ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS

Effective 30 April 2013.

Adopted by Council of Ministers Decree No 97 of 19 April 2013.

Promulgated in the State Gazette No 40 of 30 April 2013; amended and supplemented, SG No 66 of 8 August 2014, amended and supplemented, SG No 92 of 7 November 2014; amended, SG No 107 of 24 December 2014, amended and supplemented SG No 92 of 27 November 2015, supplemented SG No 3 of 12 January 2016, amended SG No 14 of 19 February 2016, amended SG No 32 of 22 April 2016; amended and supplemented, SG No 62 of 9 August 2016; amended, SG No 74 of 20 September 2016; amended and supplemented, SG No 2 of 6 January 2017, amended and supplemented SG No 8 of 24 January 2017, amended and supplemented SG No 102 of 22 December 2017, amended SG No 94 of 13 November 2018, amended and supplemented SG No 26 of 29 March 2019, amended SG No 58 of 23 July 2019, amended and supplemented SG N. 62 of 6 August 2019, supplemented SG No 19 of 6 March 2020, ***amended and supplemented SG N. 28 of 6 April 2021.***

Chapter One.
GENERAL DISPOSITIONS

Article 1. The ordinance defines:

1. terms and rules for regulating prices of medicinal products subject to medical prescription included in the Positive Drug List (PDL) and reimbursable with public funds;

2. terms and rules for regulating ceiling prices of medicinal products subject to medical prescription not included in PDL, at retail sale;

3. terms and procedure for registering prices of over-the-counter medicinal products;

4. terms, rules and criteria for inclusion, change and/or exclusion of medicinal products from PDL;

5. (new - SG No 92/2015) terms, rules and criteria for maintaining the reimbursement status of medicinal products included in PDL;

6. (new - SG No 92/2015, amended SG No 26/2019, effective 01.04.2019) the procedure for submitting contracts for granting discounts for medicinal products under Art. 45, para. 10, 13 and 21 of the Health Insurance Act (HIA) and the agreements under Art. 262, para. 12 of the Law on Medicinal Products in Human Medicine;

7. (previous Item 5 – SG No 92/2015; supplemented SG No 26/2019, effective 01.04.2019) the terms and conditions according to which the Ministry of Health (MoH) and the National Health Insurance Fund (NHIF) can submit proposals before the National Council on Prices and Reimbursement of Medicinal Products, hereafter referred to as "the Council", for reviewing medicinal products included in PDL, as well as reasonably requesting the assessment of health technologies for medicinal products included in PDL;

8. (previous Item 6 – SG No 92/2015, amended – SG No 26/2019, effective 01.04.2019) terms and procedure for assessment of health technologies;

9. (new - SG No 26/2019, effective 01.04.2019) terms, procedure and criteria for defining medicinal products for which the effect of the therapy, its duration and the medical-treatment establishments where the therapy takes place are monitored.

10. (new - SG No. 28 of 2021) the order in which it is generated and entered in the register under Art. 7, para. 1, item 4 national identification number of each medicinal product;

11. (new - SG No. 28 of 2021) the procedure by which the Medicines Executive Agency (EMA) provides the Council with information on medicinal products authorized for use and registered on the territory of the Republic of Bulgaria and authorized for use under a centralized procedure medicinal products pursuant to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 establishing Community procedures for the authorization and control of medicinal products for human and veterinary use and for the establishment of a European Agency for the medicines.

Article 2. (1) The price for a medicinal product included in PDL and reimursable with public funds shall be the price in BGN, as approved by the Council.

(2) The price under paragraph 1 shall furthermore be the ceiling price of the medicinal products at retail sale.

(3) The ceiling price for a medicinal product subject to medical prescription not included in PDL shall be the price in BGN, as approved by the Council, which is the maximum permissible at retail sale thereof.

(4) The price for an over-the-counter medicinal product shall be the maximum selling price in BGN at retail sale, as declared by the holder of the Marketing Authorization and registered by the Council.

(5) In respect of medicinal products for which a parallel import authorization has been obtained, a price shall be approved/registered in accordance with the procedure laid down in this ordinance.

Article 3. Where the marketing authorisation specifies the prescription status as “dispensed subject to medical prescription or over-the-counter”, the price of the medicinal product shall be formed according to the procedure laid down in Chapter Three.

Article 4. (supplemented SG No 26/2019, effective 01.04.2019) A medicinal product may be sold within the territory of a country solely after the entry into effect of a decision of the Council on approving a price/ceiling price or registering a price, with the exception of medicinal products under Article 9 and Article 266a of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

Article 5. (1) (amended SG No 92/2014, effective 07.11.2014) A medicinal product may be sold at a price not higher than the approved price under Article 2, paragraph 1, the ceiling price under Article 2, paragraph 3 or the registered price under Article 2, paragraph 4.

(2) Each retailer shall be obliged to indicate the selling price on the packaging of the medicinal product, at a place designated by the manufacturer.

(3) Prices for medicinal products comprised in the value of medical care provided by medicaltreatment establishments may not be higher than the price at which the medical-treatment establishment has purchased the medicinal product from a wholesaler.

(4) (new – SG No 26/2019, effective 01.04.2019, repealed – SG No 62/2019, effective 06.08.2019)

(5) (new - SG No 62/2019, effective 01.11.2019) A medicinal product may not be sold to medicaltreatment establishments under Article 5 of the Medical-Treatment Establishments Act and to medicaltreatment establishments with state and / or municipal ownership involvement under Article 9 and 10 of the Medical-Treatment Facilities Act at a price higher than the value specified in accordance with Article 55.

(6) (new - SG No 92/2015, effective 01.01.2017, amended regarding the entry into force - SG No 3/2016, effective 01.12.2015, amended regarding the entry into force – SG No 14/2016, effective 16.02.2016, amended regarding the entry into force – SG No 74/2016, effective 01.09.2016, repealed - SG No 2/2017, effective 01.01.2017, repealed, previous paragraph 4, amended - SG No 26/2019, effective 01.04.2019, previous paragraph 5 - SG No 62/2019, effective 01.11.2019) For medicinal products included in PDL under Article 262, paragraph 6, item 1 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE with a reimbursement level of 100 percent, no mark-up should be charged to the retailer, when dispensed in a pharmacy.

Article 6. (1) The Positive Drug List includes medicinal products authorized for use under the order of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, classified by pharmacological groups according to the Anatomical Therapeutic Chemical Classification (ATC) code.

(2) The Positive Drug List shall consist of four annexes and shall include:

1. (amended SG No 92/2015) medicinal products intended for treatment of diseases reimbursable in accordance with the procedure established in HIA;

2. medicinal products reimbursable from the budget of the medical-treatment facilities, covered under Article 5 of the Medical-Treatment Facilities Act, and from the budget of the medical-treatment facilities where the state and/or a municipality holds a participating interest under Articles 9 and 10 of the MedicalTreatment Facilities Act;

3. medicinal products intended for the treatment of AIDS, or infectious diseases, or diseases beyond the scope of HIA which are reimbursable according to the procedure established in Item 8 of Article 82, paragraph 1 of the Health Act, as well as vaccines for compulsory immunisations and boosters, vaccines on special indications and in an emergency, specific sera, immunoglobulins, designated by the ordinance referred to in Article 58, paragraph 2 of the Health Act;

4. the ceiling price for the medicinal products, referred to in Article 2, paragraph 2, disaggregated by element.

(3) (Amended - SG No. 92 of 2015, amended - SG No. 26 of 2019, in force from 01.04.2019, supplemented - SG No. 28 of 2021) in the PDL applications under para. 2, items 1 - 3 indicate: ATS code, international non-proprietary name (INN), name of the medicinal product, dosage form and quantity of the active medicinal substance, final packaging, marketing authorization holder, DDD/therapeutic course/concentration/volume, the price according to Art. 261a, para. 1 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, reference value, packaging value calculated on the basis of the reference value, level of payment for the medicinal product, therapeutic indications and diseases according to

the International Code of Diseases (ICD), manufacturer/manufacturers, information on restrictions on the way of prescribing in various indications, national medicinal product identification number and additional information.

(4) (Amended - SG No. 26 of 2019, in force from 01.04.2019) For medicinal products, the reference value is determined on the basis of a certain defined daily dose or therapeutic course, or concentration, or volume.

(5) (New - SG No. 28 of 2021) The positive drug list contains information about the type of medicinal product determined in the procedure for its authorization for use. The information on the type of medicinal product is submitted by the Bulgarian Drug Agency (BDA) within 7 days from the receipt of an inquiry by the Council for each specific medicinal product.

Article 7. (1) The Council shall maintain and update public registers for:

1. the prices of medicinal products under Article 2, paragraph 1;
2. the prices of medicinal products under Article 2, paragraph 3;
3. the prices of medicinal products under Article 2, paragraph 4.
4. (new - SG No. 28 of 2021) national identification numbers for medicinal products.

(2) The Council shall maintain and update the Positive Drug List.

(3) The registers under paragraph 1 and the PDL shall be posted on the Council's website .

(4) (repealed - SG No 26/2019, effective 01.04.2019)

(5) (amended - SG No 26/2019, effective 01.04.2019) The Council shall publish on its website information on the public institutions responsible for pricing and reimbursement and the statutory instruments of the Member States under Article 8, paragraph 1, item 1, as well as the website addresses where prices of medicinal products are published.

(6) (new - SG No 26/2019, effective 01.04.2019) The Council shall publish on its website summaries of health technology assessment reports. Health technology assessment reports may only be published after written consent given by the relevant marketing authorization holder for the medicinal product being assessed.

Art. 7a. (New - SG No. 28 of 2021) (1) A marketing authorization holder or his authorized representative may submit to the Council a notification according to a form approved by the Council, of an intention to submit an application for inclusion in the PDL of a medicinal product, belonging to a new international non-proprietary name for which a health technology assessment will be carried out according to Art. 30a.

(2) The notification under para. 1 is submitted within a period of up to 3 years before the expected date of submission of an application under Art. 32, para. 1 for the inclusion of the medicinal product in the PDS and assessment of health technologies and contains the information specified in Annex No. 1.

(3) The Council annually publishes on its website summary information on medicinal products for which a notification has been submitted under para. 1.

Chapter Two.
FORMATION OF THE PRICE OF A MEDICINAL PRODUCT INCLUDED IN THE POSITIVE DRUG LIST AND REIMBURSABLE WITH PUBLIC FUNDS

Article 8. (1) The price of a medicinal product included in PDL and reimbursable with public funds shall be fixed on the basis of the following elements:

1. (amended - SG 26/2019, effective 01.04.2019) the ex-factory price which cannot be higher than the BGN equivalent of the lowest ex-factory price for the same medicinal product product in Belgium, Greece, Spain, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and France;

2. (amended - SG 26/2019, effective 01.04.2019) the mark-up for the wholesaler at the rate of 7, 6 and 4 percent of the price declared under item 1 according to the criterion established in Article 9;

3. (amended - SG 26/2019, effective 01.04.2019) the mark-up for the retailer at the rate of 20, 18 and 16 percent of the price declared under item 1 according to the criterion established in Article 9.

(2) The price for a medicinal product included in PDL shall be calculated as a sum total of the elements referred to in Items 1, 2 and 3 of paragraph 1 plus value added tax.

(3) (amended and supplemented, SG No 92/2014, effective 07.11.2014, repealed - SG No 26/2019, effective 01.04.2019)

(4) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 26/2019, effective as of 01.04.2019) Where an ex-factory price for the same medicinal product cannot be found in the countries listed in paragraph 1, Item 1, the declared ex- factory price may not be higher than the lowest ex-factory price entered in the marketing authorisation/ the decision of the European Commission issued according to the procedure established by 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 (OJ L 136 of 30 April 2004) for a medicinal product with the same pharmaceutical form and quantity of active ingredient in a dosage unit in the countries referred to in paragraph 1, Item 1.

(5) (new - SG No 92/2015, effective 01.01.2018, amended regarding the entry into force - SG No 74/2016, effective 01.09.2016, amended regarding the entry into force - SG No 2/2017, effective 01.01.2017, amended regarding the entry into force - SG No 8/2017, amended - SG No 94/2018, amended – SG No 26/2019, effective 01.04.2019) Where an ex-factory price for the same medicinal product cannot be found in the countries specified in paragraph 1, Item 1, as well as an ex-factory price according to paragraph 4, the declared ex-factory price may not be higher than the lowest ex-factory price of a medicinal product with the same international non-proprietary name, pharmaceutical form and quantity of active ingredient in a dosage unit, considered to be a reference within the meaning of Article 28 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE and included in PDL.

(6) (New - SG No. 26 of 2019, in force from 01.04.2019, repealed - SG No. 28 of 2021)

(7) (new - SG No 26/2019, effective 01.04.2019) The ex-factory price in the countries under paragraph 1, item 1, paragraphs 4 - 6 shall be:

1. the price declared as the ex-factory price and notified by the relevant state institutions, including at the website addresses where prices of medicinal products are published and/or in the EURIPID Collaboration database;

2. the price calculated on the basis of the statutory instruments in the states referred to in paragraph 1, item 1, in cases where the state institutions have notified a wholesaler/retailer price.

Article 8a. (new - SG No 62/2016) (1) (amended - SG 26/2019, effective 01.04.2019) When verifying the ex-factory price for a medicinal product under Article 8, the Council shal make reference to the prices published by the state institutions, as well as the information contained in the EURIPID Collaboration database (Agreement for Joint Action on Pricing and Reimbursement for Medicinal Products).

(2) In the event of discrepancy between the prices published by the country concerned and those in the EURIPID Collaboration Agreement database, the more favorable price shall be charged to the applicant.

(3) (new - SG No 102 of 2017) Where, during the verification under paragraph 1, an ex-factory price for a medicinal product/medicinal products has only been established in the database under the EURIPID Collaboration Agreement, the price shall be taken into account after confirmation by the state institution of the country concerned.

Article 9. (1) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price does not exceed 10.00 levs, the amounts of the mark-ups for the wholesaler and for the retailer to be added theretro shall be 7 and 20 percent, respectively.

(2) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price falls within the range between 10.01 BGN - 30.00 BGN, the amounts of the mark-ups for the wholesaler and for the retailer to be added thereto shall be 6 and 18 percent, respectively.

(3) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price exceeds 30.00 BGN, the amounts of the mark-ups for the wholesaler and for the retailer to be added thereto shall be 4 per cent, but not more than 10 BGN, and 16 per cent, but not more than 25 BGN, respectively.

Chapter Three.
FORMATION OF THE CEILING PRICE FOR A MEDICINAL PRODUCT DISPENSED ON MEDICAL PRESCRIPTION, REFERRED TO IN ARTICLE 2 (3)

Article 10. (1) The ceiling price for a medicinal product disoensed on medical prescription which is not included in PDL shall be fixed using the following elements:

1. (amended - SG No 26/2019, effective 01.04.2019) the ex-factory price which cannot be higher than the BGN equivalent of the lowest ex-factory price for the same medicinal product product in Belgium, Greece, Spain, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and France;

2. (amended - SG No 26/2019, effective 01.04.2019) the mark-up for the wholesaler at the rate of 7,

6 and 4 percent of the price declared under item 1 according to the criterion established in Article 11;

3. (amended - SG No 26/2019, effective 01.04.2019) the mark-up for the retailer at the rate of 20, 18

and 16 percent of the price declared under item 1 according to the criterion established in Article 11.

(2) The ceiling price for a medicinal product shall be calculated as the sum total of the elements under paragraph 1, items 1, 2 and 3 plus value added tax.

(3) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 26/2019, effective 01.04.2019) The ex-factory price in the countries under paragraph 1, item 1 shall be:

1. the price declared as the ex-factory price and notified by the relevant state institutions, including at the website addresses where prices of medicinal products are published and/or in the EURIPID Collaboration database;

2. the price calculated on the basis of the statutory instruments in the states referred to in paragraph 1, item 1, in cases where the state institutions have notified a wholesaler/retailer price.

Article 11. (1) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price does not exceed 10.00 BGN, the amounts of the mark-ups for the wholesaler and for the retailer to be added theretro shall be 7 and 20 percent, respectively.

(2) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price falls within the range between 10.01 BGN - 30.00 BGN, the amounts of the mark-ups for the wholesaler and for the retailer to be added thereto shall be 6 and 18 percent, respectively.

(3) (amended - SG No 26/2019, effective 01.04.2019) In case the declared ex-factory price exceeds 30.00 BGN, the amounts of the mark-ups for the wholesaler and for the retailer to be added thereto shall be 4 per cent, but not more than 10 BGN, and 16 per cent, but not more than 25 BGN, respectively.

Article 12. (1) (amended - SG No 26/2019, effective 01.04.2019) When preparing a medicinal product as a magistral and officinal formula in a pharmacy, a mark-up shall not be added to the value of the medicinal substances, incipients and packaging used.

(2) The prices for medicinal products prepared as a magistral and officinal formula in a pharmacy shall be determined by an act of the manager of the pharmacy, which shall be prominently displayed in the medical-treatment facility.

(3) The price referred to in Paragraph (2) for a medicinal product prepared as a magistral and officinal formula shall also include a component to the amount of BGN 2.50 for the pharmaceutical service of dispensing the medicinal product, provided by the retailer.

Chapter Four.
TERMS AND CONDITIONS FOR REGULATING THE LIMIT PRICES FOR MEDICINAL PRODUCTS UNDER ARTICLE 2, PARAGRAPH 3

Article 13. (1) (amended, SG No 92/2014, effective 07.11.2014) For the formation of a ceiling price under Article 2, paragraph 3, the marketing authorisation holder or an authorised representative thereof shall submit an application for the formation of a ceiling price in accordance with a model approved by the Council.

(2) The application referred to in Paragraph 1 shall state the price disaggregated by element, conforming to the rules specified in Article 10.

Article 14. (1) The following shall be attached to the application referred to in Article 13, paragraph 1:

1. a copy of a marketing authorisation for the medicinal product compliant with the requirements of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, in cases where the marketing authorisation has been issued according to the procedure established in Regulation (EC) No 726/2004, Annex I "Summary of product characteristics", Annex II "Marketing authorisation holder responsible for batch release. Conditions of the marketing authorisation" and Annex III "Particulars to appear on the outer packaging and text of the package leaflet"; the annexes shall be presented on an electronic data medium;

2. information regarding the Uniform Identification Code of the corporation or cooperative from the Commercial Register or, applicable to corporations registered in a Member State of the European Union or in a State which is a Contracting Party to the Agreement on the European Economic Area, a copy of a document on current registration under the national legislation, issued by a competent authority of the relevant State to the persons referred to in Article 13, paragraph 1 not later than six months prior to the submission of the application;

3. explicit notary authorisation, in case the application is submitted by authorised representative of marketing authorisation holder; when the authorisation is not issued in the Republic of Bulgaria, it should be translated into Bulgarian by a translator that is authorised by the Ministry of Foreign Affairs to deal with official translations;

4. evidence regarding the representative authority of the person who has signed the power of attorney referred to in Item 3;

5. (amended - SG No. 92 of 2014, in force from 07.11.2014, amended - SG No. 28 of 2021) declaration-reference according to a model approved by the Council, regarding the producer price of the medicinal product in the relevant currency and euro in the countries under Art. 10, para. 1, item 1;

6. (amended - SG No. 28 of 2021) document for paid state tax

(2) (amended - SG No 26/2019, effective 01.04.2019) The ex-factory prices in the declarationinformation under paragraph 1, item 5 must be dated as of the month of submission of the application under Article 13, paragraph 1.

(3) The authorization under paragraph 1, item 1, as well as Annexes I, II and III thereto shall also be presented accompanied by a translation into the Bulgarian language.

(4) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 26/2019, effective 01.04.2019) For a product that has received a parallel import authorization or a parallel distribution authorization from the European Medicines Agency, in the presence of identical or similar medicinal product pursuant to Article 214 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE with a ceiling price approved by the Council, the same or a lower price, calculated in accordance with the quantity of active ingredient per dosage unit, shall be applied, upon submission of an explicit written application in accordance with a model approved by the Council by the holder of authorization / notification for parallel import / parallel distribution.

(5) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in effective from 23.07.2019, new - SG No. 28

from 2021) To the application under para. 4, the permit/notification for parallel import/parallel distribution and the documents under para. 1, items 2 - 4 and 6.

(6) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in force from 23.07.2019, new - SG No. 28 of 2021) The requested price of the medicinal product under para. 4 cannot be higher than the limit price approved by the Council for the same or similar medicinal product under Art. 214 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

(7) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in force from 23.07.2019, new - SG No. 28 of 2021) For medicinal products under para. 4 the provisions of art. 15 - 18.

(8) (New - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) The Council ex officio reduces the marginal price of a medicinal product that has received authorization for parallel import or permission for parallel distribution by the European Medicines Agency, in case of formation of a lower or reduction of the marginal price of the same or similar medicinal product under Art. 214 of the Law on Medicinal Products in Human Medicine. The Council shall notify the holder of a parallel import permit or a parallel distribution permit of the initiation of administrative proceedings.

Article 15. (1) Within thirty days after the date of submission of the application, the Council shall examine the application and the documents attached thereto and shall adopt a decision endorsing or refusing to endorse a ceiling price for the medicinal products referred to in Article 2, paragraph 3.

(2) In case the application for the formation of a ceiling price for a medicinal product as submitted does not conform to the requirements of Article 14, the Council shall have the right to require from the applicant to cure the deficiencies and non-conformities in the documents, as well as to present additional information. In such case, the time limit referred to in Paragraph 1 shall cease to run until the date of curing of the deficiencies and non-conformities in the documents.

(3) In case the applicant fails to cure the deficiencies or non-conformities ascertained by the Council

or to present additional information within thirty days after the date of notification under Paragraph 2, the procedure for the endorsement of a ceiling price for a medicinal product dispensed on medical prescription shall be terminated.

(4) The Council shall notify the applicant in writing of the termination of the procedure under Paragraph 3.

Article 16. (1) A legal and economic evaluation of each application received for the formation of a ceiling price for a medicinal product shall be prepared by experts of a directorate in the specialised administration of the Council.

(2) (amended, SG No 92/2014, effective 07.11.2014) The experts shall preview the applications and the accompanying documents and shall prepare an opinion on each application, completed in a standard form endorsed by the Council. A legal evaluation shall be made first, and it shall be followed by an economic evaluation.

(3) (amended and supplemented, SG No 92/2014, effective 07.11.2014) The member of the Council, designated by the Chairperson as a rapporteur, shall summarise the expert opinions and shall prepare an expert report in a standard form endorsed by the Council within seven days after receiving the opinions on each application.

Article 17. (1) The decision of the Council on endorsement of a ceiling price for the medicinal product shall contain:

1. (repealed, SG No 26/2019, effective 01.04.2019)
2. international non-proprietary name of the medicinal product;
3. registration number entered in the marketing authorisation;
4. name of the medicinal product;
5. pharmaceutical form and quantity of the active ingredient in the final packaging;
6. name of the marketing authorisation holder and of the manufacturer/manufacturers of the medicinal product;
7. endorsed ceiling price for the medicinal product disaggregated by element according to Article 10, paragraph 2.

(2) The refusal of the Council to approve the ceiling price of the medicinal product shall be motivated.

(3) (Amended - SG No. 92 of 2015, amended - SG No. 28 of 2021) The decision of the Council to approve the maximum price of a medicinal product, as well as the refusal under para. 2 are subject to appeal:

1. administratively before the Transparency Commission;
2. before the relevant court in accordance with the ADMINISTRATIVE PROCEDURE CODE.

Article 18. (amended — SG No 62/2016) The Council shall make public the decisions which have entered into effect in the register referred to in Article 22 on the 2nd day of each month.

Article 19. (1) The marketing authorisation holder or an authorised representative thereof may apply for reasoned changes in the endorsed ceiling price for a medicinal product referred to in Article 2, paragraph 3 not earlier than twelve months after the endorsement of the last ceiling price for a medicinal product. Any such change shall follow the procedure established by Articles 13 to 16, attaching only the documents relevant to the change

(2) The time limit referred to in Paragraph 1 shall not apply to cases in which the marketing authorisation holder submits an application for reduction of the endorsed ceiling price for a medicinal product referred to in Article 2, paragraph 3.

(3) (Amendment - State Gazette, no. 26 of 2019, in force from 01.04.2019, amended. - State Gazette, no. 28 of 2021) Increase of the approved marginal price of a medicinal product under Art. 2, para. 3 can be claimed up to the amount of the lowest price for the same medicinal product, determined in accordance with Art. 10, and in the absence of such - with the percentage of the statistically reported inflation for the period of effect of the last established marginal price

(4) Upon any change of the circumstances entered in the register referred to in Article 22, the marketing authorisation holder or an authorised representative thereof shall present an application to the Council, whereupon the time limit referred to in Paragraph 1 shall not apply. Any such change shall follow the procedure established by Articles 14 to 16, attaching only the documents relevant to the change.

(5) (amended and supplemented, SG No 92/2014, effective 07.11.2014) Within two working days after receiving the decision of the Council on a change of a ceiling price for a medicinal product, the marketing authorisation holder or an authorised representative thereof shall be obligated to notify, in an appropriate manner, the Bulgarian Pharmaceutical Union (BPU) and the wholesalers, and the wholesalers shall be obligated to notify the retailers of medicinal products.

Article 20. (1) For the striking of a ceiling price for a medicinal product dispensed on medical prescription, the marketing authorisation holder for the medicinal product concerned or an authorised representative thereof shall submit an application to the Council.

(2) The following shall be attached to the application referred to in Paragraph 1:

1. information regarding the Uniform Identification Code of the corporation or cooperative in the Commercial Register or, applicable to corporations registered in a Member State of the European Union or in a State which is a Contracting Party to the Agreement on the European Economic Area, a copy of a document on current registration under the national legislation, issued by a competent authority of the relevant State to the persons referred to in Paragraph 1 not later than six months prior to the submission of the application;

2. an express notarised power of attorney, in case the application is submitted by authorised representative of marketing authorisation holder; when the authorisation is not issued in the Republic of Bulgaria, it should be translated into Bulgarian by a translator authorised by the Ministry of Foreign Affairs to deal with official translations;

3. evidence regarding the representative authority of the person who has signed the power of attorney referred to in Item 2.

3. The striking shall follow the procedure established by Articles 15 and 16, and the decisions shall be subject to appeal according to the procedure established by Article 17, paragraph 3.

4. Upon termination, withdrawal or expiry without renewal of the marketing authorisation for a medicinal product, the ceiling price for the said product shall be stricken by the Council ex officio.

5. Under the terms established by Article 55, paragraph 6 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE a medicinal product referred to in Paragraph 4 may be sold for a period not longer than one year at the ceiling price endorsed prior to the striking of the said price.

6. The Bulgarian Drug Agency shall notify the Council by electronic means within three days after the entry into effect of the act referred to in Paragraph 4 or after the expiry of the marketing authorisation, as the case may be.

Article 21. Within the limits of the endorsed ceiling price for medicinal products authorised for marketing, referred to in Article 2, paragraph 3, the pricing of the wholesaler and of the retailer shall be implemented as follows:

1. the retailer shall sell at a price not higher than the ceiling price as endorsed;
2. (amended - SG No 26/2019, effective 01.04.2019) the wholesaler shall sell medicinal products at an agreed price whereof the amount may not be higher than the amount of the declared price for the medicinal product concerned, net of the value of the retailer mark-up, as specified in the decision of the Council on endorsement of a ceiling price.

Article 22. The Council shall keep a public register of the ceiling prices for medicinal products, referred to in Article 2, paragraph 3, which shall contain the following information:

1. (amended - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) national identification number of the medicinal product;
2. international non-proprietary name;
3. registration number entered in the marketing authorization;
4. name of the medicinal product;
5. pharmaceutical form and quantity of the active ingredient in the final packaging;
6. name of the marketing authorisation holder;
7. name of the manufacturer of the medicinal product;
8. declared ex-factory price, on the basis of which the ceiling price was formed;
9. ceiling price as endorsed, disaggregated by element, the number and date of issue of the decision on endorsing the price;
10. effective date of the decision of the Council;
11. additional information.

Chapter Five.
REGISTRATION OF PRICES FOR OVER-THE-COUNTER MEDICINAL PRODUCTS, REFERRED TO IN ARTICLE 2, PARAGRAPH 4

Article 23. (1) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 26/2019, effective 01.04.2019) To register the price of an over-the-counter medicinal product, the holder of the marketing authorization or the authorized representative thereof shall submit an application for registration in accordance with a model approved by the Council, indicating the maximum selling price of the medicinal product in BGN, including VAT.

(2) (Amended - SG No. 28 of 2021) To the application under para. 1, the documents under Art. 14, para. 1, items 1 - 4 and document for paid state fee

(3) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 26/2019, effective 01.04.2019) for a medicinal product under Article 2, paragraph 4 that has received a parallel import authorization or a parallel distribution authorization from the European Medicines Agency, in the presence of the same or similar medicinal product under Article 214 of the LAW ON MEDICINAL PRODUCTS IN

HUMAN MEDICINE with a ceiling price registered by the Council, the same or a lower price, calculated in accordance with the quantity of active ingredient per unit dose, shall be applied, upon submission of an explicit written application in accordance with a model approved by the Council by the holder of the authorization/notification for parallel import/parallel distribution.

(4) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in force from 23.07.2019, new - SG No. 28 of 2021) To the application under para. 3, the permit/notification for parallel import/parallel distribution, the documents under Art. 14, para. 1, items 2 - 4 and document for paid state fee.

(5) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in force from 23.07.2019, new - SG No. 28 of 2021) The requested price of the medicinal product under para. 3 cannot be higher than the maximum sales price registered by the Council for the same or a similar medicinal product under Art. 214 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

(6) (New - SG No. 92 of 2014, in force from 07.11.2014, repealed by Decision No. 9346 of 18.06.2019 of the Supreme Administrative Court - SG No. 58 of 2019, in force from 23.07.2019, new - SG No. 28 of 2021) For medicinal products under para. 3 the provisions of Art. 24 - 26.

(7) (New - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) The Council ex officio reduces the maximum selling price of a medicinal product that has received permission for parallel import or permission for parallel distribution from the European Medicines Agency, upon registration of a lower or reduction of the maximum selling price of the same or similar medicinal product under Art. 214 of the Law on Medicinal Products in Human Medicine. The Council shall notify the holder of a parallel import permit or a parallel distribution permit of the initiation of administrative proceedings.

Article 24. (1) Within thirty days after the submission of the application and the documents, the Council shall adopt a decision on registration of a price for the over-the-counter medicinal product.

(2) Where the application and documents as submitted do not conform to the requirements, the Council may require from the applicant to cure the deficiencies and non- conformities. In such case, the time limit referred to in Paragraph 1 shall cease to run until the date of curing of the deficiencies and nonconformities in the documents.

(3) In case the applicant fails to cure the deficiencies or non-conformities ascertained by the Council

within thirty days after the date of notification, the procedure for registration of a price of an over-the-counter medicinal product shall be terminated.

(4) The Council shall notify the applicant in writing of the termination of the procedure under Paragraph 3.

Article 24a. (New - SG No. 19 of 2020) The marketing authorization holders for use or their authorized representatives may not request an increase in the registered prices of medicinal products, dispensed without a doctor's prescription, by a greater percentage than the statistically recorded inflation for the period per action from the last recorded price.

Article 25. (1) A legal evaluation of each application received for registration of a price for an over-the-counter medicinal product shall be prepared by experts of a directorate in the specialised administration of the Council.

(2) (Amended and supplemented — SG No 92 of 2014, effective as from 07.11.2014) The experts shall preview the applications and the accompanying documents and shall prepare an opinion on each application, completed in a standard form endorsed by the Council.

(3) (Amended and supplemented — SG No 92 of 2014, effective as from 07.11.2014) The member of the Council, designated by the Chairperson as a rapporteur, shall prepare an expert report in a standard form endorsed by the Council within seven days after receiving the opinions on each application.

Article 26. (1) The decision on registration of a price for an over-the-counter medicinal product shall contain:

1. (repealed, SG No 26/2019, effective 01.04.2019)
2. (supplemented, SG No 26/2019, effective 01.04.2019) international non-proprietary name / or active ingredient / substances;
3. registration number of the marketing authorisation;
4. name of the medicinal product;
5. pharmaceutical form and quantity of the active ingredient in the final packaging;
6. name of the marketing authorisation holder and of the manufacturer/ manufacturers of the medicinal product;
7. maximum selling price, as registered.

(2) The refusal of the Council to register a price for an over-the-counter medicinal product shall be reasoned.

(3) (Amended - SG No. 92 of 2015, amended - SG No. 28 of 2021) The decision of the Council to register the price of a medicinal product dispensed without a prescription, as well as the refusal under para. 2 are subject to appeal:

1. administratively before the Transparency Commission;
2. before the relevant court in accordance with the ADMINISTRATIVE PROCEDURE CODE.

(4) Upon any change of the circumstances entered in the register referred to in Article 28, the marketing authorisation holder or an authorised representative thereof shall present an application to the Council. Any such change shall follow the procedure established by Articles 23 to 25, attaching only the documents relevant to the change.

(5) (Amended — SG No 62 of 2016) The Council shall make public the decisions referred to in Paragraph 1 which have entered into effect in the register referred to in Article 28 on the 2nd of each month.

(6) (Amended and supplemented, SG No 92/2014, effective 07.11.2014) Within two working days after receiving the decision of the Council on a change of the maximum selling price for a medicinal product, the marketing authorisation holder or an authorised representative thereof shall be obligated to notify, in an appropriate manner, the Bulgarian Pharmaceutical Union (BPU) and the wholesalers, and the wholesalers shall be obligated to notify the retailers of medicinal products.

Article 27. (1) An application for the deletion of a registered price for an over-the-counter medicinal product shall be submitted to the Council by the marketing authorisation holder for the medicinal product concerned or an authorised representative thereof.

(2) The following shall be attached to the application referred to in Paragraph 1:

1. information regarding the Uniform Identification Code of the corporation or cooperative in the Commercial Register or, applicable to corporations registered in a Member State of the European Union or in a State which is a Contracting Party to the Agreement on the European Economic Area, a copy of a document on current registration under the national legislation, issued by a competent authority of the relevant State to the persons referred to in Paragraph 1 not later than six months prior to the submission of the application;

2. explicit notary authorisation, in case the application is submitted by authorised representative of marketing authorisation holder; where the power or attorney has not been granted in the Republic of Bulgaria, the said power of attorney shall be presented accompanied by a translation into the Bulgarian language, executed by a translator who has concluded a contract with the Ministry of Foreign Affairs for the execution of official translations;

3. evidence regarding the representative authority of the person who has signed the power of attorney referred to in Item 2.

(3) The striking shall follow the procedure established by Articles 24 and 25, and the decisions shall be subject to appeal according to the procedure established by Article 26, paragraph 3.

(4) Upon termination, withdrawal or expiry without renewal of the marketing authorisation for a medicinal product, the registered price for the said product shall be stricken by the Council ex officio.

(5) Under the terms established by Article 55 (6) of LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, a medicinal product referred to in Paragraph 4 may be sold for a period not longer than one year at the registered price endorsed prior to the striking of the said price.

(6) (Amendment - State Gazette, no. 28 of 2021) The Bulgarian Drug Agency shall notify the Council electronically within 3 days of the entry into force of the act under para. 4, respectively from the expiry of the authorization for use.

Article 28. The Council shall keep a public register of the maximum retail selling prices for medicinal products, referred to in Article 2, paragraph 4, which shall contain the following information:

1. (amended - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) national identification number of the medicinal product;

2. (supplemented - SG 26/2019, effective 01.04.2019) international non-proprietary name /or active ingredient /ingredients;

3. registration number of the marketing authorization;

4. name of the medicinal product;

5. pharmaceutical form and quantity of the active ingredient in the final packaging;

6. name of the marketing authorisation holder;

7. name of the manufacturer of the medicinal product;

8. the maximum selling price, as registered, the number and date of issue of the decision on registration;

9. effective date of the decision of the Council;

10. additional information.

Chapter Six.

TERMS, RULES AND CRITERIA FOR INCLUSION, CHANGES AND / OR EXCLUSION OF MEDICINAL PRODUCTS FROM THE POSITIVE DRUG LIST AND TERMS AND PROCEDURE FOR REGULATION OF PRICES FOR MEDICINAL PRODUCTS REFERRED TO IN ARTICLE 2, PARAGRAPH 1. MONITORING THE EFFECTS OF MEDICINAL PRODUCT THERAPY. EVALUATION OF HEALTH TECHNOLOGIES (TITLE SUPPLEMENTED - SG No 26/2019, EFFECTIVE 01.04.2019)

Section I.

Terms, rules and criteria for inclusion of medicinal products in the Positive Drug List. Monitoring the effects of therapy (Title supplemented - SG No 26 / 2019, effective 01.04.2019)

Article 29. (1) To be included in the Positive Drug List, medicinal products must fulfil the following conditions:

1. they must be authorised for marketing according to the requirements of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE;

2. (supplemented - SG No 26/2019, effective 01.04.2019) the summary of product characteristics must specify indications for treatment, prevention or diagnosis of the diseases paid for according to the procedure established by Article 6, paragraph 2;

3. (repealed by Decision No. 13049 of 03.12.2015 - SG No. 32 of 2016, in force from 22.04.2016, new - SG No. 26 of 2019, in force from 01.04.2019 , amended - SG No. 28 of 2021) the international non-proprietary name to which the medicinal product/combination belongs (for combined medicinal products), with the exception of generic medicinal products and medicinal products that contain an active substance or active substances with well-established use in medical practice, is paid by a public health insurance fund for the same therapeutic indications in at least five of the following countries: Belgium, Greece, Denmark, Estonia, Spain, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia, Hungary, Finland, France and the Czech Republic . The international non-proprietary name to which a medicinal product intended for the treatment of rare diseases belongs is paid for by a public health insurance fund and/or with public funds for the same therapeutic indications in at least 5 of all member states;

4. the medicinal products must be in pharmaceutical form with a method and route of administration suitable for treatment of the diseases specified in Article 6, paragraph 2;

5. an evaluation has been made according to the procedure established by Article 30 .

(2) (amended - SG No 62/2016, amended - SG No 26/2019, effective 01.04.2019) PDL shall include generic medicinal products for which the stated ex-factory price under Article 8 does not exceed 70 per cent and, as concerns the medicinal products under Article 29 of the LAW ON MEDICINAL

PRODUCTS IN HUMAN MEDICINE – which does not exceed 80 percent of the ex-factory price of a medicinal product with the same international non-proprietary name, pharmaceutical form and quantity of the active ingredient in a dosage unit included in PDL, and which is considered as a reference medicinal product within the meaning of Article 28 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

(3) (amended - SG No 62/2016, supplemented - SG No 26/2019, effective 01.04.2019) The requirement of paragraph 2 shall not apply to generic medicinal products and to medicinal products under Article 29 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE for which the price under Article 261a, paragraph 1 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE of the reference medicinal product within the meaning of Article 28 THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, within one year before the expiration of the patent and/or the data protection term, has been reduced, except in the case of a decrease in accordance with Article 43.

(4) (new - SG No 92/2015) Medicinal products under Article 45, paragraphs 10, 13 and 19 of HIA for which no discounts are negotiated according to the ordinance pursuant to Article 45, paragraph 9 of HIA shall not be included in PDL.

(5) (new - SG No 26/2019, effective 01.04.2019) The medicinal products under Article 6, paragraph 2, item 3 with a new international non-proprietary name for which no preliminary framework agreement has been concluded under Article 262, paragraph 12 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE shall not be included in PDL.

(6) (new - SG No 92/2015, previous paragraph 5, amended - SG No 26/2019, effective 01.04.2019) The respective part of PDL shall include medicinal products belonging to a new international non-proprietary name for which an evaluation of health technologies has been carried out in accordance with Article 30a and for which there is at least one positive evaluation of health technologies by a public institution in Great Britain, France, Germany and Sweden.

Article 30. (1) The Positive Drug List shall include medicinal products which have been evaluated under the following criteria:

1. availability or lack of a medicinal alternative for treatment of the disease for which the medicinal product is indicated;

2. criteria of efficacy and therapeutic effectiveness:

(a) evaluation of the therapeutic benefit of the medicinal product;

(b) gain of life years;

(c) improvement of the quality of life;

(d) additional therapeutic benefits;

(e) decreased complications of the principal disease;

(f) convenience for the patient;

(g) effectiveness of the medicinal product related to the specific pharmaceutical form and route of administration;

3. criteria for safety of the medicinal products:

(a) the frequency of occurrence of adverse reactions;

(b) severity of adverse reactions;

(c) susceptibility to and behaviour upon occurrence of adverse reactions;

(d) need to apply additional preventive or therapeutic measures to avoid adverse reactions;

4. pharmaco-economic indicators:

(a) costs of therapy using the medicinal product;

(b) comparison of the costs of therapy using the available alternatives; (c) cost-benefit ratio;

(d) economic evaluation of the additional benefits;

(e) analysis of the budget impact on the basis of expected number of patients;

5. the medicinal product is for treatment of diseases of high risk to the public.

(2) In respect of a medicinal product for which a medicinal alternative for treatment of the disease for which it is indicated is available, the evaluation of the criteria covered under Paragraph 1 shall be conducted as a comparative analysis with the medicinal alternative.

(3) (new - SG No 92/2015, repealed - SG No 26/2019, effective 01.04.2019)

(4) (previous paragraph 3, SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) Where one or more medicinal products with the same international non-proprietary name, pharmaceutical form and concentration of the active ingredient have already been included in the respective part of PDL, the evaluation under Paragraph 1 shall not be conducted.

Article 30a. (new - SG No 26/2019, effective 01.04.2019) (1) Medicinal products belonging to a new international non-proprietary name for which an evaluation of health technologies has been performed shall be included in PDL. The Health Technology Evaluation shall be part of the procedure for including a medicinal product in PDL, consisting of a clinical and pharmacoeconomic evaluation and shall include:

1. analysis of the health problem;

2. comparative analysis of the therapeutic efficacy, effectiveness and safety of the medicinal product;

3. analysis of pharmaco-economic indicators;

4. analysis of the impact on the budget.

(2) The assessment of health technologies shall be performed according to the following criteria:

1. presence or absence of alternative treatment of the disease;

2. presence or absence of a medicinal alternative for the treatment of the disease;

3. efficacy and therapeutic effectiveness of the treatment - evaluation of the therapeutic benefit, prolongation of life expectancy and improvement of quality of life, reduction of complications from the underlying disease;

4. number of potential patients;

5. safety of the medicinal product - frequency and severity of adverse reactions, need for additional

preventive or therapeutic measures for prevention of adverse reactions;

6. pharmaco-economic indicators - cost of therapy with the medicinal product and comparison with

the costs of therapy with the available alternatives, cost-outcome ratio, economic evaluation of the additional benefits;

7. benefits of the health technology represented by Life Years Gained (LYG), Quality Adjusted Life Years (QALY), or in the absence of data on outputs, by providing interim ones;

8. analysis of the budget impact on the basis of the expected number of patients;

9. estimation of the expenditure of public funds for a five-year period;

10. analysis of the health perspective for the institution paying for the respective treatment with public funds or the public perspective;

11. moral and ethical considerations (for specific disease groups).

(3) The health technology evaluation shall not be carried out for generic medicinal products and for medicinal products containing active ingredient / substances with well established use in medical practice.

Article 31. (1) Medicinal products shall be included in the Positive Drug List in compliance with the following rules:

1. where the said products conform to the terms established by Article 29;

2. (supplemented - SG No 26/2019, effective 01.04.2019) an evaluation has been conducted on the basis of the criteria covered under Article 30 according to Annex 5 or a Health Technology Evaluation.

(2) Combination medicinal products shall be included in PDL where the combination ensures therapeutic advantages and/or convenience in the method of administration while the cost is equal or lower cost of an average length of a treatment course, or is proved to ensure substantial therapeutic advantages compared to the separate administration of the components of the combination, or leads to reduction of the medicinal product resistance upon treatment of infections and parasitic diseases.

(3) (new - SG No 102/2017) Combination medicinal products shall be included in PDL, where the combination does not contain any ingredient which, when administered separately, has a prescription regime without medical prescription.

Article 31a. (new - SG No 8/2017) (1) (amended - SG No 26/2019, effective 01.04.2019) The medicinal products under Article 30a for which no evidence of therapeutic efficacy has been provided and / or the cost-benefit ratio is ineffective, shall be included in the respective apendix to PDL with an obligation to monitor the effect of therapy.

(2) (New, SG No 26/2019, effective 01.04.2019) The Council may ex officio establish an obligation to also monitor the effect of therapy for medicinal products already included in PDL, where:

1. the medicinal product is a comparative alternative to a medicinal product under paragraph 1;

2. a need has arisen for the respective paying institution to carry out an analysis of the effective and appropriate spending of public funds for a medicinal product.

(3) (Previous para. 2 - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) Monitoring the effect of the therapy of medicinal products under para. 1 is carried out for a period until the

initial maintenance of the reimbursement status of the medicinal product in accordance with the order of chapter six "a".

(4) (new - SG 26/2019, effective 01.04.2019) Monitoring the effect of the therapy with the medicinal products under paragraph 2 shall be performed for a period of 1 to 3 years, depending on the therapeutic regimen (duration of the therapeutic course of treatment) for the respective medicinal product or the duration of follow-up of the medicinal product with which it is compared.

(5) (previous paragraph 3, amended - SG No 26/2019, effective 01.04.2019) (Previous para. 3, amended - SG No. 26 of 2019, in force from 01.04.2019) When including the medicinal products under para. 1 The Council also determines the conditions and criteria for monitoring the effect of therapy with them, as well as the estimated number of patients for the period under para. 3

(6) (new - SG No 26/2019, effective 01.04.2019) In the cases under paragraph 2, the Council shall also set out both terms and criteria for monitoring the effect of the drug therapy.

(7) (new - SG No 26/2019, effective 01.04.2019) In respect of the need arising under paragraph 2, item 2, the respective paying institution shall notify the Council in writing thereof, indicating the specific circumstances that led to it.

Article 31b. (new - SG No 8/2017, amended - SG No 26/2019, effective 01.04.2019) (1) Monitoring the effect of the therapy with the medicinal products under Article 31a, paragraphs 1 and 2 shall be carried out by medical-treatment establishments for hospital care and medical-treatment establishments under Article 5, paragraph 1, Article 10, items 3, 3a, 3b and 6 of the Medical Institutions Act, which have established structures on the disease profile.

(2) The Council shall notify the medical-treatment establishments under paragraph 1 about the medicinal products for which monitoring the effect of the therapy has been determined.

(3) Within one month from entry into force of a decision to monitor the effect of the therapy, the medical-treatment establishments under paragraph 1 shall ensure the compatibility of their hospital information system with the Council information system.

(4) In the course of monitoring the effect of the therapy the medical-treatment establishments under paragraph 1 collect the information for each specific medicinal product and provide it daily to the Council by transfer from the hospital information system.

(5) (Amended - SG No. 28 of 2021) The Council collects, stores and analyzes the information under para. 4..

(6) (Amended - SG No. 28 of 2021) The Council annually provides the analyzed information under para. 5 of the NHIF/MOH for the purposes of efficient and appropriate spending of public funds. Based on the analysis, the NHIF/MOH can make proposals under Art. 32, para. 2 and 3.

(7) (Repealed - SG No. 28 of 2021)

(8) (Repealed - SG No. 28 of 2021)

Section II.

Procedure for inclusion, change and / or exclusion of medicinal products in the Positive Drug List and terms and procedure for regulating the prices of medicinal products under Article 2, paragraph 1. Assessment of health technologies (Title supplemented - SG No 26/2019, effective 01.04.2019)

Article 32. (1) (amended and supplemented - SG No 92/2014, effective 07.11.2014, supplemented - SG No 26/2019, effective 01.04.2019) For inclusion, changes and/or exclusion of a medicinal product in PDL, as wel as for the evaluation of health technologies for medicinal products already included in PDL, the marketing authorisation holder for the medicinal product concerned or an authorised representative thereof shall submit an application to the Council, completed in a form endorsed by the Council.

(2) NHIF and MoH may make reasoned written proposals to the Council for exclusion, for change of the indications, for change related to the procedure for reimbursement, for change in the manner of formation of the reference value or the level of reimbursement, with which a medicinal product under an INN has been included in PDL.

(3) (new - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) MoH and NHIF may reasonably initiate before the Council an evaluation of the health technologies for medicinal products included in PDL for which they pay, in the following cases:

1. to ensure predictability, sustainability and rational spending of the budget of the respective institutions;
2. to optimize the treatment of patients for diseases for which the respective institutions pay.

(4) (new - SG No 26/2019, effective 01.04.2019) An evaluation of health technologies in accordance with Article 30a shall be carried out for medicinal products included in PDL for which an extension of therapeutic indications has been requested and which have not been paid for so far.

(5) (new - SG No 26/2019, effective 01.04.2019) The evaluation of health technologies for medicinal products under paragraph 1 and 3, which have already been included in PDL, shall be carried out in accordance with Article 30a, paragraph 1. The Health Technology Evaluation shall contain a clinical and a pharmaco-economic part.

Article 33. (1) In their application for inclusion of a medicinal product in PDL, the holder of the marketing authorization or the authorized representative thereof shall also request formation of a price under Article 2, paragraph 1, specifying the price by elements in accordance with the rules laid down in Article 8.

(2) (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) A declaration-reference conforming to a model approved by the Council regarding the ex-factory prices in the respective currency and in Euro - in the countries referred to in Article 8, paragraph 1, item 1, as well as the circumstances under Article 8, shall be attached to the application under paragraph 1.

(3) (amended - SG No 26/2019, effective 01.04.2019) Ex-factory prices in the declaration under paragraph 2 must refer to the month of submitting the application.

Article 34. (amended - SG No 92/2014, effective 07.11.2014) (1) (amended - SG No 26/2019, effective 01.04.2019) For medicinal product which has been authorised for parallel import or parallel distribution by the European Medicines Agency, if the same or similar medicinal product pursuant to Article 214 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE is included in the Positive Drug List is available at a price endorsed by the Council pursuant to Article 2, paragraph 1, the same or lower price shall be charged, formed in accordance with the amount of active ingredient in a dose unit and included within the same annexes of PDL upon submission of an application by the holder of authorisation/notification for parallel import/parallel distribution in a form endorsed by the Council

(2) (amended - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) The authorization / notification for parallel import / parallel distribution and the documents under Article 35, paragraph 1, items 2, 3, 6 and 9 and paragraph 4 shall be attached to the application under paragraph 1.

(3) The declared price of the medicinal product under paragraph 1 may not be higher than the price approved by the Council under Article 2, paragraph 1 for the identical or similar medicinal product under Article 214 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

(4) (amended - SG No 92/2015, supplemented - SG No 26/2019, effective 01.04.2019) For the medicinal products under paragraph 1, the Council shall make a pronouncement within 30 days of the receipt of the application, applying the provisions of Article 35, paragraph 5 and Articles 37, 38 and 40.

(5) (New - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) The Council ex officio reduces the maximum price of a medicinal product that has received authorization for parallel import or permission for parallel distribution by the European Medicines Agency, in case of formation of a lower or reduction of the marginal price of the same or similar medicinal product under Art. 214 of the Law on Medicinal Products in Human Medicine, including in cases of change pursuant to Art. 43. The Council shall notify the holder of a parallel import permit or a parallel distribution permit of the initiation of administrative proceedings.

Article 35. (1) The following shall be attached to the application referred to in Article 32, paragraph 1:

1. a copy of a marketing authorisation for the medicinal product where the marketing authorisation has been issued according to the procedure established by Regulation (EC) No 726/2004, Annex I Summary of product characteristics, Annex II Marketing authorisation holder responsible for batch release. Conditions of the marketing authorisation and Annex III Particulars to appear on the outer packaging and text of the package leaflet; the annexes shall be presented on an electronic data medium;

2. (amended — SG No 92 of 2015) information regarding the Uniform Identification Code of the corporation or cooperative in the Commercial Register or, applicable to corporations registered in a Member State of the European Union or in a State which is a Contracting Party to the Agreement on the European Economic Area, a copy of a document on current registration under the national legislation, issued by a competent authority of the relevant State to the persons referred to in Article 32, paragraph 1 not later than six months prior to the submission of the application;

3. Explicit notary authorisation, in case the application is submitted by authorised representative of marketing authorisation holder; where the power or attorney has not been granted in the Republic of Bulgaria, the said power of attorney shall be presented accompanied by a translation into the Bulgarian

language, executed by a translator who has concluded a contract with the Ministry of Foreign Affairs for the execution of official translations;

4. (repealed - SG No 62/2016, new - SG No 26/2019, effective 01.04.2019) a statement of the circumstances under Article 29, paragraph 1, item 3 in the form approved by the Council;

5. data on clinical trials and pharmacological tests of the medicinal product conducted in the Republic of Bulgaria or abroad according to the rules of Good Clinical Practice;

6. declaration to the effect that the necessary quantities of the medicinal product will be procured depending on the specific demand in the country;

7. (amended - SG 26/2019, effective 01.04.2019) An evaluation / evaluations of the health technology by a state institution in Great Britain, France, Germany and Sweden (an evaluation of the health technology carried out by a state institution in each of the listed countries, if any, shall be presented);

8. (repealed - SG No. 26 of 2019, in force from 01.04.2019)

9. (amended - SG No. 28 of 2021) document for paid state tax;

10. pharmacoeconomic analysis, prepared for or adapted to the country, accompanied by a comparative analysis, provided a medicinal alternative is available for treatment of the disease;

11. (new - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) a copy of a contract concluded with NHIF for granting a discount for the medicinal products under Article 45, paragraph 10, 13 and 21 of HIA, certified by the holder of the marketing authorization or the authorized representative thereof;

12. (new - SG No 26/2019, effective 01.04.2019) a copy of a framework agreement with the Ministry of Health under Article 262, paragraph 12 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, certified by the holder of the marketing authorization or by the authorized representative thereof.

(2) (amended - SG No 26/2019, effective 01.04.2019) The documents under paragraph 1, items 5 and 10 shall apply only to medicinal products belonging to the international non-proprietary name, pharmaceutical form and concentration of the active ingredient not included in the relevant part of PDL.

(3) (new - SG No 92/2015, amended - SG 26/2019, effective 01.04.2019) For medicinal products belonging to a new international non-proprietary name that is not included in the relevant part of PDL, a health technology evaluation report shall be presented in accordance with the guidance given in Annex 6. The data in the analysis must be up-to-date within one month prior to the date of submission of the application. The analysis shall be submitted on paper and electronically.

(4) (previous paragraph 3 — SG No 92 of 2015) To authenticate the data stated in the application and in the accompanying documents under Paragraph 1, the marketing authorisation holder or the authorised representative thereof shall present a declaration completed in a standard form endorsed by the Council.

(5) (previous paragraph 4, SG No 92/2015, supplemented - SG No 26/2019, effective 01.04.2019) The Council may reasonably request additional information from the applicant, necessary for making a decision to include, change and/or exclude a medicinal product from PDL, as well as to form a price under Article 2, paragraph 1, and when making an assessment of health technologies.

(6) (previous paragraph 5, SG No 92/2015, supplemented - SG No 26/2019, effective 01.04.2019) In the event of a change to a medicinal product included in PDL, the documents related to the change shall be attached. When extending the therapeutic indications of a medicinal product not previously paid for in the relevant part of PDL, an analysis shall be prepared to evaluate the health technology in accordance with

guidance in accordance with Annex 6. The data in the analysis must be up-to-date within one month prior to the date of submission of the application. The analysis shall be submitted on paper and electronically.

(7) (new - SG No 26/2019, effective 01.04.2019) Where the holder of the marketing authorization has requested an evaluation of health technologies for a medicinal product, the documents under paragraph 1, items 1 – 3 and item 9 and an analysis under paragraph 3 shall be attached.

(8) (new - SG No 26/2019, effective 01.04.2019) When evaluating the health technologies in the cases under Article 32, paragraph 3, the Marketing Authorization Holder shall be obliged to supply the Council with the necessary information requested by the Council.

Article 35a. (New - SG No. 92 of 2015 (*), amended - SG No. 26 of 2019, in force from 01.04.2019) (Amended - SG No. 28 from 2021) When expanding the therapeutic indications of a medicinal product, for which up to now it has not been paid for in the relevant application of the PDS, an obligation to monitor the effect of the therapy of the medicinal product is added for these indications as well, if no evidence of therapeutic effectiveness and/or the cost-outcome ratio is cost-ineffective

(2) The Council may ex officio impose an obligation to monitor the effect of the therapy and the therapeutic indications for medicinal products already included in PDL, in cases where:

1. the medicinal product is a comparative alternative to an indication under paragraph 1;
2. a need has arisen for the institution concerned to carry out an analysis of the effective and appropriate spending of public funds for a medicinal product.

(3) (Amendment - SG, No. 28 of 2021) The monitoring of the effect of the therapy for therapeutic indications of the medicinal products under para. 1 is carried out for the period under Art. 31a, para. 3 and Art. 57a, para. 4. The monitoring of the effect of the therapy for the therapeutic indications of the medicinal products under para. 2 is carried out for a period of 1 to 3 years depending on the therapeutic scheme (the duration of the therapeutic course of treatment) of the relevant medicinal product or for the period of follow-up of a medicinal product with which it is compared.

(4) In cases of extension of the therapeutic indications for medicinal products under paragraph 1 and 2, the Council shall define both the conditions and the criteria for monitoring the effect of the therapy.

(5) The concerned paying institution shall notify the Council in writing of the need arising under paragraph 2, item 2, indicating the specific circumstances that led to it.

(6) Monitoring the effect of the therapy on the therapeutic indications for the medicinal products under paragraph 1 and 2 shall be carried out by medical-treatment establishments for hospital care and medical-treatment establishments under Article 5, paragraph 1 and Article 10, items 3, 3a, 3b and 6 of the Medical Institutions Act which have established structures on the disease profile.

(7) The Council shall notify the medical-treatment establishments under paragraph 6 of the medicinal products for which monitoring the effect of treatment has been determined.

(8) Within one month from the entry into force of a decision to monitor the effect of a therapy, the medical-treatment establishments under paragraph 6 must ensure compatibility of their hospital information system with the Council’s information system.

(9) In the course of monitoring the effect of the therapy the medical-treatment establishments under paragraph 6 shall collect information on each individual medicinal product and made available the information on a daily basis to the Council by transfer from the hospital information system.

10) (Amended - SG No. 28 of 2021) The Council collects, stores and analyzes the information under para. 9.

(11) (Amended - SG No. 28 of 2021) The Council annually provides the analyzed information under para. 10 of the NHIF/MOH for the purposes of efficient and appropriate spending of public funds. Based on the analysis, the NHIF/MOH can make proposals under Art. 32, para. 2 and 3.

(12) (Repealed - SG No. 28 of 2021)

(13) (Repealed - SG No. 28 of 2021)

Article 36. (1) Medicinal products shall be excluded from the Positive Drug List for which:

1. a change has occurred in the criteria on the basis of which the medicinal product has been included in PDL;

2. suspected unexpected serious adverse drug reactions and unfavourable changes in the safety of the

medicinal product have been established;

3. new data have been presented regarding the comparative pharmacoeconomic justification of the use of the said products;

4. the disease is no longer paid for by public funds;

5. a request has been submitted by the marketing authorisation holder or by the authorised representative thereof;

6. a written notification has been submitted to the Bulgarian Drug Agency on discontinuation of the sales of the medicinal product according to Article 54, paragraph 2 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINEfor a period longer than sixty days;

7. a written notification has been submitted by the Bulgarian Drug Agency to the effect that the medicinal product has not been placed on the market for more than thirty days after the date stated in the notification referred to in Article 54, paragraph 1 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE;

8. a written notification has been submitted to the effect that the marketing authorisation for the medicinal product has been terminated prior to the expiry thereof according to the procedure established by Article 55, paragraph 3 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE;

9. a reasoned proposal has been submitted under Article 32, paragraph 2;

10. an application according to the procedure established by the ordinance referred to in Article 45, paragraph 9 of the Health Insurance Act has not been submitted within one month after the inclusion of the medicinal product in PDL;

11. (new - SG No 92/2015, repealed - SG No 26/2019, effective 01.04.2019)

12. (new - SG No 92/2015 (*), repealed - SG No 26/2019, effective 01.04.2019)

13. (new - SG No 92/2015 (*), repealed - SG No 26/2019, effective 01.04.2019)

14. (new - SG No 92/2015) in the procedure under Chapter Six "a" no positive evaluation when they are included shall be proven;

15. (new - SG No 92/2015) no application has been submitted for maintaining the reimbursement status under Article 57b;

16. (new - SG No 92/2015) the procedure under Chapter Six "a" has been terminated;

17. (previous item 11 - SG No 92/2015) the conditions under Article 264, paragraph 7 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE

have been fulfilled.

(2) (amended - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) In the case under paragraph 1, item 10, the medicinal product shall be excluded only from PDL under Article 6, paragraph 2, item 1.

Article 37. (1) (supplemented - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) Within sixty days after the date of submission of the application referred to in Article 32, paragraph 1, the Council shall consider the application and the documents attached thereto and shall adopt a decision, thereby endorsing a price for a medicinal product referred to in Article 2, paragraph 1 and including the said product in PDL, or refusing to endorse a price for a medicinal product referred to in Article 2, paragraph 1, and to include the said product in PDL. In the cases referred to in Article 30a, the Council shall pronounce within 180 days.

(2) (amended - SG No 92/2015) In the cases under Article 30, paragraph 4, the Council shall pronounce within 30 days.

(3) (supplemented - SG No 26/2019, effective 01.04.2019) Within thirty days after receiving an

application for a change or exclusion of a medicinal product included in PDL, the Council shall consider the application and shall pronounce thereon, notifying the applicant of the decision thereof. When extending the therapeutic indications for a medicinal product not yet paid for in the relevant part of PDL, the Council shall pronouns within 90 days.

(4) Upon the exclusion of a medicinal product from all annexes to PDL, the price of the said product, referred to in Article 2, paragraph 1, shall be stricken as well.

(5) Upon the exclusion of a medicinal product in pursuance of Item 5 of Article 36, paragraph 1 from all annexes to PDL, the marketing authorisation holder or an authorised representative thereof may apply for the entry of the price referred to in Article 2, paragraph 1 as a ceiling price in the register referred to in Article 22. The entry of the ceiling price in the register referred to in Article 22 shall be affected by decision of the Council.

(6) Upon striking of the price for a medicinal product under paragraph 4 in the cases of exclusion of the said product from PDL in pursuance of Items 4 and 9 of Article 36, paragraph 1 the price for the medicinal product, referred to in Article 2, paragraph 2, shall be valid for a period of two months solely provided the marketing authorisation holder submits a written application to the Council within the time limit for appeal of the decision.

(7) (new — SG No 92 of 2014, effective as from 07.11.2014) Under the terms established by Article 55, paragraph 6 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, a medicinal product referred to in Item 8 of Article, 36, paragraph 1 may be sold for a period not longer than one year at the ceiling price endorsed prior to the striking of the said price.

(8) (previous paragraph 7 — SG No 92/2014, effective 07.11.2014) Where, upon consideration of the applications referred to in paragraphs 1, 2 and 3, the Council ascertains any non-conformities or deficiencies in the documents presented, the Council shall have the right to require from the applicant to cure the deficiencies and non- conformities in the documents, as well as to present additional information, and

shall notify the applicant according to the procedure established by the Administrative Procedure Code. In such case, the time limits referred to in Paragraphs 1, 2 and 3 shall cease to run.

(9) (previous paragraph 8 — SG No 92/2014, effective as from 07.11.2014) In case the applicant fails to cure the non-conformities and deficiencies ascertained by the Council within thirty days reckoned from the date of notification under Paragraph 8, the procedure shall be terminated.

(10) (amended — SG No 92/2014, effective 07.11.2014) The Council shall notify the applicant in writing of the termination of the procedure under Paragraph 9.

Article 37a. (new - SG No 26/2019, effective 01.04.2019) Within 90 days, the Council shall evaluate the health technologies for a medicinal product and adopt a report by a decision.

Article 38. (1) (amended - SG No 26/2019, effective 01.04.2019) A legal, medical, pharmacoeconomic and economic evaluation of each application received shall be prepared by experts of the specialised administration of the Council.

(2) (amended and supplemented - SG No 92/2014, effective 07.11.2014, amended and supplemented - SG No 26/2019, effective 01.04.2019) The experts shall carry out a preliminary examination of the applications and the accompanying documentats and shall prepare opinions on the applications in accordance with a model approved by the Council. A legal evaluation shall be conducted first, which shall then be followed by a medical, pharmaco-economic and economic evaluation.

(3) (supplemented - SG No 26/2019, effective 01.04.2019) The activity of the Council shall be assisted by external experts outside the administration, who have attained higher education in Medicine, Pharmacy and Economics, designated by the Council.

(4) On a particular application for a medicinal product, the experts referred to in Paragraph 3 must not participate in activities related to the development, manufacture, marketing, wholesale and retail of the said product, on which the said expert shall sign a declaration completed in a standard form endorsed by the chairperson of the Council.

(5) (amended - SG No 26/2019, effective 01.04.2019) Where necessary, the chairperson of the Council shall designate an expert under paragraph 3 to conduct a medical / pharmacoeconomic evaluation and deliver an opinion.

(6) (New - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) When assessing health technologies, the chairman of the Council shall determine by order a group to prepare a clinical and pharmaco-economic assessment for the assessed medicinal product according to a model approved by the Council, and an assessment of criteria under Art. 30 according to Annex No. 5 . The working group includes one representative each of the NHIF and the Ministry of Health, experts under para. 3 in the specialty "Medicine" and may include experts under para. 3 in the specialties "Pharmacy" and "Economics".

(7) (new - SG No 26/2019, effective 01.04.2019) The chairman of the working group under paragraph 6 shall take part in the Council’s meeting where the relevant procedure for the medicinal product being evaluated is discussed.

(8) (amended - SG No 102/2017, previous paragraph 6, supplemented - SG No 26/2019, effective 01.04.2019) On applications for inclusion, exclusion , change of indications or name, as well as when imposing an obligation to monitor the effect of the therapy of medicinal products in PDL under Article 262,

paragraph 6, items 1 and 2 – as concerns medicines used in the treatment of malignancies, paid for in the hospital medical care system in addition to the value of the medical services provided, and under item 3 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, the Council shall require an opinion from NHIF/MoH. Any such opinion shall be provided within ten days after being requested.

(9) (repealed - SG No 92/2015, new - SG No 8/2017, previous paragraph 7, amended - SG No 26/2019, effective 04/01/2019) In their opinion on the medicinal products under Article 31a and on changing the therapeutic indications under Article 35a, NHIF/MoH must specify the medical institutions in which the effect of the therapy will be monitored, the conditions and criteria for monitoring the effect of the therapy therewith, as well as the estimated number of patients.

(10) (amended and supplemented, SG No 92/2014, effective 07.11.2014, previous paragraph 8, amended and supplemented - SG No 26/2019, effective 01.04.2019) The member of the Council, designated by the Chairperson as a rapporteur, shall summarise the expert opinions, the clinical and pharmacoeconomic evaluation, as well as the opinion under paragraph 8 and 9, and shall prepare an expert report in a standard form endorsed by the Council within seven days after receiving the opinions on each application.

(11) (amended - SG No 102/2017, previous paragraph 9, supplemented - SG No 26/2019, effective 01.04.2019) On applications for inclusion, exclusion, change of indications or name, as well as when imposing an obligation to monitor the effect of the therapy of medicinal products in PDL under Article 262, paragraph 6, items 1 and 2 – as concerns medicines used in the treatment of malignancies, paid for in the hospital medical care system in addition to the value of medical services provided by THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, a representative of NHIF shall obligatorily take part in the Council's meeting while presenting the opinion given by NHIF on each application.

(12) (amended - SG No 102/2017, previous paragraph 10, supplemented - SG No 26/2019, effective 01.04.2019) When considering applications for inclusion, exclusion, change of indications or name, as well as when imposing an obligation to monitor the effect of the therapy of medicinal products in PDL under Article 262, paragraph 6, item 3 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, a representative of MoH/NHIF shall obligatorily take part in the Council's meeting while presenting the opinion given by MoH/NHIF on each application.

(13) (new - SG No 26/2019, effective 01.04.2019) A representative / representatives of NHIF, MoH and BDA shall be obliged to attend the meetings of the Council in cases where an evaluation of health technologies is being performed.

Article 38a. (new - SG No 26/2019, effective 01.04.2019) (1) In connection with their obligation under Article 38, paragraph 8, the director of NHIF may set up a Committee to assist them in drafting an opinion. The rules governing the work of the Committee shall be endorsed by the director of NHIF.

(2) External experts may be recruited to assist the work of the Committee.

(3) The members of the Committee under paragraph 1, as well as the persons under paragraph 2 may not be involved in activities related to development, production, marketing, wholesale and retail trade for the respective medicinal product.

(4) The members of the Committee under paragraph 1, as well as the persons under paragraph 2 shall be obliged not to disclose any facts and circumstances, which became known to them in the course of, or in connection with, the fulfillment of their obligations under this Ordinance.

Article 39. (1) The external experts referred to in Article 38, paragraph 3 shall receive remuneration for the work thereof at the Council.

(2) The specific amount of the remuneration shall be determined by the Council.

(3) The financial resources for the operation of the Council shall be provided according to Article 258, paragraph 2 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

Article 40. (1) Upon refusal to include, to change or to exclude a medicinal product from PDL, the Council shall reason the decision thereof in accordance with the criteria, terms and rules established in the Ordinance, notifying the applicant according to the procedure established by the Administrative Procedure Code.

(2) Upon refusal to include a medicinal product in PDL, the Council shall likewise refuse to endorse a price under Article 2, paragraph 1.

(3) (Amended - SG No. 92 of 2015, amended - SG No. 28 of 2021) The decisions of the Council under para. 1 and 2 are subject to appeal:

1. administratively before the Transparency Commission;

2. before the relevant court in accordance with the Code of Administrative Procedure.

(4) (new - SG No 26/2019, effective 01.04.2019) The Council shall officially notify MoH/NHIF of the provisionally enforceable decisions within 3 days of their issuance.

Article 41. (1) The marketing authorisation holder or an authorised representative thereof may apply for reasoned changes in the endorsed price for a medicinal product referred to in Article 2, paragraph 1 not earlier than twelve months after the endorsement of the last price.

(2) The time limit referred to in paragraph 1 shall not apply to the cases in which the marketing authorisation holder submits an application for reduction of the endorsed price for a medicinal product referred to in Article 2, paragraph 1.

(3) (Amendment - State Gazette, no. 26 of 2019, in force from 01.04.2019, amended. - State Gazette, no. 28 of 2021) Increase in the established price of a medicinal product under Art. 2, para. 1 can be claimed up to the amount of the lowest price determined in accordance with Art. 8, and in the absence of such, with the percentage of statistically reported inflation for the period of effect from the last formed price

(4) (Amended and supplemented, SG No 92/2014, effective 07.11.2014) Within two working days after receiving the decision of the Council on a change of a price for a medicinal product referred to in Article 2, paragraph 1, the marketing authorisation holder or an authorised representative thereof shall be obligated to notify, in an appropriate manner, the Bulgarian Pharmaceutical Union (BPU) and wholesalers, and wholesalers shall be obligated to notify the retailers of the medicinal products.

Article 42. Within the limits of the endorsed price for medicinal products referred to in Article 2, paragraph 1, the pricing of the wholesaler and of the retailer shall be implemented as follows:

1. the retailer shall sell at a price not higher than the price as endorsed;

2. (amended - SG No 26/2019, effective 01.04.2019) the wholesaler shall sell medicinal products at a price, the amount of which cannot be higher than the amount of the notified price for the respective medicinal product less the value of the retailer's mark-up.

Article 43. (1) (amended - SG No 66/2014, effective 08.08.2014, amended - SG No 92/2014, effective 07.11.2014, supplemented - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) In the absence of change of the prices indicated in the declaration-information under Article 33, paragraph 2, on the basis of which a price has been established under Article 2, paragraph 1, for a medicinal product included in PDL, except for medicinal products authorised for use under Article 11 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, the marketing authorisation holder or an authorised representative thereof shall submit a declaration according to a form endorsed by the Council certifying these circumstances every 24 months from the date of approval of the last price.

(2) (New - SG No. 66 of 2014, in force from 08.08.2014, amended - SG No. 92 of 2014, in force from 07.11.2014, supplement - SG, no. 92 of 2015, amended - SG No. 26 of 2019, in force from 01.04.2019, supplemented - SG No. 28 of 2021) In case of lack of change of the prices indicated in the declaration-reference under Art. 33, para. 2, on the basis of which the price under Art. 2, para. 1 of a medicinal product for which the reference value is calculated by grouping in which medicinal products of other marketing authorization holders included in the PDL do not participate, with the exception of medicinal products authorized for use in accordance with Art. 11 and those under para. 3 THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, the marketing authorisation holder or an authorised representative submits every six months from the date of approval of the last price a declaration on a form approved by the Council certifying these circumstances. The declaration is submitted in the month in which the six-month period expires.

(3) (New - SG No. 28 of 2021) For a medicinal product included in a medicinal product containing an active substance/substances with well-established use in medical practice, for the treatment of diseases for which there is no medicinal alternative or the existing alternatives are with a higher value under Art. 55 and for which the reference value is calculated by grouping, in which medicinal products of other marketing authorization holders do not participate, the marketing authorization holder or his authorized representative shall submit every twenty-four months from the date of approval of the last price submit a declaration to a form endorsed by the Council, certifying these circumstances. The declaration is submitted in the month in which the twenty-four month period expires.

(4) (Previous para. 2, amended - State Gazette, no. 66 of 2014, in force from 08.08.2014, add. - State Gazette, no. 92 of 2014, in force from 07.11.2014, add. - State Gazette, no. 92 of 2015, amended - State Gazette, no. 62 of 2016, amended - State Gazette, no. 102 of 2017, amended - State Gazette, no. 26 of 2019, in force from 01.04.2019, previous para. 3, add. - State Gazette, no. 28 of 2021) In case of a change in the prices of a medicinal product under para. 1 and 3, specified in the declaration-reference under Art. 33, para. 2, where the price per producer under Art. 8 is lower compared to the manufacturer's price, on the basis of which the price of the medicinal product was formed, with the exception of medicinal products authorized for use

pursuant to Art. 11 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, the MAH or his authorized representative annually, no later than twenty-four months after the date of approval of the last price of a medicinal product, submits to the Council an application for change to the established price. The application shall be submitted in the month in which the twenty-four month period expires

(5) (New - SG No. 66 of 2014, in force from 08.08.2014, supplement - SG No. 92 of 2014, in force from 07.11.2014, supplement - SG, no. 92 of 2015, amended - SG No. 62 of 2016, amended - SG No. 102 of 2017, amended - SG No. 26 of 2019, in force from 01.04 .2019, previous paragraph 4 - SG No. 28 of 2021) In case of a change in the prices of a medicinal product under para. 2, specified in the declaration-reference under Art. 33, para. 2, where the price per producer under Art. 8 is lower compared to the manufacturer's price, on the basis of which the price of the medicinal product was formed, with the exception of medicinal products authorized for use pursuant to Art. 11 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, the MAH or his authorized representative every six months from the date of approval of the last price of a medicinal product submits to the Council an application to change the approved price. The application is submitted in the month in which the six-month period expires.

(6) (Previous paragraph 3, amended and supplemented - SG No. 66 of 2014, in force from 08.08.2014, amended - SG No. 62 of 2016, previous paragraph 5, amended - SG No. 28 of 2021) If the marketing authorization holder or his authorized representative does not submit a declaration under para. 1 - 3 or an application under para. 4 and 5 and after inspection by experts from the specialized administration of the Council, it was established that the price per producer under Art. 8 is lower compared to the manufacturer's price, on the basis of which the price of the medicinal product was formed under Art. 2, para. 1, the Council ex officio makes a decision to change the established price of a medicinal product.

(7) (Previous paragraph 4, amended - SG No. 66 of 2014, in force from 08.08.2014, amended - SG No. 92 of 2014, in force from 07.11.2014 year, previous paragraph 6, amended - SG No. 28 of 2021) The inspection under paragraph 6 shall be carried out by the 20th of the month following the month in which the deadline for submitting a declaration or application has expired.

(8) (Previous para. 5, add. - SG No. 66 of 2014, in force from 08.08.2014, amended - SG No. 62 of 2016, previous para. 7, amend. - SG , No. 28 of 2021) When checking the submitted declarations under para. 1 - 3 the specialized administration of the Council established that the price per producer under Art. 8 is lower compared to the manufacturer's price, on the basis of which the price of a medicinal product was formed under Art. 2, para. 1, the Council notifies the holder of a use permit or his authorized representative to submit an application for a change within 14 days of the notification and of the discovered prices.

(9) (Previous para. 6, amended - SG No. 66 of 2014, in force from 08.08.2014, previous para. 8, amended - SG No. 28 of 2021) When in the term of para. 8, the applicant does not submit an application, the Council ex officio makes a decision to change the established price of a medicinal product.

(10) (Previous para. 7, amended - SG No. 66 of 2014, in force from 08.08.2014, previous para. 9, amended - SG No. 28 of 2021) When the applicant submits an application within the terms under para. 4, 5 and 8, which does not meet the requirements of Art. 33 and 35, related to the price change, the Council has the right to demand from the applicant within 14 days to remove the incompleteness and deficiencies in the documentation, as well as additional information necessary for the price change of the medicinal product.

(11) (Previous para. 8, amended - SG No. 66 of 2014, in force from 08.08.2014, previous para. 10, amended - SG No. 28 of 2021) When the applicant does not remove the incompleteness and deficiencies in the documentation, as well as if he does not provide the additional information necessary for the change in the

price of the medicinal product within the period under para. 10, the Council ex officio decides to change the established price of a medicinal product.

(12) (Previous para. 9, amended - SG No. 66 of 2014, in force from 08.08.2014, previous para. 11, amended - SG No. 28 of 2021) The decisions according to para. 6, 9 and 11 are subject to appeal pursuant to Art. 40, para. 3.

Article 43a. (New - SG No. 28 of 2021) The Chairman of the Council approves by order a list of medicinal products under Art. 43, para. 3, which is published on the Council's website. The list is updated and published on the 2nd of the month following the one in which changes occurred.

Article 44. (1) (Amend. - SG No. 28 of 2021) The National Health Insurance Fund provides the Council with complete information on the paid-for medicinal products included in the PLS under Art. 6, para. 2.

(2) (Amendment - State Gazette, no. 26 of 2019, in force from 01.04.2019, amended. - State Gazette, no. 28 of 2021) The information under para. 1 is provided to the Council monthly in an electronic medium according to a form approved by the Council. The Board may request additional information as necessary.

(3) (supplemented - SG 26/2019, effective 01.04.2019) The Ministry of Health shall provide to the Council information on the paid for medicinal products included in PDL under Article 6, paragraph 2, item 3 every three months.

(4) The medical-treatment establishments covered under Article 5 of the Medical-Treatment Establishments Act and the medical-treatment establishments w the State and/or a municipality holds a participating interest under Articles 9 and 10 of the Medical-Treatment Facilities Act shall provide to the Council full information on the reimbursed medicinal products included in PDL under Item 2 of Article 6, paragraph 2.

(5) Where necessary, the Council may request additional information from MoH, NHIF and the medical-treatment facilities.

(6) The information provided under Paragraphs 1, 3 and 4 shall be used for the preparation and updating of PDL.

(7) The information referred to in Paragraphs 3 and 4 shall be provided to the Council at the end of each quarter or upon request on an electronic data medium in a standard form endorsed by the Council.

Section III.
Rules on determination of the reference value and the level of reimbursement for medicinal products included in the Positive Drug List

Article 45. (1) (supplemented - SG No 26/2019, effective 01.04.2019) In order to determine the value of reimbursement for the medicinal products included in PDL, a reference value shall be calculated for a DDD or a therapeutic course, or concentration, or volume according to INN and pharmaceutical form.

(2) The reference value referred to in paragraph 1 shall be calculated as follows:

1. the medicinal products containing one and the same active ingredient according to INN shall be grouped according to pharmaceutical form;

2. (supplemented - SG No 26/2019, effective 01.04.2019) the value of the DDD or therapeutic course, or concentration, or volume shall be calculated for the different medicinal products according to INN and pharmaceutical form and the lowest value shall be determined;

3. the lowest value as determined under Item 2 shall be a reference value for all medicinal products with one and the same INN and one and the same pharmaceutical form.

3. (supplemented, SG No 26/2019, effective 01.04.2019) The reference value for a DDD or therapeutic course, or concentration, or volume of medicinal products containing more than one medicinal substance shall be formed on the basis of the lowest values of the DDD or therapeutic course, or concentration, or volume separately for the respective constituent active ingredients contained in the medicinal products of a single medicinal substance, calculated according to the procedure established by paragraph 2.

4. (supplemented - SG No 26/2019, effective 01.04.2019) For a DDD of a medicinal product which contains more than three active ingredients, one dosage unit shall be taken and the reference value shall be calculated according to the procedure established by paragraph 2.

Article 46. (1) (amended - SG No 92/2014, effective 07.11.2014, supplemented - SG No 26/2019, effective 01.04.2019) In order to determine the value of reimbursement of the medicinal products included in PDL under Item 2 of Article 6, paragraph 2, a reference value shall be calculated for a DDD or therapeutic course, or concentration, or volume according to INN, pharmaceutical form and concentration in a unit of volume.

(2) The reference value under paragraph 1 shall be calculated as follows:

1. (amended - SG No 92/2014, effective 07.11.2014) the medicinal products containing one and the same active ingredient according to INN shall be grouped according to pharmaceutical form, strength and volume;

2. (amended - SG No 92/2014, effective 07.11.2014, supplemented - SG No 26/2019, effective 01.04.2019) the value of the DDD or therapeutic course, or concentration, or volume shall be calculated for the different medicinal products according to INN, pharmaceutical form and concentration in a unit of volume and the lowest value shall be determined

3. (amended - SG No 92/2014, effective 07.11.2014) the lowest value as determined under Item 2 shall be a reference value for all medicinal products with one and the same INN, one and the same pharmaceutical form, strength and volume.

(3) (amended - SG No 92/2014, effective 07.11.2014, supplemented - SG No 26/2019, effective 01.04.2019) The reference value for a DDD or therapeutic course, or concentration, or volume of medicinal products containing more than one medicinal substance shall be formed on the basis of the lowest values of the DDD or therapeutic course, or concentration, or volume separately for the respective constituent active ingredients contained in the medicinal products of a single medicinal substance and concentration in an unit of volume calculated according to the procedure established by paragraph 2.

(4) (suppemented - SG No 26/2019, effective 01.04.2019) For DDD or therapeutic course, or concentration, or volume for a medicinal product containing more than three active ingredients, one dosage

unit shall be taken and the reference value shall be calculated according to the procedure established by paragraph 2.

Article 47. (1) The reference value may furthermore be determined for a chemical subgroup of the ATC Classification, where the medicinal products included t according to INN and pharmaceutical forms have a proven similar efficacy and safety for treatment of a particular disease with a similar clinical course and severity according to the summary of product characteristics.

(2) The reference value under Paragraph 1 shall be determined in the following manner:

1. (supplemented - SG No 26/2019, effective 01.04.2019) for each INN with the corresponding pharmaceutical form within the chemical subgroup according to the anatomical-therapeutic-chemical classification, a value for DDD or therapeutic course, or concentration or volume shall be determined in accordance with Article 45, paragraph 2;

2. the lowest value under Item 1 shall be taken as a reference value of the chemical subgroup.

Article 48. (1) The reference value for the medicinal products included in PDL under Item 2 of Article 6, paragraph 2 may furthermore be determined for a chemical subgroup of the ATC Classification, where the medicinal products included t have a proven similar efficacy and safety for treatment of a particular disease with a similar clinical course and severity according to the brief summary of product characteristics.

(2) The reference value under paragraph 1 shall be determined in the following manner:

1. (amended - SG No 92/2014, effective 07.11.2014, supplemented - SG No 26/2019, effective 01.04.2019) for each INN with the appropriate pharmaceutical form and concentration in unit volume within a chemical subgroup according to the anatomical-therapeutic-chemical classification, a value for DDD or therapeutic course, or concentration, or volume shall be determined in accordance with Article 46, paragraph 2;

2. the lowest value under Item 1 shall be taken as a reference value of the chemical subgroup.

Article 49. (1) Articles 45 to 48 shall not apply upon determination of the value of reimbursement of medicinal products with narrow therapeutic windows of the immunosuppressants group for the treatment of patients after organ transplantation, whereof the bioequivalence parameters (AUC and Cmax) are beyond the range of 90 to 111.11 percent. The level of reimbursement of the medicinal products shall be calculated on the basis of the price thereof under Article 261a, paragraph 1 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

(2) The Council shall require an opinion from the BDA on conformity of each medicinal product of the immunosuppressants group for the treatment of patients after organ transplantation with the criteria referred to in paragraph 1 upon determination of the value of reimbursement of any such product.

Article 49a. (New - SG No. 28 of 2021) When determining the payment value of immunological medicinal products containing vaccines or toxins or serums with the same international non-proprietary name and medicinal form, but with a different manufacturer, Art. 45 - 48. The payment value of medicinal products is calculated based on their price under Art. 261a, para. 1 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE.

Article 50. (amended - SG No 92/2014, effective 07.11.2014, repealed - SG No 26/2019, effective 01.04.2019)

Article 50a. (new - SG No 92/2014, effective 07.11.2014) When determining the value for reimbursement for medicinal products included in PDL for which there is a difference in the treatment indications, prevention or diagnostics, reference value shall be calculated pursuant to articles 45 and 46 for each indication within the brief characteristics of medicinal products.

Article 51. (amended - SG No 26/2019, effective 01.04.2019)

The value per package of the medicinal product, calculated on the basis of the reference value, shall be arrived at by multiplying the value, as determined according to the procedure established by articles 45 to 49 , by the number of DDD or therapeutic course, or number of units of volume contained in the medicinal product concerned.

Article 52. (1) The reference value for the medicinal products whereof the level of reimbursement is 100 percent shall be calculated on the basis of a price for a wholesaler of medicinal products, formed according to the procedure established by Chapter Two.

(2) The reference value for medicinal products whereof the level of reimbursement is below 100 percent shall be calculated on the basis of a price for a retailer of medicinal products, formed according to the procedure established by Chapter Two.

Article 53. The level of reimbursement for the medicinal products, grouped according to international non-proprietary name and pharmaceutical form, which are included in PDL, shall be determined in percentage terms as follows:

1. for medicinal products pursuant to Article 6, paragraph 2, item 2 and 3 - 100 percent;
2. for medicinal products for diseases with a chronic course, leading to severe disruptions in the quality or life or disablement and requiring prolonged treatment - 100 percent;
3. for medicinal products for diseases with a chronic course and widespread prevalence - 75 per cent;
4. for medicinal products for diseases other than those referred to in Items 1, 2 and 3 - up to 50 percent.

Article 54. The level of reimbursement of the medicinal products with one and the same INN and one and the same pharmaceutical form shall be determined according to an evaluation table - Annex No 8, depending on:

1. the evaluation of the criteria covered under Article 30 ;
2. the indications for administration of the medicinal product according to the summary of product

characteristics for the type of treatment:

a) essential treatment: etiologic/pathogenetic treatment;
b) symptomatic treatment;
c) preventive treatment;
d) palliative treatment;
e) maintenance treatment;
f) additional treatment;

3. the social significance of the disease in the Republic of Bulgaria, for the treatment of which the medicinal product is used;
4. length of treatment and outcome;
5. therapeutic algorithm according to the endorsed manuals of pharmacotherapy in the Republic of Bulgaria or, in the absence of such manuals, treatment standards and the Good Medical Practice in the countries of the European Union;
6. number of patients determining the share of the disease for which the medicinal product is intended, according to data on the last preceding year and trends in the variation of prevalence;
7. financial resources spent on the medicinal product for the number of patients referred to in item 6. during the last preceding year;
8. budget resources allocated for procurement of the medicinal product.

Article 55. (Amended - SG No. 26 of 2019, in force from 01.04.2019, amended - SG No. 28 of 2021) The maximum value at which the relevant medicinal product is paid for with public funds product, is formed as the level of pay, determined in accordance with Art. 53 , is multiplied by the value per package determined on the basis of a reference value.

Article 56. The Council may change the level of reimbursement of the medicinal products in the PDL once a year within the limits of the relevant budgets.

Article 57. (1) (previous text of Article 57, amended - SG No 92/2015) The Positive published on the Website site of the Council, shall be updated on the 2nd and on the 16th day of each month according to the decisions of the Council which have entered into effect on:

1. endorsement of a price referred to in Article 2, paragraph 1 and inclusion of a medicinal product in PDL;
2. change of a medicinal product included in PDL;
3. exclusion of a medicinal product from an annex to PDL;

4. exclusion from the PDL and striking of a price referred to in Article 2, paragraph 1 for a medicinal

product.

(2) (new - SG No 92/2015, amended - SG No 26/2019, effective 01.04.2019) Medicinal products with the lowest reference value determined in accordance with Section III of Chapter Six shall be marked in PDL in a different colour.

(3) (new - SG No 92/2015) Paragraph 2 shall apply also for the NHIF software in respect to the medicinal products reimbursed by NHIF.

Chapter Six "a".
TERMS RULES AND CRITERIA FOR MAINTAINING THE REIMBURSEMENT STATUS OF MEDICINAL PRODUCTS INCLUDED IN THE POSITIVE DRUG LIST (NEW - SG 92/2015)

Article 57a. (new - SG No 92/2015) (1) The Council shall maintain the reimbursable status of medicinal products at every three years as from their inclusion to PDL by carrying out an assessment based on evidence for efficiency, treatment effectiveness, safety and analysis of pharmacoeconomic indicators.

(2) (new - SG No 8/2017) The Council shall maintain the reimbursable status of medicinal products referred to in Article 31a after expiry of three years from their inclusion in PDL after carrying out an evaluation under paragraph 1 and on the basis of the effect of the therapy therewith.

(3) (previous paragraph 2 - SG No 8/2017) The Council shall maintain the reimbursable status of medicinal products included in PDL complying with the following conditions.

1. they must be authorised for marketing according to the requirements of the MPHU;

2. the summary of the product features indications for treatment, prevention or diagnosis of the diseases, paidfor in accordance with Article 6, paragraph 2;

3. (amended - SG No 62/2016) the international non-proprietary name to which the medicinal product / combination belongs (for combined medicinal products) is included in the pharmacotherapeutic guidance and medical consensus for the treatment of the respective disease;

4. (amended - SG No 8/2017) an evaluation was carried out in accordance with the Annex No 5 of the procedure in Article 30 and, for the medicinal products under Article 31a, an evaluation of the effect of the therapy therewith was also performed.

(4) (New - SG No. 28 of 2021) If in the assessment of the effect of the therapy under para. 2 it is established that such cannot be carried out on the basis of the collected data, or the assessment does not have sufficient statistical reliability, then when maintaining the reimbursement status, the Council may decide that the monitoring of the effect of the therapy should continue for a period until the next maintenance of the reimbursement status status of the medicinal product.

(5) (New - SG No. 28 of 2021) In the cases under para. 4 The Council may amend and/or supplement the conditions and criteria for monitoring the effect of therapy with medicinal products, as well as the therapeutic indications to be monitored.

Article 57b. (new - SG No 92/2015) (1) For maintenance of the reimbursable status of medicinal product included in PDL, marketing authorisation holder or an authorised representative thereof shall submit to the Council an application according to a form endorsed by the Council, at every three years as from the date of inclusion of the product in PDL. The application shall be submitted within period not earlier than four months and not later than three months before expiration of the three year term pursuant to Article 57a, paragraph 1.

(2) (amended - SG No 26/2019, effective 01.04.2019) In maintaining the reimbursement status of

the identical or similar medicinal product under Article 214 of the MPHU included in PDL, the Council shall also maintain ex officio the reimbursement status of the medicinal product under Article 34, paragraph 1. The Council shall notify the holder of the parallel import or parallel distribution authorization of the initiation of administrative proceedings.

Article 57c. (new - SG No 92/2015) (1) The following shall be attached to the application referred to

in Article 57b, paragraph 1:

1. a copy of a marketing authorisation for the medicinal product, where the marketing authorisation has been issued according to the procedure established by Regulation (EC) No 726/2004, Annex I Summary of product characteristics, Annex II Marketing authorisation holder responsible for batch release. Conditions of the marketing authorisation and Annex III Particulars to appear on the outer packaging and text of the package leaflet; the annexes shall be presented on an electronic data medium;

2. information regarding the Uniform Identification Code of the corporation or cooperative from the Commercial Register or, applicable to corporations registered in a Member State of the European Union or in a State which is a Contracting Party to the Agreement on the European Economic Area, a copy of a document on current registration under the national legislation, issued by a competent authority of the relevant State to the persons under Article 57b, paragraph 1 not later than six months before the submission of the application;

3. Explicit notary authorisation, in case the application is submitted by authorised representative of marketing authorisation holder; where the power or attorney has not been granted in the Republic of Bulgaria, the said power of attorney shall be presented accompanied by a translation into the Bulgarian language, executed by a translator who has concluded a contract with the Ministry of Foreign Affairs for the execution of official translations;

4. data on postmarketing and/or non-interventional tests of the medicinal product conducted in the

Republic of Bulgaria or abroad according to THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, if such have been carried out;

5. (amended - SG No. 28 of 2021) document for paid state tax;

6. pharmacoeconomic analysis, prepared for or adapted to the country; accompanied by a

comparative analysis, provided a medicinal alternative is available for treatment of the disease;

7. certified by the marketing authorisation holder or his authorised representative copy of a contract

with NHIF for granting discounts for medicinal products pursuant to Article 45, paragraphs 10, 13 and 19 of the HIA.

(2) (amended - SG No 26/2019, effective 01.04.2019) The documents referred to in paragraph 1, item 6 shall apply only to medicinal products belonging to an international non-proprietary name for which an evaluation has been made under Article 30, paragraph 1 and Article 30a, upon their inclusion in PDL.

(3) (Repealed - SG No 26/2019, effective 01.04.2019)

(4) To authenticate the data stated in the application and in the accompanying documents under paragraphs 1 and 3, the marketing authorisation holder or the authorised representative thereof shall present a declaration completed in a standard form endorsed by the Council.

(5) Beyond the documents referred to in items 1, 3 and 4 the Council, stating reasons, may request the applicant to present additional information necessary for taking decision on the maintenance of reimbursable status.

Article 57d. (new - SG No 92/2015) (1) Within 60 days as from the submission of Application pursuant to Art. 57b, paragraph 1 the Council shall review the application and attached documents and shall take decision for maintenance of reimbursable status of the medicinal product included in PDL, for changing the reimbursable status of the medicinal product or shall refuse the maintenance of reimbursable status.

(2) Upon refusal for maintenance of reimbursable status pursuant to paragraph 1, the Council shall exclude the medicinal product from the relevant or all annexes of PDL.

(3) Upon the exclusion of a medicinal product from all annexes to PDL, the price of the said product, referred to in Article 2, paragraph 1, shall be stricken as well.

(4) Where, upon consideration of the applications referred to in paragraph 1, the Council ascertains any non-conformities or deficiencies in the documents presented, the Council shall have the right to require from the applicant to cure the deficiencies and non-conformities in the documents, as well as to present additional information, and shall notify the applicant according to the procedure established by the Administrative Procedure Code. In such case, the time limit referred to in paragraph 1 shall cease to run.

(5) In case the applicant fails to cure the non-conformities and deficiencies ascertained by the Council within thirty days reckoned from the date of notification under paragraph 4, the procedure shall be terminated.

Article 57e. (new - SG No 92/2015) (1) For each application received under Article 57b, a legal, medical and economic evaluation shall be prepared by experts of the specialised administration of the Council.

(2) The experts shall preview the applications and the accompanying documents and shall prepare an opinion on each application, completed in a standard form endorsed by the Council. A legal evaluation shall be conducted first, and it shall be followed by a medical and economic evaluation.

(3) Where necessary, the chairperson of the Council shall designate an expert under Article 38, paragraph 3 to conduct a pharmacoeconomic evaluation and to give an opinion.

(4) On the applications for maintaining the reimbursement status of medicinal products in the PDL under Art. 262, para. 6, items 1 and 2 of the Law on Medicinal Products in Human Medicine - regarding the medicinal products applicable in the treatment of malignant diseases, paid for in hospital medical care outside the value of the medical services rendered, the Council requires an opinion from the NHIF, and for medicinal products in the PLS under Art. 262, para. 6, item 3 the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE - from the Ministry of Health. The opinion is provided within 10 days of the request.

(5) The member of the Council, designated by the Chairperson as a rapporteur, shall prepare summary of the expert opinions under paragraph 4 and shall prepare an expert report in a standard form endorsed by the Council within 14 days after receiving the opinions on each application.

(6) (Amended - SG No. 28 of 2021) When considering the applications under Art. 57b for medicinal products under Art. 262, para. 6, items 1 and 2 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE - regarding the medicinal products applicable in the treatment of malignant diseases, paid for in hospital medical care outside the value of the medical services provided, included in the PLS, the meeting of the Council must be attended by a representative of the NHIF, who presents the opinion of the NHIF on each application.

(7) Upon consideration of applications under Art. 57b for medicinal products in PDL under Item 3 of Article 262, paragraph 6 of the LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE, a representative of the NHIF shall mandatory take part in the meeting of the Council and shall present the opinion of the NHIF on each application.

Article 57f. (new - SG No 92/2015) (1) Upon refusal to maintain and exclusion of medicinal product from PDL, the Council shall state its reasons for the decision thereof in accordance with the criteria, terms and rules established in the Ordinance, notifying the applicant according to the procedure established by the Administrative Procedure Code.

(2) The decision of the Council under paragraph 1 shall be subject to administrative review before the Transparency Committee.

Chapter seven.
PROCEDURE FOR GENERATION AND ENTRY IN THE REGISTER OF A NATIONAL IDENTIFICATION NUMBER FOR MEDICINAL PRODUCTS (REPEALED - SG No. 26 OF 2019, EFFECTIVE FROM 01.04.2019, NEW - SG No. 28 OF 2021)

Article 58. (Rev. - State Gazette, no. 26 of 2019, in force from 01.04.2019, new - SG No. 28 of 2021) For all medicinal products authorized for use on the territory of the country, a national identification number is automatically generated through the information system of the Council.

Article 59. (Repealed - SG No. 26 of 2019, in force from 01.04.2019, new - SG No. 28 of 2021)

(1) The Executive Agency for Medicines provides the Council in electronic format according to a model approved by him, information on medicinal products authorized for use and registered on the territory of the Republic of Bulgaria and medicinal products authorized for use under a centralized procedure in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31 2004 establishing Community procedures for the authorization and control of medicinal products for human and veterinary use and for the establishment of the European Medicines Agency (OJ, L 136/1 of 30.04.2004).

(2) The information under para. 1 is provided monthly by the 15th of the month and contains all medicinal products authorized for use in the previous month.

(3) In the terms under para. 2 IAL provides the Council in electronic format with information on all changes in circumstances that are subject to entry in the register under Art. 60, para. 1 for medicinal products,

as well as for medicinal products with suspended, revoked and expired authorizations for use that have not been renewed.

Additional provisions

§ 1. For the purposes of this Ordinance:

1. (amended - SG No 26/2019, effective 01.04.2019) "Public Health Insurance Fund" is a public institution which collects and distributes health insurance contributions and health insurance premiums for health activities, services and goods within the territory of the country concerned.

2. (supplemented - SG No 92/2014, effective 07.11.2014, amended - SG No 92/2015, repealed - SG No 8/2017)

3. (amended - SG No 26/2019, effective 01.04.2019) “The same medicinal product” shall be a medicinal product with the same international non-proprietary name, content of active ingredient per dosage unit, pharmaceutical form in final packaging of a producer/producers entered in the marketing authorisation/the decision of the European Commission issued according to the procedure established by Regulation (EC) No 726/2004 of the European Parliament and of the Council.

4. (repealed - SG No 26/2019, effective 01.04.2019)

5. (amended - SG No 92/2014, effective 07.11.2014, amended - SG No 92/2015, repealed - SG No 26/2019, effective 01/04/2019)

6. (new - SG No 62/2016, amended - SG No 26/2019, effective 01.04.2019) "Amount of active ingredient per dosage unit" shall be the content of the active ingredient expressed quantitatively per dosage unit (tablet, capsule) or per unit weight or volume, depending on the pharmaceutical form.

§ 1a. (new - SG No 92/2014, effective 07.11.2014, repealed - SG No 92/2015)

Transitional and Final Provisions

§ 2. (1) All procedures, which have been initiated and which have not been completed according to the procedure established by the Ordinance on Regulation and Registration of Prices for Medicinal Products, the Terms, Rules and Criteria for Inclusion, Modifications and/or Exclusion of Medicinal Products from the Positive Drug List and the Terms and Procedure for Operation of the Commission on Prices and Reimbursement, adopted by Council of Ministers Decree No 390 of 2011 (State Gazette No 100 of 2011), shall be completed according to the procedure established by this Ordinance.

(2) All procedures for registration of a price for medicinal products dispensed on medical prescription, which have been initiated and which have not been completed until the entry into force of this Ordinance, shall be completed according to the procedure established by Chapter Four of the Ordinance.

(3) Within fourteen days after the entry into force of the Ordinance, the marketing authorisation holders or authorised representatives thereof shall submit the requisite documents for completion of the procedures referred to in paragraphs 1 and 2.

(4) In case the time limit referred to in paragraph 3 is not complied with, the procedure concerned

shall be terminated.

§ 3. (1) Within two months after the entry into force of this Ordinance, the marketing authorisation holders (or authorised representatives thereof) for medicinal products dispensed on medical prescription with registered maximum selling prices shall submit an application for the formation of a ceiling price according to the procedure established by Chapter Four , for which stamp duty shall not be payable.

(2) In case of non-submission of an application for the formation of a ceiling price for a medicinal product dispensed on medical prescription within the time limit referred to in paragraph 1, the maximum selling price shall be stricken by the Council *ex officio*.

§ 4. Any procedures for change of a registered price of medicinal products dispensed on medical prescription, which have been initiated and which are not completed upon the entry into force of this Ordinance, shall be terminated.

§ 5. Within a period of one year after the entry into force of this Ordinance, the marketing authorisation holders or authorised representatives thereof may not apply for an increase of the registered prices of over-the-counter medicinal products by a larger percentage than the statistically reported rate of inflation for the period of validity since the last registered price.

§ 6. Within a period of one year after the entry into force of this Ordinance, in the cases where an error has been made in the ex-factory price for a medicinal product announced in the price bulletin of medicines of Greece and a declaration attesting to this circumstance has not been presented by the marketing authorisation holder, the said price shall not be used upon the formation of a price/ceiling price according to the procedure established by Articles 8 and 10, as well as upon the change of a previously endorsed price/ceiling price.

§ 7. (1) The registers provided to the Commission on Prices and Reimbursement according to the procedure established by § 130 (4) of the Act to Amend and Supplement THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE(State Gazette No 102 of 2012) shall be considered to be registers referred to in Article 7 of this Ordinance, kept by the National Council on Prices and Reimbursement of Medicinal Products.

(2) The National Council on Prices and Reimbursement of Medicinal Products shall maintain the register of maximum selling prices for medicinal products dispensed on medical prescription until the completion of the procedures under § 3 of this Ordinance, whereafter the National Council shall delete the said register.

(3) The applications to the Commission on Prices and Reimbursement, considered until the 20th day

of March 2013, on which there are decisions which have entered into effect after that date, shall be recorded ex officio in the public registers of the National Council on Prices and Reimbursement of Medicinal Products.

§ 8. Within six months after the entry into force of this Ordinance, the National Council on Prices and Reimbursement of Medicinal Products shall bring the ICD codes in the Positive Drug List under Items 1 and 3

of Article 262, paragraph 6 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINEinto conformity with Article 1, paragraph 3 of Ordinance No 42 of the Minister of Health of 2004 on Introduction of the International Statistical Classification of Diseases and Related Health Problems 10th Revision (promulgated in the State Gazette No 111 of 2004; amended and supplemented in No 103 of 2012).

§ 9. Until the creation of an Website site of the National Council on Prices and Reimbursement of Medicinal Products, the Positive Drug List and the registers referred to in Article 7, paragraph 1 shall be published on the Website site of the Ministry of Health.

§ 9a. (new - SG No 3/2016, effective 01.12.2015, amended - SG No 14/2016, effective 16.02.2016, amended - SG No 32/2016, amended - SG No 74 of 2016, effective 01.09.2016, amended - SG No 2/2017, effective 01.01.2017 , SG No 8/2017). Article 8, paragraph 5 shall apply from 1 January 2018.

§ 9b. (new - SG No 3/2016, effective 01.12.2015) Guidelines on the implementation of the ordinance shall be given by the Minister of Health.

§ 10. This Ordinance is adopted in pursuance of Article 261a, paragraph 5 and in conjunction with Item 4 of Article 259, paragraph 1 and Article 262, paragraph 7 of the Medicinal Products for Human Use Act.

TRANSITIONAL AND FINAL PROVISIONS
TO DECREE No 233 OF 31 JULY 2014 FOR AMENDING AND SUPPLEMENTING THE ORDINANCE ON REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED — SG No 66 OF 2014, EFFECTIVE 08.08.2014, AMENDED — SG No 107 OF 2014, EFFECTIVE 24.12.2014, AMENDED — SG No 92 OF 2015, AMENDED - SG No 102 of 2017)

§ 2. (1) (amended - SG No 107/2014, effective 24.12.2014, amended - SG No 92/ 2015, amended - SG No 102/2017) Until 31 December 2019, marketing authorisation holders or their authorised representatives may not apply for an increase of registered prices of over-the-counter medicinal products by a larger percentage than the statistically reported rate of inflation for the period of validity since the last registered price.

(2) Any procedures for increase of the registered price of medicinal products dispensed without medical prescription, which have been initiated and which are not completed upon the entry into force of this Ordinance, shall be finished pursuant to the rules of paragraph 1.

§ 3. The Decree shall enter into force as from the date of promulgation in State Gazette.

Transitional and Final Provisions

TO DECREE No 348 OF 3 NOVEMBER 2014 FOR AMENDING AND SUPPLEMENTING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(Promulgated - SG No 92/2014, effective 07.11.2014)

§ 26. All initiated and incomplete procedures as of the entry into force of the decree shall be completed in accordance with the current rules.

§ 27. Within 14 days of the entry into force of the decree, the National Council on Prices and Reimbursement of Medicinal Products shall approve and publish on its website the forms of documents pursuant to articles 13, 14, 16, 23, 25, 32, 33, 34, 38 and 43.

§ 28. The decree shall enter into force on the day of its promulgation in the State Gazette.

FINAL PROVISIONS

TO DECREE No 441 of DECEMBER 22 2014, AMENDING AND SUPPLEMENTING COUNCIL OF MINISTERS DECREE No 233 OF 2014, AMENDING AND SUPPLEMENTING THE ORDINANCE

ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED – SG No 107/2014, EFFECTIVE 24.12.2014)

§ 2. The decree shall enter into force on the day of its promulgation in the State Gazette.

Transitional and Final Provisions

TO DECREE No 323 OF 20 NOVEMBER 2015, AMENDING AND SUPPLEMENTING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED – SG no 92/2015)

§ 23. The first declaration under Article 35a, paragraph 2 of the Ordinance on terms, rules and procedure for regulation and registration of prices for medicinal products (promulgated, SG No 40 of 2013; amended and supplemented, SG nos. 66, 92 and 107 of 2014) shall be submitted for the month following the month of entry into force of this Ordinance.

§ 24. The periods under Article 36, paragraph 1, Items 12 and 13 of the Ordinance pursuant to § 23 shall run as from 1 December 2015.

§ 25. (1) In the case of medicinal products for which three years have expired from their inclusion in PDL at the time of entry into force of the Decree, the marketing authorisation holders (or the authorised representatives thereof) shall submit applications pursuant to Chapter Six "a" of the Ordinance according to § 23 within six months from entry into force of the Decree.

(2) The medicinal products for which no application has been submitted within the deadline under paragraph 1 shall be excluded from PDL ex-officio by the Council, and their price pursuant to Article 2, paragraph 1 shall be deleted.

(3) For medicinal products which, pursuant to the procedure laid down in paragraph 1, are subject to decision for maintenance of the reimbursable status, the following three-year periods shall start running as from entry into force of this decision.

Final Provisions

TO DECREE No 381 OF 29 DECEMBER 2015 AMENDING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013 (PROMULGATED – SG No 3 of 2016, EFFECTIVE 01.12.2015)

§ 2. The Decree shall enter into force on 1 December 2015.

Final Provisions

TO DECREE No 32 OF 16 FEBRUARY 2016 AMENDING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013
(PROMULGATED – SG No 14/2016, EFFECTIVE 16.02.2016)

§ 2. The Decree shall enter into force on 16 February 2016.

Final Provisions

TO DECREE No 238 OF 13 SEPTEMBER 2016 AMENDING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013 (PROMULGATED – SG No 74/2016, EFFECTIVE 01.09.2016)

§ 2. The Decree shall enter into force on 1 September 2016.

FINAL PROVISIONS
TO DECREE No 380 OF 28 DECEMBER 2016 AMENDING THE ORDINANCE ON TERMS, RULES AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013 (PROMULGATED – SG No 2/2017, EFFECTIVE 01.01.2017)

§ 3. The Decree shall enter into force on 1 January 2017.

Transitional and Final Provisions
TO DECREE No 56 OF 28 MARCH 2019 AMENDING AND SUPPLEMENTING LEGISLATIVE ACTS OF THE COUNCIL OF MINISTERS

(PROMULGATED – SG No 26 of 2019, EFFECTIVE 01.04.2019)

§ 4. (1) The procedures for evaluation of health technologies for medicinal products not completed by 1 April 2019, shall be completed by the National Council for Prices and Reimbursement of Medicinal Products in accordance with the procedure laid down in this Ordinance.

(2) Any holder of a marketing authorization, who wishes the proceedings under paragraph 1 to be completed as a procedure for the evaluation of health technologies or the inclusion of a medicinal product belonging to a new international non-proprietary name in the Positive Drug List, shall submit an application to the National Council for Prices and Reimbursement of Medicinal Products by 20 April 2019.

(3) In the event that the relevant Marketing Authorization Holder did not submit an application to the National Council for Prices and Reimbursement of Medicinal Products within the term specified in paragraph 2, the ongoing procedure for evaluation of health technologies shall be terminated.

(4) The procedures for the inclusion in PDL of medicinal products belonging to a new international non-proprietary name, for which reports on the evaluation of health technologies have been submitted by the Director of the National Center for Public Health and Analyzes, already undertaken at the time of entry into force of this Decree, shall be completed under the conditions and in accordance with the procedure laid down in this Ordinance, without performing a new evaluation of health technologies and without collecting fees for performing an evaluation of health technologies.

(5) By 10 April 2019, the Director of the National Center for Public Health and Analyzes shall submit to the National Council for Prices and Reimbursement of Medicinal Products, accompanied by a takeover certificate, the applications and documents submitted for the procedures under paragraph 1, as well as the archives of completed procedures.

§ 5. (1) Within one month of the entry into force of this decree, the medical-treatment establishments designated to monitor the effect of the therapy with a medicinal product shall ensure compatibility of their hospital information system with the information system of the Council.

(2) Upon expiry of the term under paragraph 1, the medical-treatment establishments referred to in paragraph 1 shall submit to the Council, via their hospital information system, data on the medicinal products for which the effect of the therapy was monitored.

§ 6. (1) By 31 December 2020, the National Council for Prices and Reimbursement shall ex officio

verify the changes in the approved ceiling prices of the medicinal products under Article 261a, paragraph 2 of THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE. The check shall be carried out following the order of the latest approved ceiling price of the medicinal products.

(2) Where, on the basis of the verification under paragraph 1, it is found that there has been a change in the respective approved ceiling price for a medicinal product, the Council shall ex officio bring it in compliance with the requirements of Article 10 of the Ordinance on Regulation and Registration of Prices of Medicinal Products.

(3) The Council shall inform the holder of the marketing authorization of the comencment of administrative proceedings under paragraph 2.

(4) The holders of marketing authorizations shall not be obliged to pay stamp duty for the official verification referred to in paragraph 1.

. . . . . .

§ 8. (1) The periods under § 1, item 42, point "a", sub-points "aa" and "bb", point "c" and sub-points "aa" and "bb" shall start running from 1 April 2019.

(2) The declarations submitted in accordance with Article 43 of the Ordinance on Terms, Rules and Procedure for Regulation and Registration of Prices of Medicinal Products before 1 April 2019 shall be considered by the National Council for Prices and Reimbursement of Medicinal Products in accordance with the current rules. § 9. Within one month of the entry into force of this decree, the chairman of the National Council for Prices and Reimbursement of Medicinal Products shall approve the official staff schedule of the Council.

§ 10. The Decree shall enter into force on 1 April 2019.

Final Provisions

TO DECREE No 195 OF 2 AUGUST 2019 AMENDING THE ORDINANCE ON TERMS, RULES

AND PROCEDURE FOR REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED – SG No 62/2019)

§ 2. Paragraph 1, item 1 shall enter into force on the day of promulgation of the decree in the State Gazette, and § 1, items 2 and 3 shall enter into force on 1 November 2019.

Transitional provisions

TO RESOLUTION No. 30 OF FEBRUARY 28, 2020 SUPPLEMENTING THE ORDINANCE ON THE CONDITIONS, RULES AND ORDER FOR REGULATING AND REGISTERING THE PRICES OF MEDICINAL PRODUCTS, ADOPTED BY RESOLUTION No. 97 OF THE COUNCIL OF MINISTERS OF 2013.

(ANNOUNCEMENT - SG No. 19 OF 2020)

§ 2. The procedures for increasing the registered prices of medicinal products, dispensed without a doctor's prescription, initiated and not completed at the entry into force of this decree, shall be completed under the conditions of § 1.

Transitional and Final Provisions
TO RESOLUTION No. 124 OF APRIL 1, 2021 AMENDING AND SUPPLEMENTING THE ORDINANCE ON THE TERMS, RULES AND ORDER FOR REGULATING AND REGISTERING THE PRICES OF MEDICINAL PRODUCTS, ADOPTED BY RESOLUTION No. 97 OF THE COUNCIL OF MINISTERS OF 2013.

(ANNOUNCEMENT - SG No. 28 OF 2021)

§ 33. Within three months from the entry into force of the decree, the chairman of the Council approves the first list under Art. 43a.

§ 34. (1) Within two months from the entry into force of the decree, the Council ex officio reduces the prices under Art. 2, para. 1, the limit prices and the maximum sales prices of the medicinal products that have received permission for parallel import or permission for parallel distribution by the European Medicines Agency, which are higher than those of the same or similar medicinal product under Art. 214 of the Law on Medicinal Products in Human Medicine.

(2) To initiate the administrative proceedings under para. 1 The Council shall notify the holder of the authorization for use.

(3) To carry out the price change under para. 1 holders of use permits do not have to pay a state fee.

Appendix No. 1 to Art. 7a, para. 2

(Repealed - SG No. 92 of 2014, in force from 07.11.2014, new - SG No. 28 of 2021)

Information that the notification from the marketing authorization holders or their authorized representatives to the Council contains:

1. holder of the authorization for use;
2. name of medicinal product;
3. ATC code (if available);
4. international non-proprietary name;
5. therapeutic indications and indications according to ICD or Orphanet (proposed or finally approved by the regulatory body);
6. line of therapy;
7. patient population and subgroups;
8. medicinal form;

9. amount of active substance;

10. final packaging;

11. dosage (defined daily dose or therapeutic course, or concentration or volume);

12. method of application;

13. mechanism of action;

14. companion diagnostic test (companion diagnostic);

15. current therapeutic approaches;

16. comparative therapeutic alternatives;

17. name of the clinical trial that was used to submit an application for registration to the regulatory body;

18. clinical trial number;

19. clinical trial phase;

20. start date and expected end date of the clinical trial;

21. current phase of clinical development of the medicinal product (e.g. phase 3);

22. declared orphan medicinal product status (yes/no);

23. registration procedure (e.g. centralized);

24. expected date of regulatory approval (CHMP date and regulatory authority approval date);

25. expected date of initiation of pricing and reimbursement procedure;

26. suggested average dose (eg 300 mg every 6 months);

27. expected place in the therapeutic approach indicated in the pharmaco-therapeutic guidelines (for example, replacement of a certain class of current therapy);

28. expected cost (range from - to) per patient per year or per patient per episode/cycle if shorter than a year;

29. impact on the current costs of the NHIF (for example, delaying the progression to reduce the costs of something);

30. impact on patients and caregivers (eg reduce pain or improve quality of life);

31. estimated number (range from - to) of Bulgarian patients who will be treated with the therapy;

32. estimated 5-year budget impact (range from - to), plus budget model if available.

Annex No 2 to Article 14, paragraph 1, Item 5

(Repealed, SG No 92/2014, effective 07.11.2014)

Annex No 3 to Article 16, paragraph 2, Article 25, paragraph 2 and Article 38, paragraph 2

(Repealed, SG No 92/2014, effective 07.11.2014)

Annex No 4 to Article 16, paragraph 3, Article 25, paragraph 3, Article 38, paragraph 8

(Repealed, SG No 92/2014, effective 07.11.2014)

Annex No 5 to Article 31, paragraph 1, item 2

EVALUATION TABLE of the indicators under Article 30 of the Ordinance		
Indicat	Score	Note
1. Lack of a medicinal alternative for treatment of the disease for which the medicinal product is indicated: Item 1 of Article 30, paragraph 1	20 points	
2. Criteria of efficacy and therapeutic effectiveness: Item 2 of Article 30, paragraph 1:	45 points	
(a) evaluation of the therapeutic benefit of the medicinal product;	As first choice 10 points As next choice 5 points Other therapy 1 point	
(b) gain of life years;	Life-support with life-saving 10 points Results in gain of life years 6 points Has no impact on gain of life years 0 points	
(c) possibility for improvement the quality of life;	Complete recovery 10 points Partial, sustained 6 points Partial, temporary 2 points	

(d) availability and significance of additional therapeutic benefits due to the principal action of the active ingredient	Available 2 points Unavailable 0 points	
(e) decreased complications of the principal disease;	Significant: 10 points Average: 5 points Insignificant: 0 points	
(f) convenience for the patient;	Yes: 1 point No: 0 points	
(g) effectiveness of the medicinal product related to the specific pharmaceutical form and route of administration;	Effective: 2 points Ineffective: 0 points	
3. Criteria for safety of the medicinal products:	30 points	
(a) frequency of occurrence of adverse reactions;	High (very frequent; frequent) 0 points Medium (infrequent; rare) 2 points Low (very rare; of unknown frequency) 5 points	

(b) severity of adverse reactions;	Light, reversible 10 points Serious, reversible 5 points Serious, irreversible 1 point	

(c) susceptibility to and behaviour upon occurrence of adverse reactions;	Does not require discontinuance and additional treatment 10 points Does not require discontinuance, requires additional therapy 5 points Requires discontinuance of treatment without additional therapy 2 points Requires discontinuance of treatment with additional therapy 1 point	
(d) need to apply additional preventive or therapeutic measures to avoid adverse reactions;	Additional measures not needed 5 points Additional measures needed 0 points	
4. Pharmacoeconomic indicators:	40 points	
(a) costs of therapy using the medicinal product; (b) comparison of the costs of therapy using the available alternatives; (c) cost-benefit ratio; (d) economic evaluation of the additional benefits; (e) analysis of the budget impact of the expected number of patients	The costs of therapy are lower than the costs of therapy so far: 15 points or The costs of therapy using the medicinal product are higher than the costs of therapy so far, but therapy using the medicinal product reduces the total costs of treatment of the disease (e.g. shorter hospital stay, decrease of complications, less need of tests etc.): 15 points	

	and The cost-benefit ratio is lower the ratio for the therapy so far: 15 points The economic evaluation of the additional benefits ex ceeds the economic evaluation of the cost of therapy: 10 point or The economic evaluation of the additional benefits is lower than tha cost of therapy, but they are important fot the treatment: 5 points and The product saves budget ex penditures on health costs: 10 points	
5. The medicinal product is for treatment of diseases of high risk to the public.	20 points	

Inclusion in PDL for a score of 60 points and higher. Expert:

Date:

Annex 6 to Article 35, paragraphs 3 and 6

(Repealed, SG No 92/2014, effective 07.11.2014; new - SG No 26/2019, effective 01.04.2019)

Guidance on requirements for the contents of the health technology assessment analysis

The analysis may contain other data and sections that are necessary to provide the information specified in the scope of the assessment.

The main sections that the analysis should contain are as follows:

1. Introduction.
2. Clinical evaluation of the efficacy, therapeutic effectiveness and safety.

3. Pharmaco-economic evaluation.

4. Budget impact analysis.

5. Specific requirements for health technology assessment for rare diseases or specific patient groups, such as subgroups identified based on genomic information, etc.

6. Information on the moral and ethical aspects of the use of the health technology (if any).

7. Summaries and reports (attached) of decisions and evaluations by government institutions for the purposes of other national healthcare systems.

8. Evidence from the references used.

9. Description of the references used.

Information to be provided in the above sections:

1. Introduction:

1.1. Health issue:

Description of the health problem based on reliable sources of information, as well as clear positioning of the health technology in the diagnostic and therapeutic processes for the analyzed disease.

Information on the definition of the disease according to the International Classification of Diseases (ICD) shall be provided. If the assessment relates to a specific target population (e.g. with a specific stage of the disease), a brief description of the disease shall be provided, followed by detailed information regarding the particular stage of the disease.

The principles and criteria for diagnosing the disease shall be described, as well as the examinations and studies (laboratory and other) needed to make the diagnosis, identifying the relevant reliable sources - preferably clinical recommendations and guidelines based on a systematic review of scientific evidence, including such published within the Bulgarian healthcare system. If specific scales or tests are used for the purpose of diagnosis, they should be indicated, as well as which ones are financed by public funds in Bulgaria.

1.2. Epidemiological data, medical and social gravity of the disease:

Up-to-date epidemiological data, including incidence and morbidity, shall be provided, with preference given to data on the Bulgarian population, as well as information on the gravity and severity of the disease, its public relevance and the characteristics of the patients to be treated, should be provided depending on the disease, e.g. chronic disease, rare disease, disease in patients of active age.

1.3. Clinical picture, natural course of the disease, complications and prognosis:

The natural course of the disease, the prognostic factors associated with the course of the disease, and its impact on the quality of life of patients shall be described. The role of the new health technology in the natural course of the disease and its impact on its change and quality of life shall be emphasized.

1.4. Therapeutic standards:

The current treatment shall be described based on international recommendations and guidelines. The treatment algorithm according to clinical practice in Bulgaria shall be then described, followed by the relevant stages of the disease, with emphasis on the stage at which the health technology will be used.

Indicate whether the new technology is included in pharmacotherapeutic guidelines or other European therapeutic guidelines.

Information shall also be included on alternatives that are reimbursed in Bulgaria for the respective

therapeutic indication.

1.5. Target population:

The population in respect of which the health technology will be applied shall be described. If the health technology is to be applied to a specific population of patients diagnosed with a certain disease (for example, those with a specific mutation), the criteria for determining that subpopulation must be clearly stated. When defining the target population, data on Bulgaria shall be used, and methods for determining them shall be described. Indicate whether the necessary clinical and other tests will be paid for with public funds.

1.6. Description of the health technology:

1.6.1. Key features of the new technology:

INN	
Trade name	
Marketing Authorization Holder	
Therapeutic class	
Active ingredient / active ingredients	
Pharmaceutical form / pharmaceutical forms	
ATC code	
Mechanism of action	
Pharmacodynamics	
Pharmacokinetics	

1.6.2. Route of administration and dosage:

Route of administration	
Dosage	
Frequency of dosing	
Duration of treatment	
Interval between treatment courses established	
Number of recurrent courses of	

treatment established	
Dosage adjustment	

The technology being assessed should be described in detail. It should be specified whether it is authorized for use in Bulgaria, when it was first authorized and where, in how many other countries it was authorized (in the event of no centralized marketing authorization in Europe) and what specific therapeutic indications the authorization was issued for. If the assessment is for a new therapeutic indication in respect of which it has not been applied so far, this should be indicated.

The following information should be made available: type of technology (diagnosis, prevention, therapy), its main characteristics, various indications, contraindications and risks already known and described in the literature.

The following specific information should obligatorily be included:

• authorization to use the relevant health technology, including special conditions, if any, and period of validity;

• mechanism of action, therapeutic group, ATC code - for medicinal products;

• conditions under which the health technology will be applied (for example, in primary outpatient care, in specialized outpatient care, for hospital treatment, or others).

The place of the health technology in accordance with current clinical practice shall be described, as well as which therapy, including other health technologies, will be partially or completely displaced by the new technology.

In the case of a favourable decision, the following should be described: reimbursement status of the health technology in Europe, therapeutic indications, restrictions and level of reimbursement, summary of the reimbursement recommendations, whether the reimbursement concerns all therapeutic indications or only specific therapeutic indications in other countries.

1.7. Selection of comparative alternatives:

When there is a number of therapeutic approaches (including non-drug therapies and absence of treatment), these should be listed. Therapeutic approaches used as comparative alternatives should be selected based on commonly used or first-line therapy. In order to ensure international comparability, it is advisable to refer to what is perceived as the "best standard treatment" as the definition for a comparative alternative.

The following alternatives may also be used: treatment used in the current clinical practice; most commonly used therapy; most commonly used alternative medicinal products; reimbursed therapies with the same or equivalent therapeutic indication, the product most likely to be displaced or complemented by the new technology. If the new health technology belongs to an existing pharmacotherapeutic group, the comparative product should be the most commonly used product in the group or one that is most likely to be impacted by the introduction of the new technology. If the new health technology belongs to a new

pharmacotherapeutic group, the comparative product should be the most commonly used medicinal product for the same therapeutic indications.

The dose and duration of treatment with the alternatives should be according to the information in the summary of product characteristics and the pharmacotherapeutic guidelines. Non-drug therapies and lack of treatment are acceptable alternatives only, if most commonly used in therapeutic practice or when there are no other alternatives for the treatment of the target patient group.

The added value of the therapy with the new health technology, such as improved safety, improved adherence to the therapy compared to alternatives, as measured using specific clinical indicators against existing alternatives, must be clearly justified.

2. Clinical assessment of the efficacy, therapeutic effectiveness and safety:

2.1. General data.

The following sources are considered as sources of evidence as concerns the efficacy, therapeutic effectiveness and safety of new technologies:

- clinical trials that are part of the manufacturer's research program and are included in the dossier for authorization for use and / or approval of the health technology (those published in scientific journals should be indicated);

- post-registration and post-marketing tests published in the scientific literature; - other tests outside the two specified groups; - systematic reviews and meta-analyzes.

Test results of trials should be presented in tabular form containing the following information:

- trial identification data (registration number and bibliography of the publication);
- country in which the test was carried out (all countries should be indicated for multinational tests);
- number of participants (description of the number and demographic characteristics of patients, as well as specific patient subgroups, if sample or post-hoc studies are available);
- type of trial (randomized, non-randomized, case-control, case-by-case, cohort, post-marketing, etc.);
- intervention carried out;
- comparative alternatives;
- a description of the results;
- results obtained (data on the results may contain information about possible errors and limitations of the studies).

Each of the above study groups should be described in a separate table.

It is recommended that the limitations of literature be discussed and studies of lower quality identified.

2.2. Reasoned systematic analysis to identify and select relevant clinical trials and literature.

2.2.1. Criteria, methods of identification, selection and databases that ensure that all relevant randomized trials are included in the clinical assessment. Selection strategy for clinical trials.

The main objective is to identify all randomized trials which compare the new technology with the main alternative. If no direct randomized comparisons are found, randomized trials should be sought that will allow for indirect comparisons. If it is not possible to make indirect comparisons, a search for nonrandomized trials should be conducted. Any use of indirect comparisons and the inclusion of non-randomized trials must be substantiated.

Recommended databases that can be used to identify trials of the health technology being assessed are as follows:

Database	Specifid Search Period (from - to)	Search results
PubMed		Keywords and number of results obtained
Cochrane Library		Keywords and number of results obtained
ClinicalTrials.gov		Keywords and number of results obtained
European Union Clinical Trials Register		Keywords and number of results obtained
Other sources		Keywords and number of results obtained

A complete list of identified trials including the applicant technology (regardless of the comparison group) and all trials including the primary means of comparison (regardless of the comparison arm), systematic reviews and meta-analyzes should be provided.

2.2.2. Description of trials

Clinical trial	Country / countries	Participants	Type of study, duration	Intervention	Comparative alternatives	Results
Registration number or bibliography for the publication	List of the countries where the trial was conducted	Number, subgroups	RCP (number of arms, blindness, etc.), postmarketing, etc.	Description of the exact stage of the disease and characteristics covered	Description of alternatives to the indicators above	Description of the results and their main values

In addition to tabulating each of the subgroups of trials - clinical, post-marketing, systematic reviews and meta-analyzes, information on the criteria for inclusion and exclusion in the selection of clinical trials is also required: the main demographic and clinical characteristics of the participants in the trial; treatment scheme, dose details, route of administration and duration of treatment. Indicate whether the dose or the treatment scheme, including the use of concomitant treatment, is supported by the information provided in the summary of product characteristics. Justify where the determined dose differs from the recommended dose according to the summary of product characteristics.

For each trial, present data on co-medication taken (if any) and discuss its relevance to the clinical efficacy and safety data obtained.

Indicate whether the health technology is undergoing further testing for other indications or combinations and list the relevant trials and the time limit for their completion.

2.3. Comprehensive description of the results of each clinical trial and the methods for measuring them.

Notwithstanding the results given in the tabular review of the trials in this section, all results thereof,

as well as systematic reviews, meta-analyzes and other types of studies, should be illustrated and clarified in detail. The illustration may contain additional tables, figures (for example - survival) and more. The results reported in the trials are:

• primary results;

• secondary results;

• final results.

Clinically relevant outcomes that are critical to a given disease or intervention should be a priority in assessing the health benefits of the technology. Clinically relevant are three main groups of results that should be noted:

• mortality-related outcomes;

• morbidity-related outcomes;

• health-related quality of life (HRQoL) results.

Events and side effects (classified by gravity and frequency) are also clinically relevant. The reported results should:

• be defined and explained in terms of the health problem being addressed;

• be co-related to the disease being evaluated and its course;

• reflect the most important aspects of the health problem and, at the same time, make it possible to identify possible differences between the technologies compared;

• be important for clinical decision making (critical points for the health problem under consideration).

When reporting the results, describe the methods used to achieve long-term results in the absence of data (e.g. extrapolation for survival, etc.).

Therapeutic outcomes should be analyzed for as long a period as possible. Assessment of short-term treatment is appropriate for acute illnesses or illnesses entailing long-term consequences. In chronic diseases, long-term results are higher in value, but in some cases, assessment of the therapeutic effect due to long survival may also be obtained by extrapolating short-term follow-up results.

For the survival analysis, it is recommended to report the overall survival rate, as well as providing clear data on the possible crossover effect. Progression-free survival rates may also provide useful information for some diseases.

When evaluating clinical efficacy based on surrogate endpoints (intermediate, short-term results), the clinical analysis should demonstrate their relationship with clinically relevant outcomes. The validation of surrogate endpoints must be carried out in accordance with the underlying health problem.

In certain cases (e.g. analysis of a specific subpopulation), it is permissible to report the results of a post-hoc analysis, but these results should be interpreted only with respect to the subgroup concerned and not generalized. The post-hoc analysis should differ from the analysis of subgroups of patients with differing initial prognosis for the evolution of the disease.

The use of generalized endpoints is only recommended if these have been previously defined at the trial design stage. Complex endpoints are not recommended in the post-hoc analysis. If the population subgroup analysis is predetermined, the results may be more relevant than in the post hoc analysis. When summarized endpoints are reported, separate results for each component should be provided even when they do not achieve statistical significance.

Where results are obtained through a scale of questions, information on their clinical relevance must be provided. In the case of conversion of continuous or ordinal variables, or dichotomous variables (e.g. healthy-sick), the cut-off point should be specified.

Data on the results should also contain information about possible errors and limitations of the trials.

When using network meta-analyzes or indirect comparisons, the results should be considered in terms of the reliability of the data and their applicability in making decisions in the healthcare system. For each meta-analysis, the results of the homogeneity test must be reported according to the methods in the Cochrane Handbook.

The efficacy and effectiveness data, as well as those from meta-analysis or clinical trial generalizations should be discussed separately.

2.4. Outcomes reported by patients.

Patient-reported outcomes are an important part of evaluating both clinical effectiveness and healthrelated quality of life. Patient-reported outcomes include general and / or condition-specific data (e.g. respiratory conditions, depression, arthritis), quality-adjusted life year scale from 0 (death) to 1 (full health) / recovery), symptoms or functions.

The analyzes should indicate when and how outcomes reported by patients are assessed.

Provide the chart according to which patient-reported outcomes have been assessed (e.g. reported by participants, QALY, visual-analogue pain scale, visual acuity test, 6-minute walking test, etc.). All outcome measures reported by the patient should be indicated (e.g. EQ5D, HUI).

The effects of tested health technology on quality and life expectancy of patients in actual clinical practice need to be assessed.

2.5. Safety analysis.

A summary of the safety considerations, including important identified risks, important potential risks and missing information, relevant to the technology being assessed, shall be provided.

The product safety monitoring plan for the product should be summarized, listing any additional safety monitoring methods, if required at the time of marketing authorization or subsequent regulatory review. The category of post-marketing safety studies conducted should be defined.

Approved and implemented measures to minimize the risk in using the product should be presented and analyzed in the context of a possible increase in public costs for their implementation. For example, the requirement for periodic monitoring of hepatic impairment to avoid hepatotoxicity is a cost-increasing action, while the dissemination of training materials or signal cards is a risk-minimizing action that does not overburden the public and the patient's budget.

The cycle of submitting periodic safety updates for the medicinal product should be presented along with summary information on the cumulative marketing period of the product and summary exposure data.

The incidence and severity of adverse reactions should be reported according to the latest approved Summary of Product Characteristics, specifying the date of approval.

The positive benefit / risk ratio should be subject to regulatory assessment and a prerequisite for a valid marketing authorization. Any additional change to the benefit / risk ratio, whether additional benefit or additional risk, should be presented objectively and accompanied by clarifications as to whether the new information has already been submitted for inclusion through a change in the marketing authorization or, if not submitted, whether there is a plan to apply for a change.

The latest periodic safety report should be presented as an annex.

The comparative analysis of the safety profile of the evaluated health technology and the comparative alternatives should be presented in tabular form.

All adverse events of clinical or economic relevance (e.g. affecting patients' quality of life, mortality, adherence to therapy) should be included in the analysis, paying particular attention to cases where significant differences between technologies being compared exist.

The following categories of adverse events should be described:

• all adverse events;

• any adverse events leading to participants dropping out of the trial;

• all serious adverse events;

• all adverse events leading to death;

• all adverse events with a frequency or severity that stand out between the groups.

They should be presented in tabular form and the data obtained should be summarized.

Clinical trial identification					
	Observed adverse events				
Alternative	Number of patients	Absolute number of adverse events in the group	Number of patients with adverse events	Frequency of serious adverse events	Frequency of all adverse events
New technology					
Comparative alternative					
Comparative alternative					
Placebo					

A list of and supporting material from references used should be provided.

3. Pharmaco-economic assessment.

3.1. Description of pharmaco-economic analyzes conducted using the health technology being assesed in other countries.

Where health-economic assessments or pharmaco-economic analyzes have been conducted using the assessed health technology for the purposes of other healthcare systems, these should be described. A tabular type for the description and detailed written information is recommended.

The following data should be clarified in tabular form:

- source of the study;
- purpose of the study;
- method (s) used in the study, including used modeling (if any);
- compared alternatives;
- outcome measures (clinical indicators, quality of life, long-term results, etc.); - results of the analysis (e.g. value of incremental ratio, etc.); - conclusion by the authors.

The results obtained should be commented on and corelated with the assessment of the current health technology. The more singular results or the interpretation of data and results should also be clarified in a textual form.

3.2. Description of published assessments of the health technology performed by government institutions for the purposes of another national healthcare system.

Data must be provided for all countries where the technology has been assessed where the technology has received at least one positive rating from a government institution in the United Kingdom, France, Germany and Sweden.

Data on the assessments carried out should include the following information:

- the institution which carried out the assessment;
- point of view of the assessment (public funds, special funding systems, society, etc.); - the indication for which the assessment was carried out;
- affected population;
- alternatives being compared;
- assessment methods applied;
- where patient access schemes are included, these should also be indicated;
- decision reached (including limitations associated with that decision);
- clarify whether the decision taken is conclusive or whether the technology will be subject to further monitoring.

All decisions made by public institutions together with relevant references and the document containing the final assessment and conclusion should be attached.

3.3. Analysis used.

The analyzes used should reflect the Bulgarian therapeutic practice and treatment standards, as well as sources of cost data and therapeutic outcomes.

Purpose of the analysis	Specify the purpose of the analysis

Comparative alternative	List the alternative / alternatives identified according to the guidelines in point 1.7 and used in the clinical assessment.
Perspective analysis	The paying institution's perspective on health benefits and costs and, if applicable, the public perspective shall be specified.
Time horizon	Long enough to ensure that all important future cost differences and outcomes between alternatives are identified.
Methods used	Cost-effect analysis (CEA). Cost-utility analysis (CUA). Cost-minimum analysis (CMA). Cost-benefit analysis (CBA).
Outcome measurers	QALY, LYG, HRQoL or intermediate results.
Discounting	3.5 per cent per year in both cost and performance for a period longer than one year.
Modeling the evolution of the disease or therapy	Specify the type of model applied ("Decision Tree", Markov model, epidemiological, simulation, discrete choice model, etc.).
Method of assessing the uncertainty	Deterministic Sensitivity Analysis (DSA), Probabilistic Sensitivity Analysis (PSA).

Purpose of the analysis.

The stated objective must be clear and specific and be consistent with the financing institution.

3.4. Comparative alternative.

When conducting a pharmaco-economic analysis, comparative alternatives must take into account the recommended alternatives from the presentation of clinical trials, namely: - the alternative most likely to be replaced by the new technology;

- alternatives from conducted systematic reviews and meta-analyzes; - alternatives that are included in standard therapeutic guidelines; - alternatives from randomized clinical trials.

The assessed medicinal products for reimburcement should be oriented following this sequence of alternatives - the higher in the hierarchy of comparative alternatives used in the analysis, the higher its reliability.

The choice of any of the comparative alternatives should be substantiated from the viewpoint of Bulgarian therapeutic practice.

3.6. Perspective.

The analyzes should reflect the perspective of the paying institution.

The public perspective is recommended for the assessment of vaccination programs, screening programs, and prevention programs.

3.7. Time horizon.

The time horizon for the analysis should be long enough to ensure that all important future differences in costs and outcomes between alternatives are identified.

The choice of the time horizon for the analysis should be justified in terms of life expectancy for the population concerned and long-term therapeutic results should be taken into account.

3.8. Methods used.

The main economic method used in the health technology assessment must include at least a costutility analysis (CUA) or cost-effect analysis (CEA). More than one analysis may be carried out where appropriate.

A cost-minimum analysis (CMA) can be used for comparative alternatives with no superiority of

therapeutic results, as well as for the assessment of combined medicinal products when the therapeutic result is compared with that of the monoproducts. The cost-benefit analysis (CBA) method can be used for the assessment of vaccination programs, health programs, equipment, organizational measures in health care (e.g. screening programs, etc.).

The choice of analytical method should be justified from the viewpoint of the paying institution, the time horizon and the evidence regarding the therapeutic results.

The main theoretical recommendations, as well as those of the Good Research Practices should be observed in using the methods.

3.9. Costs of the health technology being assessed.

The cost of each unit of the technology being assessed and the alternatives should be reported as a unit price, the cost of a course of treatment within one year, as well as other costs required for its implementation (where necessary).

The sources of all unit prices and costs should be indicated to enable a comparison. For prices of medicinal products, the registers of the National Council for Prices and Reimbursement of Medicinal Products (NCPRM), where available, should be used; for health care prices - the National Framework Agreement and the regulations issued in connection therewith. Other types of prices of services not covered by NHIF may be derived from tariffs of hospitals and other sources and these should be indicated. In such cases, we recommend to use more than one source and calculate an average cost.

The costs of treatment should be presented in tabular form - the cost of a course of treatment for one

patient and for all potential patients to whom the medicinal product will be administered.

The cost of drug therapy should be calculated for the ceiling price at retailer level including value added tax (VAT). If the product applies for 100 per cent reimbursement in Annex No 1, the costs should be

calculated for the price at wholesaler level includig VAT. In the case of applying under Annexes 2 and 3, the costs should be calculated for the price at wholesaler level including VAT.

In cases of reimbursement at less than 100 per cent, the costs for NHIF and the patient should be calculated in a separate table for the price at wholesaler level includig VAT.

The costs of treatment with comparative alternatives should be presented in tabular form - the cost of a course for one patient per month and per year. Costs based on the wholesaler or retailer prices, depending on the level of reimbursement, should be presented. Costs for all clinically comparable alternatives to the assessed product should be included, as well as such for the treatment accepted as standard under the therapeutic guidelines or national standards. It is important to identify the medicines that are most likely to be replaced by the health technology being assessed.

Where it is required to value the work of medical and other specialists, the minimum social security standards should apply.

Direct medical costs should be presented as the sum of the costs of the technology, its implementation, the additional procedures, the costs of other health care activities, the costs of treatment in cases of adverse events and / or complications, as well as the investment and management costs. Other types of costs that may be relevant to the health technology may be added.

Indirect costs should be calculated only where significant social and economic benefits from the introduction of the new technology result, which go beyond the health benefits. In calculating indirect costs, the human capital method is recommended. Indicate what kind of indirect costs are valued - losses from incapacity to work due to temporary absence from work, losses from permanent incapacity to work, reduced working capacity, early retirement, premature mortality or others.

Indirect costs should be reported and estimated separately from direct medical costs.

All costs are presented in tabular form, indicating the type of units being assessed, their number, the scheme of application, the costs for each unit and the total costs.

3.10. Discounting.

3.5 per cent per year for both costs and results when presenting the costs and results for a period longer than one year.

3.11. Outcome measures.

Analytical techniques should be applied in compliance with the recommendations for outcome measures expected for the implementation of the health technology. Long-term outcomes (life years gain (LYG), quality-adjusted life years (QALY), followed by intermediate results (changes in clinical parameters and disease progression) should be preferred.

The choice of outcome measure should be justified from the point of view of the type of disease, the expected duration of treatment and changes during treatment.

In reporting the QALY indicator, the source of data on changes in quality of life and whether these are data from clinical trials conducted for the applicant health technology or from databases with published studies (these must be indicated) or expert assessments by medical professionals, or other sources should be indicated.

3.12. Cost-outcome ratio modeling.

Modeling should be applied where the available clinical and non-clinical data are not sufficient to determine the cost-effectiveness ratio. The structure of the model should be presented. The complexity of the model and the modeling methods should be comensurate with the complexity of the health problem.

It is recommended that the models be as simple and transparent as possible while maintaining their detailed implementation to enable the assessment of the difference in efficiency of the compared technologies. The assumptions in the model should be clear, well-founded and tested through a sensitivity analysis. Models should be developed using standard tools in order for them to be tested and verified.

In cases where no statistically significant difference in the clinical efficacy of the alternatives exist, modeling is not required. If the model includes key data for the changes of which there is no uncertainty, only those for which there is a statistically significant difference should be tested through the sensitivity analysis. The rest of the parameters should be excluded from the model or considered neutral with respect to the model.

When presenting the cost-outcome ratio, modeling may be applied, such as the Decision Tree, the Markov model, the epidemiological model, or other scientifically accepted modeling techniques. The modeling should include the following data:

Subject of analysis	Principles of good practice	Critical assessment questions
Model structure		
Health status	The structure of the model should be as simple as possible, but at the same time it should correspond to the health problem, the knowledge of the course of the disease, the causal link between the variables. The lack of data is not a reason to eliminate a health condition.	Are the health problem, the subject of the assessment and the alternatives clearly defined? Are the stages important for the course of treatment described? Are the assumptions in the model described and justified? Is the selection of health conditions justified? If so, are they consistent with the existing knowledge of the disease? Are there missing health conditions?
Comparative alternatives	The model must comply with the comparative alternatives described above.	Are comparative alternatives described? Are alternatives in line with the recommendations for their selection?
Time horizon	The time interval should be sufficient to assess the long-term cost differences and results of the alternatives being compared.	Is the time horizon defined? Is it appropriate for the situation being analyzed?
Cycle duration (using models with cyclic structure)	The duration of the cycle should be the shortest period in which changes in the studied parameters of the disease progression process are observed.	Is the cycle duration defined in the model? Does it correspond to the evolution of the disease?

Model inputs		
Identification of input data	The model should use the best available data (epidemiological, clinical costs) relevant to the knowledge and situation in Bulgaria. Input data must be obtained from objective sources. Key data include the following: -effectiveness and safety for the interventions being compared, -benefits for the health conditions, - variables for which even small changes in value have a significant impact on results. Data sources can be from clinical studies, non-clinical, economic	Are the data sources in the model represented? Is an appropriate data search method implemented? Is the data variation parameter specified? Does anything suggest that the data is being used selectively? Is there data based on an expert opinion (if yes, how are the experts selected, number, method of gathering information, conflict of interest)?
	databases, systematic reviews, etc. The sources must be indicated and justified.	
Data modeling	Data modeling should be carried out using conventional statistical methods.	Are the methods used described? Are they compatible with conventional biostatistic and epidemiological methods?
Inclusion of data in the model	Units, time intervals and population characteristics should be mutually comparable throughout the model. A half-cycle correction method may be used to standardize or eliminate the effects of time.	Are units of measure, time intervals, population characteristics described, and are they comparable to the alternatives? Is a half cycle adjustment method applied?
Sensitivity analysis		
Sensitivity analysis	Each model should have a sensitivity analysis of the key parameters and the same should be justified. The sensitivity analysis involves deterministic analysis of key parameters or probabilistic analysis. The lack of sensitivity analysis should be justified.	Has a sensitivity analysis been conducted for all uncertain parameters? Are the variation check intervals defined? Has a probabilistic or deterministic sensitivity analysis been conducted? Is the lack of probabilistic sensitivity analysis justified?

3.13. Presenting the results of analytical method applied.

When the analytical technique used is cost-effectiveness or cost-utility, the results should be presented as a cost-effectiveness ratio or an incremental cost-performance ratio.

When presenting results, the generally accepted rules for ranking alternatives in ascending order of results should be followed and the incremental cost ratio (ICER) for each of the therapies with respect to the respective compative alternative presented in the following table should be calculated:

Alternative	Total costs	Total number of years of life	QALY's total	Additional costs	Life years gained (LYG)	QALY gained	ICER vs. respective alternative or (QALY's)	NHB net health benefit (Net Health Benefit)
Alternative 1								
Alternative 2								
Alternative 3								
.....								

Where the analytical technique used is a minimum cost, evidence of equivalence of therapeutic results should be provided and the overall health costs for the selected prospect of the funding institution should be compared.

Where the analytical technique used is cost-benefit, the cost-benefit ratio, the net health benefit and other applicable indicators shall be presented.

3.14. Subgroup analyzes.

Data indicating that the efficiency and/or costs associated with the health technology differ across subgroups, if available, should be provided. If so, and there is an indication of cost-effect in the treatment of these subgroups, indicate whether the subgroups have been identified before the clinical trial is conducted or after the results of the trial have been obtained; the characteristics of the subgroups should be described and the model results for those subgroups should be indicated.

3.15. Interpretation of analysis results.

The results should be interpreted with respect to the perspective of the analysis, with respect to the cost-outcome ratio or the incremental ratio.

The possible limitations of the analysis used and the factors that which can have an impact but are not included in the analysis should be analyzed.

3.16. Comparison with other analyzes performed.

Indicate whether the results of the analysis are in line with the results of similar analyzes already published and, if not, indicate possible reasons for the differences.

4. Budget impact analysis.

The budget impact analysis (BIA) is an important part of the overall economic assessment, used to determine the financial changes in public health spending after the introduction of new health technologies.

4.1. BIA Perspective.

The budget impact analysis should be conducted from the perspective of the paying public institution. In the case of sharing the costs with the patient, it is recommended that the patient's average cost be presented. Only in duly justified cases can a budget impact analysis be conducted from another perspective.

4.2. Time horizon.

The budget impact analysis should include an assessment of the impact of the health technology being assessed on the annual public health budget within a few years of the introduction of the new technology on, or the withdrawal of available alternatives from, the market. The budget impact analysis should be presented for a period of 5 years.

4.3. Elements of the budget impact analysis.

The budget impact analysis includes the following elements:

• numbers and characteristics of the target population;

• current therapeutic practice;

• new therapeutic practice after the introduction of the new health technology / abandonment of the current one;

• costs of the current and new health technology;

• presentation of results;

• sensitivity analysis.

4.4. Data sources.

Possible data sources for the budget impact analysis can be: published epidemiological studies, national statistics, market surveys, data from registers. To this end, the search strategy, data selection criteria and methods of analysis need to be presented, as well as the strengths and weaknesses of the sources used.

It is advisable to use epidemiological data for the Bulgarian population, while the use of data from other countries should be justified. When using data from unpublished sources (e.g. expert opinions, marketing studies, patient organization data), it is mandatory to declare a conflict of interest.

The estimated actual cost of the payer associated with the new health technology and comparative alternatives should be presented.

4.5. Numbers and characteristics of the target population.

When preparing the budget impact analysis, it is imperative to assess the size of the target patient population and the distribution of any characteristics related to it that may have a budget impact. Once the target population is defined, the percentage of patients diagnosed and treated, and the severity of the disease should be determined. Usually, more restrictive inclusion criteria are applied in this regard to accurately calculate the population of patients who are reliable with regard to the new health technology. In assessing the size of the target population and the severity of the disease, it is important to anticipate the change in these

parameters over time with and without the new health technology. Such changes can alter the budget impact of new health technology. Data from clinical trials or registers should be used to evaluate these changes. The analysis should also include published data or expert assessment on any additional opportunity to determine the target population (such as the use of diagnostic tests, for example) that may increase the size of the population or change the severity of the disease.

The target population should be defined according to the following criteria:

• incidence of the disease;

• assessment on patients who are appropriate for the new health technology;

• estimate of the presumed market share of the new technology due to the target population relative to the population that uses the comparative alternatives for the given indication.

4.6. BIA scenarios.

The budget impact analysis is based on two scenarios - "A world without the new health technology" and "A world with the new health technology". The “world without the new health technology” scenario describes the current therapeutic practice, while the “world with the new health technology” scenario reflects the impact on the market after the introduction of the new technology (which may be added to existing ones or may replace some or all of them). Assumptions about both scenarios should be detailed and substantiated in the analysis.

4.7. Costs.

The cost analysis in the scope of the budget impact assessment should be consistent with the perspective of the analysis. The methods used to estimate costs must be clearly described and justified. The cost analysis should be based on the actual cost of acquiring the new health technology by the paying institution and on the additional costs associated with the health technology being assessed, with the calculations being presented at the level of wholesaler including VAT, or at the level of retailer including VAT.

When presenting public expenses, it must be ensured that these are actual costs or savings for the payer.

Depending on the type of the new health technology, it is important to describe the possible costs associated with its implementation, including, if necessary, training medical professionals or the patient, as well as changes in diagnostic principles or other functional changes in the healthcare system.

In the budget impact analysis, costs are not discounted.

When estimating total additional costs, account should be taken of the following:

• costs associated with the new health technology;

• additional costs within the healthcare system related to the implementation of the new technology;

• cost reductions associated with reducing the use of existing alternatives, if the new technology replaces the current ones;

• cost reductions associated with savings, such as fewer hospitalizations, etc.

4.8. Sensitivity analysis.

In the budget impact analysis, two types of uncertain data are expected: uncertainty in the values of input data and structural uncertainty related to the assumptions made. It is recommended that the sensitivity analysis be conducted in a way that allows changes in the values of the selected input parameters and structural assumptions, aimed at forming plausible alternative scenarios.

4.9. Presentation of results.

Table 2

Table 1

Numbers or proportion of patients, if new technology is reimbursed						Numbers or proportion of patients, if new technology is NOT reimbursed					
	Year 1	Year 2	Year 3	..	Year X		Year 1	Year 2	Year 3	..	Year X
New technology						New technology					
Alternative 1						Alternative 1					
Alternative 2						Alternative 2					
Alternative 3						Alternative 3					

Costs (Annual cost per patient * number of patients per year)						Costs (Annual cost per patient * number of patients per year)					
	Year 1	Year 2	Year 3	...	Year X		Year 1	Year 2	Year 3	...	Year X
New technology						New technology					
Alternative 1						Alternative 1					
Alternative 2						Alternative 2					
Alternative 3						Alternative 3					
Total costs						Total costs					

The budget impact represents the difference between the two scenarios in each of the respective years of analysis. Year 1 is the first full calendar year after making a decision to introduce the new technology.

Budget impact	Year 1	Year 2	Year 3	...	Year X

(+) Costs, if the new technology is reimbursed					
(-) Costs without reimbursement for the new technology, i.e. the current situation					
(-) Costs paid by the patient during outpatient treatment					
Total added cost					

The results obtained should be clearly stated and the limitations of the analysis should be indicated.

5. Assessment of health technologies for medicinal products designed for specific disease groups.

When assessing health technologies for orphan drugs, information should be provided regarding efficacy and therapeutic effectivness.

The health technology assessment for orphan medicinal products should meet the following additional criteria:

• presenting, over a period no longer than one year, additional evidence of the benefits from administering the medicinal product;

• presenting models (Markov model, etc.) which track the course of the disease;

• assessment based on the severity, gravity of the rare condition; existence of an alternative; what would the cost to the patient be, if the medicinal product is not reimbursed;

• moral and ethical considerations;

• an economic evaluation and an overall budget impact assessment should be presented for orphan drugs that are of great social benefit, are not cost effective, and their use is indicated for serious conditions for which there is no effective alternative therapy.

6. Information on the moral and ethical aspects of the use of the health technology (if any).

7. Summaries and reports (in annex) of decisions and assessments by government institutions for the purposes of other national healthcare systems.

8. Evidence from references used.

9. Description of references used.

Annex 7 to Article 44, paragraph 2

Financial resources spent on medicinal products for the number of patients suffering from the relevant diseases, for the treatment at home whereof the NHIF reimburses the medicinal products in full or in part for the period from (month) to (month)

ICD code	Name of disease	ATC code	International non-proprietary name	Brand name	Pharmaceutical Form	Number packages	Number patients	Value reimbursed by NHIF

Number of compulsorily health insured persons who approached the system about the respective diseases for the treatment at home whereof the NHIF reimburses medicines in whole or in part for the period from …….. (year) to …… (year)

ICD code	Disease	Number of compulsorily health insured persons who approached the NHIF system in connection with the disease	Share of the total number of compulsorily health insured persons who approached the system

Annex No 8 to Article 54

EVALUATION
TABLE

Indicator	Score	Remark (enter strictions and conditions under which they apply: for Part 1, mandatory ICD code under MoH Ordinance No 38)
I. Proposed level of reimbursement (Article 53) (in %)	….....%	
1. for medicinal products referred to in Items 2 and 3 of Article 6 (2): 100 percent - Item 1 of Art. 53		
2. for medicinal products for diseases with a chronic urse, leading to severe disruptions in the quality or life disablement and requiring prolonged treatment: 100 rcent — Item 2 of Art. 53		
3. for medicinal products for diseases with a chronic urse and widespread prevalence: 75 percent - Item 3 of rticle 53		
4. for medicinal products for diseases other than those ferred to in Items 1, 2 and 3: up to 50 percent.		
Parameters (Article 54):		
1. final evaluation of the criteria covered under Article	....	
2. the indications for administration of the medicinal oduct according to the summary of product aracteristics for the type of treatment:		
(a) essential treatment: etiologic/pathogenetic treatment;	5 points	
(b) symptomatic treatment;	2 points	
(c) preventive treatment;	4 points	
(d) palliative treatment;	1 points	
(e) maintenance treatment	3 points	Substitution therapy
(f) additional treatment	1 points	
3. the social significance of the disease in the Republic Bulgaria, for the treatment of which the medicinal oduct is used;	2 points: YES 0 points: NO	
4. length of treatment and outcome:	Quick and definitive: 5 ints Long and fective: 3 points Long and insufficiently fective: 1 point	

5. therapeutic algorithm according to the endorsed manuals of pharmacotherapy in the Republic of Bulgaria or, in the absence of such manuals, treatment standards and the Good Medical Practice in the countries of the European Union	2 points: YES 0 points: NO	

Total: ..... points

Level of reimbursement under Article 54 for medicinal products referred to in Items 2 and 3 of Article 6, paragraph 2: 100 percent.

Level of reimbursement under Article 54 for medicinal products referred to in Item 1 of Article 6, paragraph 2:

- Over 78 points: 100 percent;
- From 73 to 77 points: 75 percent; - From 68 to 72 points: 50 percent;
- From 62 to 67 points: up to 50 percent.