

According to the Article 6, Paragraph 1 of the Law on Medicines (« Official Gazette of the Republic of Montenegro», number 80/04), Government of the Republic of Montenegro is announcing:

DECREE ON CRITERIA FOR DETERMINATION OF MAXIMUM PRICES OF MEDICINES

The Issue of this Decree

Article 1

Criteria for determination of maximum medicines wholesale and retail prices are given by this Decree.

Criteria given by this Article of the Decree are also applied to medicines used in Montenegro, according to Decree on Supply of Medicines and Medical Devices (“Official Gazette of the Republic of Montenegro”, No. 10/7).

Criteria

Article 2

Criteria for determination of maximum wholesale prices of medicines are as follows:

1. Wholesale price of a medicine comparable to referent countries,
2. Average wholesale price of a medicine comparable to referent countries,
3. Ratio between wholesale price of a medicine in the Republic of Montenegro and average comparable wholesale price in referent countries,
4. Existing wholesale price,
5. Indicators of pharmaceutical - economic study,
6. Wholesale trade costs.

Referent countries

Article 3

Referent countries are countries whose wholesale prices are used for comparison of wholesale prices in the Republic of Montenegro (hereinafter referred to as: Crna Gora).

Referent countries, referred to in Paragraph 1 of this Article, are Republic of Slovenia, Republic of Croatia and Republic of Serbia.

Data sources, used for determination of maximum prices of medicines in the Republic of Montenegro, are the most recently published editions of registers of medicines from referent countries, such as: Register of Medicines of the Republic of Slovenia, Register of Medicines of the Republic of Croatia and Register of Medicines of the Republic of Serbia.

Comparable wholesale price of medicines in referent countries

Article 4

Comparable wholesale price of a medicine is a wholesale price of the same medicine in referent countries. Under the term same medicine, in sense of this Decree, is meant a medicine with the same international unprotected name (hereinafter referred to as: IUN), with the same pharmaceutical form and the same tenacity.

Comparable wholesale price of medicine is separately determined for each pharmaceutical form. If in referent countries exists the same pharmaceutical form, with the same tenacity, produced by different producers, with different prices, comparable price of medicine will be average price of medicine from each referent country.

When in referent country does not exist the same pharmaceutical form of medicines, generic form can be used for comparison (pellet- tablet- settling – syrup- solvate), taking into account that forms of medicines that have prolonged or controlled reaction can not be treated equally as these medicines that do not have such effect.

In a case of different number of dosage units in a package, package which is the most similar in a sense of number of units will be chosen, and comparable wholesale medicine price is calculated per dosage unit of comparable medicine, after which the price is calculated according to the number of medicine dosage on Montenegrin market.

Comparable wholesale medicine price is calculated into EURO currency in such manner that comparable wholesale medicine price, expressed in the currency of particular referent country, is multiplied by average exchange rate according to currency list of particular referent country Central Bank available on date of calculation.

Article 5

Average comparable wholesale medicine price is calculated in such manner that comparable wholesale medicine prices of referent countries are calculated into EURO currency, summed up and the total divided by the number of referent countries.

Ratio between Wholesale Medicine Price in Montenegro and Average Comparable Wholesale Medicine Prices

Article 6

Ratio between wholesale medicine price in Montenegro and average comparable wholesale medicine prices based on comparable prices in referent countries (hereinafter referred to as: parity of prices), is expressed in percentages.

Parity of prices referred to in Paragraph 1 of this Article can amount to:

1. Up to 80% for a medicine with expired patent right, i.e. of a medicine which was given trading license in accordance to its essential similarity to the innovative medicine, or according to complete documentation including the data from the literature (hereinafter referred to as: generic medicine),
2. Up to 95% for a medicine produced based on a special license agreement concluded with the owner of patent right regarding that particular medicine,
3. Up to 100% for the original medicine which contains new active substance, which significantly influences the possibility of recovery and which is put into circulation in Montenegro for the first time, based on its own and complete documentation required for obtaining license for putting this final medicine on the market, provided that there is no therapeutic- pharmaceutical parallel of that medicine in Montenegro (hereinafter referred to as: innovative medicine). After first appearance of the first therapeutic- pharmaceutical parallel on the Montenegrin market or on developed countries' markets, price parity for that medicine can amount to 95% at the maximum.

Existing Wholesale Medicine Price

Article 7

When determining wholesale medicine price for the first time according to criteria referred to in this Decree, existing wholesale price of a medicine for human consumption, referred to in Article 7 of this Decree is a wholesale price determined according to the Decree on the Highest Prices, the Highest Level of the Prices and the Manner of Determination of Prices of Medicines for Human Consumption ("Official Gazette of the Republic of Montenegro" No. 45/02 and 68/02).

If the existing wholesale price of a generic medicine is lower then 32% of average comparable wholesale price of a medicine in referent countries, criteria for determination of wholesale price of a medicine is the existing wholesale price of a medicine multiplied by quotient of 1,2.

If the existing wholesale price of a generic medicine amounts to between 32% and 80% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is the existing wholesale price of a medicine multiplied by quotient of 1.

If the existing wholesale price of a generic medicine amounts to more than 80% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is average existing wholesale price of a medicine in referent countries multiplied by quotient of 0,8.

If the existing wholesale price of a licensed medicine amounts to between 32% and 90% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is the existing wholesale price of a medicine multiplied by quotient of 1.

If the existing wholesale price of a licensed medicine amounts to more than 90% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is the average existing wholesale price of a medicine in referent countries multiplied by quotient of 0,9.

If the existing wholesale price of an innovative medicine amounts to more than 95% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is the average existing wholesale price of a medicine in referent countries multiplied by quotient of 0,95.

If the existing wholesale price of an innovative medicine amounts to more than 100% of the average comparable wholesale price of a medicine in referent countries, criteria for determination of the wholesale price of a medicine is the average existing wholesale price of a medicine in referent countries multiplied by quotient of 1.

Indicators of Pharmaceutical- economic Study

Article 8

Indicators of pharmaceutical- economic study for medicines in circulation in Montenegro, according to the Article 2, Paragraph 1, item 5 of this Decree, are as follows:

1. Wholesale price of a medicine in the original package;
2. Medicine dosages defined per day according to World Health Organization (hereinafter referred to as: DDD), such as ATC medicine codes;
3. Wholesale prices of a medicine according to DDD;
4. Ratios between wholesale prices of medicines according to DDD;
5. Economic effects of medical treatment duration, single therapeutic cycle duration, monthly therapy or total therapy, using a recommended therapeutic dosage.

If a medicine with the same INN is put in circulation on the Montenegrin market, indicators of pharmaceutical-economic study referred to in Paragraph 1 of this Article, is applied to medicines which are comparable from pharmaceutical-economic point of view.

Criteria for determination of the wholesale price of a medicine for which a comparable price is impossible to determine according to registers referred to in Article 3, Paragraph 3 of this Decree, are the indicators of pharmaceutical- economic study.

Criteria for determination of prices of new medicines, for which a comparable price in referent countries is impossible to determine are as follows: indicators of pharmaceutical-economic study, parity of prices referred to in the Article 6 of this Decree and ratio between average comparable wholesale prices in referent countries, for different forms and dosages of the same INN medicine.

Exceptionally from the criteria referred to in Articles 6 and 7 of this Decree, based on of indicators of pharmaceutical- economic study, for the purpose of protection of public interest and supplying the market with necessary medicines, i.e. medicines assigned for modern medical treatments of diseases with significant socio-economic impact, higher wholesale price of a medicine may be determined.

Wholesale Trading Costs

Article 9

Wholesale price of a medicine consists of wholesale trading costs, which amount to 6% of the price of a medicine according to this Decree.

Criteria for Determination of the Wholesale Price of a Medicine produced from Human Plasma

Article 10

Criteria for determination of the wholesale price of a medicine produced from human plasma are as follows:

1. Calculation of the wholesale price of a medicine,
2. Comparable wholesale price of a medicine in developed countries, in which the medicine is given the permission for putting on the market,
3. Existing wholesale price of a medicine,
4. Indicators of pharmaceutical-economic study,
5. Wholesale trading costs.

Article 11

Calculation of the wholesale price of a medicine referred to in the Article 10, Paragraph 2 of this Decree, for imported medicine, consists of the following: CIP price (Carriage and Insurance Paid to), customs duty costs and other dependant import costs, such as wholesale trading costs.

Calculation of the wholesale price of medicine referred to in Article 8, Paragraph 1 of this Decree, for the medicine produced in Montenegro, consists of the following: costs of inputs, salary costs, amortization costs, other business costs, as well as research and development costs, such as wholesale trading costs.

Research and development costs referred to in the Paragraph 2 of this Article, are calculated based on 2% of total costs summed up from costs of inputs, salary costs, supervision costs, amortization costs and other business costs.

CIP price referred to in Paragraph 1 of this Article is calculated into EUR currency multiplying CIP price, expressed in a currency of a referent country, with the average exchange rate according to the currency list of the referent country's Central Bank, available on a date of calculation.

Article 12

Comparable wholesale price of a medicine referred to in the Article 10, paragraph 2 of this Decree is a wholesale price of the same medicine in developed countries.

Under the same medicine, according to Paragraph 1 of this Article for the imported medicine, is considered the medicine produced by the same producer, with the same INN and the same pharmaceutical form and tenacity.

Under the same medicine, according to this Article for the medicine produced in Montenegro, is considered the medicine with the same INN and the same pharmaceutical form and tenacity, produced by different producers.

Comparable wholesale price of a medicine referred to in Paragraph 1 of this Article is calculated into EUR currency multiplying comparable wholesale price of a medicine, expressed in a currency of particular developed country, with the average exchange rate according to the currency list of the referent country's Central Bank, available on a date of calculation.

Article 13

Provisions of the Article 7, paragraph 1 and Articles 8 and 9 of this Decree are applied to determination of the wholesale price of a medicine produced from human plasma regarding to criteria referred to in the Article 10, paragraph 1, item 3, 4 and 5.

Article 14

Wholesale price of a medicine referred to in the Article 11 of this Decree can amount to comparable wholesale medicine price referred to in the Article 12 of this Decree at the maximum.

Retail Prices of Medicines

Article 15

Retail price of a medicine is determined by adding retail sale costs in the amount of 18%.

Transitional and Final provisions

Article 16

Owners of the license for putting a medicine on the market, as well as the owners of a license for wholesale trading with medicines, are obliged to submit the data, encompassed by the criteria referred to in this Decree in a forms No. 1 to 4, to relevant State institution in charge of economic development, printed together with this Decree and represents its integral part.

Data referred in Paragraph 1 of this Article are submitted within 30 days from the day of entering this Decree into force.

Article 17

Owners of the license for putting a medicine, produced from human plasma, on the market, are obliged to submit the data to relevant State institution in charge of economic development, comprised by criteria referred to in Articles 11 and 12, in forms 5 and 6, printed together with this Decree and represented as its part.

Data from the Paragraph 1 of this Article have to be proved between the 30 days from the day of enforcement of this Decree.

Article 18

This Decree enters into force eight days from the date of publishing in the “Official Gazette of the Republic of Montenegro”.

Podgorica, July 12, 2007

PRIME MINISTER,

