 1, Article 284c, Paragraph 2 and Article 287, Paragraph 2 the Bulgarian Drug Agency Executive Director shall issue an order for their withdrawal.

(2) (Amended, SG No. 102/2012, effective 2.01.2013, SG No. 84/2018, effective 12.10.2018) For failure to observe the conditions under which the registration certificate for a drugstore has been issued, as well as in the cases under Article 287, Paragraphs 4, the Director of the relevant Regional Health Inspectorate shall issue an order for withdrawal of the certificate.

(3) In case of failure to discharge notification duties under Article 204, Paragraph 3 for termination of operations by a wholesaler of medicinal products, the Bulgarian Drugs Agency Executive Director shall issue an order for withdrawal of the issued authorisation.

(4) (New, SG No. 84/2018, effective 12.10.2018) If a wholesaler dealing in medicinal products fails to comply with the requirements for exporting medicinal products set out in Chapter 9b, the Executive Director of the Bulgarian Drug Agency shall issue an order revoking the wholesaler’s authorisation, where the wholesaler has committed a recurrent violation under Articles 284e and 285c or has systematically failed to fulfill their obligations under Article 207(1)(15).

(5) (Amended, SG No. 102/2012, effective 2.01.2013, renumbered from Paragraph (4), SG No. 84/2018, effective 12.10.2018) In the event of failure to discharge the duties of notification under Article 235, Paragraph 3 for termination of operations by the holder of an authorisation for retailing of medicinal products, the Bulgarian Drugs Agency Executive Director shall issue an order for withdrawal the authorisation issued.

(6) (Renumbered from Paragraph (5), amended, SG No. 84/2018, effective 12.10.2018) The orders under Paragraphs 1 - 5 shall be subject to appeal under the Administrative Procedure Code, whereby the appeal shall not stay their enforcement.

Article 294. Anyone violating the provisions of this Act or the Ordinances for its implementation, outside the cases under Articles 281 - 293, shall be sanctioned by a fine of BGN 1,000 to BGN 3,000 and in case of repeating the same violation - by a fine of BGN 3,000 to BGN 5,000.

Article 295. (1) (Amended, SG No. 102/2018, effective 1.01.2019, SG No. 67/2020) Violations of this Act are established by citations issued by authorised officials under Article 267, Paragraph 4.

(2) (Supplemented, SG No. 84/2018, effective No. 12.10.2018, repealed, SG No. 102/2018, effective 1.01.2019).

(3) (Amended, SG No. 102/2018, effective 1.01.2019) Penal decrees shall be issued by the Minister of Health, the Chief State Health Inspector, the chairperson of the Council under Article 258, Paragraph 1, by the Bulgarian Drug Agency Executive Director or the Directors of Regional Health Inspectorates, depending on the hierarchical system of the official who has found the violation.

(4) (New, SG No. 102/2018, effective 1.01.2019) The penal decrees may be also issued by other officials, authorised by the officials under Paragraphs 3, and the Chairperson of the Council under Article 258, Paragraph 1, may authorise another member of the commission.

(5) (New, SG No. 67/2020) The Regional Health Inspectorates shall notify the Bulgarian Drug Agency about any administrative violation notices issued and about penal decrees already in force, issued pursuant to this Act.

Article 296. The drafting of acts, the issuance, appeal from and the execution of penal decrees shall be carried out in compliance with the Administrative Violations and Sanctions Act.

Article 297. (Amended, SG No. 84/2018, effective 12.10.2018) (1) In the cases under Articles 281, 282, 283, 284, 285 and 287, the sanctioning authority shall also order that the medicinal products related to a violation shall be confiscated to the benefit of the state pursuant to conditions and procedures laid down in the Administrative Violations and Sanctions Act and in accordance with Regulation No. 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269/1, 10.10.2013) and Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No. 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343/558, 29.12.2015).

(2) Medicinal products under paragraph 1 shall be destroyed pursuant to the ordinance referred to in Article 274(2).

ADDITIONAL PROVISIONS

§ 1. For the purposes of this Act:

1. (Amended, SG No. 102/2012, effective 2.01.2013) "Active substance" shall be any substance or mixture of substances intended to be used for the manufacturing of a medicinal product, which, when used for its manufacturing, shall become an active component of that product, intended to produce a pharmacological, immunological or metabolic effect with the aim of restoring, correcting or modifying physiological functions, or for specifying a medical diagnosis.
2. "Bioequivalence" shall be present where medicinal products are pharmaceutically equivalent or pharmaceutical alternatives, and if their bioavailability after administration in the same molar dose is similar to the extent that their effect in terms of efficacy and safety is substantively similar.
3. "Bioavailability" shall be the speed and level at which the active substance or its therapeutically active part are absorbed from the pharmaceutical form and become available at the location of activity. When the medicinal substance is intended to have a systemic therapeutic effect, bioavailability shall mean the speed and level at which the medicinal substance or its therapeutically active part are released from the pharmaceutical form and pass into the general circulation.

4. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Investigator's brochure" is an investigator's brochure within the meaning of Article 2(2)(23) of Regulation (EC) No. 536/2014.
5. "Valid documentation" shall be the documentation which, in terms of content and completeness, meets the requirements specified in a particular procedure hereof.
6. "A substance whose use is well established in medical practice" shall be a substance to which the following criteria may apply:
a) The period for substantiating well established use in medical practice is not less than 10 years from the date of the first systematised and documented use of the substance as a medicinal product in the European Union or in the European Economic Area;
b) The quantitative aspects of the use of the substance, taking into account its level of use in medical practice, its level of use in terms of geographical spread and its level of monitoring through the pharmacovigilance system, including the studies carried out prior to marketing and thereafter and the published scientific literature concerning epidemiological studies and, in particular, comparative epidemiological studies;
c) A high level of scientific interest in the use of the substance (based on the number of scientific publications) and uniformity of scientific evaluations within academic circles.
7. "Outer packaging" shall be the packaging not entering immediately in contact with the medicinal product.
8. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Sponsor" is a sponsor within the meaning of Article 2(2)(14) of Regulation (EC) No. 536/2014.
9. "Generic medicinal product" shall be a medicinal product of the same qualitative and quantitative composition in terms of its active substances and of the same pharmaceutical form as its reference medicinal product, and its bioequivalence with the reference medicinal product has been substantiated through suitable bioavailability tests. The various oral pharmaceutical forms of immediate release shall be considered as the same pharmaceutical form. The various salts, esthers, ethers, isomers, isomer mixtures, complexes or derivatives of an active substance shall be considered as the same active substance, unless they vary significantly in their safety and/or efficacy.
10. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Principal investigator" is a principal investigator within the meaning of Article 2(2)(16) of Regulation (EC) No. 536/2014.
11. "Defined daily dose" shall be the average daily maintenance dose of a medicinal product, which is administered to adults for the main therapeutic indication of the respective medicinal product.
12. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Good clinical practice" means good clinical practice within the meaning of Article 2(2)(30) of Regulation (EC) No. 536/2014.
13. "Good Laboratory Practice" shall be a system of internationally recognised rules on the conditions for planning, the processes of organisation, conducting, monitoring and recording laboratory trials.
14. "Good Manufacturing Practice" shall be a system of internationally recognised business rules covering all aspects of manufacturing, i.e., staff, premises, installations, material, documentation, quality control, and which is intended to ensure safety, efficacy and compliance with specifications.
15. (Supplemented, SG No. 71/2008, effective 12.08.2008) "Member State" shall be a Member State of the European Union or a state signatory to the Agreement on the European Economic Area.
16. "Label" shall be the information appearing on the immediate or outer packaging of a medicinal product.
17. "Immunological medicinal product" shall be a medicinal product containing vaccines, toxins, serums or allergens. Agents used to create active immunity or to establish a state of immunity or to cause passive immunity shall be whitin the scope of vaccines, toxins and serums. Allergens shall be

medicinal products intended to identify or stimulate a specific targeted change in the immunological response to an allergic agent.
18. "Bioequivalence study" shall be a clinical trial aimed at proving that two medicinal products are bioequivalent when these are pharmaceutically equivalent or pharmaceutical alternatives and when their bioavailability, following administration at the same molar dose, is similar to an extent that is a condition of equivalent efficacy and safety.
19. "Bioavailability study" shall be a clinical trial aimed at demonstrating what the speed and level are at which the active substance or its therapeutically significant part in the tested medicinal product reach the systemic blood circulation from the respective pharmaceutical form.
20. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Investigational medicinal product" is an investigational medicinal product within the meaning of Article 2(2)(5) of Regulation (EC) No. 536/2014.
21. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Investigator" is an investigator within the meaning of Article 2(2)(15) of Regulation (EC) No. 536/2014.
22. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Informed consent" is informed consent within the meaning of Article 2(2)(21) of Regulation (EC) No. 536/2014.
23. "Kit" shall be any substance, which prior to being used is usually dissolved, suspended, diluted or combined with radionuclides, as a result of which the ready radioactive medicinal product is obtained.
24. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Clinical trial of a medicinal product" is a clinical trial within the meaning of Article 2(2)(2) of Regulation (EC) No. 536/2014.
25. "Clinical advantage" shall be a significant therapeutic or diagnostic advantage of a medicinal product compared to another medicinal product that has already been authorised for use.
25a. (New, SG No. 84/2018, effective 12.10.2018) "Conflict of interest" is a conflict of interest within the meaning of Chapter 8, section I of the Counter-Corruption and Unlawfully Acquired Assets Forfeiture Act.
26. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
27. "Patient brochure" shall be a brochure containing information for the user, accompanying a medicinal product.
27a. (New, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 21.12.2012) "Medicinal product for modern therapy" shall be a medicinal product defined in Article 3 of Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 concerning medicinal products for modern therapy and for amendment of Directive 2001/83/EC and of Regulation (EC) No. 726/2004.
27b. (New, SG No. 84/2018, effective 12.10.2018) "Medicinal product for compassionate use" is a medicinal product for palliative use within the meaning of Article 83(2) of Regulation (EC) No. 726/2004 of the European Parliament and of the Council.
28. "Medicinal product obtained from human plasma or from human blood" shall be a medicinal product manufactured from human blood ingredients, using a method that involves an industrial process. Albumin, immunoglobulin, coagulating factors and antiproteases, solutions of plasma proteins, other plasma fractions or combinations thereof shall fall within the above.
29. "A medicinal product intended for treatment, prevention and diagnosis of rare diseases" shall be the product which:
a) is intended for the diagnosis, prevention or treatment of life-threatening diseases or chronic diseases with a progressive course affecting no more than 5 out of 10,000 people on the territory of the country, or

b) is intended for the diagnosis, prevention or treatment of life-threatening diseases and of chronic conditions that seriously damage health (diseases with a high share of disease-related inability to work and disability), evidence being attached that the sale of the product does not provide a satisfactory level of return that would justify the required investment in scientific research and development operations without further incentives for the author of the product, and
c) when there is no satisfactory method for diagnosis, prevention or treatment of the respective condition or, if one exists, the proposed medicinal product has significantly more advantages than the former and it yields significantly more benefit for the affected by said condition.
30. "Pharmaceutical form" shall be a structure that is suitable for administration and contains the active substance(s), including or not any excipients, obtained through the use of certain technological operations ensuring the desired treatment effect and stability during storage within the set shelf-life.
31. (Amended, SG No. 71/2008, effective 12.08.2008) "A person established on the territory of a Member State or of an EEA country" shall be a legal subject registered under the civil or commercial legislation of a Member State, which has been created by virtue of a legislative instrument, having a seat and a business address in a Member State or in a country under the Agreement on the European Economic Area.
32. "Magistral preparation" shall be a prescription for a medicinal product prepared in a pharmacy by prescription of a medical specialist following an approved formulation, which is intended for a particular patient.
33. "International non-patent name" shall be the recommended name of the active substances, approved and published by the WHO.
34. "Medical specialists" shall be physicians, doctors of dental medicine, masters of pharmacy, nurses, midwives, medical laboratory analysts, medical auxiliaries and assistant pharmacists.
35. "Medical commercial representative" shall be a person that has undergone special training, having scientific knowledge for the provision of accurate and full information about the medicinal product which he advertises.
35a. (New, SG No. 1/2014, effective 3.01.2014) A "Medical prescription" shall be a prescription for a medicinal product, or for a medical device, issued by a person who pactices a regulated medical profession, as defined under the § 1, item 1 of the Supplementary Provisions of the Recognition of Professional Qualifications Act, and who in accordance with the law, is authorised to prescribe within the member-state of issue of the prescription.
36. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
36a. (New, SG No. 84/2018, effective 12.10.2018) "Network and Information Security" shall be the protection of the information from unlawful or accidental access, use, amendment, destruction or making it available to third parties.
37. "The name of a medicinal product" shall be the name given to a product, which may be:
a) a freely chosen name (trade name);
b) (amended, SG No. 12/2011, effective 8.02.2011) a generally accepted one, used together with the trademark or the name of the marketing authorisation holder;
c) (amended, SG No. 12/2011, effective 8.02.2011) a scientific name, used together with the trademark or the name of the marketing authorisation holder.
37a. (New, SG No. 67/2020) "Scientific evidence" shall be specific medical and/or scientific data generated in clinical trials, and/or data proving the safety and efficiency of any medicinal product, which are published in scientific journals, national or international treatment records or health technology assessment reports.
38. "Scientific literature" shall be a publication(s) of the results from scientific research in specialised international medical publications.
38a. (New, SG No. 84/2018, effective 12.10.2018) "Shortage of a medicinal product" means the shortage of medicinal products included on the Positive Drug List established through the specialised electronic system pursuant to Article 217b.

39. "New active substance" shall be:
a) a chemical, biological or radiopharmaceutical substance, which has not been authorised as a medicinal product in the European Union;
b) an isomer, a mixture of isomers, a complex or derivative or a salt of a chemical substance, which has been authorised as a medicinal products in the European Union, but varies in terms of safety and efficacy from the previous authorised substance;
c) a biological substance which has been authorised as a medicinal product in the European Union, but has a different molecular structure and a different origin compared to the starting material, or it has been obtained through a different production process;
d) a radiopharmaceutical substance whose radionuclides or molecular ties (or ligands) that have not been authorised as a medicinal product in the European Union or the mechanism for connecting molecules and radionuclides in pairs has not been allowed in the European Union.
40. (Amended, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) "Adverse event" shall be any unfavourable change in the health condition observed with the administration of a medicinal product to a patient, which is not necessarily causally associated with the course of treatment.
41. (Amended, SG No. 102/2012, effective 21.12.2012, SG No. 84/2018, effective six months after the publication of the notice referred to in Article 82 (3) of Regulation (EU) No. 536/2014) "Adverse reaction" shall be any undesired and unexpected response to a medicinal product. The types of adverse reactions shall be:
(a) (amended, SG No. 84/2018, effective 12.10.2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "unexpected" adverse reaction is one that is not mentioned in the summary of product characteristics or a reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;
b) "suspected" - an adverse reaction, of which the notifier or marketing authorisation holder suspects a possible causal connection with the medicinal product administered;
c) "serious" - any unfavourable effect on the health condition, which has become the reason for a lethal outcome, for an imminent threat to life, hospitalisation or extension of the term thereof, for significant or lasting injuries, disability or congenital abnormalities;
d) a combination of reactions under a), b) and c).
42. "A common name" shall be the international non-patent name of the medicinal or auxiliary substance (INN) recommended by WHO; if none exists, the name in the European Pharmacopoeia shall be used and if missing there as well - another pharmacopoeian name; when no pharmacopoeian name is available, the usual accepted name shall be used.
42a. (New, SG No. 102/2012, effective 21.12.2012) "Principal documentation of the system for drug safety monitoring" shall be a detailed description of the system for drug safety monitoring used by the marketing authorisation holder with respect to one or more medicinal products having marketing authorisation.
42b. (New, SG No. 48/2015) A "health technology assessment" shall mean:
a) a form of scientific research policy examining the short- and long-term effects related to the application of health technology, and shall aim to provide information on alternative health strategies;
b) a multidisciplinary activity which systemically assesses the technical characteristics, safety, clinical efficacy and effectiveness, costs, cosf-effectiveness and the organisational, social, legal and ethical implications of the application of medicinal products in healthcare, and shall focus on value, both clinical and economic, the analysis being comparative in relation to the existing or the currently best alternative.
42c. (New, SG No. 67/2020) "Official control laboratory" shall be a laboratory, which carries out laboratory tests of medicinal products on behalf of the competent regulatory authorities in fulfilment of relevant national requirements and is independent fro manufacturers and marketing authorisation holders for medicinal products.

43. "Batch" shall be a set amount of the drug, manufactured in accordance with the established reproducible technological scheme, ensuring the required level of batch homogeneity as regards the required control indicators.
43a. (New, SG No. 102/2012, effective 21.12.2012) "Risk management plan" shall be a detailed description of the risk management system.
44. "Maintenance of the marketing authorisation of a medicinal product" shall cover all necessary operations in view of maintaining the up-to-date registration status of a medicinal product, including pharmacovigilance.
44a. (New, SG No. 48/2015) "Maintenance of reimbursement status" shall mean an assessment of a medicinal product based on evidence of efficacy, therapeutic effectiveness and safety and on pharmacoeconomic analysis.
45. "Benefit" shall be a positive outcome/therapeutic efficacy of a medicinal product for a particular patient, groups of patients or the public. The quantitative evaluation of the expected benefit shall include an approximate calculation of the probability of a positive outcome.
46. (Amended, SG No. 102/2012, effective 2.01.2013) "Auxiliary substance" shall be any ingredient of a medicinal product, which is different from the active substance and from the packaging material.
47. "Post-marketing study" shall be any study performed of the use of a medicinal product within the approved product summary in the period following its licensing for use.
47a. (New, SG No. 102/2012, effective 2.01.2013) "Intermediation in the sphere of medicinal products" shall be all activities aimed at the concluding of a contract for purchasing or sale of medicinal products, with the exception of wholesaling, which do not comprise physical holding and which consist in contractual relations independently and on behalf of another legal or natural person.
48. (Amended, SG No. 102/2012, effective 21.12.2012) "Post-marketing safety study" shall be any study connected with a medicinal product having marketing authorisation, conducted with the aim of identifying, characterising or determining the extent of the safety related risk, of confirming the safety profile of the medicinal product, or of assessing the effectiveness of the risk management measures.
49. "A potentially serious threat to the health of the population" shall exist where there is high likelihood that the use of a medicinal product may cause irremovable, unredeemable and irreversible negative consequences. The evaluation process shall identify the threat of causing damage to the health of the population and its actual exposure in the event of extensive use of the product concerned. Serious risk to health in the context of use of a particular medicinal product may be assessed under the following conditions:
a) efficacy - data submitted on the therapeutic efficacy with regard to the proposed indication(s), to the proposed target group(s) of patients and to the proposed dosage, specified in the draft patient brochure shall not fully substantiate, from a scientific perspective, claims for efficacy;
b) safety - the evaluation of data from preclinical toxicity/pharmacological safety and clinical safety may not convincingly substantiate the conclusion that all potential safety aspects with regard to the target group(s) of patients have been accurately and exhaustively reflected in the proposed patient brochure or that the absolute level of risk is unacceptable;
c) quality - the proposed manner of production and the control methods may not guarantee the lack of significant defects in product quality that may have an impact on product safety and/or efficacy;
d) the benefit/risk ratio - the evaluation of the ratio of benefits to risk is unfavourable, bearing in mind the nature of the identified risk(s) and the potential benefit with regard to the proposed indication(s) and the target group(s) of patients.
50. "Representative of the person under Article 26, Paragraph 1 or of the marketing authorisation holder" shall be a person established on the territory of the Republic of Bulgaria and designated by the person under Article 26, Paragraph 1 or by the marketing authorisation holder to represent him before the regulatory bodies on the territory of the Republic of Bulgaria.

51. "An acceptable level of safety" shall be available when the data submitted are taken at a statistically significant safety in clinical trials carried out in conformity with the Good Clinical Practice.
52. "The manufacturing of a medicinal product" shall constitute all operations for the provision of the materials, their processing during the production process, including packaging and labelling, quality control, batch release, storage, dispatching and the control operations thereto related.
53. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Clinical trial protocol" is a protocol within the meaning of Article 2(2)(22) of Regulation (EC) No. 536/2014.
54. "Market placement/release" shall be the distribution of a medicinal product for trade on the territory of the Republic of Bulgaria outside the immediate control of the marketing authorisation holder.
55. "Immediate packaging" shall be the packaging which comes into immediate contact with the medicinal product.
56. "Radiopharmaceutical" shall be a medicinal product which contains, when ready for use, one or more radionuclides (radioactive isotopes) included therein for a medical purpose.
57. "Radionuclide generator" shall be any system, including a fixed maternal radionuclide, of which a daughter radionuclide is obtained separated by elution or by other methods, and used in a radiopharmaceutical.
58. "Radionuclide precursor" shall be any other radionuclide manufactured for the radioactive marking of another substance, immediately prior to its introduction into a patient's body.
59. "A herbal medicinal product" shall be a medicinal product containing, as medicinal substances, one or more herbal substances, or one or more herbal preparations, or one or more herbal substances in combination with one or more herbal preparations.
60. "Herbal substances" shall mainly be plants or parts thereof, algae, fungi, lichens, that are entire, broken or cut down and are used unprocessed, usually desiccated, but sometimes fresh as well. Certain exudates that have not been subjected to any specific processing also belong to herbal substances. Herbal substances must have a specific botanical scientific name for the plants of which they originate in accordance with the bionominal system (genus, species, variety and author).
61. "Herbal preparation" shall be a product obtained after extraction, distillation, squeezing, fractioning, refinement, concentration or fermentation of a herbal substance. The herbal preparation may also take the form of ground or pulverised herbal substances, tinctures, extracts, ether oils, processed herbal fluids/juices.
62. "Rare diseases" shall be diseases characterised by an incidence not higher than 5 per 10,000 individuals.
63. "Reference medicinal product" shall be a medicinal product authorised in compliance with Article 23, subject to the requirements of Article 27.
64. (Amended, SG No. 67/2020) "Reference value per defined daily dose" shall be the lowest value of defined daily dose determined on the basis of the values of the defined daily dose of medicinal products under an International Nonproprietary Name in the respective pharmaceutical form.
65. "The reference value of a treatment course" shall be the lowest value of a treatment course determined on the basis of values of treatment courses with drugs under an international non-patent name in the respective pharmaceutical form.
66. "Risk associated with the use of a medicinal product" shall be:
a) a risk to the patient's health or a risk to the health of the population associated with the quality, safety or efficacy of a medicinal product;
b) a risk of adverse effects on the environment.
67. "Serious adverse event" shall be any unfavourable change in the health condition which has become the cause of lethal outcome, an immediate threat to life, hospitalisation or extension of the term thereof, significant or lasting injuries, disability and congenital abnormalities.

68. "A certificate of batch release" shall be a document issued by the qualified person to the manufacturer or to the importer for each separate batch, and it shall include the requirements as per the specification, as well as all the results from tests for release of the batch concerned.
69. "Certificate of additional protection" shall be a document affording additional patent protection to a medicinal product for no more than 5 years of the date of expiry of the main patent.
69a. (New, SG No. 102/2012, effective 21.12.2012) "A risk management system" shall be a system of measures and activities for drug safety monitoring, intended for identifying, characterising, prevention or minimising of the risks connected with the medicinal product, including evaluation of the effectiveness of these activities and measures.
69b. (New, SG No. 102/2012, effective 21.12.2012) "A drug safety monitoring system" shall be a system used by the marketing authorisation holder and by the Bulgarian Drugs Agency for discharging the tasks and responsibilities under Chapter Eight, intended for monitoring the safety of medicinal products having market authorisation and for detecting any change in the benefit/risk ratio.
69c. (New, SG No. 84/2018, effective 12.10.2018) "Systematic" shall mean a violation committed three or more times within a year from the entry into force of the first penalty assessment imposing a penalty on the perpetrator for the same type of violation.
70. "Urgent safety restriction measures" shall be provisional changes in the product information with regard to one or more parts of the product summary, indication, method of administration, contraindications and warning resulting from new information pertaining to the safe use of the medicinal product concerned.
71. "Spontaneous notification" shall be a voluntary notification sent about a suspected adverse reaction to the use of a medicinal product addressed to the marketing authorisation holder, to bodies in charge of the supervision of medicinal products or to other organisation, which does not originate in a study or in another organised system for the collection of information.
72. "The shelf life of a medicinal product" shall be the period of time during which, if stored in accordance with the prescribed conditions, a medicinal product meets the requirements of the specification produced on the basis of research in the field of stability carried out on several batches of the ready formulation.
73. (Amended, SG No. 71/2008, effective 12.08.2008) "A medicinal product corresponding to a herbal medicinal product" shall be a product containing the same active substances, notwithstanding the composition of excipients, intended for the same purpose, of an equivalent amount of the medicinal substance(s) and with the same dosage and with the same or a similar route of administration as the product for which an application has been made.
74. "Notification of an adverse reaction" shall be information recorded about one or more suspected adverse reactions related to the use of one or more medicinal products by the same patient. In order to recognise the validity of a notification of an adverse reaction, a minimum of data shall be required for the identification of the notifying subject (his initials or address, or profession/speciality), of the patient (initials or age, or date of birth, or gender), of the adverse reaction/event and of the suspected medicinal product.
75. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Substantial modification to the clinical trial protocol" is a substantial modification within the meaning of Article 2(2)(13) of Regulation (EC) No. 536/2014.
75a. (New, SG No. 102/2012, effective 21.12.2012) "Substantial changes in the protocol of a non-interventional post-marketing study" shall be changes affecting the safety, physical or psychological inviolability of the patients, or of the results of the study and their interpretation.
76. (Amended, SG No. 71/2008, effective 12.08.2008) "Third country" shall be a state that is not a Member State of the European Union, or is not a state signatory to the Agreement on the European Economic Area.

77. "Wholesaling" shall be all operations for the acquisition, storage, supply, import or export of medicinal products with the exception of the direct provision of medicinal products to the population.
78. (Amended, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014) "Subject" is a subject within the meaning of Article 2(2)(17) of Regulation (EC) No. 536/2014.
79. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
80. "Pharmacopoeia" shall be a collection of approved specifications and relevant requirements in relation to the manufacturing, testing, storage and marking of active substances, excipients, pharmaceutical forms, packaging material and ingredients of the medicinal product concerned.
81. "Official formulation" shall be a prescription for a medicinal product prepared in a pharmacy based on a formulation under the effective pharmacopoeia and intended to be provided to patients in the same pharmacy.
81a. (New, SG No. 71/2008, effective 12.08.2008, amended, SG No. 102/2012, effective 2.01.2013) "Counterfeit medicinal product" shall be any medicinal product with false presentation of:
a) its identity, including the data on its primary or outer packaging, its name or composition with respect to any of its ingredients, including the excipients, and the quantity of the active substance per dose unit;
b) its origin, including its manufacturer, the state in which the product was manufactured, the state in which it obtained its market authorisation, or its marketing authorisation holder, or
c) the chronology, including the records and documents connected with the supply chain used.
A medicinal product shall not be considered to be counterfeited if it is with unintentional deviations in the quality, as well as a medicinal product released on the market in violation of intellectual property rights.
82. "Homeopathic medicinal product" shall be a medicinal product prepared of substances referred to as homeopathic stock in accordance with the manufacturing procedures of the European Pharmacopoeia and in the absence thereof - in accordance with the national pharmacopoeia of a Member State.
83. "The price calculated on the basis of a reference value" shall be the price formed for each medicinal product on the Positive Drug List, calculated on the basis of the set reference value per defined daily dose or treatment course.
84. (Repealed, SG No. 84/2018, effective six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014).
85. "Abuse of medicinal products" shall be the permanent or occasional intentional excessive use of medicinal products accompanied by harmful physical or psychological effects.
86. (New, SG No. 41/2009, effective 2.06.2009) "Nurselings" shall be children below 12 months of age
87. (New, SG No. 41/2009, effective 2.06.2009) "Nurseling food" shall be any food intended for specific nutrition use by infants, in the first months after their birth, which, taken alone, is sufficient to satisfy the nutrition needs of such infants until the introduction of appropriate supplementary food.
88. (New, SG No. 41/2009, effective 2.06.2009) "Transitional food" shall be any food which is intended for specific nutrition use by infants, when introducing appropriate supplementary food, and which constitutes the basic liquid style food amongst the progressively increasing variety of foods for such infants.
89. (New, SG No. 12/2011, effective 8.02.2011) "Variation of type IA" shall mean a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned.
90. (New, SG No. 12/2011, effective 8.02.2011) "Variation of type IB" shall mean a variation which is neither a variation of type IA nor a variation of type II nor an extension of the scope of the marketing authorisation.

91. (New, SG No. 12/2011, effective 8.02.2011) "Variation of type II" shall mean a variation which is not an extension of the scope of the marketing authorisation and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.
92. (New, SG No. 102/2012, effective 21.12.2012) "Delegated act" shall be an act within the meaning of Article 290 of the Treaty on the Functioning of the European Union.

§ 2. The name of the Bulgarian Drugs Agency shall be written in Latin, as follows: Bulgarian Drugs Agency.

§ 3. The Council of Ministers shall specify the terms and conditions for the provision, storage and renewal of medicinal products stored by the State Reserve and Wartime Stocks State Agency.

§ 4. (Supplemented, SG No. 18/2014) This Act shall implement the provisions of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code related to medicinal products for human use, last amended by Directive 2004/27/EC of the European Parliament and of the Council and of EC Directive 2012/26/EC of the European Parliament and of the Council dated 25 October 2012 regarding the amendment of EC Directive 2001/83/EC with respect to pharmacovigilance (OB, L 299/1 of 27 October 2012).

§ 5. The periods for the protection of data on reference medicinal products shall apply in accordance with the provisions of Article 89 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council and of Article 2 of Directive 2004/27/EC of the European Parliament and of the Council.

§ 5a. (New, SG No. 60/2011, effective 30.09.2011) (1) (Amended, SG No. 102/2012, effective 1.04.2013, SG No. 85/2017) The Ministry of Health, the National Council on Prices and Reimbursement of Medicinal Products, the Bulgarian Drugs Agency and the Regional Health Inspectorates shall allow for the electronic submission of information and filing of applications and documents under this Act in pursuance of the terms and conditions laid down in the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.
(2) The electronic submission of information and filing of applications and documents shall be possible after the appropriate technical and organisational conditions, as well as the relevant software applications, have been ensured.

§ 5b. (New, SG No. 67/2020) The provisions of the Administrative Procedure Code shall apply to any matters not regulated under this Act.

TRANSITIONAL AND FINAL PROVISIONS

§ 6. The Human Medicinal Drugs and Pharmacies Act (promulgated, SG No. 36/1995; No. 61/1996 - Judgement No. 10 of the Constitutional Court/1996; amended, SG No. 38/1998, No. 30/1999, No. 10/2000, No. 37/2000 - Judgement No. 3 of the Constitutional Court/2000; amended, SG No. 59/2000, No. 78/2000 - Judgement No. 7 of the Constitutional Court/2000; amended, SG No. 41/2001, No. 107 and 120/2002; corrected, SG No. 2/2003; amended, SG No. 56, 71 and 112/2003, No. 70 and 111/2004, No. 37, 76, 85, 87, 99 and 105/2005, No. 30, 31, 34, 75 and 105/2006) shall be repealed with the exception of the provision of Article 10, Paragraph 2, which shall apply for a period of up to one year of the date of entry of this Act into force.

§ 7. (1) Authorisation for the use of medicinal products issued until the entry of this Act into force under a national procedure, which are also authorised in the Member States in compliance with the centralised procedure, shall be terminated as of 1 January 2007.
(2) Licenses for the use of medicinal products issued until the entry of this Act into force under a national procedure shall be brought in line with the requirements hereof as of the date of their renewal.
(3) Licenses for the use of medicinal products falling into the scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council and authorised in compliance with the repealed Human Medicinal Drugs and Pharmacies Act, being significantly similar products, not authorised in the European Union in compliance with the centralised procedure, shall be terminated.

(4) Medicinal products authorised in the EU in compliance with the centralised procedure, whose national marketing authorisation has been terminated under Paragraph 1, may be sold on the territory of the Republic of Bulgaria in packaging with brochures in compliance with the terminated national marketing authorisation over a period not exceeding one year of the date of termination thereof.

§ 8. (1) The approved ceiling prices and the prices registered in compliance with the repealed Human Medicinal Drugs and Pharmacies Act for medicinal products authorised in the EU in compliance with a centralised procedure whose national marketing authorisation has been terminated under § 7, Paragraph 1, shall remain valid for a period of up to one year of the date of termination thereof.

(2) The approved ceiling prices and the prices registered under the repealed Human Medicinal Drugs and Pharmacies Act for medicinal products other than those under Paragraph 1, shall remain valid until 31 December 2007.

§ 9. (1) Applications for a marketing authorisation, for renewal and change in the issued authorisation filed until the entry of this Act into force shall be examined and completed under the terms and conditions hereof.

(2) The applications and documentation filed for licensing the use of medicinal products falling within the scope of the procedure under Article 74 or Article 75 shall be brought in line with the requirements hereof within three months of the entry of this Act into force.

(3) Where, within the period under Paragraph 2, the application and the documentation under Paragraph 2 have not been brought in line with the requirements hereof, the procedure for their examination shall be terminated.

§ 10. (1) Clinical trials authorised prior to the entry of this Act into force shall be completed under the previous procedure.

(2) Applications for conducting a clinical trial on the territory of the Republic of Bulgaria shall be filed, examined and completed under the terms and conditions hereof after entry into force of the Ordinance under Article 82, Paragraph 3.

(3) Applications for changes in authorised clinical trials, filed prior to the entry of this Act into force, shall be examined and completed under the terms and conditions hereof.

§ 11. Applications for the issuance of manufacturing licenses and authorisations for wholesaling of medicinal products filed until the entry of this Act into force shall be examined and completed under the terms and conditions hereof.

§ 12. (1) Manufacturers of drugs who have obtained a manufacturing authorisation in compliance with the repealed Human Medicinal Drugs and Pharmacies Act shall bring their manufacturing operations in line with the requirements hereof in terms of the qualified person under Article 148, item 2, within three months of the entry of this Act into force.

(2) Manufacturers found as of the entry of this Act into force shall pursue their operations on the basis of licenses issued in compliance with the repealed Human Medicinal Drugs and Pharmacies Act.

§ 13. The persons who have obtained an authorisation for wholesaling of medicinal products in compliance with the repealed Human Medicinal Drugs and Pharmacies Act shall bring their operations in line with the requirements hereof within 12 months of entry of this Act into force.

(2) Until an authorisation for wholesaling of medicinal products has been issued in pursuance hereof, but not later than the expiry of the period under Paragraph 1, the persons under Paragraph 1 shall pursue their operations based on the authorisation for wholesaling of medicinal products issued in compliance with the repealed Human Medicinal Drugs and Pharmacies Act.

(3) The issuance of an authorisation for wholesaling of medicinal products in pursuance hereof or the expiry of the term under Paragraph 1 shall terminate the authorisation for wholesaling of drugs under the repealed Human Medicinal Drugs and Pharmacies Act.

§ 14. (1) Persons who have obtained an authorisation for wholesaling of drugs in compliance with the repealed Human Medicinal Drugs and Pharmacies Act may import medicinal

products onto the territory of the Republic of Bulgaria from third countries based on the said authorisation until obtaining an import authorisation in pursuance hereof, but no later than 12 months of the entry of this Act into force.
(2) Within one month of the entry of this Act into force, the persons under Paragraph 1 shall file with the Bulgarian Drugs Agency a notification of the person who shall discharge the functions of a qualified person within the meaning of Article 161, Paragraph 2, item 1.

§ 15. The term of validity of authorisations for wholesaling of medical products issued in compliance with the repealed Human Medicinal Drugs and Pharmacies Act shall be extended ex officio until 31 December 2007.

§ 16. (Repealed, SG No. 71/2008, effective 12.08.2008).

§ 17. (1) Drugstores found until the entry of this Act into force shall carry out their operations based on certificates issued in compliance with the repealed Human Medicinal Drugs and Pharmacies Act.
(2) Applications for the issuance of certificates of registration for drugstores filed until the entry of this Act into force, shall be examined and completed under the terms and conditions hereof.

§ 18. (1) (Amended, SG No. 71/2008, effective 14.04.2008, SG No. 10/2009, effective 29.1.2009) The Positive Drug List under this Act shall be produced in pursuance hereof and shall enter into force on 31 March 2009.
(2) (Amended, SG No. 71/2008, effective 14.04.2008) Until the entry into force of the Positive Drug List under Paragraph 1, the effective Positive Drug List shall be the Positive Drug List adopted with the Ordinance for Establishing a Positive Drug List in the Republic of Bulgaria (promulgated, SG No. 113/2003; amended, No. 18/2004, No. 4/2005 and No. 8, 107 and 112/2007).
(3) (New, SG No. 71/2008, effective 14.04.2008, amended, SG No. 23/2009, effective 30.03.2009) Within two months following the entry into force of the List referred to in Paragraph (1), healthcare providers shall prescribe and National Health Insurance Fund shall reimburse the medicinal products on the National Health Insurance Fund list of medicinal products adopted with Decision No. РД-УС-04-127 of 27 December 2007 laying down the conditions to be met by healthcare providers, the procedure for concluding contracts with healthcare providers, and other conditions referred to in Article 55, Paragraph (2), items 2, 4, 6 and 7 of the Health Insurance Act.

§ 19. (1) Within a period of three months of the entry of this Act into force:
1. the Council of Ministers shall amend and supplement the Structural Regulation of the Bulgarian Drugs Agency, bringing it in line with this Act;
2. the Minister of Health shall issue the Ordinance under Article 82, Paragraph 3.
(2) Within a period of up to 6 months of the entry of this Act into force, the Council of Ministers shall adopt and the Minister of Health shall issue the other legislative instruments for the enforcement of this Act.

§ 20. After expiry of the first two years of the term of office of the members of Commissions under Article 103, 107, 259 and 261, half of the members whose term of office will be terminated shall be drawn by lot.

§ 21. (Amended, SG No. 71/2008, effective 12.08.2008) Within a period of up to two years of the entry of this Act into force, the Bulgarian Drugs Agency shall take the necessary action to have its laboratory for the control of medicinal products and active substances accredited by the European Directorate for the Quality of Medicines and Healthcare.

§ 22. (Effective 14.04.2008 - SG No. 31/2007) The following amendments shall be made to the Health Insurance Act (promulgated, SG No. 70/1998; amended, SG No. 93 and 153/1998, SG No. 62, 65, 67, 69, 110 and 113/1999, SG No. 1, 31 and 64/2000, SG No. 41/2001, SG No. 1, 54, 74, 107, 112, 119 and 120/2002, SG No. 8, 50, 107 and 114/2003, SG No. 28, 38, 49, 70, 85 and 111/2004, SG No. 39, 45, 76, 99, 102, 103 and 105/2005, SG No. 17, 18, 30, 33, 34, 59, 95 and 105/2006, SG No. 11/2007, SG No. 26/2007 - Judgement SG No. 3/2007 of the Constitutional Court):
1. In Article 45:
a) Paragraphs 4, 5, 6, and 7 shall be repealed;

b) Paragraph 8 shall be amended as follows:
"(8) The terms and conditions for the reimbursement of medicinal products on the Positive Drug List under Article 262 of the Medicinal Products in Human Medicine Act, of medical products and of dietary food for special medical purposes shall be regulated in an Ordinance of the Minister of Health".
2. In Article 55, Paragraph 2, item 7 shall be amended as follows:
"7. The lists of medical products and dietary foods for special medical purposes and the prices up to which the National Health Insurance Fund shall provide full or partial reimbursement; the conditions for prescription and obtainment of drugs, medical products and dietary foods for special medical purposes."

§ 23. In the Medical-Treatment Facilities Act (promulgated, SG No. 62/1999; amended, SG No. 88 and 113/1999; corrected, SG No. 114/1999; amended, SG No. 36, 65 and 108/2000; SG No. 51/2001 - Judgement No. 11/2001 of the Constitutional Court; amended, SG No. 28 and 62/2002, SG No. 83, 102 and 114/2003, SG No. 70/2004, SG No. 46, 76, 85, 88 and 105/2005, SG No. 30, 34, 59 and 105/2006) the following supplements shall be made:
1. In Article 17, a paragraph 4 shall be created:
"(4) Clinical trials may be conducted in the diagnostic and consultative centre in compliance with the Medicinal Products in Human Medicine Act."
2. In Article 26, a paragraph 4 shall be created:
"(4) Clinical trials may be conducted in dispensaries in compliance with the Medicinal Products in Human Medicine Act".

§ 24. In § 14 of the Transitional and Final Provisions to the Amendment Act to the Doctors and Dentists Professional Organisations Act (SG No. 76/2005), the following amendments and supplements shall be made:
1. The existent text shall become paragraph 1 and shall be amended as follows:
"(1) Individual and group dental practices, stomatological and medical and stomatological centres registered as traders under the Commerce Act or as cooperatives under the Cooperatives Act shall bring their names in line with § 2 hereof and shall enter the change on the commercial register, the BULSTAT register and in the respective Regional Health Centre no later than 31 December 2007."
2. Paragraphs 2, 3 and 4 shall be created:
"(2) Individual dental practices that are not registered as traders under the Commerce Act shall bring their names in line with § 2 hereof and shall enter the change on the BULSTAT register and in the respective Regional Health Centre within the period under Paragraph 1."
(3) Entry of the change in the name for practices and centres under Paragraph 1 on the commercial register and on the BULSTAT register shall be made, as follows:
1. Until 1 July 2007, in compliance with the Commerce Act, the Cooperatives Act and the BULSTAT Register Act;
2. After 1 July 2007, in compliance with the Commercial Register Act.
(4) No state fees shall be owed for the registration of changes under Paragraphs 1 and 2."

§ 25. In the Patents and Utility Models Registration Act (promulgated, SG No. 27/1993; amended, SG No. 83/1996, SG No. 11/1998, SG No. 81/1999, SG No. 45 and 66/2002, SG No. 17, 30 and 64/2006), Article 20, item 7 shall be repealed.

§ 26. Item 9 in Article 5 of the Professional Organisation of Masters of Pharmacy Act (promulgated, SG No. 75/2006; amended, SG No. 105/2006) shall be amended as follows:
"9. Give opinions about the opening of pharmacies in accordance with Article 228, Paragraph 1, item 9 of the Medicinal Products in Human Medicine Act."

§ 27. In § 1, item 7 of the Additional Provision to the Integration of Persons with Disabilities Act (promulgated, SG No. 81/2004; amended, SG No. 28, 88, 94, 103 and 105/2005, SG No. 18, 30, 33, 37, 63, 95, 97 and 108/2006) sentence two shall be amended as follows: "Medical products shall not be auxiliary equipment, devices and installations."

§ 28. In the Excise Duties and Tax Warehouses Act (promulgated, SG No. 91/2005; amended, SG No. 105/2005, SG No. 30, 34, 63, 81, 105 and 108/2006), in Article 22, Paragraph 3,

item 2 the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."

§ 29. In the Genetically Modified Organisms Act (promulgated, SG No. 27/2005; amended, SG No. 88 and 99/2005, SG No. 30/2006) in Article 2, Paragraph 2, item 3 the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."

§ 30. In the Consumer Protection Act (promulgated, SG No. 99/2005; amended, SG No. 30, 51, 53, 59, 105 and 108/2006) in Article 186, Paragraph 2, item 4 the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act".

§ 31. In the Health Act (promulgated, SG No. 70/2004; amended, SG No. 46, 76, 85, 88, 94 and 103/2005, SG No. 18, 30, 34, 59, 71, 75, 81, 95 and 102/2006) the following amendments shall be made:

1. In Article 4, the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."
2. In Article 21, Paragraph 3, the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."

§ 32. In the Narcotic Substances and Precursors Control Act (promulgated, SG No. 30/1999; amended, SG No. 63/2000, SG No. 74, 75 and 120/2002, SG No. 56/2003, SG No. 76, 79 and 103/2005, SG No. 30, 75, and 82/2006) the following amendments shall be made:

1. In Article 32, Paragraph 3 the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."
2. In Article 33, Paragraph 1, item 1, the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."
3. In Article 34, after the word "issue" the words "to a master of pharmacy" shall be deleted.
4. In Article 39, Paragraph 2 the words "Article 55, item 2 of the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "Article 197, item 2 of the Medicinal Products in Human Medicine Act."
5. Paragraph 3 in Article 44a shall be repealed.
6. In Article 44b the words "master of pharmacy" shall be deleted.
7. In § 1, item 14 of the Additional provision, the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."

§ 33. In the Blood, Blood Donation and Blood Transfusion Act (promulgated, SG No. 102/2003; amended, SG No. 70/2004, SG No. 30 and 65/2006) in Article 8, Paragraph 4 the words "the Human Medicinal Drugs and Pharmacies Act" shall be replaced by "the Medicinal Products in Human Medicine Act."

§ 34. In the Environmental Protection Act (promulgated, SG No. 91/2002; corrected, SG No. 98/2002; amended, SG No. 86/2003, SG No. 70/2004, SG No. 74, 77, 88, 95 and 105/2005, SG No. 30, 65, 82, 99, 102 and 105/2006) in Article 140, the words "pharmaceutical products and medical products within the meaning of § 1, item 40 of the additional provisions to the Human Medicinal Drugs and Pharmacies Act shall be replaced by "medicinal products, within the meaning of the Medicinal Products in Human Medicine Act."

§ 35. In the Foodstuffs Act (promulgated, SG No. 90/1999, amended, SG No. 102/2003, SG No. 70/2004, SG No. 87, 99 and 105/2005, SG No. 30, 31, 34, 51, 55 and 96/2006), item 4, in Article 2, Paragraph 3 shall be amended as follows:

"4. Medicinal products within the meaning of the Medicinal Products in Human Medicine Act."

§ 36. Until the entry into force of the instruments under § 19, legal instruments issued for the implementation of the repealed Human Medicinal Drugs and Pharmacies Act shall apply, insofar as they do not stand in contradiction hereto.

§ 37. This Act shall become effective on the day of its promulgation in the State Gazette, with the exception of § 22, which shall enter into force one year after the entry of this Act into force.

This Act was adopted by the 40th National Assembly on 30 March 2007 and the official seal thereof has been affixed hereunder.

TRANSITIONAL AND FINAL PROVISIONS
to the Amendment and Supplementing Act of the Medicinal Products in Human Medicine Act
(SG No. 71/2008, effective 12.08.2008)

§ 65. (1) The marketing authorisations of medicinal products, issued in compliance with the repealed Drugs and Pharmacies in Human Medicine Act (promulgated, SG No. 36/1995; amended, SG No. 61/1996, SG No. 38/1998, SG No. 30/1999, SG No. 10, 37, 59 and 78/2000, SG No. 41/2001, SG No. 107 and 120/2002, SG No. 2, 56, 71 and 112/2003, SG No. 70 and 111/2004, SG No. 37, 76, 85, 87, 99 and 105/2005, SG No. 30, 31, 34, 75 and 105/2006; repealed, SG No. 31/2007), which fall within the scope of the repealed Regulation (EC) No. 2309/93 of the Council of 22 July 1993, which stipulates the procedure in the Community for issuing authorisations (licences) and for exercising supervision over medicinal products used in human and veterinary medicine, and a European Agency for the Evaluation of Medicinal Products is established, but the medicinal products are not authorised in the other Member States under the procedure stipulated with the repealed Directive 87/22/EEC of the Council of 22 December 1986 concerning the harmonisation of the national measures connected with the market release of highly technological products, especially those obtained through biotechnology, or under Regulation (EC) No. 2309/93, shall be terminated.

(2) The marketing authorisations of medicinal products, issued in compliance with the repealed Drugs and Pharmacies in Human Medicine Act, which fall within the scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, but not authorised in compliance with the centralised procedure, shall be terminated.

§ 66. (1) Masters of pharmacy and assistant pharmacists who have obtained authorisation to open a pharmacy as sole traders, the treatment establishments, as well as the municipalities that had obtained authorisation to open a pharmacy in compliance with the repealed Drugs and Pharmacies in Human Medicine Act, shall conduct their activities on the basis of the authorisations issued to them.

(2) The applications for the issuance of authorisation for retailing of medicinal products, filed prior to the entry into force of this Act, shall be considered in compliance with its provisions.

(3) Outside the cases under Paragraph 1, the persons who had obtained authorisation to open a pharmacy prior to the entry into force of this Act, shall bring their activities in line with its requirements within one year of its entry into force.

(4) The persons under Paragraph 3 shall file an application for re-registration with the Ministry of Health, together with:

1. an application for the issuing of authorisation for retailing of medicinal products by the persons under Article 222, Paragraph 1, following a model endorsed by the Minister of Health;
2. up-to-date certificate of entry in the Commercial Register, or document for up-to-date registration of the person under Article 222, Paragraph 1;
3. a copy of the authorisation for the opening of a pharmacy, issued under the repealed Drugs and Pharmacies in Human Medicine Act;
4. notarised copy of the labour contract or of the contract for assigning the management to the head of the pharmacy - in the cases when this is required;
5. declaration from the persons under Article 222, Paragraph 1, that the conditions under which the authorisation for retailing of medicinal products of the persons under Paragraph 2 was issued have been preserved;
6. document for paid one-off fee of BGN 100.

§ 67. The persons who had filed applications for re-registration under the repealed § 16 of the Transitional and Final Provisions, who are to conduct their activities in compliance with the

requirements of this Act, shall file the following documents with the Ministry of Health within three months of its entry into force:
1. an application based on a model endorsed by the Minister of Health;
2. up-to-date certificate of entry in the Commercial Register, or a document for up-to-date registration, or a notarised transcript of a similar document under the national legislation of an EU Member State, or under the legislation of another state signatory to the Agreement on the European Economic Area, under Article 222, Paragraph 1;
3. a labour contract or a contract for management of the pharmacy concluded with a master of pharmacy or with an assistant pharmacist.

§ 68. (1) A master of pharmacy or an assistant pharmacist who has obtained authorisation to open a pharmacy in compliance with the repealed § 16 of the Transitional and Final Provisions, may transfer the authorisation issued to him to a person under Article 222, Paragraph 1.
(2) The transfer may be effected by the persons under Paragraph 1 filing an application to the Ministry of Health, accompanied by:
1. an application for the issuing of an authorisation for retailing of medicinal products by the persons under Article 222, Paragraph 1, in a model-based form endorsed by the Minister of Health;
2. an up-to-date certificate for entry into the commercial register, accordingly a document for up-to-date registration of the person under Article 222, Paragraph 1;
3. a copy of the authorisation to open a pharmacy, issued under the repealed Human Medicinal Drugs and Pharmacies Act, or a permission for re-registration under the repealed § 16 of the Transitional and Final Provisions;
4. a notarised copy of the labour contract or of the management contract of the head of the pharmacy;
5. a declaration by the persons under Article 222, Paragraph 1, that the conditions under which the authorisation for retailing of medicinal products had been issued to the persons under Paragraph 1 have been preserved.
(3) The transfer under Paragraph 1 may be effected within one year from the entry of this Act into force.

§ 69. The drugstores existing at the time of entry into force of this Act shall continue to function on the grounds of the registration certificates issued to them.

§ 70. The Commission for the Positive Drug List, appointed prior to the entry of this Act into force, shall continue to function until its new composition has been determined under Article 261, Paragraph 6.

§ 71. The products covered by Article 37 - traditional herbal medicinal products that have been released on the country's market prior to the date of entry of this Act into force - shall be brought in compliance with its requirements not later than 30 April 2011.

§ 72. (1) Until 31 December 2008, the dossier under Article 27 on the marketing authorisation of a medicinal product under a mutual recognition procedure or under a decentralised procedure may be filed in a General Technical Document format.
(2) Until 31 December 2009, the dossier under Article 27 on the marketing authorisation of a medicinal product under a national procedure may be filed in a General Technical Document format.

§ 75. This Act shall enter into force as of the day of its promulgation in the State Gazette, with the exception of the provision under § 64, item 2, which shall enter into force on 14 April 2008, and of the provisions of § 9, item 4, § 41, 42 and 43, which shall enter into force on 26 July 2008.

TRANSITIONAL AND FINAL PROVISIONS
to the Amendment and Supplementing Act of the Medicinal Products in Human Medicine Act
(SG No. 23/2009, effective 30.03.2009)

§ 4. Any persons who have been granted an authorisation for retail of food supplements under Article 229, Paragraph (2) prior to the entry into force of this Act may also retail dietetic foods for special medical purposes.

§ 5. Within two months following the entry into force of this Act the Ministry of Health shall ex officio send copies of the authorisations granted under Article 229, Paragraph (2) prior to the entry into force of this Act to relevant RHIs in charge of pharmacies for entry into the register provided for in Article 14, Paragraph (1) of the Foodstuffs Act.

TRANSITIONAL AND FINAL PROVISIONS
to the Amendment and Supplementing Act of the Health Act
(SG No. 41/2009, effective 2.06.2009)

§ 92. (1) Persons who, prior to the entry into force of this Act, obtained an authorisation under Article 229 (2) of the Medicinal Products in Human Medicine Act, including trading in food supplements, may also retail infant formulae and follow-on formulae.

(2) Two months following the entry into force of this Act, copies of the authorisations under Article 229(2) of the Medicinal Products in Human Medicine Act issued prior to the entry into force of this Act shall be sent, ex officio, by the Ministry of Health to the relevant RHI according to the location of the pharmacies which retail infant formulae and follow-on formulae under Article 1. The copies shall be used for the purpose of recordation in the register under Article 14(1) of the Foodstuffs Act.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Medicinal Products in Human Medicine Act
(SG No. 102/22.12.2009, effective 12.12.2009)

§ 4. (1) Incumbent (prior to the entry into force of this Act) Masters of Pharmacy and assistant pharmacists who have obtained authorisation to open a pharmacy in populated areas referred to in Article 228(4) as per the procedure of the repealed Human Medicinal Drugs and Pharmacies Act (promulgated, SG No. 36/1995; SG No. 61/1996 - Judgement No. 10 of the Constitutional Court/1996; amended, SG No. 38/1998, SG No. 30/1999, SG No. 10/2000, SG No. 37/2000 - Judgement No. 3 of the Constitutional Court/2000; amended, SG No. 59/2000, No. 78/2000 - Judgement No. 7 of the Constitutional Court/2000; amended, SG No. 41/2001, Nos 107 and 120/2002; corrected, SG No. 2/2003; amended, SG No. 56, 71 and 112/2003, No. 70 and 111/2004, No. 37, 76, 85, 87, 99 and 105/2005, No. 30, 31, 34, 75 and 105/2006, repealed, No. 31/2007) and who have not submitted a re-registration application within the timeline under § 66, Paragraph 3 of the Act to Amend and Supplement the Medicinal Products in Human Medicine Act (SG No. 71/2008) shall bring their operations into compliance with the requirements laid down by this Act by 31 January 2010.

(2) The persons referred to in Paragraph 1 shall submit to the Ministry of Health a re-registration application enclosing:

1. a request for issuance of an authorisation for retailing of medicinal products submitted by the persons under Article 222(1) as per a template form approved by the Minister of Health;
2. an up-to-date statement attesting to the recordation in the Commercial Register, or a document of up-to-date registration of the person under Article 222(1), respectively;
3. a copy of the authorisation to open a pharmacy issued as per the procedure of the repealed Human Medicinal Drugs and Pharmacies Act;
4. a certified copy of the employment agreement or the management assigning contract of the head of the pharmacy, where required;
5. a statement by the persons under Article 222(1) verifying the retainment of conditions in respect of which the authorisation for retailing of medicinal products was granted to the persons referred to in Paragraph 1;

6. a document issued by the mayor of the relevant municipality certifying the number of residents in the populated area concerned;
7. a document attesting to the one-time payment of the relevant fee of BGN 1,000.

§ 5. Within three months upon the entry into force of this Act, the Minister of Health shall amend and supplement the Ordinance under Article 219(2).

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 98/2010, effective 1.01.2011)

§ 106. In the Medicinal Products in Human Medicine Act (promulgated, SG No. 31/2007, amended, SG No. 19/2008, Judgment No. 5/2008 of the Constitutional Court of the Republic of Bulgaria - SG No. 65/2008, amended, SG No. 71/2008, SG No. 10/2009, SG No. 23/2009, SG No. 41/2009, SG No. 88/2009, SG No. 102/2009, SG No. 59/2010) the words "the Regional Inspectorates for the Protection and Control of Public Health", "the Regional Inspectorate for the Protection and Control of Public Health" and "RHI" wherever used, shall be replaced by the words "the Regional Health Inspectorates", "the Regional Health Inspectorate" and "Regional Health Inspectorate" respectively.

§ 121. This Act shall enter into force as of 1 January 2011, excluding:
1. paragraphs 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44; § 56(1) and (2); §65, 68, 70, 76, 80, 81, 90, 92, 96; §102, sub-paragraphs 3, 4, 5, 7 and 8; §105, sub-paragraphs 1, 3 and 5; § 107, sub-paragraphs 1, 2, 3, 4, 6(a), 7, 10, 11, 13 and 15(a); § 109, 110, 112, 113; §115(5), §116, sub-paragraphs 4 and 6; §117, sub-paragraphs 5 and 7 and § 118(1), which shall enter into force as from the State Gazette promulgation date of this Act.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Medicinal Products in Human Medicine Act
(SG No. 12/2011, effective 8.02.2011)

§ 24. Any valid applications and notifications for changes to marketing authorisations submitted prior to the entry into force of this Act shall be reviewed as per the grandfathering procedure.

§ 25. The Minister of Health shall bring the Ordinance referred to in Article 42 in compliance with this Act within three months from the date of its entry into force.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending the Medicinal Products in Human Medicine Act
(SG No. 60/2011, effective 5.08.2011)

§ 66. (1) Manufacturers referred to in § 12, Paragraph 2 of the Transitional and Final Provisions shall bring themselves into conformity with the requirements under Article 148 and of the Good Manufacturing Practice laid down in pursuance of Article 152 within six months of the date on which this Act came into force.
(2) Upon expiration of the period provided for in Paragraph 1 the Bulgarian Drugs Agency shall perform a check on the process of achieving conformity with the requirements under Article 148 and of the Good Manufacturing Practice laid down in pursuance of Article 152.
(3) Where following the check performed under Paragraph 2 the Bulgarian Drug Agency finds that the conditions for manufacturing, control, and storage of starting materials for manufacture and of the ready medicinal products do not conform to the requirements of this Act and the Good Manufacturing Practice, it shall inform in writing the concerned person referred to in Paragraph 1 and shall give written prescriptions.
(4) Where the relevant person referred to in Paragraph 1 fails to eliminate the discrepancies found within a period of sixty days, the Bulgarian Drugs Agency Executive Director shall withdraw the manufacturing authorisation issued under the repealed Human Medicinal Drugs and Pharmacies Act (promulgated, SG No. 36/1995; Ruling No. 10 of the Constitutional Court of 1996, No. 61/1996;

amended, No. 38/1998, 30/1999, 10/2000; Ruling No. 3 of the Constitutional Court of 2000, No. 37/2000; amended, No. 59/2000; Ruling No. 7 of the Constitutional Court of 2000 - No. 78/2000; amended, No. 41/2001, 107 and 120/2002; corrected, No. 2/2003; amended, No. 56, 71, and 112/2003, No. 70 and 111/2004, No. 37, 76, 85, 87, 99, and 105/2005, No. 30, 31, 34, 75, 80, and 105/2006; repealed, No. 31/2007) in pursuance of Article 160a.

(5) Where following the check performed under Paragraph 2 it has been found that the concerned person referred to in Paragraph 1 has not brought himself in compliance with the requirements under Article 148 and of the Good Manufacturing Practice laid down in pursuance of Article 152, the Bulgarian Drug Agency shall withdraw the manufacturing authorisation issued in pursuance of Article 160a.

(6) Where following the check performed under Paragraph 2 it has been found that the concerned person referred to in Paragraph 1 has brought himself in compliance with the requirements under Article 148 and of the Good Manufacturing Practice laid down in pursuance of Article 152, the Bulgarian Drug Agency shall issue a new manufacturing authorisation in pursuance of this Act, once:

1. an application and the documentation under Articles 150 and 151 have been submitted; and
2. a document evidencing the payment of a fee in the amount of BGN 1,500 has been produced.

(7) Where the person referred to in Paragraph 6 has not submitted an application and the documentation under Articles 150 and 151 within one month of completion of the check provided for in Paragraph 2, the manufacturing authorisation issued under the repealed Human Medicinal Drugs and Pharmacies Act shall be terminated.

§ 67. (1) Any procedures for issuing of or variation to medicinal products retail authorisations initiated and not completed before the date on which this Act came into force shall be examined and completed under the current procedure without presentation of proposal by the High Pharmacy Council.

(2) Within two months of the date on which this Act came into force the Ministry of Health shall hand over to the Bulgarian Drugs Agency by means of a transfer record the archive of completed procedures.

(3) Within two months of the date on which this Act came into force the Ministry of Health shall hand over to the Bulgarian Drugs Agency by means of a transfer record the register of issued authorisations for retailing of medicinal products in a pharmacy kept by the Ministry of Health.

(4) Within three days of issuing any authorisation in pursuance of Paragraph 1 the Ministry of Health shall ex officio send a copy thereof to the Bulgarian Drugs Agency for entry into the register of issued authorisations for retailing of medicinal products.

(5) Upon completion of the procedures referred to in Paragraph 1 the Ministry of Health shall hand over to the Bulgarian Drugs Agency by means of a transfer record their archive.

§ 68. (1) Any application for issuing or variation to drugstore registration certificates submitted prior to the date on which this Act came into force shall be examined under the terms and conditions laid down in it.

(2) Within one month of the date on which this Act came into force the Bulgarian Drugs Agency shall hand over to the relevant Regional Health Inspectorates by means of a transfer record any applications and documents submitted for procedures for issuing drugstore registration certificates, as well as the archive of any completed procedures.

(3) Within one month of the date on which this Act came into force the Bulgarian Drugs Agency shall hand over to the Ministry of Health by means of a transfer record the register of issued drugstore registration certificates kept by the Bulgarian Drugs Agency.

(4) Within one month of the transfer of the register referred to in Paragraph 3 the Ministry of Health shall prepare and publish on its website the national register of drugstore registration certificates issued prior to the date on which this Act came into force.

§ 69. (1) Within three months of the date on which this Act came into force any procedures for endorsement or registration of medicinal product prices shall be conducted by the Commission for the Prices of Medicinal Products under the current rules.

(2) Upon expiration of the period provided for in Paragraph 1 the Commission for the Prices of Medicinal Products shall hand over to the Price and Reimbursement Commission by means of a transfer record any applications and documents submitted for the procedures referred to in Paragraph 1, as well as the archive of completed procedures for endorsement or registration of medicinal product prices.
(3) Upon expiration of the period provided for in Paragraph 1 the Commission for the Prices of Medicinal Products shall hand over to the Price and Reimbursement Commission by means of a transfer record the register of issued decisions for endorsement or registration of medicinal product prices kept by the Commission for the Prices of Medicinal Products.

§ 70. (1) Within three months of the date on which this Act came into force any procedures for inclusion, deletion and/or variation of medicinal products on the Positive Drug List shall be conducted by the Positive Drug List Commission under the current rules.
(2) Upon expiration of the period provided for in Paragraph 1 the Positive Drug List Commission shall hand over to the Price and Reimbursement Commission by means of a transfer record any applications and documents submitted for the procedures referred to in Paragraph 1, as well as the archive of completed procedures for inclusion, deletion and/or variation of medicinal products on the Positive Drug List.

§ 71. The state fees paid for the procedures under § 69, Paragraph 1, and § 70, Paragraph 1, shall be spent on securing the relevant administrative procedures, as well as the activities of the Transparency Commission.

§ 72. (1) The prices established in pursuance of Article 258, Paragraph 1, of medicinal products which, at the date on which this Act came into force, were on the Positive Drug List shall also be deemed their retail price ceilings pursuant to Article 258, Paragraph 3.
(2) Within three months of the date on which this Act came into force the Price and Reimbursement Commission shall delete ex officio from the price ceiling register any established price ceilings for the medicinal products referred to in Paragraph 1.
(3) Until 31 December 2012 marketing authorisation holders may not alter the price of any medicinal product apart from decreasing it in the case of products which, as of the date on which this Act came into force, had a price ceiling, but were not on the Positive Drug List.

§ 73. (1) With this Act's entry into force any established price ceilings for medicinal products subject to medical prescription and registered prices of medicinal products not subject to medical prescription shall be deemed their registered prices under Article 258, Paragraph 2.
(2) Except for the cases falling under Paragraph 1, with this Act's entry into force any estimated price ceilings for medicinal products falling under an international nonproprietary name on the Positive Drug List, apart from the products listed in Annex 2 to the List, shall also be deemed their retail price ceilings and may not be altered until the adoption of the Ordinance provided for in Article 258, Paragraph 5.
(3) Within three months of the date on which this Act came into force the Price and Reimbursement Commission shall prepare the register provided for in Article 261, Paragraph 3, and enter the prices referred to in Paragraph 1 therein.

§ 74. Within three months of the date on which this Act came into force the Positive Drug List Commission shall bring the List into conformity with the requirement laid down in Article 262, Paragraph 5, Items 1 - 3.

§ 75. Within three months of the date on which this Act came into force the Council of Ministers shall determine the membership of the Price and Reimbursement Commission.

§ 76. Within three months of the date on which this Act came into force:
1. the Minister of Health shall amend and supplement the Ordinances provided for in Article 82, Paragraph 3, Article 219, Paragraph 2, and Article 243 in accordance with this Act.
2. The Council of Ministers shall adopt the Ordinance provided for in Article 258, Paragraph 5, and amend the tariff provided for in Article 21, Paragraph 2, and the Structural Regulation of the Ministry of Health in accordance with this Act.
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§ 84. This Act shall enter into force on the day of its publication in "State Gazette" with the exception of § 65, which came into force on September 30, 2011.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Civil Servants Act
(SG No. 38/2012, effective 1.07.2012)

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§ 84. (Effective 18.05.2012 - SG No. 38/2012) Within one month after the promulgation of this Act in the State Gazette:

1. the Council of Ministers shall bring the Classifier of Positions in the Administration into conformity with this Act;
2. the competent authorities shall bring the organic acts of the respective administration into conformity with this Act.

§ 85. (1) The legal relationships with the persons of the administrations under the Radio and Television Act, the Independent Financial Audit Act, the Electronic Communications Act, the Financial Supervision Commission Act, the Access to and Disclosure of the Documents and Announcing the Affiliation of Bulgarian Citizens with the State Security Service and the Intelligence Services of the Bulgarian Popular Army Act, the Criminal Assets Forfeiture Act, the Conflict of Interest Prevention and Ascertainment Act, the Social Insurance Code, the Health Insurance Act, the Agricultural Producers Support Act and the Roads Act shall be settled under the terms established by § 36 of the Transitional and Final Provisions of the Act to Amend and Supplement the Civil Servants Act (State Gazette No. 24 of 2006).

(2) The act on appointment of the civil servant shall:

1. award the lowest rank designated in the Classifier of Positions in the Administration for occupation of the position, unless the servant holds a higher rank;
2. fix an individual monthly basic salary.

(3) The additional resources required for social and health insurance contributions of the persons referred to in Paragraph (2) shall be provided within the limits of the expenditures on salaries, remunerations and compulsory social and health insurance contributions under the budgets of the spending units concerned.

(4) The Council of Ministers shall effect the requisite modifications under the off-budget account of State Fund Agriculture arising from this Act.

(5) The governing bodies of the National Social Security Institute and of the National Health Insurance Fund shall effect the requisite modifications under the respective budgets arising from this Act.

(6) Any unused leaves under the employment relationships shall be retained and shall not be compensated by cash compensations.

§ 86. (1) Within one month after the entry into force of this Act, the individual monthly basic salary of the servant shall be fixed in such a way that the said salary, net of the tax due and the compulsory social and health insurance contributions for the account of the insured person, if they were due, would not be lower than the gross monthly salary received theretofore, net of the compulsory social and health insurance contributions for the account of the insured person, if they were due, and the tax due.

(2) The gross salary referred to in Paragraph (1) shall include:

1. the monthly basic salary or the monthly basic remuneration;
2. supplementary remunerations which are paid constantly together with the monthly basic salary or monthly basic remuneration due and which are contingent solely on the time worked.

§ 87. This Act shall enter into force as from the 1st day of July 2012 with the exception of § 84 herein, which shall enter into force as from the day of promulgation of the Act in the State Gazette.

ACT to Amend and Supplement the Medicinal Products in Human Medicine Act
(SG No. 102/2012, effective 21.12.2012)

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Additional Provision

§ 118. This Act shall introduce the requirements under Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 concerning the amendment related to the pharmacovigilance in Directive 2001/83/EC with a view to approving a Community Code related to medicinal products for human use (OJ, L 348/74 of 31 December 2010) and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, amending Directive 2001/83/EC with a view to approving a Community Code related to medicinal products for human use, aimed at preventing the influx of counterfeited medicinal products into the legitimate supply chain (OJ, L 174/74 of 1 July 2011).

Transitional and Final Provisions

§ 119. (1) After 2 January 2013, the manufacturers, importers and wholesalers in active substances shall file with the Bulgarian Drugs Agency an application and documents for registration under Article 167b not later than 2 March 2013.

(2) The manufacturers and the importers who manufactured or imported active substances on the basis of their manufacturing/import authorisations prior to 2 January 2013 shall not pay a fee for their entry into the Register under Article 167d.

(3) Until 2 March 2013, the persons under Paragraph 2 shall conduct their activities involving manufacturing and import of active substances based on the manufacturing/import authorisations issued to them.

§ 120. The persons engaged in intermediation in the sphere of medicinal products, who had started their activities prior to 2 January 2013, shall be registered under the terms and procedure of Article 212a not later than 2 March 2013.

§ 121. The procedures for issuing marketing authorisations, initiated prior to the coming into force of this Act, shall be completed in compliance with the terms and procedures specified in it.

§ 122. (1) The marketing authorisation holders shall not apply a risk management system under Article 192, Paragraph 1, item 2 for medicinal products whose marketing authorisations were issued prior to 21 July 2012, except in the cases under Paragraph 2.

(2) The Bulgarian Drugs Agency may impose an obligation to the marketing authorisation holder to create and to apply a risk management system when he deems that there are apprehensions concerning a concrete medicinal product, which may affect the benefit/risk ratio. In that case, the Bulgarian Drug Agency shall demand the marketing authorisation holder to submit also a detailed description of the risk management system that he intends to introduce for the relevant medicinal product.

(3) In the cases under Paragraph 2, the Bulgarian Drugs Agency shall notify in writing the marketing authorisation holder, indicating the motives for imposing the obligation and the deadline for submitting the detailed description of the risk management system.

(4) Within 30 days of receiving the notification under Paragraph 3, the marketing authorisation holder may request the Bulgarian Drugs Agency to provide an opportunity for information to be submitted with respect to the obligation imposed under Paragraph 2.

(5) Following the receipt of the notification under Paragraph 3, the Bulgarian Drugs Agency shall set a deadline for presentation of the information by the marketing authorisation holder.

(6) Based on the information presented, the Bulgarian Drugs Agency may confirm the obligation imposed under Paragraph 2 or revoke it.

(7) The Bulgarian Drugs Agency shall notify the marketing authorisation holder of the decision reached on Paragraph 6.

(8) When the Bulgarian Drugs Agency confirms the obligation, its Executive Director shall issue ex officio a modification in the marketing authorisation, including as a condition in it the obligation under Paragraph 2.

§ 123. The holders of marketing authorisations for medicinal products, issued prior to 21 July 2012, shall fulfil the obligation under Article 192, Paragraph 1, item 1 as of 21 July 2015 or of the date of renewal of the marketing authorisation of the relevant medicinal product, whichever date comes first.

§ 124. Non-interventional studies that have started prior to the coming of this Act into force shall be completed under the earlier procedure.

§ 125. (1) Prior to the onset of the terms and deadline under Article 2, item 3 of Directive 2010/84/EU, the marketing authorisation holder shall send the notifications of serious adverse reactions occurring on the territory of the Republic of Bulgaria to the Bulgarian Drugs Agency and to the European Medicines Agency within 15 days after their receipt.

(2) The Bulgarian Drugs Agency shall check the fulfilling of the obligations under Paragraph 1.

(3) When the notification concerns a serious adverse reaction occurring on the territory of a third country, the marketing authorisation holders shall notify the European Medicines Agency within the time period under Paragraph 1.

§ 126. (1) The marketing authorisation holders shall file to the Bulgarian Drugs Agency periodic updated safety reports in compliance with the time intervals under Article 194j, Paragraph 3 for medicinal products whose marketing authorisations were issued prior to 21 July 2012 and for which the frequency and the dates for filing the periodic updated safety reports are not specified as conditions in the marketing authorisation.

(2) The provision of Paragraph 1 shall be enforced until a different frequency or different dates for filing the reports are specified in the marketing authorisation, or until dates and a frequency are specified under Articles 194k - 194m.

§ 127. (1) The marketing authorisation holders shall submit periodic updated safety reports under Article 194h, Paragraph 1 following the expiry of 12 months from the date on which the European Medicines Agency announces its functioning.

(2) Prior to the deadline under Paragraph 1, the marketing authorisation holders shall submit the periodic updated safety reports to the Bulgarian Drug Agency and to the regulatory bodies of the other Member States in which the respective medicinal product has marketing authorisation.

§ 128. The holders of authorisation/certificate for retailing of medicinal products in a pharmacy or drugstore under Article 234, Paragraph 5 shall post the logo under Article 234, Paragraph 6 on the website within one year from the date of the promulgation of the Act under Article 85c, Paragraph 3 from Directive 2001/83/EC.

§ 129. The Bulgarian Drugs Agency shall conduct the first audit of the system under Article 183, Paragraph 1 and shall submit to the European Medicines Agency a report with its results not later than 21 September 2013.

§ 130. (1) Until 20 March 2013, the procedures that have started before the Price and Reimbursement Commission but are not completed shall be completed by it under the earlier procedure.

(2) After 1 April 2013, the unfinished procedures before the Price and Reimbursement Commission shall be completed by the National Council on Prices and Reimbursement of Medicinal Products under the terms and provisions of this Act.

(3) Before 31 March 2013, the Price and Reimbursement Commission shall submit by means of a transfer record to the National Council on Prices and Reimbursement of Medicinal Products the applications and the documents filed for the procedures under Paragraph 1, as well as the archives of the completed procedures.

(4) Before 31 March 2013, the Price and Reimbursement Commission shall submit the registers kept by the Commission with a transfer record to the National Council on Prices and Reimbursement of Medicinal Products.

§ 131. (1) Before 20 March 2013, the fees for filing applications for approval of prices/price ceilings, for registration of prices of medicinal products, for inclusion, deletion or modifying of medicinal products in the Positive Drug List shall be collected by the Ministry of Health in amounts specified in the Tariff under Article 21, Paragraph 2.

(2) The financial means under Paragraph 1, collected prior to 20 March 2013, shall be spent for the activities of the Price and Reimbursement Commission and of the Transparency Commission.

§ 132. Within three months after the coming into force of this Act, the Council of Ministers, on a proposal by the Minister of Health, shall:

1. appoint the Chairperson and the members of the National Council on Prices and Reimbursement of Medicinal Products;
2. adopt the statutory rules of the National Council on Prices and Reimbursement of Medicinal Products.

§ 133. (1) Within two months of the coming of this Act into force, the Council of Ministers shall amend the Tariff under Article 21, Paragraph 2.

(2) Before 1 April 2013, the Council of Ministers shall adopt the Ordinance under Article 261a, Paragraph 5.

§ 134. The obligations under Article 159, Paragraph 4, Article 168, Paragraph 8, Articles 168a and 168b shall begin to be implemented three years after the date of the publication of the delegated acts under Article 54a of Directive 2001/83/EC in the Official Journal of the European Union.

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§ 138. This Act shall come into force as of the date of its promulgation in the State Gazette, with the exception of:

1. § 9, item 1, a), § 29 - 36, § 38 - 43, § 44 concerning Articles 167a, 167b, 167c, 167d, 167e, Article 167f, Paragraph 1 and Paragraph 2, item 1 and Article 167h, § 65 - 76, § 98, items 1 and 2, § 101, item 1, a) and b), § 102, 103, 106 - 108, 111, 116, § 117, item 1, a), f), j) and k), which come into force on 2 January 2013;
2. § 20 and § 117, item 2, which come into force as of 1 April 2013;
3. § 44 concerning Article 167f, Paragraph 2, item 2 and Paragraph 3 and Article 167g, which come into force as of 2 July 2013.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 1/2014, effective 3.01.2014)

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§ 17. Within one month from coming into force of this act the Minister of Health issues the orders under:

1. Article 37, Paragraph 8, Article 52 and Article 114a, Paragraph 2;
2. Article 80e, Paragraph 4 of the Health Insurance Act.

§ 18. Within one month from coming into force of this act the Minister of Health puts into conformity with it the Ordinance referred to in Article 221, Paragraph 1 of the Medicinal Products in Human Medicine Act.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Insurance Act
(SG No. 48/2015)

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§ 40. (1) The Minister of Health shall determine the criteria under Article 45, Paragraph 3 within three months of this Act’s entry into force.

(2) The Supervisory Board of the NHIF shall approve the list under Article 45, Paragraph 4 within three months after the criteria referred to in Paragraph 1 are determined.

(3) Within one month of the entry into force of the list under Article 45, Paragraph 4 the National Council on Prices and Reimbursement of Medicinal Products shall ex officio exclude from the Positive Drug List the medicinal products designated for treatment of diseases not included in the list.

(4) The National Health Insurance Fund shall pay for the medicinal products, medical products and dietetic foods for special medical purposes designated for the diseases under the ordinance referred to in the previous Article 45, Paragraph 3 prescribed until the expiry of the period referred to in Paragraph 3.
(5) No appeal against the acts or deeds of the National Council on Prices and Reimbursement of Medicinal Products referred to in Paragraph 3 shall halt the enforcement thereof.

§ 41. Until a basic and supplementary package is established in accordance with the procedure provided for by Article 45, Paragraph 2, the basic package applicable as at the time of this Act's entry into force shall apply.

§ 42. (1) In relation to medicinal products under Article 45, Paragraphs 10, 13 and 1 included in the Positive Drug List for which no discounts have been agreed upon, discounts shall be agreed upon within 6 months of this Act's entry into force.
(2) Within one month of the expiry of the time limit referred to in Paragraph 1, the National Council on Prices and Reimbursement of Medicinal Products shall ex officio exclude from the Positive Drug List any medicinal products for which no discounts have been agreed upon.
(3) No appeal against the acts or deeds of the National Council on Prices and Reimbursement of Medicinal Products referred to in Paragraph 2 shall halt the enforcement thereof.

§ 43. Under contracts between medical treatment facilities and medicinal product suppliers on hospital treatment of malignant diseases, the NHIF shall pay the cost of the medicinal products, regardless of whether discounts have been agreed upon in respect thereof, until the expiry of the period agreed upon in the contracts as at the time of this Act's entry into force, but for no more than 6 months thereafter.

§ 44. (1) The National Framework Agreements, the volumes and prices of medical and dental activities, the methods for estimation of the value of and payment for medical care and the resolutions under Article 54, Paragraphs 8 and/or 9 aplicable as at the time of this Act's entry into force shall apply until new National Framework Agreements are adopted.
(2) Until new National Framework Agreements are adopted, the NHIF shall pay for the medical care referred to in Item 2 of Article 55, Paragraph 2 within the volumes applicable as at the time of this Act's entry into force.

§ 45. (1) Until new National Framework Agreements are adopted under Article 53, Paragraph 1, checks by financial inspectors, medical doctors and dentists acting as controllers shall be performed, and penalties shall be imposed and appealed against, in accordance with the hitherto applicable procedure.
(2) Any checks as referred to in Paragraph 1, any imposition of sanctions and any appeals against such sanctions which have started prior to the adoption of new National Framework Agreements under Article 53, Paragraph 1 shall be finalised in accordance with the hitherto applicable procedure.

§ 46. (1) Within three months of this Act's entry into force medical research societies shall provide the National Council on Prices and Reimbursement of Medicinal Products with the manuals and algorithms under Item 4 of Article 259, Paragraph 1 of the Medicinal Products in Human Medicine Act.
(2) Where medical research societies fail to provide the manuals and algorithms under Item 4 of Article 259, Paragraph 1 of the Medicinal Products in Human Medicine Act within the time limit referred to in Paragraph 1, the National Council on Prices and Reimbursement of Medicinal Products shall arrange for them to be drawn up by the national consultants or other medical specialists experienced in the relevant field.
(3) The National Council on Prices and Reimbursement of Medicinal Products shall endorse the manuals and algorithms under Item 4 of Article 259, Paragraph 1 of the Medicinal Products in Human Medicine Act within three months of the expiry of the time limit referred to in Paragraph 1.

§ 47. (1) Within three months of this Act's entry into force the Minister of Health shall issue the ordinance under Article 262, Paragraph 4 of the Medicinal Products in Human Medicine Act.

(2) Within 6 months of this Act's entry into force, medicinal products with new International Nonproprietary Names may be included in the Positive Drug List without a health technology assessment.

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TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Medicinal Products in Human Medicine Act
(SG No. 84/2018, effective 12.10.2018)

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§ 70. Clinical trials authorised prior to the entry into force of this Act which involve medicinal products containing narcotic substances shall be conducted at medical treatment facilities for which authorisations had been obtained to conduct the clinical trials concerned according to the previously existing procedures.

§ 71. (1) The Minister of Health shall determine the criteria under Article 103, Paragraph 1 within three months of this Act's entry into force.

(2) The committee referred to in Article 103(1) is the legal successor of the Ethics Committee for Multi-centre Trials.

(3) The committee referred to in Article 103(1) shall also give opinions in pending procedures before ethics committees established under medical treatment facilities, while following the previously existing procedures.

(4) Pending the final decision on the members of the committee referred to in Article 103(1), the Ethics Committee for Multi-centre Trials shall continue to function according to the previously existing procedures.

§ 72. (1) The Central Ethics Committee shall wind up its activity after the finalization of all procedures brought before it.

(2) On the basis of a handover protocol, the Chair of the Central Ethics Committee shall transfer the archive of the Central Ethics Committee to an official of the Ministry of Health designated by the Minister of Health in an order; the transfer shall be completed within one month after the winding up of the Central Ethics Committee.

§ 73. (1) Within three months of the entry into force of Article 107a, the heads of medical treatment facilities where clinical trials are conducted under the procedures of this Act shall designate a contact person according to the requirements set out in Article 107a.

(2) The ethics committees established under medical treatment facilities according to the previously existing procedures shall continue to carry out their activities until the designation of a contact person under Article 107a(1).

(3) Following the designation of the contact person under Article 107a(1), the functions of ethics committees established under medical treatment facilities according to the previously existing procedures shall be performed by the contact person under Article 107a(1), except for the function related to giving opinions under Article 83 which shall be discharged by the committee referred to in Article 103(1).

(4) The archives of ethics committees established under medical treatment facilities according to the previously existing procedures shall be transferred and stored at the medical treatment facility concerned.

§ 74. Within 6 months after the publication date of the notice under Article 82(3) of Regulation (EU) No. 536/2014, clinical trials shall be authorised and conducted according to the previously existing procedures, except in the cases referred to in Article 98 of Regulation (EU) No. 536/2014.

§ 75. (1) The Bulgarian Drug Agency shall create the specialized electronic system referred to in Article 217b(1) in compliance with the requirements laid down in this Act, within 4 months of its entry into force.

(2) The initial list of medicinal products included on the Positive Drug List in respect of which a shortage has been be established in the territory of the Republic of Bulgaria shall be drawn up in

compliance with the requirements of Article 217c; the shortage of medicinal products shall be established on the basis of the quantities needed to meet the healthcare needs of the population over one month which are calculated (using the specialized electronic system pursuant to Article 217b) on the basis of the average monthly consumption of the medicinal product concerned in the preceding 6 months.
(3) In order to draw up the initial list under Article 217c(1), the information referred to in Article 217b, paragraph 3(1) to (3) shall be provided for the 6 months preceding the date of creation of the specialized electronic system under paragraph 1. (This date shall be disclosed on the website of the Bulgarian Drug Agency.) The information shall be made available within two months from the date of creation of the electronic system referred to in paragraph 1.
(4) The list referred to in paragraph 2 shall also be sent to the Customs Agency ex officio by the Bulgarian Drug Agency.
(5) The Minister of Health shall assist the Bulgarian Drug Agency in the creation of the specialized electronic system referred to in Article 217b(1).

§ 76. The statutory instruments of secondary legislation for the application of this Act shall be adopted or, respectively, issued and brought into conformity with this Act within 6 months from the entry into force of this Act.

§ 77. Any notices submitted before the entry into force of this Act in relation to medicinal products included on the Positive Drug List referred to in Article 262(1) and exported from the Republic of Bulgaria shall be reviewed and finalized according to the previously existing procedures.

§ 78. The law shall enter into force on the date of its publication in the Official Gazette, excluding § 5, § 7 - 12, § 14 - 21, § 27 - 30, § 31(2), § 32, § 39 - 41, § 56, § 60 and § 66(1) - (8), (10), (12), (15) - (17), (19) - (22) which shall enter into force six months after the publication date of the notice referred to in Article 82(3) of Regulation (EC) No. 536/2014.

TRANSITIONAL AND FINAL PROVISIONS
to the Act on Amending and Supplementing the Medicinal Products in Human Medicine Act
(SG No. 67/2020)

§ 68. Within three months from entry of this Act into force the Bulgarian Drug Agency shall enter into the register under Article 19, paragraph 1, item 3 the medicinal products that have been authorised for marketing under a centralised procedure in accordance with the provisions of Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

§ 69. (1) Within three months from entry into force of this Act the Bulgarian Drug Agency shall enter national identification numbers under Article 19, paragraph 3 of all medicinal products entered in the register under Article 19, paragraph 1, item 3.
(2) With regard to medicinal products included in the Positive Drug List, in the register of price ceilings and in the register of maximum sale prices the Bulgarian Drug Agency shall enter in the register under Article 19, paragraph 1, item 3 as national identification number of the medicinal product the identification number indicated in the respective register, kept by the National Council on Prices and Reimbursement of Medicinal Products.
(3) Within 18 months from the expiration of the period under paragraph 1. the marketing authorisation holders shall ensure the introduction of the unique identification number under Article 19, paragraph 3 for each of their medicinal products as part of the unique identifier under Article 68a.

§ 70. (1) Any incumbent persons (prior to the entry into force of this Act) who are simultaneously holders of an authorisation for wholesaling and an authorisation for retailing of medicinal products in a pharmacy, shall bring their operations into compliance with the requirements of Articles 195a and 222a within 6 months from entry of this Act into force.
(2) Where a person has failed bring its operations into compliance within the period under paragraph 1, the Executive Director of the Bulgarian Drug Agency shall withdraw the authorization, which was issued at a later date. Where the second type of activity is retailing of medicinal

products, the Executive Director of the Bulgarian Drug Agency shall withdraw the authorizations issued to such person for all pharmacies.
(3) The requirements of Articles 195a and 222a shall also apply to applications for wholesaling and/or retailing of medicinal products filed prior to the entry of this Act into force.

§ 71. (1) Within 12 months from entry of this Act into force, the National Council on Prices and Reimbursement of Medicinal Products shall enter the information under Article 262^{1}, paragraph 2 of the medicinal products included in the Positive Drug List.
(2) The Bulgarian Drug Agency shall provide the necessary information to the National Council on Prices and Reimbursement of Medicinal Products under paragraph 1 within 6 months from the entry of this Act into force.

§ 72. (1) The methodology under Article 227b, paragraph 5 shall be issued within six months from the entry of this Act into force.
(2) The National Pharmacy Map referred to in Article 227a, paragraph 1 shall be adopted within one year from entry of this Act into force.

§ 73. Within three months from entry of this Act into force, the Manager of National Health Insurance Fund may set only once a new amount of individual base salaries of district health insurance fund directors, without exceeding the maximum amount of the base monthly salary of the respective level and degree, within the personnel costs in the budget of NHIF for the respective year, regardless of the already made or forthcoming monthly salary increases in the respective year.

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§ 78. (1) The statutory instruments of secondary legislation for the implementation of this Act, the Health Insurance Act, the Medical Devices Act, the Persons with Disabilities Act shall be adopted, respectively published and aligned within three months from the entry of this Act into force.
(2) Until the statutory instruments of secondary legislation referred to in paragraph 1 are adopted, respectively published and aligned, the statutory instruments of secondary legislation.

TRANSITIONAL AND FINAL PROVISIONS
to the 2021 National Health Insurance Fund Budget Act
(SG No. 103/2020, effective 1.01.2021)

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§ 20. (1) Within three months of the entry of this Act into force the Bulgarian Drug Agency shall submit to the National Council on Prices and Reimbursement of Medicinal Products in an electronic format using a standard form approved by the Council information regarding the medicinal products authorised for use and registered on the territory of the Republic of Bulgaria and regarding the medicinal products authorised for use in accordance with a centralised procedure according to the procedure laid down in Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
(2) The National Council on Prices and Reimbursement of Medicinal Products shall approve the standard form referred to in Paragraph 1 within 7 days of the entry into force of this Act.

§ 21. (1) The identification numbers of the medicinal products included in the Positive Drug List, in the register of price ceilings and in the register of maximum sale prices shall be considered to be a national identification number of the medicinal product within the meaning of Article 259^{1}(1) of the Medicinal Products in Human Medicine Act.
(2) Within six months of the provision of the information set out in § 20(1), the National Council on Prices and Reimbursement of Medicinal Products shall publish on its website the register referred to in Article 259(2)(4) of the Medicinal Products in Human Medicine Act.
(3) Within three months of the entry of this Act into force, the holders of marketing authoriations/registration certificates for medicinal products shall submit to the Bulgarian Drug Agency, in respect of all medicinal products for which a marketing authorisation/registration certificate has been received, through the specialised electronic system referred to in Article

217b(1) of the Medicinal Products in Human Medicine Act, information about the product code within the meaning of Article 4(b)(i) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ, L 32/1 of 9.2.2016), hereinafter referred to as "Delegated Regulation (EU) 2016/161", for medicinal products set out in Delegated Regulation (EU) 2016/161.

(4) Within three months of the entry of this Act into force the holders of authorisations for parallel import shall provide to the Bulgarian Drug Agency, in respect of all medicinal products authorised for parallel import in the territory of the country, through the specialised electronic system referred to in Article 217b(1) of the Medicinal Products in Human Medicine Act, information about the product code within the meaning of Article 4(b)(i) of Commission Delegated Regulation (EU) 2016/161 for medicinal products set out in the Regulation.

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