

Pursuant to the Article 7 of the Law on Amending the Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of Macedonia , No. ____) the Minister of Health issues the

RULES

on determination of prices of medicinal products for human use

I. GENERAL PROVISIONS

Article 1

(1) These Rules shall determine and regulate:

- principal characteristics of the national pricing model based on external referencing and/or other mechanisms of demand and supply side measures;
- level of marketing at which the price is regulated;
- applicants for the determination of the maximum allowed price and approved price
- the criteria, methods and technical details of the procedure for the determination and change of the maximum allowed and approved price and approved price of medicinal products financed from public funds;
- obligatory components of the application for the determination of the maximum allowed and approved price of medicinal product;
- period for which the maximum allowed price is determined;
- the level of wholesale margins and the type and level of the administratively; recognized share or a fixed amount intended to cover costs of retail trade
- the method of publishing and communicating the information on regulated prices of medicinal products
- calculation of retail prices of medicinal products
- parameters determined according to the provisions of Second paragraph of Article 7 of the Law.

Article 2

In addition to the terms defined in Article 1 of the Law on Amending the Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of Macedonia No. ____; hereinafter: the Law), the following terms shall also be used in these Rules:

1. The person subject to the formation of regulated ceiling prices of medicinal products according to this Rule and to the submission of an application for the determination of prices to the Competent Authority (hereinafter: applicant) shall be:

- the marketing authorisation holder or his representative,
- the holder of import authorisation for medicinal products without marketing authorisation, financed from public funds or intended for such financing.

2. Maximum allowed wholesale price is the regulated ceiling price of a medicinal product determined by the Competent Authority according to the provisions of these Rules and shall be used in wholesale trade if no other lower wholesale price exists determined according to these Rules or is agreed according to the provisions of the Article 4 of the Law .

3. Approved wholesale price is the regulated ceiling price of a medicinal products determined by the Competent Authority based on applicant's submission according to the provisions of these Rules. It can be equal or lower than the maximum allowed wholesale price and shall be used in wholesale trade if no other lower wholesale price of the product has been agreed according to the provisions of the Article 4 of the Law.

4. The comparative wholesale price of a medicinal product is an administrative price entity based on the information determined on the basis of:

- the wholesale prices of medicinal products in comparative countries, excluding value added tax (hereinafter: VAT), obtained using publicly available data, or
- the wholesale prices of medicinal products of other countries of the region and other EU Member states, excluding VAT, obtained using publicly available data or verifiable data of the applicant where no publicly available data exist.

5. The "CIP buyer" mark shall mean that the wholesale price of a medicinal product includes administratively acknowledged costs of the manufacturer and the transport and insurance of goods up to the end buyer and the share for covering the costs of wholesale trading.

Article 3

For the purpose of these Rules, in addition to the terms defined in Article 1 of the Law of Medicinal Products and Medical Devices, the following terms shall also be used in these Rules:

1. original medicinal product shall be a medicinal product that has obtained the marketing authorisation pursuant to Article 20 of the Law on Medicinal Products and Medical Devices. Original medicinal products shall also include original medicinal products manufactured on the basis of license agreements and medicinal products that have obtained marketing authorization pursuant to first paragraph of the Article 22 of the Law on Medicinal Products and Medical Devices and for which the linkage to the original manufacturer is or has been demonstrated to the Competent Authority.

2. generic medicinal product shall be a medicinal product that has obtained the marketing authorisation pursuant to second paragraph of the Article 22 of the Law on Medicinal Products and Medical Devices.

3. similar biological medicinal product shall be a medicinal product that has obtained is marketing authorisation pursuant to Article 24 of the Law on Medicinal Products and Medical Devices.

Article 4

- (1) These Rules regulate the maximum allowed wholesale prices and approved wholesale prices of medicinal products, CIP buyer, excluding value added tax.
- (2) These Rules determine the method of formation of retail prices of medicinal products

III. FORMATION AND DETERMINATION OF THE MAXIMUM ALLOWED WHOLESALE PRICES AND APPROVED WHOLESALE PRICES OF MEDICINAL PRODUCTS

Article 5

(1) The maximum allowed wholesale price of medicinal products shall be formulated and determined on the basis of:

- comparison of the wholesale prices of medicinal products in a complete set of comparative countries or in cases where products are not listed in the data sources of particular individual comparative country stated in second paragraph of Article 9 of these Rules, any partial set of selected comparative countries in which products are listed, or
- comparison of the wholesale prices of medicinal products in a set of other countries of the region or other EU member states, if the medicinal products are not listed in the official pricing information sources in any of the comparative countries.

(2) The approved wholesale price shall be determined by the Competent Authority as a wholesale price which is equal or lower than the maximum allowed wholesale price and shall be determined as such on the basis of the application.

(3) The approved wholesale price may be decreased on the basis of a new application which may be submitted any time.

Article 6

(1) The determined maximum allowed wholesale price and approved wholesale price shall be valid until the enforcement of a new determined maximum allowed wholesale price and approved wholesale price of the medicinal product on the basis of application submitted according to the timelines set in Article 20 of these Rules.

(2) The provisions of the former paragraph of this Article apply also for allowed wholesale price and approved wholesale price of medicinal products for which the provisions of the third paragraph of Article 8, fourth paragraph of Article 9, and fourth paragraph of article 10 of the Law, apply.

(3) The period of validity of the approved wholesale price shall not exceed the validity of the maximum allowed wholesale price.

Article 7

(1) If the person acting as the applicant is changed during the course of validity of regulated ceiling prices, the maximum allowed wholesale price and approved wholesale already determined for the medicinal product concerned shall continue to be used for the period of validity of the prices in question. The stated prices, however, may be decreased any time based on the application submitted by the new applicant according to the provisions of these Rules.

1. Criteria, method and technical details of the procedure for the formation and determination of the maximum allowed wholesale prices of medicinal products

Article 8

(1) The proposals for maximum allowed wholesale prices and approved wholesale prices of medicinal products shall be formulated in accordance with these Rules by the applicants and shall be submitted to the Competent Authority which shall in accordance with these Rules determine the stated prices upon receipt of a complete application.

(2) The share or an amount intended to cover costs of wholesale (hereinafter: wholesale margin) shall be explicitly stated by the applicant in the application from the former paragraph of this Article, and shall not exceed the maximum allowed value of wholesale margin in accordance with the Table 1 in the Annex II of these Rules, which is a constituent part of these Rules.

Article 9

(1) The maximum allowed wholesale price shall be calculated on the basis of the comparative wholesale price of a medicinal product.

(2) The basis for the calculation of the comparative wholesale prices of medicinal products shall be the wholesale prices of medicinal products financed from public funds, depending on the presence of data in the sources listed in this paragraph, in the complete or any partial of comparative countries Bulgaria, Croatia, Serbia and Slovenia (hereinafter: comparative countries). Data from the pertinent websites updated according to the provisions of third paragraph of article 22 of these Rules, specifying the comparative wholesale prices of medicinal products, as well as the dates on which the data was collected from the stated sources, shall be used for determining the wholesale price of medicinal products are as follows:

- Bulgaria (website of the Ministry of Health), calculation using the wholesale prices of medicinal products,

URL (general): <http://www.mh.government.bg>

URL (specific): <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=383&categoryid=1409>

- Croatia (website of the Health Insurance Fund), calculation using the wholesale prices of medicinal products,

URL (general): <http://www.hzzo-net.hr>

URL (specific): http://www.hzzo-net.hr/01_04.php

- Serbia (website of the Ministry of Health), calculation using the wholesale prices of medicinal products,

URL (general): <http://www.minzdravlja.info/>

URL (specific): <http://www.minzdravlja.info/downloads/Zakoni/Odluke/Septembar%202009%20Spisak%20Cena%20Lekova.pdf>

- Slovenia (electronic website of the Agency for Medicinal Products of the Republic of Slovenia), calculation using the wholesale prices of medicinal products;

URL (general): <http://www.jazmp.si>

URL (specific): http://www.jazmp.si/files/farmakoekonomika/cene_2007hist.htm

(3) When specific URL addresses in the former paragraph of this article are changed by the relevant national authorities, the applicants shall consult the information for the actual specific URL addresses of the above sources as provided on the webpage of the Competent Authority of the Republic of Macedonia.

Article 10

(1) The maximum allowed wholesale price of medicinal product shall be determined on the basis of the comparative wholesale price of the same medicinal product, which shall be the lowest wholesale price of the same medicinal product in any of the comparative countries and shall be determined:

- for original medicinal product by the provisions of the first paragraph of Article 13 using Equation 13.1.1. and parameter a_{orig} listed in Annex III which is a constitutive part of these Rules;
- for generic medicinal product by the provisions of the second paragraph of Article 13 using Equation 13.2.1. and parameter a_{gen} listed in Annex III of these Rules; and
- for similar biological medicinal product by the provisions of the second paragraph of Article 13 using Equation 13.3.1. and parameter a_{bsim} listed in Annex III of these Rules.

(2) Notwithstanding the provisions of the former paragraph, the maximum allowed wholesale price of a medicinal product may exceed the comparative wholesale price stated in the former paragraph of this Article for medicinal products where comparative wholesale price is obtained from a comparative country with at least twice larger population size relative to the population of the Republic of Macedonia, however not exceeding the value determined:

- for original medicinal product by the provisions of the first paragraph of Article 13 using Equation 13.1.2. and parameter a_{orig} listed in Annex III of these Rules;
- for generic medicinal product by the provisions of the second paragraph of Article 13 using Equation 13.2.2. and parameter a_{gen} listed in Annex III of these Rules; and
- for similar biological medicinal product by the provisions of the second paragraph of Article 13 using Equation 13.3.2. and parameter a_{bsim} listed in Annex III of these Rules.

(3) Notwithstanding the provisions of paragraphs 1 to 3 of this Article, in cases where the medicinal product is not listed in any of the comparative countries' price data sources stated in the second paragraph of Article 9, the range of wholesale prices in other countries of the region and all other EU member states in which the product is present on the market shall be used for external referencing. Comparative price of the medicinal product shall be the lowest wholesale price in that price range and may in cases, where the lowest price is obtained from a country with at least three times larger population size relative to the population of the Republic of Macedonia, exceed the comparative price by the value determined as follows:

- for original medicinal product by not more than c_{orig} percent as listed in Annex III of these Rules;
- for generic medicinal product by not more than c_{gen} percent as listed in Annex III of these Rules; and
- for similar biological medicinal by not more than c_{bsim} percent as listed in Annex III of these Rules.

Article 11

In cases from the third paragraph of Article 10 of these rules, the publicly available information sources in pertinent countries or, in the absence of such sources, verifiable data of the applicant, can be used and shall be listed in the application. The applicant shall in such cases provide the justification for the selected set of the countries in the region.

Article 12

(1) For medicinal products not present on the markets of comparative countries and neither on the markets of other countries of the region and other EU Member states, the basis of calculation of the comparative wholesale price of the medicinal product will be the price of the pertaining therapeutically comparable medicinal product recognized as such by the Competent Authority on the basis of the

applicant's justified proposal. Comparative price shall in such cases be equal to the wholesale price of the comparative product. The maximum wholesale price of the medicinal product under consideration shall in such cases be in the interval of $\pm c$ percent of the comparative price. Parameter c shall be determined for such medicinal products on the basis of second paragraph of Article 7 of the Law and shall be as such listed in Annex III of these Rules.

(2) The Agency may request an expert opinion on the application and proposal of comparative medicinal product stated in the former paragraph of this Article from medical specialists affiliated to legal or natural persons providing healthcare services financed from public funds in the Republic of Macedonia who are competent in the area of the relevant pharmacotherapy.

Article 13

(1) For the calculation of the wholesale price of original medicinal products according to the provisions of the first and second paragraph of Article 10 of these Rules let:

P_{ci} be the wholesale price of the product in the i -th pertinent country

P_{min} be the minimal price of the product in any of the pertinent countries;

P_{avg} be the arithmetic mean of the wholesale price of the product in the pertinent countries;

$CWP = P_{min}$ be the comparative wholesale price of the original product;

a_{orig} be the proportionality factor for original medicinal products set on the basis of provisions of Second paragraph of Article 7 of the Law, and

$CWP_{adj} = a_{orig} \cdot CWP$ be the adjusted comparative wholesale price of the original product.

Then $MAWP$ shall be the maximal allowed price of the original product:

$$MAWP = CWP \quad (\text{Eq. 13.1.1})$$

or

$$MAWP = \min(CWP_{adj}, P_{avg}) \quad (\text{Eq. 13.1.2})$$

Where $\min()$ designates the minimum value of arguments in the parentheses.

(2) For the calculation of the wholesale price of generic medicinal products according to the provisions of the first and second paragraph Article 10 of these Rules let the parameters adopt the meaning of the former paragraph of this article and let in addition:

Q_{ci} be the wholesale prices of the least expensive generic medicinal product with the same composition in i -th pertinent country;

Q_{avg} be the arithmetic mean of the wholesale price of the generic products of the former indent in the pertinent countries;

a_{gen} and b_{gen} be the proportionality factors for generic medicinal products set on the basis of provisions of Second paragraph of Article 7 of the Law

CWP = P_{min} be the comparative wholesale price of the generic product

CWP_{adj} = a_{gen} . CWP be the adjusted comparative wholesale price of generic product

Then MAWP be the maximal allowed price of the generic product:

$$\text{MAWP} = \text{CWP} \quad (\text{Eq. 13.2.1})$$

or

$$\text{MAWP} = \min(\text{CWP}_{\text{adj}}, (\text{P}_{\text{avg}} - \text{b}_{\text{gen}} \cdot (\text{P}_{\text{avg}} - \text{Q}_{\text{avg}})) \quad (\text{Eq. 13.2})$$

Where min() designates the minimum value of arguments in the parentheses.

(3) For the calculation of the wholesale price of similar biological medicinal products according to the provisions of the first and second paragraph Article 10 of these Rules let the parameters adopt the meaning of the first and second paragraphs of this article and let in addition:

a_{bsim} be the proportionality factor for similar biological medicinal products set on the basis of provisions of Second paragraph of Article 7 of the Law;

CWP = P_{min} be the comparative wholesale price of the similar biological product

CWP_{adj} = a_{bsim} . CWP be the adjusted comparative wholesale price of the similar biological product .

Then MAWP be the maximal allowed price of the similar biological product:

$$\text{MAWP} = \text{CWP} \quad (\text{Eq. 13.3.1})$$

or

$$\text{MAWP} = \min(\text{CWP}_{\text{adj}}, \text{P}_{\text{avg}}) \quad (\text{Eq. 13.3.2})$$

Where min() designates the minimum value of arguments in the parentheses.

Article 14

(1) In the case of a different number of packaged dosage units of the medicinal product, the packaging containing a comparable number of units shall be used. The comparative wholesale price of the medicinal product shall then be presented in the application as comparative wholesale per unit and calculated for the relevant product in the application per number of dosage units in that product.

(2) The comparative price of a medicinal product shall be defined for every pharmaceutical form separately. If there is no comparable pharmaceutical form in the comparative countries, a similar pharmaceutical form may be compared (e.g. tablet – coated tablet, capsule), whereby pharmaceutical forms with controlled release of active ingredients cannot be equated with pharmaceutical forms with immediate release.

(3) The comparative price of a medicinal product shall be defined for each strength separately. If no identical strength exists in the comparative countries, the calculations of prices of other strengths shall be used mutatis mutandis.

Article 15

For the determination of values of parameters established on the basis of provisions of Second paragraph of Article 7 of the Law as listed in the Annex III of these Rules, the opinion may be obtained from the Committee for the proposals on the opinion on prices of medicinal products.

Article 16

(1) The applicants shall submit to the Agency the application for determining the maximum allowed wholesale price and approved wholesale price for medicinal products which are financed or are intended to be financed from public funds according to the provisions of Article 8 of the Law.

(2) The application from the former paragraph of this Article shall contain explicit proposal for the approved wholesale price of the product, expressed as the amount in national currency, which shall be equal or lower from the formulated proposal for the maximum allowed wholesale price.

(3) A constituent part of the application from the previous paragraph of this Article shall be the completed Form A from Annex I of these Rules, submitted in both written and electronic form in PDF and XLS or convertible formats.

(4) Supporting evidence for the data denoted in the application such as the description of sources of data, the times of sampling of data, the data verification information, other supportive data, shall be attached to the application in both written and electronic form in .PDF format.

(5) The applications from the first paragraph of this Article may be submitted any time.

II. CHANGES TO THE MAXIMUM ALLOWED WHOLESALE PRICES AND APPROVED WHOLESALE PRICES OF MEDICINAL PRODUCTS

Article 17

(1) The applicants may apply for a decrease the approved wholesale prices any time, according to the provisions of these Rules if it is in their business interest

(2) The applicants are obliged to file the applications for a decrease of the maximum allowed wholesale prices and approved wholesale prices of medicinal products twice a year according to the provisions of these Rules for medicinal products for which:

– a decrease of the wholesale price of a medicinal product occurred in at least one of the comparative countries, affecting the comparative wholesale price of the medicinal product used ;

– a decrease of the wholesale prices occurred in pertinent countries for medicinal products which were not listed in any of the comparative countries' price data sources stated in the second paragraph of Article 9 of these Rules, and whose maximum allowed wholesale price was determined on the basis of prices of pertaining products on the markets of other countries in the region or in other EU Member States, or if the range of pertinent countries has changed;

Applications submitted according to the provisions of this paragraph shall be treated according to the provisions of Article 10 of the Law.

Article 18

Applicants may file applications for the increase of the maximum allowed price and approved price for medicinal products twice a year according to the provisions of these Rules by filing an application at the Competent Authority for medicinal products stated in the two indents of the former paragraph of this Article whereby an increase of price has been observed. The applications shall be treated according to the provisions of Article 9 of the Law.

Article 19

Applicants are obliged to report to the Competent Authority twice a year the unchanged prices for the products of their portfolio that are not listed in the second and third paragraph of his Article according to the provisions of these Rules.

Article 20

(1) The applicants shall submit the applications stated in the second paragraph of Article 17, Article 18 and Article 19 in accordance with the criteria laid down in these Rules. The timelines for submittal of stated applications to the Competent Authority shall be the following:

- from 01. March to and including 01. April, and
- from 01. September to and including 01. October.

(2) The applications stated in the second to fourth paragraph of the former Article for the change of the maximum allowed wholesale prices and approved wholesale prices of medicinal products shall contain:

- the proposals for maximum allowed wholesale prices and proposals for approved wholesale prices of the medicinal products calculated and presented on form A from Annex I of these Rules in both written and electronic forms,
- the calculation of the maximum allowed wholesale prices and approved wholesale prices of the other medicinal products of the applicant's portfolio which shall not be changed, presented separately on form A from Annex I of these Rules in both written and electronic forms,
- complete supporting evidence for the information stated in the application in written and electronic form in PDF format .

(3) The website content of the information sources listed in Article 9 of these Rules will not be used for preparing the application later than three weeks prior to the date of submittal of the application from the previous paragraph of this article.

(4) Any other information content on the prices in other countries in the region and other EU Member states shall use sources valid on date not earlier than one month prior to the date of submittal of the application from the second paragraph of this article.

(5) The maximum allowed wholesale prices and approved prices of medicinal products shall be amended in the manner specified in this Article also for the period in which according to the provisions of the Article 35 of the Law on Medicinal Products and Medical Devices the marketing authorisation

for the medicinal products has already expired but where the medicinal products may be marketed after its expiry date, however for not longer than 18 months.

Article 21

For the applications stated in the first paragraphs of the Article 17 of these Rules the proposed maximal allowed wholesale prices and approved wholesale prices on Form A of Annex I of these Rules and the proposed date of the enforcement of the proposed reduced price shall be sufficient. These applications shall be processed according to the provisions of Article 10 of the Law.

III. PUBLICATION AND FORWARDING OF INFORMATION ON PRICES OF MEDICINAL PRODUCTS

Article 22

(1) The Agency shall at least once a month publish the maximum allowed wholesale prices of medicinal products and approved wholesale prices of medicinal products which have been determined in accordance with these Rules on its website in the catalogue of information of public character, specifying the following:

- the identification mark of the medicinal product;
- name and presentation of the medicinal product;
- the general/international non-proprietary name of the medicinal product;
- the ATC classification code of the medicinal product;
- the name of the applicant;
- maximum allowed wholesale price of the medicinal product;
- approved wholesale price of the medicinal product;
- the date of entry into force of the regulated ceiling prices of the medicinal product;
- the status of the original or generic medicinal product;

(3) The Agency shall submit to the Health Insurance Fund (FZOM) the maximum allowed wholesale prices, the approved wholesale prices including the wholesale margins stated according to the provisions of second paragraph of Article 8 of these Rules, of medicinal products in electronic form in .XLS or convertible format at least once a month.

(4) The FZOM shall at least once a month send the Agency the wholesale prices of medicinal products agreed on, pursuant to the first paragraph of Article 4 of the Law, and data on the valid classifications of medicinal products on the lists with public financing in .XLS or convertible form.

(5) The FZOM shall at least once a year send to the Agency data regarding the consumption of the medicinal products in .XLS or convertible forms.

Article 23

The applicants shall inform the relevant wholesalers on the maximum allowed wholesale prices and approved wholesale prices of medicinal products, formed in accordance with these Rules, immediately and not later than within seven days after the receipt of the decision on the determination of the maximum allowed wholesale prices or approved wholesale prices of the medicinal products and at least three business days prior to the first placement of the product on the market during the period of validity of stated prices..

IV. FORMATION OF RETAIL PRICES OF MEDICINAL PRODUCTS

Article 24

(1) Retail prices of medicinal products without value added tax that shall be valid for pharmacies performing health services financed by public funds, shall be established as the sum of of the approved wholesale price determined according to these Rules and the fixed amount intended to cover costs of retail taken from Table 2 in Annex II of these Rules.

(2) Notwithstanding the provisions of the former paragraph of this Article, for medicinal products for which the provisions of the second paragraph of the Article 4 of the Law apply, the retail price of the medicinal product without value added tax that shall be valid for the pharmacies that perform health services financed by public funds, shall be established as the sum of agreed lower wholesale price and the fixed amount intended to cover costs of retail taken from Table 2 in Annex II of these Rules.

(3) Retail prices formulated according to these Rules shall become valid on the seventh day following the forwarding of the information on wholesale prices of medicinal products by the applicants to the wholesalers according to the provisions the Article 23 of these Rules and not later than on the third day following the publication of wholesale prices by the Competent Authority on the web site according to the provisions of first paragraph of Article 22 of these Rules, or, where applicable, on the third day following the dissemination of information on agreed lower prices of medicinal products by the Health Insurance Fund to pharmacies for the products in question.

(4) Retail prices formulated according to the provisions of this paragraph will remain valid for the period of validity of the pertaining approved wholesale prices or, where applicable, for the duration of pertaining agreed lower wholesale prices of the medicinal products from the second paragraph of this Article.

V. TRANSITORY AND FINAL PROVISIONS

Article 25

(1) The valid wholesale prices of medicinal products determined pursuant to the provisions of the Law on Medicinal Products and Medical Devices shall become the approved wholesale prices of medicinal products as of the date of entry into force of these Rules and will remain valid until the decision o determination of prices issued according to the provisions of these Rules.

(2) For the determination of the maximum allowed wholesale price and approved price pursuant to these Rules, applicants must file the application in accordance with these Rules in the first calendar period stated in the first paragraph of Article 20 of these Rules following its entry into force.

(3) If the Agency foresees an extended deadline due to an exceptional number of applications for determination of the regulated prices of medicinal products in the period stated in the second paragraph of this article, it shall issue a decision implementing extended deadline of 60 days prior to the expiration of the 90-day deadline from the previous paragraph.

Article 26

These Rules shall enter into force on DDth day after their publication in the Official Gazette of the Republic of Macedonia.

Minister of Health

Republic of Macedonia