Pursuant to Article 8 paragraph 1 item 1 of the Law on Medicinal Products* (Official Gazette of Montenegro, number 80/20), the Government of Montenegro, at its session held on 1 December 2021, passed the

Decree on criteria for setting maximum prices of medicinal products*

The Decree was published in the Official Gazette of Montenegro, no. 130/2021 of 16 December 2021, and came into effect on 24 December 2021 and 9/2022 - corrigendum.

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*The Council Directive of 21 December 1989 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance system was transposed into this Decree

I. BASIC PROVISIONS

Subject matter

Article 1

This Decree regulates the criteria for setting maximum prices of medicinal products for human use (hereinafter: "medicinal products"), which are marketed in Montenegro and are included in the essential and in the co-payment list of medicines.

Definitions

Article 2

The terms and expressions used in this Decree have the following meanings:

1) **reference countries** means countries whose wholesale prices of medicinal products are used for comparison with wholesale prices of medicinal products in Montenegro;

2) **original medicinal product** means a medicinal product that was the first to be granted a marketing authorization in the world on the basis of complete documentation on quality, safety and efficacy according to the applicable requirements;

3) **generic medicinal product** means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. Different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of active substances shall be considered to be the same active substance, unless there are significant differences in their properties with regard to safety of use and/or efficacy. Where there are significant differences, additional information providing proof of the safety of use and/or efficacy of the various salts, esters or derivatives of the approved active substance shall be submitted. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form;

4) **biologically similar medicinal product** means a medicinal product of biological origin similar to a reference medicinal product of biological origin that does not meet the conditions for a generic medicinal product in relation to differences in raw materials and differences in manufacturing processes of the biologically similar medicinal product and reference medicinal product of biological origin;

5) **pharmaceutical form** means a form of medicinal product suitable for use (tablet, capsule, ointment, solution for injection, premix, etc.);

6) **international non-proprietary name (generic name)** of a medicinal product means an international non-proprietary name (INN) recommended by the World Health Organization (hereinafter: "WHO") or if one does not exist, another common name;

7) **drug strength** means the content of the active substance expressed quantitatively per dosage unit, per unit of volume or weight according to the pharmaceutical form;

8) **outer packaging** means the packaging in which the inner packaging of the medicinal product is placed.

Maximum wholesale price of medicinal product

Article 3

The maximum wholesale price of a medicinal product shall be the wholesale price of the medicinal product excluding value added tax.

The maximum wholesale price of a medicinal product shall be set in relation to the wholesale price of the medicinal product in Montenegro and the average comparable wholesale price of the medicinal product in the reference countries.

Maximum retail price of medicinal product

Article 4

The maximum retail price of a medicinal product shall be set by adding the retail margin of up to 18% to the wholesale price.

II. CRITERIA FOR SETTING MAXIMUM WHOLESALE PRICES OF MEDICINAL PRODUCTS

Criteria for setting maximum wholesale prices of medicinal products

Article 5

The criteria for setting maximum wholesale prices of medicinal products, except for medicinal products derived from blood and human plasma, shall be:

1) comparable wholesale price of the medicinal product in the reference countries;

2) average comparable wholesale price of the medicinal product in the reference countries;

3) the ratio of the wholesale price of the medicinal product in Montenegro and the average comparable wholesale price of the medicinal product in the reference countries (hereinafter: "price parity");

4) pharmacoeconomic study indicators;

5) wholesale margin.

Reference countries

Article 6

The reference countries shall be: the Republic of Serbia, the Republic of Croatia and Romania.

The sources of data on the basis of which the maximum wholesale prices of medicinal products in Montenegro are set shall be:

1) the Rulebook on the list of medicinal products prescribed and issued at the expense of compulsory health insurance funds, published in the Official Gazette of the Republic of Serbia, as well as the website of the National Health Insurance Fund, for requested data on wholesale prices of medicinal products in the Republic of Serbia;

2) the Decision determining the Essential List of Medicinal Products of the Croatian Health Insurance Institute, and the Decision determining the Supplementary List of Medicinal Products of the Croatian Health Insurance Institute, published in the Official Gazette, as well as the website of the Croatian Health Insurance Institute, for requested data on wholesale price of medicinal products in the Republic of Croatia;

3) Catalogul Public national al preturilor maximale ale medicamentelor de uz uman, published in "Monitorul Official", as well as the website of the Romanian Ministry of Health, for requested data on the wholesale price of medicinal products in Romania.

In the case where the medicinal product has a set wholesale price in only one reference country referred to in paragraph 1 of this Article, that medicinal product price shall be taken as a comparable price.

If it is not possible to determine a comparable wholesale price of a medicinal product based on the data sources referred to in paragraph 2 of this Article, the reference country shall be the European Union country with the lowest comparable price of the medicinal product, in which the medicinal product is manufactured or in which the medicinal product was granted the marketing authorization.

Sources of data on wholesale prices of medicinal products in the reference country referred to in paragraph 4 of this Article shall be the applicable regulations of that country governing the prices of medicinal products, as well as the website of the authority responsible for setting the price of medicinal products in that country.

By way of derogation, when it is not possible to determine a comparable wholesale price of a medicinal product in the reference countries in accordance with paragraphs 2 and 4 of this Article, the criteria for setting maximum wholesale price of the medicinal product shall be the pharmacoeconomic study indicators referred to in Article 13 of this Decree.

Comparable wholesale price of medicinal products in reference countries

Article 7

Comparable wholesale price of a medicinal product shall be the wholesale price of the same original, generic or biologically similar medicinal product in the reference countries used to set the wholesale price of the original, generic or biologically similar medicinal product in Montenegro.

Comparable wholesale price of a medicinal product shall be set for each pharmaceutical form separately.

If there is the same or a similar pharmaceutical form in the reference countries, of the same strength, from different manufacturers, with different prices, the average price of the medicinal product in each reference country shall be taken as a comparable price of the medicinal product.

When the same pharmaceutical form does not exist in the reference countries, a similar form may be compared (tablet - dragee - capsule or suspension - syrup - solution or solution for injection - concentrate for solution for injection or powder for solution for injection - lyophilisate for solution for injection, etc.).

Pharmaceutical forms of extended-release or controlled-release medicinal products may not be compared with forms of medicinal products that do not have such release.

Gastro-resistant pharmaceutical forms and oral dispersible pharmaceutical forms shall be compared with the same forms in the reference countries, and if there are no gastro-resistant or oral dispersible forms, the comparison shall be made with a medicinal product of the same INN, similar pharmaceutical form and the same strength.

The comparable wholesale price of a medicinal product shall be calculated per unit of the pharmaceutical form of a comparable medicinal product, after which the price shall be recalculated according to the number of units of the pharmaceutical form in the packaging of the medicinal product used to set the price on the Montenegrin market.

In the case of a different number of units of pharmaceutical form in the packaging of a comparable medicinal product in the reference countries in relation to the number of units of pharmaceutical form in the packaging of the medicinal product on the Montenegrin market, the packaging that has the closest number of units to the packaging of the medicinal product used to set the price on the Montenegrin market shall be taken for comparison.

A medicinal product containing more than 50 times larger or 50 times smaller number of units of pharmaceutical form in packaging in relation to the number of units of pharmaceutical form in packaging of the medicinal product for which the price is set on the Montenegrin market shall not be taken as a comparable medicinal product referred to in paragraph 8 of this Article.

In case there is only one comparable medicinal product with a packaging containing more than 50 times larger or 50 times smaller number of units of pharmaceutical form, the comparable price of the medicinal product shall be determined by calculating the unit price of pharmaceutical form of that comparable medicinal product and multiplying it by the number of pharmaceutical units of the medicinal product in the packaging of the medicinal product for which the price is set on the Montenegrin market.

The comparable wholesale price of a medicinal product shall be converted into Euros by multiplying the comparable wholesale price of the medicinal product in the currency of the reference country, or the European Union country, by the middle exchange rate of that currency against the Euro on the day of conversion, according to the exchange rates published by the Central Bank of Montenegro, in accordance with the law.

Comparable wholesale price of original medicinal product

Article 8

Comparable wholesale price of an original medicinal product in the reference countries shall be the wholesale price of the same original medicinal product used to set the wholesale price of the medicinal product in Montenegro.

Comparable wholesale price of an original medicinal product shall be the average comparable price of the same original medicinal product in the reference countries.

The same original medicinal product referred to in paragraphs 1 and 2 of this Article shall be considered to be a medicinal product of the same INN, of the same or similar pharmaceutical form, of the same strength and of the same manufacturer in reference countries, including different places of manufacture, or a medicinal product of the same proprietary name, of the same or similar pharmaceutical form and of the same strength.

Comparable wholesale price of generic medicinal product

Article 9

Comparable wholesale price of a generic medicinal product in the reference countries shall be the wholesale price of the same generic medicinal product used to set the wholesale price of the generic medicinal product in Montenegro.

Comparable wholesale price of a generic medicinal product shall be the average price of the same generic medicinal product in the reference countries.

The average price of the same generic medicinal product in the reference countries shall be calculated by summing the prices of the same generic medicinal products in the reference countries and dividing the sum by the number of these medicinal products.

The same generic medicinal product referred to in paragraphs 1, 2 and 3 of this Article shall be considered to be a medicinal product of the same INN, of the same or similar pharmaceutical form and of the same strength in the reference countries.

If it is not possible to determine a comparable wholesale price of a generic medicinal product in the reference countries, or in the European Union country referred to in Article 6 paragraph 4 of this Decree, the comparable price shall be the comparable wholesale price of the original medicinal product of the same INN, of the same or similar pharmaceutical form and of the same strength in the reference countries.

Comparable wholesale price of biologically similar medicinal product

Article 10

Comparable wholesale price of a biologically similar medicinal product in the reference countries shall be the wholesale price of the same biologically similar medicinal product used to set the wholesale price of the biologically similar medicinal product in Montenegro.

Comparable wholesale price of a biologically similar medicinal product shall be the average price of the same biologically similar medicinal product in the reference countries.

The average price of the same biologically similar medicinal product in the reference countries shall be calculated by summing the prices of the same biologically similar medicinal products in the reference countries and dividing the sum by the number of those medicinal products.

If it is not possible to determine a comparable wholesale price of a biologically similar medicinal product in the reference countries, or in the European Union country referred to in Article 6 paragraph 4 of this Decree, the comparable price shall be the comparable wholesale price of the original medicinal product of the same INN, of the same or similar pharmaceutical form and of the same strength in the reference countries.

Average comparable wholesale price of medicinal product in reference countries

Article 11

The average comparable wholesale price of a medicinal product shall be calculated by converting comparable wholesale prices of the medicinal product in the reference countries into Euros, summing and dividing the sum by the number of reference countries in which the data on the comparable wholesale price was determined.

Price parity

Article 12

Price parity shall be expressed as a percentage and shall amount:

1) up to 80% for a generic medicinal product whose patent has expired, or which has been granted a marketing authorization on the basis of its substantial similarity to the original medicinal product or on the basis of complete documentation;

2) up to 70% for a medicinal product referred to in Article 9 paragraph 5 of this Decree;

3) up to 95% for an original medicinal product in the reference countries which contains a completely new active substance that significantly increases the possibility of healing and which is on the market in Montenegro for the first time on the basis of its own documentation for obtaining a marketing authorization for the finished product;

4) up to 100% of the price of an original medicinal product:

- which is registered in only one of the reference countries,
- if the price of that medicinal product is the same in the reference countries;
- referred to in Article 6 paragraph 4 of this Decree;

5) up to 95% for biologically similar medicinal products;

6) up to 80% for a medicinal product referred to in Article 10 paragraph 4 of this Decree.

Pharmacoeconomic study indicators

Article 13

Pharmacoeconomic study indicators referred to in Article 5 paragraph 1 item 4 of this Decree shall be:

1) wholesale price of the medicinal product per packaging of the medicinal product;

2) defined daily doses of medicinal products according to the WHO data (hereinafter: "DDD"), as well as the ATC code of medicinal products;

3) wholesale prices of medicinal products per DDD;

4) ratios of wholesale prices of medicinal products per DDD;

5) economic effects of the duration of treatment, one therapeutic cycle, monthly or total therapy using the recommended therapeutic dose;

6) comparative analysis of costs and outcomes of medicinal product use from the pharmacological-toxicological, health and economic aspects.

If a medicinal product of the same INN is on the market in Montenegro, the pharmacoeconomic study indicators referred to in paragraph 1 of this Article shall refer to medicinal products of the same INN.

If there is no medicinal product of the same INN on the market in Montenegro, the pharmacoeconomic study indicators referred to in paragraph 1 of this Article shall refer to therapeutically and pharmacologically comparable medicinal products.

In order to protect the public interest and supply the market with necessary medicinal products, or medicinal products for treatment with modern therapy, for diseases of greater socio-medical importance, and based on pharmacoeconomic study indicators, a higher wholesale price of the medicinal product may be set compared to the price set in accordance with Article 12 of this Decree.

The wholesale price of a medicinal product referred to in paragraph 4 of this Article may not be higher than the highest comparable wholesale price of the same medicinal product in the European Union countries where the medicinal product has been granted a marketing authorization.

Wholesale margin for medicinal products

Article 14

Wholesale margin for medicinal products shall be included in the wholesale price of medicinal products in the amount of 6% of the price.

The price of imported medicinal products shall include customs costs and other importation costs.

III. CRITERIA FOR SETTING WHOLESALE PRICE OF MEDICINAL PRODUCTS DERIVED FROM BLOOD AND HUMAN PLASMA

Criteria for setting wholesale prices of medicinal products derived from blood and human plasma

Article 15

Criteria for setting wholesale prices of medicinal products derived from blood and human plasma, which have been granted a marketing authorization by the Institute of Medicines and Medical Devices (hereinafter: the "Institute"), and which are of general public health interest and are intended for treatment of diseases of greater socio-medical importance shall be:

1) calculation of wholesale prices of the medicinal product;

2) comparable wholesale price of the medicinal product in the European Union countries in which the medicinal product has been granted a marketing authorization;

3) pharmacoeconomic study indicators;

4) wholesale margin.

Wholesale price calculation for medicinal products

Article 16

Wholesale price calculation for a medicinal product shall include:

1) for an imported medicinal product: CIP price (Carriage and Insurance Paid to), customs costs and other inherent import costs, as well as wholesale margin;

2) for a medicinal product manufactured in Montenegro: costs of materials, salaries, controls, depreciation, operations, research and development, as well as wholesale margin.

The CIP price referred to in paragraph 1 item 1 of this Article shall be converted into Euros by multiplying the CIP price in the currency of the country from which the medicinal product is imported by the middle exchange rate of that currency against the Euro on the day of conversion, according to the exchange rates published by the Central Bank of Montenegro, in accordance with the law.

Research and development costs referred to in paragraph 1 item 2 of this Article shall be calculated in the amount of 2% of the total costs incurred on the basis of material costs, salaries, control, depreciation and other operating costs.

The wholesale price of the medicinal product referred to in paragraph 1 of this Article may be up to the amount of the comparable wholesale price of the medicinal product referred to in Article 17 of this Decree.

Comparable wholesale price of medicinal product in European Union countries where medicinal product has been granted marketing authorization

Article 17

Comparable wholesale price of a medicinal product in the European Union countries where the medicinal product has been granted a marketing authorization shall be the wholesale price of the same medicinal product in those countries used to set the wholesale price of the medicinal product in Montenegro.

The same medicinal product referred to in paragraph 1 of this Article shall be considered to be:

1) for an imported medicinal product: a medicinal product of the same manufacturer, the same INN, the same pharmaceutical form and strength;

2) for a medicinal product manufactured in Montenegro: a medicinal product of the same INN, of the same pharmaceutical form and strength, from different manufacturers.

The comparable wholesale price of the medicinal product referred to in paragraph 1 of this Article shall be converted into Euros by multiplying the comparable wholesale price of the medicinal product in the currency of each European Union country by the middle exchange rate of that currency against the Euro on the day of conversion, according to the exchange rates published by the Central Bank of Montenegro, in accordance with the law.

Analogous application

Article 18

The provisions of Articles 13 and 14 of this Decree shall apply by analogy to the setting of wholesale prices of medicinal products derived from blood and human plasma.

IV. SETTING MAXIMUM PRICE OF MEDICINAL PRODUCTS

Application for setting wholesale price of medicinal product

Article 19

Holders of marketing authorizations for medicinal products and holders of wholesale marketing authorizations for medicinal products (hereinafter: "marketing authorization holder") shall submit an application to the Institute for setting the wholesale price of medicinal products.

The application referred to in paragraph 1 of this Article shall contain information on:

1) the applicant;
2) the medicinal product (ATC code, INN, proprietary name, pharmaceutical form, medicinal product strength, packaging);
3) data sources in reference countries where the price of the medicinal product is set;
4) data sources in the European Union country referred to in Article 6 paragraph 4 of this Decree;
5) data sources in the European Union country referred to in Article 17 paragraph 1 of this Decree;
6) the middle exchange rate of the state currency against the Euro on the day of conversion, according to the exchange rates published by the Central Bank of Montenegro, in accordance with the law;
7) medicinal product (whether original/generic/biologically similar/derived from blood and human blood plasma);
8) pharmaceutical form and unit of pharmaceutical form of the medicinal product on the market in the reference country;
9) wholesale price of the medicinal product in the currency of the reference country, per packaging;
10) wholesale price of the medicinal product in Euros, per packaging in the reference country;
11) price of a unit of pharmaceutical form of the medicinal product (pcs/g/ml), in Euros;
12) the average unit price of the pharmaceutical form of the medicinal product, in Euros;
13) pharmaceutical form and unit of pharmaceutical form of the medicinal product on the market in Montenegro;
14) the wholesale price of the medicinal product per packaging in Euros in Montenegro;
15) the average comparable wholesale price in Montenegro.

In the case referred to in Article 13 paragraph 4 of this Decree, in addition to the data referred to in paragraph 1 of this Article, the authorization holder shall submit information on facts or circumstances that justify the application for price increase.

The application referred to in paragraph 1 of this Article shall be submitted on the Form which is an integral part of this Decree.

The Form referred to in paragraph 4 of this Article shall be published on the website of the Institute.

Deciding on applications

Article 20

The Institute shall set the maximum price of the medicinal product within 90 days from the day of receipt of the complete application, in accordance with this Decree.

Notwithstanding paragraph 1 of this Article, in the case of a large number of applications, the deadline for setting the maximum price of a medicinal product may be extended once by 60 days, of which the applicant shall be notified by the Institute before the deadline referred to in paragraph 1 of this Article.

If the application referred to in Article 19 of this Decree is incomplete, the Institute shall notify the authorization holder to supplement it within 30 days from the day of receipt of the notification.

The time required for submitting additional documentation or providing additional explanations at the request of the Institute (clock stops) shall not be counted within the deadline referred to in paragraph 3 of this Article.

If such a decision is not taken within the above deadlines, the applicant shall have the right to fully apply the requested price increase.

If the Institute fails to set the maximum price of the medicinal product within the period referred to in paragraph 1 of this Article, the authorization holder may market the medicinal product at the proposed price.

Adjustment of maximum prices of medicinal products

Article 21

The adjustment of the maximum prices of medicinal products in accordance with this Decree shall be done at least once a year, and more frequently if necessary, on the basis of the application referred to in Article 19 of this Decree.

V. PUBLICATION OF MAXIMUM PRICES OF MEDICINAL PRODUCTS AND DELIVERY OF LIST OF MEDICINAL PRODUCTS

Publication of set maximum prices of medicinal products

Article 22

The set maximum price of the medicinal product shall be valid from the day of setting the maximum price and shall be published on the Institute's website.

Delivery of medicinal product list

Article 23

At least once a year, the Institute shall submit to the European Commission a list of medicines with set prices for a certain period.

VI. TRANSITIONAL AND FINAL PROVISIONS

Procedures initiated and applications for adjustment

Article 24

Procedures for setting the maximum prices of medicinal products initiated before the date of entry into force of this Decree shall be completed in accordance with this Decree.

Authorization holders shall submit to the Institute an application for adjustment of the maximum price of medicinal products in accordance with this Decree, within 90 days from the effective date of this Decree.

Deferred application

Article 25

The provision of Article 23 of this Decree shall apply from the date of accession of Montenegro to the European Union.

Repeal

Article 26

The Decree on criteria for setting maximum prices of medicinal products (Official Gazette of Montenegro, no. 44/15, 65/15 and 57/16) shall be repealed as of the date of entry into force of this Decree.

Entry into force

Article 27

This Decree shall enter into force on the eighth day following that of its publication in the Official Gazette of Montenegro.

Number: 04-6313

Podgorica, 1 December 2021

Government of Montenegro

Prime Minister,

Prof. **Zdravko Krivokapić**, PhD, sgd.

EDITOR'S NOTE: *You can download the form in PDF format by clicking on the following link:*

Form (Subject: Setting the maximum wholesale price of medicinal product)

FORM

Subject: Setting the maximum wholesale price of medicinal product
Applicant:

*Data source: Reference countries/EU Article 6 paragraph 4/EU Article 17 paragraph 1	INFORMATION ON MEDICINAL PRODUCT							INFORMATION ON PRICES OF MEDICINAL PRODUCT				CALCULATION OF PRICE IN MONTENEGRO	
Middle exchange rate of the currency of the country against the Euro on the conversion date, according to the exchange rates published by the Central Bank of Montenegro, in accordance with the law	ATC code	(INN) International non-proprietary name	PROPRIETARY NAME OF MEDICINAL PRODUCT				Pharmaceutical form and unit of pharmaceutical form of medicinal product marketed in the reference country	Wholesale prices in Euros				Pharmaceutical form and unit of pharmaceutical form of medicinal product marketed in Montenegro	Wholesale price of medicinal product per packaging in Euros in Montenegro
								Wholesale price of medicinal product in the currency of the reference country, per packaging	Wholesale price of medicinal product in Euros, per packaging in the reference country	Price of unit of pharmaceutical form of medicinal product (pcs/g/ml) in Euros	Average price of unit of pharmaceutical form of medicinal product, in Euros		
1	2	3	4a	4b	4c	4d	5	6	7	8	9	10	11
			Original medicinal product	Generic medicinal product	Biologically similar medicinal product	Medicinal product derived from blood and human plasma							

AVERAGE COMPARABLE WHOLESALE PRICE IN MONTENEGRO:													

***Data source: Reference countries/EU Article 6 paragraph 4/EU Article 17 paragraph 1**

Please indicate the name of the reference country or EU country with the mandatory middle exchange rate of the country against the Euro on the conversion date, according to the exchange rates published by the Central Bank of Montenegro

****Shaded fields are not to be filled**