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

Effective as from 30 April 2013

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Chapter One
GENERAL DISPOSITIONS

Article 1. This Ordinance establish:

1. the terms and rules for regulation of prices for medicinal products dispensed on medical prescription, included in the Positive Drug List (PDL) and paid for by public funds;

2. the terms and27 rules for regulation of ceiling prices for medicinal products dispensed on medical prescription, which are not included in the PDL, upon the retail sale of the said products;

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

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

5. (New — SG No 92 of 2015) the terms, rules and criteria for maintenance of reimbursement status of medicinal products included in PDL;

6. (New — SG No 92 of 2015) order for receiving of contracts for granting discounts for medicinal products pursuant to Art. 45 (10), (13) and (19) of the Health Insurance Act (HIA);

7. (Previous Item 5 — SG No 92 of the terms under which and the procedure according to which the Ministry of Health (MoH) and the National Health Insurance Fund (NHIF) can make proposals to the National Council on Prices and Reimbursement of Medicinal Products, hereinafter referred to as "the Council", for review of medicinal products included in the PDL;

8. (Previous Item 6 — SG No 92 of 2015) the terms and procedure for endorsement, revocation or modification of manuals of pharmacotherapy, including criteria for evaluation of the efficacy of the therapy administered, as well as recommendations for algorithms for treatment with medicinal products, proposed by the relevant national consultants, medical learned societies and expert boards.

Article 2. (1) "Price for a medicinal product included in the PDL and paid for by public funds" shall be the price in Bulgarian lev terms as endorsed by the Council.

(2) The price referred to in Paragraph (1) shall furthermore be a ceiling price for the medicinal products upon the retail sale of the said products.

(3) The ceiling price for a medicinal product dispensed on medical prescription, which is not included in the PDL, shall be the price in Bulgarian lev terms, as endorsed by the Council, which is the highest permissible one upon the retail sale of the said product.

(4) The price for an over-the-counter medicinal product shall be the maximum retail selling price in Bulgarian lev terms, as declared by the marketing authorisation holder and as registered by the Council.

(5) In respect of the medicinal products for which a parallel import authorisation has been obtained, a price shall be endorsed/registered according to the procedure established by the Ordinance.

Article 3. Where the marketing authorisation specifies the prescribing requirements as “dispensed on medical prescription and over-the-counter”, the price for the medicinal product shall be formed according to the procedure established by Chapter Three herein.

Article 4. A medicinal product may be sold within the territory of the country solely after the entry into effect of the decision of the Council on endorsement and of a price/ceiling price or registration of a price.

Article 5. (1) (Amended — SG No 92 of 2015, in force from 07.11.2014) A medicinal product may be sold at a price not higher than the endorsed price referred to in Article 2 (1) herein, the ceiling price referred to in Article 2 (3) herein, or the registered price referred to in Article 2 (4) herein.

(2) Each retailer shall be obligated to state the selling price on the packaging of the medicinal product in a place designated by the manufacturer.

(3) The prices for medicinal products included in the value of medical care provided by medical-treatment facilities may not be higher than the price at which the medical-treatment facility has purchased the medicinal product from the wholesaler.

(4) A pharmacy mark-up shall not be added on upon the dispensing at a pharmacy of any medicinal products included in the PDL under Item 1 of Article 262 (6) of the Medicinal Products for Human Use Act (MPHUA) with 100 percent level of reimbursement.

(5) (New — SG No 92 of 2015; *in force from 01.01.2017, SG 3 of 2016, in force from 27 November 2015, amended concerning entering in force from 01.01.2017; in force from 01.12.2015, amended concerning entering into force – SG 14 of 2016, in force from 16.02.2016; amended concerning entering in force – SG 74 of 2016, in force from 01.09.201; repealed 0 SG 2 of 2017, entering into force from 01.01.2017.*

Article 6. (1) Medicial products authorised for marketing according to the procedure established by the MPHUA, classified by pharmacological group according to the Anatomical Therapeutic Chemical Classification (ATC), shall be included in the Positive Drug List.

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

1. (Amended — SG No 92 of 2015) medicinal products intended for treatment of diseases which are paid for according to the procedure established by the HIA;

2. medicinal products paid for 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 wherein the State and/or a municipality holds a participating interest under Articles 9 and 10 of the Medical-Treatment Facilities Act.

3. medicinal products intended for treatment of AIDS, of infectious diseases, of diseases beyond the scope of the HIA which are paid for according to the procedure established by Item 8 of Article 82 (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 (2) of the Health Act;

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

(3) (Amended — SG No 92 of 2015) The annexes to the PDL referred to in Items 1 to 3 of Paragraph (2) shall state: ATC code, international non-proprietary name (INN), name of the medicinal product, pharmaceutical form and quantity of the active ingredient, final packaging, marketing authorisation holder, DDD for a treatment course, the price under Article 261a (1) of the MPHUA, reference value for DDD for a treatment course, level of reimbursement of the medicinal product, diseases according to International Classification of Diseases (ICD) code, information on the restrictions in the prescribing method varying by indication and additional information.

(4) For medicinal products for which a DDD has not been defined, the reference value shall be determined on the basis of treatment course, strength or volume.

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

1. the prices for medicinal products, referred to in Article 2 (1) herein;
2. the prices for medicinal products, referred to in Article 2 (3) HEREIN;
3. the prices for medicinal products, referred to in Article 2 (4) herein.

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

(3) The registers referred to in Paragraph (1) and the PDL shall be made public on the Internet site of the Council.

(4) The Council shall publish on the Internet site thereof the manuals of pharmacotherapy endorsed according to the procedure established by Chapter Seven, recommendations for algorithms for treatment with medicinal products and criteria for evaluation of the efficacy of the therapy.

(5) The Council shall publish on the Internet site thereof the statutory instruments of the Member States referred to in Article 8 (3) and Article 33 (2) herein, which are applicable upon the determination of the ex-factory price for the same medicinal product.

Chapter Two
FORMATION OF PRICE FOR MEDICINAL PRODUCT INCLUDED IN POSITIVE DRUG LIST AND PAID FOR BY PUBLIC FUNDS

Article 8. (1) The price for a medicinal product included in the PDL and paid for by public funds shall be formed of the following elements:

1. ex-factory price, which may not be higher than the lev equivalent of the lowest ex- factory price for the same medicinal product in the countries specified in the information referred to in Article 33 (2) herein;

2. wholesale mark-up at the rate of 7, 6 and 4 percent of the price declared under Item 1 according to the criterion established in Article 9 herein;

3. pharmacy mark-up at the rate of 20, 18 and 16 percent of the price declared under Item 1 according to the criterion established in Article 9 herein;

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

(3) (Amended and supplemented — SG No 92 of 2014, effective as from 07.11.2014) Where there is no ex-factory price in the countries specified in Article 33 (2) herein, the ex-factory price may not be higher than the lowest price for the same medicinal product in Belgium, the Czech Republic, Poland, Hungary, Denmark, Finland and Estonia.

(4) (Amended — SG No 92 of 2014, in force from 07.11.2014) Where an ex-factory price for the same medicinal product cannot be found in the countries specified in Article 33 (2) and in the countries referred to in Paragraph (3), the ex- factory price may not be higher than the lowest price of a manufacturer/manufacturers 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 of the same pharmaceutical and dosage form and in a final packaging nearest to the declared one, paid for by the public health insurance funds of the countries referred to in Article 33 (2) herein.

(5) (New — SG No 92 of 2015, in force from 01.01.2017, amended concerning entering into force – SG 74 of 2016, in force from 01.09.2016) Where an ex-factory price for the same medicinal product cannot be found pursuant to this Article, the declared ex-factory price cannot be higher than twice the ex-factory price of the medicinal product with the same international non-proprietary name and pharmaceutical form which has the lowest value for DDD for treatment course defined pursuant to Section III as at the moment of submission of the application according to Art. 33 (1).

(5) relating to the formation of price of the products included in PDL, shall enter into force from 01.01.2017. Vz. § 9a

Art. 8a.(New — SG No 62 of 2016) Checking the ex-factory price of a medicinal product according to Article 8, the Council shall use the published prices and calculation methods published by the institutions of the respective state, as well as information from the EURIPID Collaboration database (Agreement on Joint Activity regarding the Pricing and Reimbursement of Medicinal Products) and shall use the most favourable price for the applicant.

Article 9. (1) In case the declared ex-factory price does not exceed BGN 10.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 7 and 20 percent, respectively.

(2) In case the declared ex-factory price is within the range from BGN 10.01 to BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 6 and 18 percent, respectively.

(3) In case the declared ex-factory price exceeds BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 4 percent but not more than BGN 10 and, respectively, 16 percent but not more than BGN 25.

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

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

1. ex-factory price, which may not be higher than the lev equivalent of the lowest ex- factory price for the same medicinal product in the countries specified in the information referred to in Item 5 of Article 14 (1) herein;

2. wholesale mark-up at the rate of 7, 6 or 4 percent of the price declared under Item 1 according to the criterion established in Article 11 herein;

3. pharmacy mark-up at the rate of 20, 18 or 16 percent of the price declared under Item 1 according to the criterion established in Article 11 herein.

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

(3) (Amended and supplemented — SG No 92 of 2014, effective as from 07.11.2014) Where there is no ex-factory price in the countries specified in Article 14 (5) herein, the ex-factory price may not be higher than the lowest price in Belgium, the Czech Republic, Poland, Hungary, Denmark, Finland and Estonia.

Article 11. (1) In case the declared ex-factory price does not exceed BGN 10.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 7 and 20 percent, respectively.

(2) In case the declared ex-factory price is within the range from BGN 10.01 to BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 6 and 18 percent, respectively.

(3) In case the declared ex-factory price exceeds BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 4 percent but not more than BGN 10 and, respectively, 16 percent but not more than BGN 25.

Article 12. (1) Upon preparation of a medicinal product as a magistral and officinal formula in a pharmacy, a mark-up shall not be added on to the value of the medicinal substances, incipients and the 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 at the health-care facility.

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

Chapter Four
TERMS AND PROCEDURE FOR REGULATION OF CEILING PRICES FOR MEDICINAL PRODUCTS, REFERRED TO IN ARTICLE 2 (3) HEREIN

Article 13. (1) (Amended — SG No 92 of 2014, effective as from 07.11.2014) For the formation of a ceiling price referred to in Article 2 (3) herein, the marketing authorisation holder or an authorised representative thereof shall submit an application for the formation of a ceiling price according to a form endorsed 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 herein.

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

1. a copy of a marketing authorisation for the medicinal product according to the requirements of the MPHUA, 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 referred to in Article 13 (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, effective as from 07.11.2014) a declaration-information, completed in a standard form according to Annex 2 hereto, regarding the ex-factory price for the medicinal product in the respective currency terms and in euro — in Romania, France, Latvia, Greece, Slovakia, Lithuania, Portugal, Italy,
Slovenia and Spain;

6. documentary proof of stamp duty paid for each separate medicinal product for establishing the prices for medicinal products, referred to in Article 2 (3) herein.

(2) The ex-factory prices in the declaration-information referred to in Item 5 of Paragraph (1) must be valid as at a date not earlier than one month prior to the date of submission of the application referred to in Article 13 (1) herein.

(3) The authorisation referred to in Item 1 of Paragraph (1), as well as Annexes I, II and III thereto, shall be presented accompanied by a translation into the Bulgarian language.

(4) (Amended — SG No 92 of 2014, effective as from 07.11.2014) For the formation of a ceiling price of a medicinal product which has been authorised for parallel import or parallel distribution by the European Medicines Agency, in the presence of identical or similar medicinal product pursuant to Art. 214 of the MPHUAhaving price endorsed by the Council, an application shall be submitted by the Holder of authorisation/notification for parallel import/parallel distribution, according to a form endorsed by the

Council.

(5) (New — SG No 92 of 2014, effective as from 07.11.2014) The authorisation/notification for parallel import/parallel distribution and documents referred to in paragraph 1, item 2 —4 and 6 shall be attached to the application referred to in paragraph 4.

(6) (New — SG No 92 of 2014, effective as from 07.11.2014) The declared price of medicinal product referred to in paragraph 4 cannot be higher that the ceiling price endorsed by the Council for the identical or similar medicinal product pursuant to Art. 214 of the MPHUA.

(7) (New — SG No 92 of 2014, effective as from 07.11.2014) The provisions of Art. 15 — 18 shall apply for medicinal products referred to in paragraph 4.

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 (3) herein.

(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 herein, 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 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. A legal evaluation shall be made first, and it shall be followed by an economic evaluation.

(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 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. sequential number in the register;
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 (2) herein.

(2) The refusal of the Council to endorse a ceiling price for the medicinal product shall be reasoned.

(3) (Amended — SG No 92 of 2015) Council decision pursuant to PARAGRAPH 1, as well as the

refusal referred to in paragraph 2 shall be subject to administrative appeal before the Transparency Commission.

Article 18. The Council shall make public the decisions which have entered into effect in the register referred to in Article 22 herein 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 (3) herein 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 herein, attaching only the documents relevant to the change.

(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 ceiling price for a medicinal product referred to in Article 2 (3) herein.

(3) It shall be inadmissible to apply for an increase of a ceiling price for a medical product referred to in Article 2 (3) herein by a larger percentage than the statistically reported rate of inflation for the period of validity since the last formed ceiling price.

(4) Upon any change of the circumstances entered in the register referred to in Article 22 herein, 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 herein, attaching only the documents relevant to the change.

(5) (Amended and supplemented — SG No 92 of 2014, effective as from 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 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 that is 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 herein, and the decisions shall be subject to appeal according to the procedure established by Article 17 (3) herein.

(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 (6) of the MPHUA, 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 (3) herein, 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. 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 pharmacy 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 (3) herein, which shall contain the following information:

1. sequential number in the register;
2. international non-proprietary name;
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;
7. name of the manufacturer of the medicinal product;
8. the declared ex-factory price, on the basis of which the ceiling price is formed;
9. the ceiling price as endorsed, disaggregated by element, the number and issue date of the decision on endorsement of a price;
10. effective date of the decision of the Council;
11. additional information.

Chapter Five
REGISTRATION OF PRICE FOR OVER-THE-COUNTER MEDICINAL PRODUCTS, REFERRED TO IN ARTICLE 2 (4) HEREIN

Article 23. (1) (Amended — SG No 92 of 2014, effective as from 07.11.2014) For registration of a price for an over-the-counter medicinal product, the marketing authorisation holder or an authorised representative thereof shall present at the Council an application for registration, completed in a standard form according to Annex 1 hereto, stating therein an ex-factory price in foreign currency/euro terms and in Bulgarian lev terms, as well as a maximum selling price for the medicinal product in lev terms, inclusive of value added tax.

(2) The documents referred to in Items 1 to 4 of Article 14 (1) herein and documentary proof of stamp duty paid for each separate medicinal product shall be attached to the application referred to in Paragraph (1).

(3) (Amended — SG No 92 of 2014, effective as from 07.11.2014) For registering a maximum selling price in respect of a medicinal product which has been authorised for parallel import or parallel distribution by the European Medicines Agency if the same medicinal product pursuant to Art. 214 of the MPHUAis available at a maximum selling price registered by the Council, the holder of authorisation/notification for parallel import/parallel distribution shall submit an application in a standard form endorsed by the Council.

(4) (New — SG No 92 of 2014, effective as from 07.11.2014) The authorisation/notification for parallel import/parallel distribution and documents referred to in Art. 14 (1), item 2 —4 and 6 shall be attached to the application referred to in PARAGRAPH 3.

(5) (New — SG No 92 of 2014, effective as from 07.11.2014) The declared price of medicinal product referred to in paragraph 3 cannot be higher than the maximum selling price registered by the Council for the identical or similar medicinal product pursuant to Art. 214 of the MPHUA.

(6) (New — SG No 92 of 2014, effective as from 07.11.2014) The provisions of Art. 24 — 26 shall apply for medicinal products referred to in paragraph 3.

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 non-conformities 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 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. sequential number in the register;
2. international non-proprietary name;
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) The decision of the Council pursuant to paragraph 1, as well as the refusal referred to in paragraph 2 shall be subject to administrative appeal before the Transparency Commission;

(4) Upon any change of the circumstances entered in the register referred to in Article 28 herein, 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 herein, attaching only the documents relevant to the change.

(5) 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 herein on the 2nd of each month.

(6) (Amended and supplemented — SG No 92 of 2014, effective as from 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 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 herein, and the decisions shall be subject to appeal according to the procedure established by Article 26 (3) herein.

(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 the MPHUA, 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) The Bulgarian Drug Agency (BDA) 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 28. The Council shall keep a public register of the maximum retail selling prices for medicinal products, referred to in Article 2 (4) herein, which shall contain the following information:

1. sequential number in the register;
2. international non-proprietary name;
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;
7. name of the manufacturer of the medicinal product;
8. the maximum selling price as registered, the number and issue date 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 POSITIVE DRUG LIST AND TERMS AND PROCEDURE FOR REGULATION OF PRICES FOR MEDICINAL PRODUCTS REFERRED TO IN ARTICLE 2 (3) HEREIN

Section I.
Terms, Rules and Criteria for Inclusion of Medicinal Products in Positive Drug List

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 MPHUA;

2. 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 (2) herein;

3. (repealed – Decision № 13049 of 03.12.2015 – SG 32 of 2016, in force from 22.04.2016);

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 (2) herein;

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

(2) The Positive Drug List shall include medicinal products for which the declared ex-factory price referred to in Article 8 herein does not exceed 70

(3) percent of the ex-factory price for a medicinal product pertaining to the same international non-proprietary name, content of active ingredient per dosage unit, per unit of volume or per unit of weight, or in percentage terms, pharmaceutical form in final packaging, included in the PDL, and which is considered a reference medicinal product within the meaning given by Article 28 of the MPHUA.

(4) The requirement of Paragraph (2) shall not apply to any generic medicinal products for whose reference medicinal product, within the meaning given by Article 28 of the MPHUA, the price referred to in Article 261a (1) of the MPHUAhas been reduced, except in the case of reduction according to the procedure established by Article 43 herein, as well as where the PDL has already included one or more generic medicinal products.

(5) (New — SG No 92 of 2015) Medicinal products under Art. 45 (10) (13) and (19) of HIA for which no discounts are negotiated according to the ordinance pursuant to Art. 45 (9) of HIA shall not be included in the PDL.

(6) (New — SG No 92 of 2015) Within the relevant part of PDL shall be included medicinal products belonging to a new international non-proprietary name upon positive health technologies assessment according to the ordinance under Art. 262 (4) of MPHUA.

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) 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. pharmacoeconomic 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 of 2015) For medicinal products belonging to a new international non-proprietary name, evaluation pursuant to paragraphs (1) and (2) shall be carried out based on the health technologies assessment made according to the ordinance under Art. 262 (4) of MPHUA.

(4) (Previous paragraph 3 — SG No 92 of 2015) Where one or more medicinal products with the same international non- proprietary name, pharmaceutical form and strength, with the exception of the medicinal products referred to in Article 29 of the MPHUA, have already been included in the respective part of the PDL, the evaluation under Paragraph (1) shall not be conducted.

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 herein;

2. an evaluation has been conducted on the basis of the criteria covered under Article 30 herein according to Annex 5 hereto.

(2) Combination medicinal products shall be included in the 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.

Section II.
Procedure for Inclusion, Change and/or Exclusion of Medicinal Products in Positive Drug List and Terms and Procedure for Regulation of Medicinal Products Referred to in 2, Article 2 (1) herein

Article 32. (1) (Amended and supplemented — SG No 92 of 2014, effective as from 07.11.2014) For inclusion, changes and/or exclusion of a medicinal product in the 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) The NHIF and the 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 the PDL.

(3) (New — SG No 92 of 2015) The National Health Insurance Fund shall make reasoned written proposals to the Council for exclusion of medicinal products from PDL pursuant to Art. 262 (6), item 1 of MPHUAwhere the information according to Art. 44 (1) indicates that medicinal products are not reimbursed by HNIF within the relevant six month period or where NHIF analysis finds that for the relevant six month period NHIF has reimbursed for the relevant medicinal product less than 1 percent of total cost of medicinal products within the respective group of PDL according to INN and pharmaceutical form.

Article 33. (1) By the application for inclusion of a medicinal product in the PDL, the marketing

authorisation holder or an authorised representative thereof shall furthermore apply for the formation of a price under Article 2 (1) herein, stating the price disaggregated by element conforming to the rules under Article 8 herein.

(2) (Amended — SG No 92 of 2014, effective as from 07.11.2014, amended — SG No 92 of 2015) A declaration-information, completed in a standard form endorsed by the Council, regarding the ex-factory prices in the respective currency terms and in euro terms in Romania, France, Latvia, Greece, Slovakia, Lithuania, Portugal, Italy, Slovenia and Spain, shall be attached to the application referred to in Art. 8.

(3) The ex-factory prices in the declaration referred to in Paragraph (2) must be valid as at a date not earlier than one month prior to the date of submission of the application.

Article 34. (Amended — SG No 92 of 2014, effective as from 07.11.2014) For medicinal product which has been authorised for parallel import or parallel distribution by the European Medicines Agency if the same medicinal product pursuant to Art. 214 of the MPHUAincluded in the Positive Drug List is available at a price endorsed by the Council pursuant to Art. 2 (1) a price shall be formed 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 of 2015) The authorisation/notification for parallel import/parallel distribution, declaration pursuant to Art. 33 (2) and documents referred to in Art. 35 (1), item 2, 3, 6 and 9 and paragraph (4) shall be attached to the application referred to in paragraph 1.

(3) The declared price of medicinal product referred to in paragraph 1 cannot be higher than the price endorsed by the Council according to Art. 2 (1) for the identical or similar medicinal product pursuant to Art. 214 of the MPHUA.

(4) (Amended — SG No 92 of 2015) The provisions of Art. 35 (5) and Art. 37, 38 and 40 shall apply for medicinal products under paragraph (1).

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

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 (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 62/2016);

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. defined daily dose according to the latest data of the World Health Organisation (WHO),

number of DDDs in the respective packaging, and where there is no such dose, a recommended daily dose shall be defined according to the indications in the summary of product characteristics;

8. recommended therapeutic daily dose, if different from the DDD; average length of the treatment for the indications endorsed in the summary of product characteristics; need of background pharmacotherapy in the indication according to the summary of product characteristics;

9. documentary proof of stamp duty paid for each separate medicinal product;

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 of 2015) certified by the marketing authorisation holder or his authorised representative copy of a contract with NHIF for granting discount for medicinal products pursuant to Art. 45 (10), (13) and (19) of HIA.

(2) The documents referred to in Items 5 and 10 of Paragraph (1) shall be attached solely in respect of medicinal products which belong to an international non-proprietary name, pharmaceutical form and strength which is not included in the respective part of the PDL, and in respect of medicinal products referred to in Article 29 of the MPHUA.

(3) (New — SG No 92 of 2015) For medicinal products belonging to a new international non-proprietary name that is not included in the relevant part of PDL a Health technology assessment report shall be presented. This report shall be endorsed pursuant to the ordinance under Art. 262 (4) of MPHUAnot earlier than six months as from submission of the application.

(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 of 2015) The Council, stating reasons, may request the applicant to present additional information necessary for the adoption of a decision on inclusion, changes and/or exclusion of a medicinal product from the PDL, as well as for the formation of a price under Article 2 (1) herein.

(6) (Previous paragraph 5 — SG No 92 of 2015) Upon change of a medicinal product included in the PDL, the relevant documents related to the change shall be attached. where:

Article 35a. (New — SG No 92 of 2015) (1) Marketing authorisation holders or their authorised representatives shall submit on monthly basis declaration to BDA stating the delivered quantities medicinal products included in the PDL divided into number of packages and entities dealing with wholesale trade with the relevant medicinal products where those medicinal products are designated to.

(2) The information covers relevant calendar month and shall be provided within 20th day of the next month according to a form endorsed by the BDA Executive Director.

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 the 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 (2) of the MPHUAfor 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 (1) of MPHUA.

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 (3) of the MPHUA;

9. a reasoned proposal has been submitted under Article 32 (2) herein;

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

11. (New — SG No 92 of 2015) no declaration pursuant to Art. 35A has been submitted;

12. (New — SG No 92 of 2015) no reimbursement has been made by NHIF for six month period for medicinal products pursuant to Art. 262 (6), item 1 of MPHUAaccording to the information under Art. 44 (1) and (2);

13. (New — SG No 92 of 2015) during the last six months NHIF has reimbursed for the medicinal product less than 1 percent of the total cost of medicinal products within the relevant PDL group under Art. 262 (6), item 1 of MPHUApursuant to INN and pharmaceutical form;

14. (New — SG No 92 of 2015) no positive assessment under the procedure referred to in Chapter Six "a" is proven upon their inclusion;

15. (New — SG No 92 of 2015) no application has been submitted for maintenance of reimbursable status under Art. 576;

16. (New — SG No 92 of 2015) the procedure referred to in Chapter Six is terminated;

17. (Previous Item 11 — SG No 92 of 2015)the conditions referred to in Article 264 (7) of the MPHUAhave occurred.

(2) (Amended — SG No 92 of 2015) In the case referred to in Item 10 — 13 of Paragraph (1), the medicinal product shall be excluded only from the PDL under Item 1 of Article 6 (2) herein.

Article 37. (1) (Amended — SG No 92 of 2015) Within sixty days after the date of submission of the application referred to in Article 32 (1) herein, 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 (1) herein and including the said product in the PDL, or refusing to endorse a price for a medicinal product referred to in Article 2 (1) herein and to include the said product in the PDL. In the cases referred to in Article 30 (3) herein, the Council shall pronounce within thirty days.

(2) (Amended — SG No 92 of 2015) In the cases referred to in Article 30 (4) herein, the Council shall pronounce within thirty days.

(3) Within thirty days after receiving an application for a change or exclusion of a medicinal product included in the PDL, the Council shall consider the application and shall pronounce thereon, notifying the applicant of the decision thereof.

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

(5) Upon the exclusion of a medicinal product in pursuance of Item 5 of Article 36 (1) herein from all annexes to the PDL, the marketing authorisation holder or an authorised representative thereof may apply for the entry of the price referred to in Article 2 (1) herein as a ceiling price in the register referred to in Article 22 herein. The entry of the ceiling price in the register referred to in Article 22 herein 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 the PDL in pursuance of Items 4 and 9 of Article 36 herein, the price for the medicinal product, referred to in Article 2 (2) herein, 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 (6) of the MPHUA, 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.

(8) (Previous paragraph (7) — SG No 92 of 2014, effective as from 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 of 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 (7), the procedure shall be terminated.

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

Article 38. (1) A legal, medical 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 of 2014, effective as from 07.11.2014) The experts shall preview the applications and the accompanying documents and shall prepare an opinion addressed to the Council 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) The activity of the Council shall be assisted by external experts outside the administration who have attained higher education in Medicine and Pharmacy, 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) Where necessary, the chairperson of the Council shall designate an expert under Paragraph (3) to conduct a pharmacoeconomic evaluation and to give an opinion.

(6) On applications for inclusion, change or exclusion of medicinal products in the PDL under Items 1 and 3 of Article 262 (6) of the MPHUA, the Council shall require an opinion from the NHIF/MoH. Any such opinion shall be provided within ten days after being requested.

(7) (Repealed — SG No 92 of 2015)

(8) (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 summarise the expert opinions, as well as the opinion referred to in Paragraph (6), and shall prepare an expert report in a standard form endorsed by the Council within seven days after receiving the opinions on each application.

(9) Upon consideration of applications for inclusion, change or exclusion of medicinal products in the PDL under Item 1 of Article 262 (6) of the MPHUA, 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.

(10) Upon consideration of applications for inclusion, change or exclusion of medicinal products in the PDL under Item 3 of Article 262 (6) of the MPHUA, a representative of the MoH/NHIF shall mandatory take part in the meeting of the Council and shall present the opinion of the MoH/NHIF on each application.

Article 39. (1) The external experts referred to in Article 38 (3) herein 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 (2) of MPHUA.

Article 40. (1) Upon refusal to include, to change or to exclude a medicinal product from the 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 the PDL, the Council shall likewise refuse to endorse a price under Article 2 (1) herein.

(3) (Amended — SG No 92 of 2015) Council decision pursuant to paragraph 2 shall be subject to administrative appeal before the Transparency Commission.

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 (1) herein 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 (1) herein.

(3) It shall be inadmissible to apply for an increase of a price for a medical product referred to in Article 2 (1) herein by a larger percentage than the statistically reported rate of inflation for the period of validity since the last formed price.

(4) (Amended and supplemented — SG No 92 of 2014, effective as from 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 (1) herein, the marketing authorisation holder or an authorised representative thereof shall be obligated to notify, in an appropriate manner, Bulgarian Pharmaceutical Union (BPU) and wholesalers, and the wholesalers shall be obligated to notify the retailers of medicinal products.

Article 42. Within the limits of the endorsed price for medicinal products referred to in Article 2 (1) herein, 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. 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 pharmacy mark-up.

Article 43. (1) (Amended — SG No 66 of 2014, effective as from 08.08.2014, amended — SG No 92 of 2014, effective as from 07.11.2014, supplemented — SG No 92 of 2015) In the absence of change of the price indicated in the report-declaration under Article 33, paragraph 2, on the basis of which a price has been established under Article 2, paragraph 1, of a medicinal product included in the PLC, except for medicinal products authorised under Article 11 of MPHUA, the marketing authorisation holder or his authorised representative shall submit to the Council a declaration according to a form endorsed by the Council certified these circumstances every twelve months from the date of approval of the last price. This declaration shall be submitted in the month in which the twelve-month period expires. For medicinal products pursuant to Art. 34 (1) the declaration shall be submitted within the deadline concerning the identical or similar medicinal product under Art. 214 of MPHUA.

(2) (Amended — SG No 66 of 2014, effective as from 08.08.2014, amended — SG No 92 of 2014, effective as from 07.11.2014, supplemented — SG No 92 of 2015) In the absence of change of the price indicated in the report-declaration under Article 33, (2), on the basis of which a price has been established under Article 2, (1) of a medicinal product that is unique with international non-proprietary name, included in the PLC, except for medicinal products authorised under Article 11 of MPHUA, the marketing authorisation holder or his authorised representative shall submit to the Council a declaration according to a form endorsed by the Council certified these circumstances every twelve months from the date of approval of the last price. This declaration shall be submitted in the month in which the twelve-month period expires. For medicinal products pursuant to Art. 34 (1) the declaration shall be submitted within the deadline concerning the identical or similar medicinal product pursuant to Art. 214 of MPHUA.

(3) (Previous paragraph (2), amended — SG No 66 of 2014, effective as from 08.08.2014, supplemented — SG No 92 of 2014, effective as from 07.11.2014, supplemented — SG No 92 of 2015)

In case of change of the price of medicinal product indicated in the report-declaration under Article 33, paragraph 2, on the basis of which the reference price under Art. 8 (1), item 1 is lower than the reference price on the basis of which has been formed the price of medicinal product, except for medicinal products authorised under Art. 11 of MPHUA, the marketing authorisation holder or his authorised representative shall submit not later than twelve months as from the date of endorsement of the last price of medicinal product, an application to the Council for change of the established price. This application shall be submitted in the month in which the twelve-month period expires. For medicinal products referred to in Art. 34 (1) the declaration shall be submitted within the deadline concerning the identical or similar medicinal product pursuant to Art. 214 of MPHUA.

(4) (New — SG No 66 of 2014, effective as from 08.08.2014, amended — SG No 92 of 2014, effective as from 07.11.2014, supplemented — SG No 92 of 2015) In case of change of the price of a medicinal product under paragraph (2) indicated in the report-declaration under Article 33, paragraph 2, on the basis of which the reference pursuant to Art. 8 (1), item 1 is lower than the reference price on the basis of which has been formed the price of medicinal product, except for medicinal products authorised under Art. 11 of MPHUA, the marketing authorisation holder or his authorised representative shall submit not later than six months as from the date of endorsement of the last price of medicinal product,
an application to the Council for change of the established price. This application shall be submitted in the month in which the six-month period expires. For medicinal products pursuant to Art. 34 (1) the declaration shall be submitted within the deadline concerning the identical or similar medicinal product pursuant to Art. 214 of MPHUA.

(5) (Previous paragraph (3) amended and supplemented — SG No 66 of 2014, effective as from 08.08.2014) In case the marketing authorisation holder or his authorised representative fails to submit the declaration referred to in paragraphs (1) and (2) or the application referred to in paragraphs (3) and (4) and after checking by experts of the specialized administration of the Council it is established that the reference price under Article 8, Paragraph (1), point 1, is lower than the reference price on the basis of which the price of the medicinal product has been formed under Article 2, paragraph 1, the Council shall take an ex officio decision for change of the approved price of the medicinal product.

(6) (Previous paragraph (4), amended — SG No 66 of 2014, effective as from 08.08.2014, amended — SG No 92 of 2014, effective as from 07.11.2014) The check referred to in paragraph 5 shall be performed not later than the 20th day of the month following the month in which the deadline for submission of a declaration or respective application.

(7) (Previous paragraph (5), amended — SG No 66 of 2014, effective as from 08.08.2014) Where the review of the submitted declarations referred to in paragraphs 1 and 2 the specialised administration of the Council established that the reference price under Article 8, paragraph 1, point 1, is lower than the reference price on the basis of which the price of the medicinal product has been formed under Article 2, paragraph 1, the Council shall notify the marketing authorisation holder or his authorised representative to submit an application for change within 14 days from the notice and about the found prices.

(8) (Previous paragraph (6); amended — SG 66/2014, effective as from 08.08.2014) Where within the deadline referred to in paragraph 7 the applicant fails to submit an application, the Council shall take decision for change of the approved price of the medicinal product ex officio.

(9) Previous paragraph (7), amended — SG No 66 of 2014, effective as from 08.08.2014) Where an applicant fails to submit an application within the deadlines referred to in paragraphs (3), (4) and (7), compliant with the requirements of Articles 33 and 35, attributable to change of price, the Council shall have the right to request the applicant to remedy the deficiencies and defects in the documentation, as well as to provide additional information necessary to the change of the price of the medicinal product within 14 days.

(10) (Previous paragraph (8), amended — SG No 66 of 2014, effective as from 08.08.2014) Where the applicant fails to remedy the deficiencies and defects in the documentation, as well as fails to provide additional information necessary for a change of price of a medicinal product within the deadlines under paragraph 9, the Council shall take a decision for change of the approved price of the medicinal product ex officio.

(11) (Previous paragraph (9); amended — SG 66/2014, effective as from 08.08.2014) The decisions referred to in paragraphs (5), (8) and (10) shall be subject to appeal under Article 40 (3).

Article 44. (1) The National Health Insurance Fund shall provide to the Council full information on the reimbursed medicinal products included in the PDL under Item 1 of Article 6 herein.

(2) The information referred to in PARAGRAPH (1) shall be provided to the Council at the end of each quarter or upon request on an electronic data medium in a standard form according to Annex 7 hereto.

(3) The Ministry of Health shall provide to the Council information on the reimbursed medicinal products included in the PDL under Item 3 of Article 6 (2) herein.

(4) The medical-treatment establishments covered under Article 5 of the Medical-Treatment Establishments Act and the medical-treatment establishments wherein 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 the PDL under Item 2 of Article 6 (2) herein.

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

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

(7) The information referred to in Paragraphs (3) and (3) 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 reference value and level of reimbursement of medicinal products included in the Positive Drug List

Article 45. (1) In order to determine the value of reimbursement of the medicinal products included in the PDL, a reference value shall be calculated for a DDD 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. the value of the DDD 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) The reference value for a DDD of medicinal products containing more than one medicinal substance shall be formed on the basis of the lowest values of the DDD 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) For a DDD of a medicinal product which contains more than three active ingredients, the reference value shall be calculated per dosage unit according to the procedure established by Paragraph (2).

Article 46. (1) (Amended — SG No 92 of 2014, effective as from 07.11.2014) In order to determine the value of reimbursement of the medicinal products included in the PDL under Item 2 of Article 6 (2) herein, a reference value shall be calculated for a DDD according to INN, pharmaceutical form, strength and volume.

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

1. (Amended — SG No 92 of 2014, effective as from 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 of 2014, effective as from 07.11.2014) the value of the DDD shall be calculated for the different medicinal products according to INN, pharmaceutical form, strength and volume and the lowest value shall be determined;

3. (Amended — SG No 92 of 2014, effective as from 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 of 2014, effective as from 07.11.2014) The reference value for a DDD of medicinal products containing more than one medicinal substance shall be formed on the basis of the lowest values of the DDD separately for the respective constituent active ingredients contained in the medicinal products of a single medicinal substance, strength and volume, calculated according to the procedure established by Paragraph (2).

(4) For a DDD of a medicinal product which contains more than three active ingredients, the reference value shall be calculated per dosage unit 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 therein 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. a value for a DDD shall be determined according to the procedure established by Article 45 (2) herein for each INN with the respective pharmaceutical form within a chemical subgroup under the Anatomical Therapeutic Chemical Classification;

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 the PDL under Item 2 of Article 6 (2) herein may furthermore be determined for a chemical subgroup of the ATC Classification, where the medicinal products included therein 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 of 2014, effective as from 07.11.2014) a value for a DDD shall be determined according to the procedure established by Article 46 (2) herein for each INN with the respective pharmaceutical form within a chemical subgroup under the Anatomical Therapeutic Chemical Classification;

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 herein 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 (1) of the MPHUA.

(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 50. (Amended — SG No 92 of 2014, effective as from 07.11.2014) In order to determine the value of reimbursement of the medicinal products included in the PDL for which a DDD has not been determined, a reference value shall be calculated for a treatment course according to INN, pharmaceutical form, strength and volume, using the recommended daily dose as endorsed in the brief summary or product characteristics.

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

Article 51. The value per package of the medicinal product, calculated on the basis of the reference value for the DDD, shall be arrived at by multiplying the value as determined according to the procedure established by Articles 45 to 50 herein by the number of DDD/recommended daily doses 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 herein.

(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 herein.

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

1. for medicinal products pursuant to Art. 6 (2), item 2 and 3 — 100 percent;
2. of the 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. of the medicinal products for diseases with a chronic course and widespread prevalence: 75 percent;
4. of the 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

with one and the same pharmaceutical form shall be determined according to an evaluation table: Annex 8 hereto, depending on:

1. the evaluation of the criteria covered under Article 30 herein;

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. The level of reimbursement, determined according to the procedure established by Article 53 herein, shall be multiplied by the value per package, determined on the basis of a reference value for DDD, and shall form the value at which the medicinal product concerned is paid for by public funds.

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 Art. 57, amended — SG No 92 of 2015) The Positive published on the Internet 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 (1) herein and inclusion of a medicinal product in the PDL;

2. change of a medicinal product included in the PDL;

3. exclusion of a medicinal product from an annex to the PDL;

4. exclusion from the PDL and striking of a price referred to in Article 2 (1) herein for a medicinal product.

(2) (New — SG No 92 of 2015) Medicinal products in PDL with lowest value for DDD for

(3) treatment course defined pursuant to Section III of Chapter Six are marked with different colour.

(4) (New — SG No 92 of 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 MAINTENANCE OF REIMBURSEMENT STATUS OF MEDICINAL PRODUCTS INCLUDED IN PDL (NEW — SG, No 92 OF 2015)

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

(2) The Council shall maintain the reimbursable status of medicinal products included in PDL complying with following conditions:

1. they must be authorised for marketing according to the requirements of the;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 (2) herein;

2. the international non-proprietary name whereto the medicinal product/combination (applicable to combination medicinal products);

3. an evaluation has been made pursuant to Article 30, Annex No 5 herein.

Article 57b. (New — SG No 92 of 2015) (1) For maintenance of the reimbursable status of medicinal product included in the 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 Art. 57A (1).

(2) For medicinal products referred to in Art. 34 (1) the application for maintenance of reimbursable status shall be submitted within the deadline concerning the identical or similar medicinal product according to Art. 2014 of MPHUAby the holder of authorisation/notification for parallel import/parallel distribution.

Article 57c. (New — SG No 92 of 2015) (1) The following shall be attached to the application referred to in Article 57b (1) herein:

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, 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 (1) herein 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. data on postmarketing and/or non-interventional tests of the medicinal product conducted in the Republic of Bulgaria or abroad according to the MPHUA, if such have been carried out;

5. documentary proof of stamp duty paid for each separate medicinal product;

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 Art. 45 (10), (13) and (19) of the HIA;

(2) The documents referred to in Items 6 of Paragraph (1) shall be attached solely in respect of medicinal products which belong to an international non-proprietary name, which has been subject to assessment according to Art. 30 (1) upon inclusion in the PDL, and in respect of medicinal products referred to in Article 29 of the MPHUA.

(3) For medicinal products which belong to an international non-proprietary name and are included in the PDL which have been subject to Health technologies assessment, a new report shall be presented on the health technology assessment. This report shall be endorsed pursuant to the ordinance under Art. 262 (4) of MPHUAnot earlier than six months as from submission of the application.

(4) To authenticate the data stated in the application and in the accompanying documents under Paragraph (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, 2 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 of 2015) (1) Within 60 days as from the submission of Application pursuant to Art. 57B (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 the 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 the PDL, the price of the said product, referred to in Article 2 (1) herein, 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 of 2015) (1) A legal, medical and economic evaluation of each application received 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 Art. 38 (3) to conduct a pharmacoeconomic evaluation and to give an opinion.

(4) On applications for maintenance of reimbursable status of medicinal products in the PDL under Item 1 of Article 262 (6) of the MPHUA, the Council shall require an opinion from the NHIF, and for medicinal products in PDL under Item 3 of Article 262 (6) — by MoH. Any such opinion shall be provided within ten days after being requested.

(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) Upon consideration of applications under Art. 57b for medicinal products in the PDL under Item 1 of Article 262 (6) of the MPHUA, 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.

(7) Upon consideration of applications under Art. 57b for medicinal products in the PDL under Item 3 of Article 262 (6) of the MPHUA, 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 of 2015) (1) Upon refusal to maintain and exclusion of medicinal product from the 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) Decision of the Council pursuant to paragraph (1) shall be subject to administrative appeal before the Transparency Commission.

Chapter Seven
TERMS AND PROCEDURE FOR ENDORSEMENT, REVOCATION OR AMENDMENT OF MANUALS OF PHARMACOTHERAPY, RECOMMENDATIONS FOR ALGORITHMS FOR TREATMENT WITH MEDICINAL PRODUCTS AND CRITERIA FOR EVALUATION OF EFFECTIVENESS OF THERAPY

Article 58. (1) Acting on a proposal by the respective national consultants, medical learned societies and expert boards, the Council shall endorse, revoke or amend manuals of pharmacotherapy, including criteria for evaluation of the efficacy of the therapy administered, as well as recommendations for algorithms for treatment with medicinal products paid for by public funds.

(2) The manuals of pharmacotherapy endorsed by the Council shall be mandatory for medical care providers.

Article 59. (1) The manuals of pharmacotherapy, which have been received at the Council for endorsement/amendment, shall be transmitted for an opinion to the MoH, the NHIF, the Bulgarian Medical Association, the Bulgarian Dental Association, the Bulgarian Pharmaceutical Union and the organisations of the pharmaceutical industry. Where necessary, the Council may require an opinion from external experts as well.

(2) Opinions under Paragraph (1) shall be presented to the Council within one month after being requested.

(3) The Council shall endorse, revoke or amend manuals of pharmacotherapy, including criteria for evaluation of the effectiveness of the therapy administered, as well as recommendations for algorithms for treatment with medicinal products, within six months after the receipt of the proposal under Article 58 (1) herein.

(4) The Council may return with directions the manuals of pharmacotherapy to the persons who or which proposed the said manuals for endorsement or for amendment, both on the basis of the opinions referred to in Paragraph (1) and for bringing the said manuals into conformity with endorsed manuals in the countries of the European Union.

(5) In the cases referred to in Paragraph (4), the time limit referred to in Paragraph (3) shall cease to run until the fulfilment of the directions given within a time limit established by the Council.

(6) Once every three years, the persons referred to in Article 58 (1) herein shall review the manuals of pharmacotherapy endorsed and, where necessary, shall propose to the Council to amend the said manuals according to the procedure established by this Chapter.

(7) The decisions of the Council, whereby the Council endorses, revokes or amends manuals of pharmacotherapy, including criteria for evaluation of the efficacy of the therapy administered, as well as recommendations for algorithms for treatment with medicinal products, shall be subject to appeal:

1. according to an administrative procedure before the Transparency Commission;
2. before the competent court according to the procedure established by the Administrative Procedure Code.

Supplementary provisions

§ 1. Within the meaning given by this Ordinance:

1. "Public health insurance fund" shall be a public institution which collects and distributes health insurance contributions and health insurance premiums for health-care activities, services and goods for the largest number of health insured persons within the territory of the respective country.

2. (Amended — SG No 92 of 2014, effective as from 07.11.2014, amended — SG No 92 of 2015) "Ex-factory price" shall be the price at which a wholesaler purchases the medicinal product from the manufacturer and which is declared by the marketing authorisation holder or by an authorised representative thereof, excluding any discounts or other incentives offered by the manufacturer to the trader.

3. "The same medicinal product" shall be a medicinal product with the same international non-proprietary name, content of active ingredient per dosage unit, per unit of volume or per unit of weight, or in percentage terms, pharmaceutical form in final packaging of manufacturer/manufacturers, which is/are 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. "Final packaging" of a medicinal product shall be the total quantity of active ingredients, expressed qualitatively and quantitatively per dosage unit or, according to the pharmaceutical form, per unit of weight or per unit of volume, or in percentage terms.

5. (Amended — SG No 92 of 2014, effective as from 07.11.2014, amended — SG No 92 of 2015) "Final packaging nearest to the declared one" shall be packaging whereof the number of dosage units are within one and the same range with the number of dosage units in the declared packaging, not exceeding the following limits:

(a) from 1 to 3 (tablets, capsules, vials, doses etc.);

(b) from 4 to 9 (tablets, capsules, vials, doses etc.);

(c) from 10 to 15 (tablets, capsules, vials, doses etc.);

(d) from 16 to 30 (tablets, capsules, vials, doses etc.);

(e) from 31 to 60 (tablets, capsules, vials, doses etc.);

(f) over 60 (tablets, capsules, vials, doses etc.).

6. (New, SG 62 of 2016) A medicinal product that is unique in the INN is such that:

7. a) has the same international non-proprietay name , the same invented name irrespective of the pharmaceutical for, quantity of the medicinal substance (strength) or final packaging;

b) same international non-proprietary name but with the same marketing authorization holder;

c) same international non-proprietary name but in a different pharmaceutical form irrespective of the quantity of the medicinal substance (strength) or final packaging.

Transitional and final provisions

§ 1a. (New — SG No 92 of 2014, effective as from 07.11.2014, repealed — SG No 92 of 2015)

§ 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 herein, 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. (2) 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 herein, 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 MPHUA(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 (6) of the MPHUAinto conformity with Article 1 (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 Internet site of the National Council on Prices and Reimbursement of Medicinal Products, the Positive Drug List and the registers referred to in Article 7 (1) herein shall be published on the Internet site of the Ministry of Health.

§ 9a. (New – SG 3 of 2016 in force from 01.12.2015; amended - SG 14 of 2016, in force from 16.02.2016; amended – SG 32 of 2016; amended – SG 74 of 2016, in force from 01.09.2016; amended – SG 2 of 2017, in force from 01.01.2017 г.) Article 8 (5) shall be appliued from 1 January 2017.

§ 9б. (New – SG 3 of 2016 in force from 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 (5) and in conjunction with Item 4 of Article 259 (1) and Article 262 (7) of the Medicinal Products for Human Use Act.

Transitional and final provisions
TO PROVISION No 233 OF 31 JULY 2014 FOR AMENDMENT AND SUPPLEMENT OF 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 AS FROM 08.08.2014, AMENDED — SG No 107 OF 2014, EFFECTIVE AS FROM 24.12.2014, AMENDED — SG No 92 OF 2015)

§ 2. (1) (Amended — SG No 107 of 2014, effective as from 24.12.2014, amended — SG No 92 of 2015) Within 31 December 2017 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.

(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 Ordinance shall enter into force as from the date of promulgation in State Gazette.

Transitional and final provisions
TO ORDINANCE No 348 OF 3 NOVEMBER 2014 FOR AMENDMENT AND SUPPLEMENT OF THE ORDINANCE ON REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED — SG No 92 OF 2015, EFFECTIVE AS FROM 07.11.2014)

§ 26. (2) All procedures which have been initiated and which have not been finished until the entry into force of this Ordinance, shall be completed pursuant to the current rules.

§ 27. Within 14 days as from entry into force of the Ordinance National Council on Prices and Reimbursement of Medicinal Products shall endorse and publish on its Internet site the forms of documents pursuant to Art. 13, 14, 16, 23, 25, 32, 33, 34, 38 and 43.

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

Final provisions

Final provisions
TO ORDINANCE № 381 OF 29 DECEMBER 2015 AMENDING AND SUPPLEMENTING THE ORDINANCE ON THE CONDITIONS, RULES AND ORDER FOR REGULATION AND REGISTRATION OF PRICES OF MEDICINAL PRODUCTS, ADOPTED BY ORDINANCE OF THE COUNCIL OF MINISTERS OF 2013.
(PROMULGATED - SG 3 OF 2016, IN FORCE FROM 01.12.2015)
§ 2. This Ordinance shall enter into force from 1 December 2015.

Final provisions
TO ORDINANCE № 32 OF 16 FEBRUARY 2016 AMENDING AND SUPPLEMENTING THE REGULATION ON THE CONDITIONS, RULES AND ORDER FOR REGULATION AND REGISTRATION OF PRICES OF MEDICINAL PRODUCTS, ADOPTED BY ORDINANCE № 97 OF THE COUNCIL OF MINISTERS OF 2013.
(PROMULGATED - SG 14 OF 2016, IN FORCE FROM 16.02.2016)
§ 2. This Ordinance shall enter in force from 16 February 2016

Final provisions
TO ORDINANCE № 238 OF 13 SEPTEMBER 2016 AMENDING AND SUPPLEMENTING THE REGULATION ON THE CONDITIONS, RULES AND ORDER FOR REGULATION AND REGISTRATION OF PRICES OF MEDICINAL PRODUCTS, ADOPTED BY ORDINANCE № 97 OF THE COUNCIL OF MINISTERS OF 2013.
(PROMULGATED – SG 74 OF 2016 Г., IN FORCE FROM 01.09.2016)
§ 2. This Ordinance shall enter into force from 1 September 2016.

Final provisions
TO ORDINANCE № 238 OF 13 SEPTEMBER 2016 AMENDING AND SUPPLEMENTING THE REGULATION ON THE CONDITIONS, RULES AND ORDER FOR REGULATION AND REGISTRATION OF PRICES OF MEDICINAL PRODUCTS, ADOPTED BY ORDINANCE № 97 OF THE COUNCIL OF MINISTERS OF 2013.
(PROMULGATED – SG 2 OF 2017, IN FORCE FROM 01.01.2017)
§ 3. This Ordinance shall enter into force from 1 January 2017.

TO ORDINANCE No 441 OF 22 DECEMBER 2014 FOR AMENDMENT OF COUNCIL OF MINISTERS' ORDINANCE No 233 OF *2014* FOR AMENDMENT AND SUPPLEMENT OF THE ORDINANCE ON REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013 (PROMULGATED — SG No 17 OF 2014, EFFECTIVE AS FROM 24.12.2014)

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

Transitional and Final provisions
TO ORDINANCE No 323 OF 20 NOVEMBER 2015 FOR AMENDMENT AND SUPPLEMENT OF THE ORDINANCE ON REGULATION AND REGISTRATION OF PRICES FOR MEDICINAL PRODUCTS, ADOPTED BY COUNCIL OF MINISTERS DECREE No 97 OF 2013

(PROMULGATED — SG No 92 OF 2015)

§ 23. The first declaration under Art. 35A (2) of the Ordinance on Regulation and Registration of Prices for Medicinal Products (promulgated, SG No 40 of 2013; amended and supplemented, SG No 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 Art. 36 (1), Items 12 and 13 of the Ordinance pursuant to § 23 shall run as from 1 December 2015.

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

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

(3) Medicinal products that pursuant to the procedure under paragraph (1) are subject to decision for maintenance of reimbursable status, the following three year periods shall start as from entry into force of this decision.

Annex No 1 to Art. 13 (1), Article 23 (1) and Article 32 (1)

(Repealed — SG No 92 of 2014, effective as from 07.11.2014)

Annex No 2 to Item 5 of Article 14 (1)

(Repealed — SG No 92 of 2014, effective as from 07.11.2014)

Annex No 3 to Article 16 (2), Article 25 (2) and Article 38 (2)

(Repealed — SG No 92 of 2014, effective as from 07.11.2014)

Annex No 4 to Article 16 (3), Article 25 (3) and Article 38 (8)

(Repealed — SG No 92 of 2014, effective as from 07.11.2014)

Annex No 5 to Item 2 of Article 31 (1)

EVALUATION TABLE
of the indicators under Article 30 of the Ordinance

Indicator	Score	Remark
1. Lack of a medicinal alternative for treatment of the disease for which the medicinal product is indicated: Item 1 of Article 30 (1)	20 points	
2. Criteria of efficacy and therapeutic effectiveness: Item 2 of Article 30 (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 than the ratio for the therapy so far: 15 points or

	The economic evaluation of the additional benefits exceeds the economic evaluation of the costs of therapy: 10 points or The economic evaluation of the additional benefits is lower than the costs of therapy, but they are important for the treatment: 5 points and The product saves budget expenditures on health costs: 10 points
5. The medicinal product is for treatment of diseases of high risk to the public.	20 points

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

Expert:
Date

Annex No 6 to Article 33 (2)

(Repealed — SG No 92 of 2014, effective as from 07.11.2014)

Annex No 7 to Art. 44 (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 Name of disease code	ATC code	International non-proprietary	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)

Code ICD	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 Art. 54

EVALUATION TABLE

Indicator	Score	Remark (enter restrictions 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. of the medicinal products referred to in Items 2 and 3 of Article 6 (2): 100 percent: Item 1 of Art. 53		
2. of the 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 — Item 2 of Art. 53		
3. of the medicinal products for diseases with a chronic course and widespread prevalence: 75 percent: Item 3 of Article 53		
4. of the medicinal products for diseases other than those referred to in Items 1, 2 and 3: up to 50 percent.		
Parameters (Article 54):		
1. final evaluation of the criteria covered under Article 30 herein;	…… …..	
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;	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 of Bulgaria, for the treatment of which the medicinal product is used;	2 points 2 points: YES 0 points: NO	
4. length of treatment and outcome:	Quick and definitive: 5 points Long and effective: 3 points	
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 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 (2): 100 percent.

Level of reimbursement under Article 54 for medicinal products referred to in Item 1 of Article 6 (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.