

RESOLUTION OF THE MINISTRY OF ANTIMONOPOLY REGULATION
AND TRADE OF THE REPUBLIC OF BELARUS

No. 83 dated November 19, 2018

**On approval of the Instruction on the method for
calculating manufacturers' marginal selling prices for
medicinal products**

According to subclause 1.3 of clause 1 of the Decree of the President of the Republic of Belarus No. 345 "On registration of prices for medicinal products" of 22 August 2018, paragraph three of clause 2, subclauses 4.5 and 4.6 of clause 4, clause 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 776 "On registration of manufacturers' marginal selling prices for medicinal products" of 31 October 2018, subclause 6.49 of clause 6 of the Regulation on the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 702 "Questions of the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus" of 6 September 2016, the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus DECIDES:

1. To approve the enclosed Instruction on the method for calculating manufacturers' marginal selling prices for medicinal products.
2. This resolution becomes effective after its official publication and is valid until December 31, 2020.

Minister

V.V. Koltovich

APPROVED

by the Minister of Health
of the Republic of Belarus

V.A. Malashko

19.11.2018

APPROVED

By the Resolution
of the Ministry of Antimonopoly
Regulation and Trade
of the Republic of Belarus

No. 83 of 19 November 2018

INSTRUCTION

**on the method for calculating manufacturers'
marginal selling prices for medicinal products**

**CHAPTER 1
GENERAL PROVISIONS**

1. This Instruction establishes the procedure for calculating by the organizations engaged in the manufacturing of medicinal products (hereinafter referred to as the "manufacturers", unless otherwise specified), marginal selling prices for medicinal products registered as prescribed by law and subject to registration in accordance with the Decree of the President of the Republic of Belarus No. 345 "On registration of prices for medicinal products" of 22 August 2018 (National Legal Internet Portal of the Republic of Belarus, August 25, 2018, 1/17898).

2. For the purposes of this Instruction, terms and their definitions are used in the meanings established by the Law of the Republic of Belarus "On medicinal products" of 20 July 2006 (National Register of Legal Acts of the Republic of Belarus, 2006, No. 122, 2/1258) and the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 776 "On registration of manufacturers' marginal selling prices for medicinal products" of 31 October 2018 (National Legal Internet Portal of the Republic of Belarus, November 2, 2018, 5/45755).

3. The manufacturer's marginal selling price for the original medicinal product in dosage forms specified in accordance with clause 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products is calculated on the basis of the manufacturer's minimum selling prices (excluding manufacturing sites participating in the manufacturing process) on the appropriate dosage form of such a medicinal product in the countries from the list of countries in respect for which information on the level of the minimum selling prices for medicinal products is provided, in accordance with Annex 1 to this Instruction.

If the manufacturer's marginal selling price for the original medicinal product is registered in accordance with clause 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, the calculation of marginal selling prices for generic, similar biological medicinal product is carried out for each dosage form taking into account manufacturers' marginal selling prices for the medicinal product (hereinafter referred to as the "marginal selling price" unless otherwise specified) for the corresponding dosage forms of the original medicinal product.

4. In order to carry out an economic analysis of marginal selling price calculations, the following information shall be compiled:

information on the volumes of sale and selling prices for the circulating in the Republic of Belarus medicinal products of manufacturers of the Eurasian Economic Union member states and (or) foreign manufacturers engaged in the primary and (or) the secondary packaging of the medicinal product in the Republic of Belarus, according to the form provided for in the Annex 2 to this Instruction;

calculation of the manufacturer's marginal selling price for the medicinal product according to the form provided for in the Annex 3 to this Instruction;

information on the volumes of import and the contract price (CIP), converted in Belarusian rubles at the official exchange rate of the National Bank of the Republic of Belarus, established on the date of release of goods in accordance with the customs procedure of release for domestic consumption (if such goods are subject to customs declaration) or on the date of delivery of goods to the customer's warehouse specified in the invoice (if such goods are not subject to customs declaration) (hereinafter, referred to as the "contract price", unless otherwise specified), in respect of the foreign medicinal product circulating within the territory of the Republic of Belarus, according to the form provided for in the Annex 4 to this Instruction;

information on the availability of registered marginal selling prices of the claimed medicinal product according to the form provided for in the Annex 5 to this Instruction;

calculation of the marginal selling price for a generic, similar biological medicinal product according to the form provided for in the Annex 6 to this Instruction.

5. For the economic justification of information on the volume of delivery (import) and selling (contract) prices for the medicinal products circulating in the Republic of Belarus, specified in Annexes 2 and 4 to this Instruction, are used:

goods consignment notes for the medicinal product shipped by the manufacturers of the Eurasian Economic Union member states, as well as foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, for the period determined in accordance with clause 6 of this Instruction, – all goods consignment notes, if the number of shipments of the medicinal product does not exceed 25, or not less than 25 goods consignment notes with the largest share in the sales volume of a specific medicinal product, if the number of shipments exceeds 25;

invoices for the supply of the medicinal product by foreign manufacturers, except for foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, for the period determined in accordance with clause 6 of this Instruction – all invoices, if the number of supplies of the medicinal product does not exceed 25, not less than 25 invoices with the largest share in the sales volume of a specific medicinal product, if the number of supplies exceeds 25.

6. For the calculation, a period equal to the duration of the calendar year, preceding the day of filing the application for registration of the marginal selling price, is taken.

7. Data for all actual prices in the currency of the Eurasian Economic Union member state, used in the calculation, are determined taking into account conversion to Belarusian rubles at the exchange rate set by the National Bank of the Republic of Belarus on the day when the manufacturer actually sold the medicinal product within the territory of the Republic of Belarus.

CHAPTER 2 CALCULATION OF THE MARGINAL SELLING PRICE FOR THE ORIGINAL MEDICINAL PRODUCT

8. The marginal selling price of the manufacturers of the Eurasian Economic Union member states and (or) foreign manufacturers who carry out or plan to carry out the primary and (or) secondary packaging of the medicinal product within the territory of the Republic of Belarus for the original medicinal product is calculated as the lowest (minimum) value resulting from the comparison:

8.1. the weighted average actual selling price for the original medicinal product calculated in accordance with clauses 9 and 10 of this Instruction on the basis of the information on the volumes of sale and selling prices for the circulating in the Republic of Belarus medicinal products produced by the manufacturers of the Eurasian Economic Union member states and (or) foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, according to Annex 2 to this Instruction for the period determined in accordance with clause 6 of this Instruction, adjusted for the consumer price index calculated on a cumulative total for each month of the period determined in accordance with clause 6 of this Instruction;

8.2. the arithmetic mean of manufacturers' minimum selling prices (excluding manufacturing sites involved in the manufacturing process) for the original medicinal product in the countries listed in Annex 1 to this Instruction, calculated in accordance with Chapter 4 of this Instruction, on the basis of the marginal selling price calculation specified in Annex 3 to this Instruction, - if the medicinal product is sold in countries listed in Annex 1 to this Instruction.

9. When calculating the weighted average actual selling price, information on the volumes of sale and selling prices for the medicinal product for the period determined in accordance with clause 6 of this Instruction for each manufacturer under one registration certificate of the medicinal product in accordance with clauses 15 and 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, is taken into account.

10. The weighted average actual selling price of manufacturers of the Eurasian Economic Union member states and (or) foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus, under a registration certificate for the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume), delivered within the period determined in accordance with clause 6 of this Instruction, to the territory of the Republic of Belarus (weighted average actual selling price for delivery n , BYN) is calculated by the formula

$$\text{weighted average actual selling price for delivery } n = \frac{\sum (\text{actual delivery price} * \text{number of deliveries})}{\text{total number of deliveries}}$$

where: an actual delivery price (BYN) is the actual selling price of the manufacturer of the Eurasian Economic Union member state and (or) a foreign manufacturer engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus, for one secondary package of the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume);

a number of deliveries (packages) is the number of packages of the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) of the manufacturer shipped for the period determined in accordance with clause 6 of this Instruction, at a single price;

a total number of deliveries (packages) is the total number of packages of the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) of manufacturers under a registration certificate of the medicinal product manufactured and shipped within the period determined in accordance with clause 6 of this Instruction. Herewith the export deliveries, deliveries made under various types of humanitarian and charity (grant) assistance, deliveries of medicinal products with the remaining shelf-life of less than 25 percent, as well as delivery of medicinal products at an actual selling price exceeding the registered marginal selling price, are excluded from the total number of the medicinal product packages.

11. The marginal selling price of foreign manufacturers, except for foreign manufacturers carrying out or planning to carry out the primary and (or) secondary packaging of the medicinal product within the territory of the Republic of Belarus, for the original medicinal product is calculated as the lowest (minimum) value resulting from the comparison:

11.1. the weighted average actual contract price for the original medicinal product calculated in accordance with clauses 12 and 13 of this Instruction on the basis of the information on the volumes of import and the contract price for a foreign medicinal product circulating in the Republic of Belarus, according to Annex 4 to this Instruction, for the period determined in accordance with clause 6 of this Instruction, adjusted for the consumer price index calculated on a cumulative total for each month of the period determined in accordance with clause 6 of this Instruction;

11.2. the arithmetic mean of the minimum selling prices of a foreign manufacturer, except for foreign manufacturer engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus (excluding manufacturing sites involved in the manufacturing process) for the original medicinal product in the countries listed in Annex 1 to this Instruction, calculated in accordance with Chapter 4 of this Instruction, on the basis of the marginal selling price calculation specified in Annex 3 to this Instruction, - if the medicinal product is sold in the countries listed in Annex 1 to this Instruction.

12. When calculating the weighted average actual contract price of the medicinal product, information on the volumes of import and contract prices for the medicinal product for the period determined in accordance with clause 6 of this Instruction for each foreign manufacturer, except for foreign manufacturer engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus under one registration certificate of the medicinal product in accordance with clauses 15 and 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, is taken into account.

13. The weighted average actual contract price of the medicinal product (by specific trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) imported for a period determined in accordance with clause 6 of this Instruction, to the territory of the Republic of Belarus (weighted average actual contract price for import_n, BYN), is calculated by the formula

$$\text{weighted average actual contract price for import}_n = \frac{\sum (\text{actual import price} * \text{number of imports})}{\text{total number of imports}}$$

where: an actual import price (BYN) is the actual contract price of one secondary package of the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) of a foreign manufacturer;

a number of imports (packages) is the number of packages of the medicinal product of a foreign manufacturer, excluding foreign manufacturer engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) imported by a foreign manufacturer (importer) at the same price for the period determined in accordance with clause 6 of this Instruction;

a total number of imports (packages) is the total number of packages of the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity in the secondary package (number of doses per a package, volume) of a foreign manufacturer, excluding foreign manufacturer engaged in the primary and (or) secondary packaging of the medicinal products in the Republic of Belarus, under the registration certificate of the medicinal product imported for the period determined in accordance with clause 6 of this Instruction. Herewith the deliveries made under various types of humanitarian and charity (grant) assistance, deliveries of medicinal products with the remaining shelf-life of less than 25 percent, as well as delivery of medicinal products at an actual contract price exceeding the registered marginal selling price, are excluded from the total number of the medicinal product packages.

CHAPTER 3

CALCULATION OF THE MARGINAL SELLING PRICE FOR GENERIC, SIMILAR BIOLOGICAL MEDICINAL PRODUCT

14. The marginal selling price for generic, similar biological medicinal product for all manufacturers of the medicinal product without taking into account the dosage form of the medicinal product, except for the cases specified in clause 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, is calculated as the lowest (minimum) value resulting from the comparison:

14.1. the weighted average actual selling (contract) price of a generic, similar biological medicinal product for the period determined in accordance with clause 6 of this Instruction, adjusted for the consumer price index calculated on a cumulative total for each month of the period determined in accordance with clause 6 of this Instruction:

14.1.1. for manufacturers of the Eurasian Economic Union member states, foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, - calculated in accordance with clauses 9 and 10 of this Instruction on the basis of the information on the volumes of sale and selling prices for the medicinal products circulating in the Republic of Belarus as specified in Annex 2 to this Instruction;

14.1.2. for foreign manufacturers, excluding foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, -calculated in accordance with clauses 12 and 13 of this Instruction on the basis of the information on the volumes of import and the contract price for the medicinal product circulating in the Republic of Belarus as specified in Annex 4 to this Instruction;

14.2. the arithmetic mean of the minimum selling prices for generic, similar biological medicinal product of the manufacturer of the Eurasian Economic Union member state and the foreign manufacturer (excluding manufacturing sites involved in the manufacturing process) in the countries listed in Annex 1 to this Instruction, calculated in accordance with Chapter 4 of this Instruction, on the basis of the marginal selling price calculation specified in Annex 3 to this Instruction, - if the medicinal product is sold in the countries listed in Annex 1 to this Instruction;

14.3. the marginal selling price calculated in accordance with clauses 15-18 of this

Instruction, by the international non-proprietary name (in the absence thereof, by chemical or groupe name), dosage form, dosage (concentration, activity in action units) and total quantity in the secondary package using the reduction factor to:

14.3.1. the registered marginal selling price for the original medicinal product on the basis of the calculation of the marginal selling price for the generic, similar biological medicinal product according to Annex 6 to this Instruction;

14.3.2. the arithmetic mean of the minimum selling prices of the manufacturer for the corresponding original medicinal product in the countries listed in Annex 1 to this Instruction, calculated in accordance with the first part of clause 18 of this Instruction.

15. If under one registration certificate, the generic, similar biological medicinal product is manufactured in the Eurasian Economic Union member state and by a foreign manufacturer, the price for such a medicinal product is calculated preserving its belonging to the Eurasian Economic Union member state or a foreign manufacturer, taking into account the reduction factor in the order specified in clause 17 of this Instruction.

16. If the manufacturer's marginal selling price for the original medicinal product has been reduced in a case specified in clause 17 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products, the marginal selling price after the reduction is taken into account.

17. Marginal selling price for the generic, similar biological medicinal product (P_{mar} , BYN), in case of the registered marginal selling price for the corresponding original medicinal product, is calculated by the formula

$$P_{\text{mar}}=P_{\text{or}}*F_r,$$

where: P_{or} is a marginal selling price for the secondary packaging of the original medicinal product with the same dosage (concentration, activity in action units) and the same number of doses and (or) volume in the secondary packaging, registered at the date of filing the application for registration of the marginal selling price for the generic, similar biological medicinal product, taking into account the dosage forms in cases specified in clause 16 of the Regulation on the procedure for registration of manufacturers' marginal selling prices for medicinal products;

F_r is a reduction factor determined on the basis of P_{or} converted in base values, in accordance with calculation of the reduction factor used in calculating the marginal selling price for the generic, similar biological medicinal product, according to Annex 7 to this Instruction.

18. If the marginal selling price for the original medicinal product is not registered, then P_{or} is calculated as the arithmetic mean of the minimum selling price of the manufacturer (excluding the manufacturing sites involved in the manufacturing process) for the corresponding original medicinal product in the countries listed in Annex 1 to this Instruction, calculated on the basis of information on the minimum selling prices of the manufacturer for the medicinal product specified in Table 1 of Annex 3 to this Instruction.

If marginal selling prices for the original medicinal product with the same number of dosage forms in the secondary package as the claimed generic, similar biological medicinal product are not registered, P_{or} is calculated as the arithmetic mean of the manufacturer's selling price for the original medicinal product in the manufacturer's country and other countries listed in Annex 1 to this Instruction, based on the arithmetic mean of the cost of one dosage form of medicinal products that have the nearest adjacent quantities of dosage forms in the secondary package, on the basis of the information on the minimum selling prices according to Table 1 of Annex 3 to this Instruction.

If marginal selling prices for the original medicinal product with the same dosage (concentration, activity in action units) as a generic, similar biological medicinal product are not registered, P_{or} is calculated based on the arithmetic mean of the cost of the active substance unit of medicinal products that have the nearest adjacent dosages, on the basis of information on the minimum selling prices according to Table 1 of Annex 3 to this Instruction.

CHAPTER 4

CALCULATION OF THE ARITHMETIC MEAN OF THE MINIMUM SELLING PRICE OF MANUFACTURER FOR A MEDICINAL PRODUCT IN COUNTRIES LISTED IN ANNEX 1 TO THIS INSTRUCTION

19. Calculation of the arithmetic mean of the manufacturer's minimum selling price for the medicinal product (by trade name, international non-proprietary name, dosage (concentration, activity in action units), dosage form, quantity of dosage forms in the secondary package (number of doses per a package, volume) is made on the basis of the information on the minimum selling prices for a medicinal product (excluding the manufacturing sites involved in the manufacturing process) specified in Table 1 of Annex 3 to this Instruction, in countries listed in Annex 1 to this Instruction.

20. In Table 1 of Annex 3 to this Instruction, the minimum selling prices of the manufacturer for the medicinal product in countries listed in Annex 1 to this Instruction are given in Belarusian rubles. The conversion of the price in foreign currency in Belarusian rubles is carried out at the average exchange rate of the corresponding foreign currency to the Belarusian ruble set by the National Bank of the Republic of Belarus for 3 calendar months preceding the month of filing the application for registration of the minimum selling price which is given in column 4 of Table 2 of Annex 3 to this Instruction.

21. If the medicinal product is sold in countries listed in Annex 1 to this Instruction under a different trade name, a corresponding trade name is given in column 2 of Table 1 of Annex 3 to this Instruction, and the minimum selling prices of the manufacturer for the medicinal product are given in columns 8-21 of Table 1 of Annex 3 to this Instruction.

22. In case of registration of the marginal selling price for a medicinal product in the Republic of Belarus with the quantity of dosage forms and dosage (concentration, activity in action units, volume) in secondary package that are not available in countries listed in Annex 1 to this Instruction, the minimum selling prices of the manufacturer for medicinal products that have the nearest adjacent quantities of dosage forms and adjacent dosages in secondary packages (regardless the availability of their registration in the Republic of Belarus), which are sold in the countries listed in Annex 1 to this Instruction, are given in Table 1 of Annex 3 to this Instruction.

Herewith the minimum selling price of the manufacturer for a medicinal product is calculated by the lowest value resulting from the calculation of the arithmetic mean of the cost of:

one dosage form of the medicinal products that have the nearest adjacent quantities in secondary packages in each of the countries listed in Annex 1 to this Instruction (column 6 of Table 1 of Annex 3 to this Instruction);

one unit of active substance of the medicinal products that have the nearest adjacent dosages in each of the countries listed in Annex 1 to this Instruction (column 7 of Table 1 of Annex 3 to this Instruction).

Annex 1
to the Instruction on the method for calculating
manufacturers' marginal selling prices for
medicinal products

LIST

**of countries for which information on the minimum selling prices
for medicinal products is provided**

1. Republic of Armenia
2. Republic of Bulgaria
3. Hungarian People's Republic
4. Republic of Kazakhstan
5. Kyrgyz Republic
6. Republic of Latvia
7. Republic of Lithuania
8. Republic of Moldova
9. Republic of Poland
10. Russian Federation
11. Romania
12. Czech Republic
13. Republic of Estonia
14. Country of manufacturer

Annex 2
to the Instruction on the method for calculating
manufacturers' marginal selling prices for
medicinal products

Form

Information on the volumes of sale and selling prices for the circulating in the Republic of Belarus medicinal products of manufacturers of the Eurasian Economic Union member states and (or) foreign manufacturers engaged in the primary and (or) secondary packaging of the medicinal product in the Republic of Belarus, for the period* from 20__ to 20__.

(full name of the legal entity; surname, first name, patronymic (if any) of an Individual Entrepreneur)

I. Information on the medicinal product

| | |
|---|--|
| 1. Registration certificate No. | |
| 2. International non-proprietary name, or group name, or chemical name; | |
| 3. Trade name | |
| 4. Dosage form, dosage or concentration, volume, activity in action units | |
| 5. Total quantity in the secondary package | |

II. Calculation of marginal selling price for the secondary package

| Ser. No. | Quantity of the delivered medicinal product | | Weighted average actual selling price of the medicinal product for the secondary packaging (excluding VAT**), BYN | Registered marginal selling price of the medicinal product for the secondary packaging (excluding VAT**), BYN | Current consumer price index | Calculated marginal selling price for the secondary packaging (excluding VAT**), BYN |
|----------|---|-----|---|---|------------------------------|--|
| | packages | BYN | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | | | | | | |

III. Calculation of the weighted average actual selling price of the medicinal product for the period*
from 20__ to 20__.

| Ser. No. | Trade name (dosage form, dosage, quantity in the secondary package) | Manufacturer | Supplier | Consignment note No. | Consignment note date | Date of the actual sale of the medicinal product within the territory of the Republic of Belarus | Quantity of the delivered goods, packages | Delivery price for a package (excluding VAT**), BYN | Sales volume of the medicinal product (excluding VAT**), thousand BYN | Remaining shelf-life of the delivered medicinal product, percent |
|---|---|--------------|----------|----------------------|-----------------------|--|---|---|---|--|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| | | | | | | | | | | |
| | Total | | | | | | Σ | | Σ | |
| Weighted average actual selling price of the medicinal product for the secondary packaging (excluding VAT**), BYN | | | | | | | | | $\Sigma \text{ col.10} \times 1000 / \Sigma \text{ col.8}$ | |

* According to clause 6 of this Instruction.

** Value added tax

Annex: _____

Head of the legal entity
Individual Entrepreneur

(initials, surname)

(signature)

(phone, email)

Contractor

(initials, surname)

(signature)

(phone, email)

Annex 3
to the Instruction on the method for calculating
manufacturers' marginal selling prices for
medicinal products

Form

Calculation of the manufacturer's marginal selling price for the medicinal product

(full name of the legal entity; surname, first name, patronymic (if any) of an Individual Entrepreneur)

I. Information on the medicinal product

| | |
|---|--|
| 1. Registration certificate No. | |
| 2. International non-proprietary name, or group name, or chemical name; | |
| 3. Trade name | |
| 4. Dosage form, dosage or concentration, volume, activity in action units | |
| 5. Total quantity in the secondary package | |

II. Calculation of marginal selling price for the secondary package

| Ser. No. | FEACN EEU code* | Arithmetic average selling price of the manufacturer for the medicinal product in the countries listed in Annex 1 to this Instruction in accordance with Table 1 of this Annex, BYN | Calculated manufacturer's marginal selling price for the secondary packaging excluding VAT**, BYN |
|----------|-----------------|---|---|
| 1 | 2 | 3 | 4 |
| | | | |

*A product code according to the single Foreign Economic Activity Commodity Nomenclature of the Eurasian Economic Union.

** Value added tax

Table 1. Calculation of the arithmetic mean of the minimum selling prices of the manufacturer for the medicinal product

| Ser. No. | Trade name of the medicinal product | Dosage form, dosage or concentration, volume, activity in action units | Quantity in the secondary package | Arithmetic mean of the minimum selling price as in columns 8 - 21, BYN | | | Minimum selling price of the manufacturer for the medicinal product after recalculating the price of the medicinal product in a foreign currency in Belarusian rubles at the exchange rate specified in Table 2 of this Annex, BYN | | | | | | | | | | | | | |
|---|-------------------------------------|--|-----------------------------------|--|-------------------------------|--|--|----------------------|-----------------------------|------------------------|-----------------|--------------------|-----------------------|---------------------|--------------------|--------------------|---------|----------------|---------------------|-------------------------|
| | | | | for package | calculation for a dosage form | calculation for an active substance unit | Republic of Armenia | Republic of Bulgaria | Hungarian People's Republic | Republic of Kazakhstan | Kyrgyz Republic | Republic of Latvia | Republic of Lithuania | Republic of Moldova | Republic of Poland | Russian Federation | Romania | Czech Republic | Republic of Estonia | Country of manufacturer |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| | | | | | | | | | | | | | | | | | | | | |
| The minimum (calculation taking into account the arithmetic mean) calculated selling price of the manufacturer for one dosage form with the nearest adjacent quantities in the secondary package of a medicinal product, calculated in case of registration of the marginal selling price for a medicinal product with the quantity of dosage forms in the secondary package (number of doses per a package, volume), that is not available in countries listed in Annex 1 to this Instruction, BYN | | | | | | | | | | | | | | | | | | | | |
| The minimum (calculation taking into account the arithmetic mean) calculated manufacturer's selling price for an active substance unit of a medicinal product with the nearest adjacent dosages, calculated in case of registration of the marginal selling price for a medicinal product with a dosage that is not available in the countries listed in Annex 1 to this Instruction, BYN | | | | | | | | | | | | | | | | | | | | |
| The arithmetic mean of the minimum selling prices of the manufacturer for the medicinal product in the countries listed in Annex 1 to this Instruction (taking into account the recalculation), BYN | | | | | | | | | | | | | | | | | | | | |

Table 2. Exchange rate for calculating of the minimum selling prices for medicinal products for the period* from 20__ to 20__.

| Ser. No. | Country | Currency | Average currency rate |
|----------|---------|----------|-----------------------|
| 1 | 2 | 3 | 4 |
| | | | |

* According to clause 20 of this Instruction.

Head of the legal entity, Individual Entrepreneur

(initials, surname)

(signature)

(phone, email)

Contractor

(initials, surname)

(signature)

(phone, email)

Annex 4
to the Instruction on the method for calculating manufacturers' marginal selling prices for medicinal products

Form

Information on the volumes of import and the contract price in respect of the foreign medicinal product circulating within the territory of Republic of Belarus, for the period* from _____ to _____.

(full name of the legal entity; surname, first name, patronymic (if any) of an Individual Entrepreneur)

I. Information on the medicinal product

| | |
|---|--|
| 1. Registration certificate No. | |
| 2. International non-proprietary name, or group name, or chemical name; | |
| 3. Trade name | |
| 4. Dosage form, dosage or concentration, volume, activity in action units | |
| 5. Total quantity in the secondary package | |

II. Calculation of the weighted average actual contract price for the medicinal product for the period* from 20__ to 20__.

| Ser. No. | Manufacturer | Invoice number | Invoice date | Date of goods release in accordance with the customs procedure of release for domestic consumption or the date of receipt of the goods to the customer's warehouse specified in the invoice | Quantity of packages | The contract price of one secondary package (excluding VAT**), BYN | Cost of imported goods (excluding VAT**), thousand BYN |
|--|--------------|----------------|--------------|---|----------------------|--|--|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | |
| | | | | | | | |
| | Total: | _____ | _____ | _____ | Σ | _____ | Σ |
| Total: The weighted average actual contract price of the medicinal product for the secondary package (excluding VAT **), BYN | | | | | | | Σ col.8 x1000 / Σ col.6 |

* According to clause 6 of this Instruction.

** Value added tax

Annex: _____

Head of the legal entity, Individual Entrepreneur

(initials, surname)

(signature)

(phone, email)

Contractor

(initials, surname)

(signature)

(phone, email)

Annex 5
to the Instruction on the method for
calculating manufacturers' marginal
selling prices for medicinal products

Form

Information on the availability of the registered marginal selling prices of the claimed medicinal product

(full name of the legal entity; surname, first name, patronymic (if any) of an Individual Entrepreneur)

I. Information on the medicinal product

| | |
|---|--|
| 1. Registration certificate No. | |
| 2. International Non-proprietary Name, or group name, or chemical name; | |
| 3. Trade name | |
| 4. Dosage form, dosage or concentration, volume, activity in action units | |
| 5. Total quantity in the secondary package | |

II. Calculation of the marginal selling price of the medicinal product

| Ser. No. | Registration certificate Holder, manufacturer, packer, issuing control | Dosage form, dosage | Quantity in the secondary package | Number and date of the Order of the Ministry of Health of the Republic of Belarus on the registration of the marginal selling price | Registered manufacturer's marginal selling price for the medicinal product (excluding VAT*), BYN | | |
|---|---|---------------------------|--|---|--|---------------------------------------|---|
| | | | | | calculation for a secondary package | calculation for one dosage form | calculation for an active substance unit |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | |
| | | | | | | | |
| The value calculated on the basis of the arithmetic mean of the cost of one dosage form of the medicinal product that have the nearest adjacent quantities in the secondary package (excluding VAT*), BYN | | | | | | | |
| The value calculated on the basis of the arithmetic mean of the cost of an active substance unit of the medicinal product that have the nearest adjacent dosage (excluding VAT*), BYN | | | | | | | |
| The calculated marginal selling price of the claimed medicinal product for the secondary package (excluding VAT*), for the dosage and the total quantity in the secondary package, specified in clauses 4 and 5, section I of this Annex, BYN | | | | | | | |

* Value added tax

Head of the legal entity, Individual Entrepreneur

(initials, surname) (signature) (phone, email)

Contractor

(initials, surname) (signature) (phone, email)

Annex 6
to the Instruction on the method for calculating
manufacturers' marginal selling prices for
medicinal products

Form

Calculation of the marginal selling price for generic, similar biological medicinal product

(full name of the legal entity; surname, first name, patronymic (if any) of an Individual
Entrepreneur)

I. Information on the medicinal product

| | |
|---|--|
| 1. Registration certificate No. | |
| 2. International Non-proprietary Name, or group name, or chemical name; | |
| 3. Trade name | |
| 4. Dosage form, dosage or concentration, volume, activity in action units | |
| 5. Total quantity in the secondary package | |

II. Price calculation

| Ser. No. | Manufacturer | Information on the original medicinal product | | | | | Reduction factor, F_r | Calculated marginal selling price for a generic, similar biological medicinal product (excluding VAT*), BYN (P_{mar}) |
|----------|--------------|---|------------------------|--|-----------------------------------|---|-------------------------|---|
| | | manufac turer | medicinal product name | dosage form, dosage or concentration, volume, activity in action units | quantity in the secondary package | marginal selling price (P_{or}) registered or calculated in accordance with clause 18 of this Instruction (excluding VAT*), BYN | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | | | | | | | | |
| | | | | | | | | |

* Value added tax

Head of the legal entity, Individual Entrepreneur

(initials, surname)

(signature)

(phone, email)

Contractor

(initials, surname)

(signature)

(phone, email)

Annex 7
to the Instruction on the method for
calculating manufacturers' marginal selling
prices for medicinal products

Calculation of the reduction factor used in the calculation of the marginal selling price for a generic, similar biological medicinal product

| Conversion factor of the registered marginal selling price for the secondary package of the original medicinal product, base values (BV) | Reduction factor |
|--|---|
| up to 0.1 incl. | 1 |
| 0.1 – 0.25 (incl.) | $1 - ((P_{or} - 0.1 \times BV) / 0.1 \times BV) \times 0.2$ |
| more than 0.25 | 0.7 |