

TARIFF OF THE FEES COLLECTED UNDER THE LAW ON THE MEDICINAL PRODUCTS IN HUMAN MEDICINE

(Promulgated, SG 106 of 14 December 2007; amended, SG 102 of 30 December 2010, amended and supplemented, SG 39 of 22 May 2012; amended, SG 61 of 25 July 2014)

Section III.

Fees collected by the National Council on Prices and Reimbursement of medicinal products (title amended, SG 61/2014)

Article 28. (Amended, SG 39/2012). (1) (amended, SG 61/2014) For the assessment of the documentation for inclusion of a medicinal product in the Positive Drug List and formation of a price under Article 261a, paragraph 1 of LMPHM, a fee of BGN 1,500 shall be collected.

(2) For the assessment of the documentation for inclusion of a medicinal product in the Positive Drug List for a different indication, a fee of BGN 800 shall be collected.

(3) For the assessment of the documentation in case of change of a medicinal product included in the Positive Drug List, the following fee shall be collected:

1. in case of change of the name of a medicinal product – BGN 150;
2. in case of a change of the Marketing Authorisation Holder of a medicinal product – BGN 150;
3. in case of change of manufacturer(s) of a medicinal product – BGN 150;
4. in case of change of indications of a medicinal product – BGN 400;
5. (amended, SG 61/2014.) in case of change of price under Article 261a, paragraph 1 of LMPHM – BGN 400;
6. in case of change of any other circumstances registered in the Positive Drug List – BGN 150.

(4) For the assessment of the documentation for the formation of a price of a medicinal product, a fee of BGN 750 shall be collected.

(5) For the assessment of the documentation in case of change of the formed ceiling price of a medicinal product, a fee of BGN 350 shall be collected.

(6) For the assessment of the documentation in case of change of the circumstances in a decision for a ceiling price, the following fees shall be collected:

1. in case of change of the name of a medicinal product – BGN 150;
2. in case of change of the Marketing Authorisation Holder of a medicinal product – BGN 150;
3. in case of change of manufacturer(s) of a medicinal product – BGN 150;
4. in case of change of any other circumstances inscribed in the register of ceiling price circumstances – BGN 150.

(7) For the assessment of the documentation of a medicinal product that has received authorisation for parallel import, a fee of BGN 375 shall be collected for the application of the formed ceiling price.

(8) (repealed, SG 61/2014)

(9) (repealed, SG 61/2014)

(10) (repealed, SG 61/2014)

(11) For the assessment of the documentation for the registration of a price of a medicinal product sold without medical prescription, a fee of BGN 200 shall be collected.

(12) For the assessment of the documentation in case of change of a registered price of a medicinal product sold without medical prescription, a fee of BGN 100 shall be collected.

(13) For the assessment of the documentation in case of change of any other circumstances in a decision for a registered price of a medicinal product sold without medical prescription, the following fees shall be collected:

1. in case of change of the name of a medicinal product – BGN 100;
2. in case of change of the Marketing Authorisation Holder of a medicinal product – BGN 100;

3. in case of change of manufacturer(s) of a medicinal product – BGN 100;
4. in case of change of any other circumstances inscribed in the register of prices – BGN 100.

(14) For the assessment of the documentation of a medicinal product that has received authorisation for parallel import, a fee of BGN 100 shall be collected for the application of a registered ceiling price.

(15) (New, SG 61/2014) For assessment of documentation for inclusion of a medicinal product that has received authorisation for parallel import in the Positive Drug List, a fee of BGN 800.

(16) (New, SG 61/2014) For issuing a certified copy of a document, a fee of BGN 10 per copy.

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Article 30. (amended, SG 39/2012) For issuing a certified copy of a decision, opinion or other document, a fee of BGN 10 per copy shall be collected.