(Unofficial translation)

RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS
No. 776 dated October 31, 2018

On the Registration of Maximum Selling Prices for the Manufacturers of Medicinal Products

Amendments and additions:
Resolution of the Council of Ministers of the Republic of Belarus dated July 6, 2023, No. 444 (National Legal Internet Portal of the Republic Belarus, 11/7/2023, 5/51886)

Based on part one of sub-clause 1.1 of clause 1 of the Decree of the President of the Republic of Belarus dated August 22, 2018 No. 345 "On Registration of Prices for Medicinal products", the Council of Ministers of the Republic of Belarus SHALL RESOLVE TO:

1. Generate a state register of manufacturers' maximum selling prices for medicinal products.

2. Approve the Regulation on the procedure for registration of manufacturers' maximum selling prices for medicinal products (see Appendix).

2^1. Establish the list of medicinal products for which the maximum selling prices are subject to registration, see appendix.

3. This resolution shall become effective after its official publication.

Prime Minister of the Republic of Belarus **S. Rumas**

Appendix
To Resolution
Of the Council of Ministers
Of the Republic of Belarus
31.10.2018 No. 776
(As amended by resolution
Of the Council of Ministers
Of the Republic of Belarus
6.7.2023 No. 444)

LIST
Of the medicinal products for which the maximum selling prices are subject to registration

International Nonproprietary Name	Formulation, dosage
1. Amlodipine	5 mg tablets
	10 mg tablets
2. Amoxicillin + Clavulanic Acid	Film-coated tablets/Coated tablets, 500 mg/125 mg (625 mg)
	Film-coated tablets/Coated tablets, 875 mg/125 mg (1000 mg)
3. Atorvastatin	Film-coated tablets/Coated tablets, 10 mg
	Film-coated tablets/Coated tablets, 20 mg

4. Acetylsalicylic acid	Enteric-coated tablets/Film-coated tablets/Gastro-resistant film-coated tablets, 75 mg Film-coated tablets/Gastro-resistant film-coated tablets/Film-coated tablets/ Enteric-coated tablets, 150 mg 500 mg tablets
5. Betahistine	16 mg tablets 24 mg tablets
6. Bisoprolol	Film-coated tablets, 2.5 mg Film-coated tablets, 5 mg Film-coated tablets, 10 mg
7. Valsartan	Film-coated tablets/Coated tablets, 80 mg Film-coated tablets/Coated tablets, 160 mg
8. Heparin	Gel for external use 1000 IU/g
9. Donepezil	Film-coated tablets/Coated tablets, 5 mg Film-coated tablets/Coated tablets, 10 mg
10. Iron (III) Polymaltose Hydroxide	Chewable tablets 100 mg
11. Zopiclone	Film-coated tablets/Coated tablets, 7.5 mg
12. Ibuprofen	Film-coated tablets/film-coated tablets/200 mg capsules Film-coated tablets/Coated tablets, 400 mg Oral suspension (For internal use) 100 mg/5 mL
13. Candesartan	8 mg tablets 16 mg tablets 32 mg tablets
14. Carbamazepine	200 mg tablets
15. Carvedilol	Tablets/Capsules 6.25 mg Tablets/Capsules 12.5 mg Tablets/Capsules 25 mg
16. Lactulose	Syrup 667 mg/mL Syrup 670 mg/mL
17. Lamotrigine	25 mg tablets 50 mg tablets 100 mg tablets
18. Latanoprost	Eye drops (Solution) 0.05 mg/ml
19. Levetiracetam	Film-coated tablets/Coated tablets, 250 mg Film-coated tablets/Coated tablets, 500 mg Film-coated tablets/Coated tablets, 1000 mg

20. Leflunomide	Film-coated tablets, 20 mg
21. Lisinopril	5 mg tablets
	10 mg tablets
	20 mg tablets
22. Losartan	Film-coated tablets/Coated tablets, 50 mg
	Film-coated tablets/Coated tablets, 100 mg
23. Losartan + Hydrochlorothiazide	Film-coated tablets/Coated tablets, 50 mg/12.5 mg
	Film-coated tablets, 100/12.5 mg
	Film-coated tablets/Coated tablets, 100 mg/25 mg
24. Meloxicam	Intramuscular Solution/Solution for Injection 15 mg/1.5 ml
	7.5 mg tablets
	15 mg tablets
25. Metoprolol	25 mg tablets
	50 mg tablets
	100 mg tablets
26. Metformin	Tablets/Coated tablets/Film-coated tablets, 500 mg
	Film-coated tablets/Coated tablets, 850 mg
	Film-coated tablets/Coated tablets, 1000 mg
27. Moxonidine	Film-coated tablets/Coated tablets, 0.2 mg
	Film-coated tablets/Coated tablets, 0.4 mg
28. Molsidomin	2 mg tablets
	4 mg tablets
29. Nimesulide	Powder (granules) for oral suspension (for internal use) in 100 mg/2 g sachets
	100 mg tablets
30. Nicergoline	Film-coated tablets/5 mg capsules
	Film-coated tablets/10 mg capsules
	Film-coated tablets/Capsules 30 mg
31. Omeprazole	Capsules/enteric capsules 20 mg
32. Ramipril	2.5 mg tablets
	5 mg tablets
	10 mg tablets
33. Rivaroxaban	Film-coated tablets/Coated tablets, 2.5 mg
	Film-coated tablets/Coated tablets, 10 mg
	Film-coated tablets/Coated tablets, 15 mg
	Film-coated tablets/Coated tablets, 20 mg
34. Rosuvastatin	Film-coated tablets/Coated tablets, 10 mg
	Film-coated tablets/Coated tablets, 20 mg

35. Spironolactone	Tablets/Capsules 25 mg 50 mg tablets/Capsules Tablets/Capsules 100 mg
36. Trimetazidine	Modified-release film-coated tablets/Film-coated modified-release tablets, 35 mg
37. Ursodeoxycholic acid	250 mg capsules 300 mg capsules

APPROVED
Decree
Of the Council of Ministers
Of the Republic of Belarus
31/10/2018 No. 776
(As amended by Resolution
Of the Council of Ministers
Of the Republic of Belarus
6/7/2023 No. 444)

DECREE
On the Procedure for Registration of Maximum Selling Prices for the Manufacturers of Medicinal Products

1. This Regulation shall determine the procedure for registration of manufacturers' maximum selling prices for medicinal products (hereinafter the maximum selling prices, unless otherwise specified) included in the list of medicinal products for which the maximum selling prices are subject to registration as established by the resolution approving this Regulation (hereinafter the List).

2. For the purposes of this Regulation, the terms and their definitions are used in the meanings established by Law of the Republic of Belarus of July 20, 2006 No. 161-Z "On Circulation of Medicines" and Decree of the President of the Republic of Belarus No. 345 of August 22, 2018.

3. The registration of maximum selling prices is accomplished by the Ministry of Health (hereinafter the Ministry of Health).

4. In order to register the maximum selling price for a medicinal product, the Marketing Authorization holder (an authorized person) shall submit the documents to the Republican Unitary Enterprise "Center for Examinations and Tests in Health Service" (hereinafter the UE "Center for Examinations and Tests") as follows:

An application for registration of the manufacturer's maximum selling price for a medicinal product in the form specified in Appendix (hereinafter the application);

Documents required for the administrative procedure provided for in subparagraph 9.4.12 of paragraph 9.4 of the Unified List of Administrative Procedures Executed in Relation to Business Entities, approved by Resolution of the Council of Ministers of the Republic of Belarus dated September 24, 2021 No. 548;

A document containing maximum selling prices calculated by the method for calculating the maximum selling prices of manufacturers for medicinal products as established by the Ministry of Antimonopoly Regulation and Trade (hereinafter the MART) as agreed by the Ministry of Health (hereinafter the method), the maximum selling price value.

5. The application and the documents specified in paragraphs 3 and 4 of clause 4 of this Regulation (hereinafter the documents, unless otherwise specified) shall be submitted on paper (in two copies) and/or electronically.

6. Within three working days from the date of submission of the application, the UE "Center for Examinations and Tests" shall review the application and check the submitted documents and the information contained therein for completeness.

In case of non-compliance with the procedure for submission of the application and documents, the UE "Center for Examinations and Tests", within the period established in part one of this clause should send a notice of elimination of inconsistencies to the Marketing Authorization holder (an authorized person) in writing and/or electronically within two working days.

Within one working day, the UE "Center for Examinations and Tests" shall review the additionally submitted documents.

7. Within one working day, the UE "Center for Examinations and Tests" shall notify the Ministry of Health (with enclosed documents submitted by the Marketing Authorization holder (an authorized person):

In the cases established in paragraphs two and three of paragraph 1 of Article 17 of Law of the Republic of Belarus of October 28, 2008 No. 433-Z "On the Principles of Administrative Procedures";

In case of failure to eliminate inconsistencies as shown in part two of clause 6 of these Regulations.

In the cases specified in part one of this paragraph, the Ministry of Health shall resolve to refuse the Marketing Authorization holder (an authorized person) to accept the application and within two working days from the date of adoption of such a resolution notify the Marketing Authorization holder (an authorized person) in writing and/or electronically.

8. Once the application has been accepted, the UE "Center for Examinations and Tests" shall send a copy of the application and documents to the Ministry of Health and the MART within two working days.

9. Within 10 working days from the date following the date of receipt of the application and documents, the MART shall make an economic analysis of the maximum selling price calculated by the Marketing Authorization holder (an authorized person) and send the approved maximum selling price or refusal to do so to the Ministry of Health.

10. During the economic analysis, the MART shall use:

The information on selling prices obtained from official sources (Internet websites). A list of these sources is available on the MART official website;

Documents confirming the selling price value.

11. The grounds for refusal to approve the maximum selling price by the MART include:

Submission of the inaccurate or incomplete information;

The above-limit value of the maximum selling price submitted for registration compared to that calculated by the MART using the method.

12. Within three working days from the date of receipt of the MART approved maximum selling price or refusal to do so, the Ministry of Health shall resolve:

On the registration of the maximum selling price;

On refusal to register the maximum selling price (the grounds for refusal shall be provided).

The grounds for refusal to register the maximum selling price by the Ministry of Health include:

Cases established in paragraphs two and three of Article 25 of the Law of the Republic of Belarus “On the Principles of Administrative Procedures”;

Refusal of the MART to approve the maximum selling price, except for cases provided for in parts three and four of this paragraph.

In order to decide to register or refuse to register the maximum selling price, the Ministry of Health shall additionally assess the benefit ratio resulting from the registration of the maximum selling price and preserved availability of the medicinal product, and the risk associated with the refusal to register the maximum selling price and the lack of the medicinal product (hereinafter the benefit-to-risk ratio) in the cases below:

The MART refusal to approve the maximum selling price;

Changes in the registered maximum selling price as set forth in clause 19 of these Regulations.

In the case of unfavorable benefit-to-risk ratio, the MART refusal to approve the maximum selling price shall not prevent the Ministry of Health from deciding on its registration.

The decision shall be formalized by the order of the Ministry of Health. The registration date of the maximum selling price shall be deemed the date of the respective order issued by the Ministry of Health.

13. Within three working days from the date of the decision to register the maximum selling price or refusal to do so, the Ministry of Health shall notify the Marketing Authorization holder (an authorized person) of the decision made in writing and/or electronically.

Should the Ministry of Health decide on the registration of the maximum selling price, the UE “Center for Examination and Tests”, within the period established in part one of this clause shall add this information to the state register of maximum selling prices of manufacturers for medicinal products (hereinafter the register of maximum selling prices).

14. The decision of the Ministry of Health to refuse to register the maximum selling price may be appealed in court.

15. The Ministry of Health shall cancel the decision on the registration of the maximum selling price in case inaccurate data were found to be submitted by the Marketing Authorization holder (an authorized person) which affected the final decision.

16. In case the State Register of Medicinal Products of the Republic of Belarus or the Unified Register of Registered Medicinal Products of the Eurasian Economic Union (hereinafter the Registers of Medicinal Products) contain the information stating that:

More than one participant might be involved in the manufacturing of a medicinal product for which the maximum selling price is subject to registration as per the list, one maximum selling price shall be registered irrespective of the number of such participants;

A medicinal product for which the maximum selling price is subject to registration as per the list may be manufactured in the same dosage form and different dosages, presentations, primary packages with the maximum selling prices be registered for each dosage form, presentation, and primary packaging;

A medicinal product for which the maximum selling price is subject to registration as per the list may be manufactured in the same dosage form, dosage, primary packaging, and presentation but different strengths of the medicinal product in the primary package and the number of primary packages contained in the secondary package, with one maximum selling price to be registered for all the combinations.

17. In case the information on novel medicinal products is added to the registers of medicinal products for which the maximum selling prices are subject to registration, the Marketing Authorization holder (an authorized person) shall submit, within two months from the date of adding the information to the registers of medicinal products an application and documents as prescribed in clauses 5-12 of this Regulation.

18. The maximum selling prices shall be registered in Belarusian rubles.

If the medicinal product is marketed in the Republic of Belarus under a contract that expresses the ordered amount in a foreign currency (hereinafter the contract currency), the Marketing Authorization holder (an authorized person) might indicate the contractual currency when submitting the application.

When adding the information to the register of maximum selling prices as set forth in clause 13 of this Regulation, UE “Center of Examination and Tests” shall also indicate the information on the equivalent price in the contractual currency calculated based on the registered maximum selling price at the official exchange rate of the National Bank of the Republic of Belarus as on the date of registration of the maximum selling price.

In case the official exchange rate of the National Bank of the Republic of Belarus as on the release date of the medicinal product under the customs procedure of release for domestic consumption (if such medicinal product is subject to customs declaration) or on the date of receipt of the medicinal product at the buyer's warehouse stated in the invoice (if such medicinal product is not subject to customs declaration) has increased compared to the official exchange rate of the National Bank of the Republic of Belarus as on the date of registration of the maximum selling price, the equivalent price in the contractual currency calculated as shown in part three of this paragraph shall be deemed as the registered maximum selling price.

19. If the modification of the registered maximum selling price is required, the Marketing Authorization holder (an authorized person) might submit an application and documents as prescribed in clause 5 of this Regulation specifying a different maximum selling price value with the justification of doing so, if the maximum selling price value calculated using the method is not cost-effective.

The application and documents submitted according to part one of this paragraph shall be reviewed as determined by this Regulation.

20. The medicinal products for which the registration certificate valid date has expired shall be marketed based on the registered maximum selling prices effective until the expiration of their shelf lives.

Appendix
to the regulation on the procedure
of registration of maximum
selling prices for the manufacturers
of Medicinal products
(as amended by the resolution
of the Council of Ministers
of the Republic of Belarus
6/7/2023 No. 444)

Form

Ministry of Health
Republic of Belarus

APPENDIX
On the registration of the maximum selling price for the manufacturer of a medicinal product

Marketing Authorization holder (Authorized person)

_____

(Full name of the Marketing Authorization holder (Authorized person), address, e-mail)

Person submitting documents for the maximum selling price registration,

_____

(Full name of the legal entity,

_____

Full name

_____

(if any) of a sole proprietor,

_____

Address, e-mail, phone numbers)

Marketing Authorization number	International nonproprietary (generic) name of the medicinal product	Pharmaceutical manufacturing phase	Name of the participants involved in the production of a medicinal product	Location of the participants involved in the production of a medicinal product	The Anatomical Therapeutic-Chemical (ATC) classification code by the World Healthcare Organization
1	2	3	4	5	6

Medicinal product trade name	Dosage form	Dosage	Quantity in the secondary packaging	Manufacturer's maximum selling price for secondary packaging, ex VAT, bel. rubles	Note*
7	8	9	10	11	12

_____

* For the purposes specified in part two of clause 18, part one of clause 19 of this Regulation.

Head of a legal entity, Sole proprietor
(Representative by power of attorney) _____ _____
(Signature) (Initials, surname)

Date _____