

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

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.

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.

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

If a medicine with the same INN is put in circulation on the Montenegrin market, indicators of pharmaceuticals-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.

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

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

