

Approved
by Decision No. 4
of the Tariff (price) Council
of the Republic of Azerbaijan
dated July 21, 2015.

INSTRUCTIONS on the methods of calculation of medicine prices

1. General

1.1. These Instructions have been prepared in accordance with sub-clause 2.1.2 of the “Statute on the Tariff (price) Council of the Republic of Azerbaijan” approved by Decree No. 341 of the President of the Republic of Azerbaijan dated December 26, 2005, clause 2.2 of the “Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices” approved by Order No. 209 of the Cabinet of Ministers of the Republic of Azerbaijan dated June 3, 2015, and determine methods of setting reference prices for medicines passed state registration and calculating wholesale and retail sale prices.

1.2. These Instructions shall apply to persons specified in Articles 1.0.10-1.0.12 of the Law of the Republic of Azerbaijan “On Medicines”.

2. Determination of reference countries and reference prices

2.1. Regulation of prices for medicines shall be implemented based on the reference prices.

2.2. In order to determine the reference prices, the Tariff (price) Council of the Republic of Azerbaijan (hereinafter referred to as the “Council”) shall, each year, choose at least 5 reference countries from among different countries and approve them. Any change to the list of reference countries shall be made with 2 months prior notification.

2.3. Reference countries include Turkey, France, Italy, Spain, Portugal, Greece, Poland, Hungary, Bulgaria and Slovenia.

2.4. Reference countries of the following year shall be announced by the Council until 31 October of the current year. In the event that new countries will not be announced before the deadline, reference countries of the current year will remain unchanged for the next year.

2.5. Reference prices of medicine shall be determined using the following methods, depending on each case based on prices of the medicines currently on sale:

2.5.1. as a rule, the lowest official selling price of the medicine to the wholesale pharmaceutical companies (hereinafter referred to as “WPC”), excluding value added tax (hereinafter referred to as “VAT”), in each of the reference countries;

2.5.2. in case of no official sale of the medicine in the reference countries, a lowest official selling price excluding VAT to the WPC in the countries where it is produced, imported, or acquired in a pharmaceutical form;

2.5.3. in the event that the official selling price of medicine to the WPC in the countries where it is produced, imported, or acquired in a pharmaceutical form is lower than those in the reference countries, a lowest official selling price excluding VAT to the WPC in such country;

2.5.4. in case of no official sale of the medicine in the countries where it is produced, imported, or acquired in a pharmaceutical form, a lowest official selling price excluding VAT to the WPC in other countries;

2.5.5. a lowest official selling price excluding VAT to the WPC of the original medicine without a generic among the countries where it is on official sale.

2.6. In case of impossibility of determining the official selling price of medicine to the WPC, the selling price to the WPC shall be determined by deducting taxes and other additions provided for by the legislation from the retail selling price.

2.7. In case of impossibility of confirming retail selling price of the medicine and additions thereto, the selling price to the WPC indicated in the price declaration, by adding official documents submitted by manufacturers of the medicines or their authorized representatives (hereinafter referred to as the “producers”) in accordance with these Instructions, shall be taken as a basis.

2.8. Documents indicated in clause 4.3 to the “Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices” approved by Order No. 209 of the Cabinet of Ministers of the Republic of Azerbaijan dated June 3, 2015 shall be attached to the declaration form for original and generic medicines (Annexes No. 1 and No. 2 to these Instructions).

2.9. US Dollar shall be used as a currency for the reference price in declarations. Prices for the countries where the currency is different shall be calculated based on the official exchange rates of the Central Bank of the Republic of Azerbaijan indicated on their official website on the date of issue of the declaration. In case of no exchange rate set by the Central Bank, the official website of the European Central Bank or Central Bank of the mentioned country shall be referred to.

2.10. The Council’s Secretariat (hereinafter referred to as “Secretariat”) shall conduct monitoring of the information used for the purpose of medicines’ price regulation and reference prices in reference countries.

3. Setting the upper limit of conditional selling prices of medicines to the domestic WPC

3.1. The conditional selling price of medicine to the domestic WPC shall be calculated based on the reference price of medicines, taking into account an official exchange rate of US Dollar indicated on the official website of the Central Bank of the Republic of Azerbaijan on the date of issue of the declaration, and the control mark’s amount.

3.2. The conditional selling price of medicine to the domestic WPC is calculated using the following method subject to each specific case:

3.2.1. If medicine is manufactured in the European Union member countries (excluding the countries mentioned in sub-clause 3.2.2 of the Instruction), United States, Canada, Japan, Australia, Israel, Norway and Turkey, without regard to sub-clause 2.5.3 of these Instructions:

3.2.1.1. by adding the price of the control mark to the arithmetic mean of the five lowest reference prices determined in accordance with sub-clause 2.5.1 of these Instructions, in the event that from two to five reference prices are determined to the arithmetic mean of these prices, in the event that only one reference price is determined to the result obtained by multiplying of this reference price with coefficient 1.1;

3.2.1.2. by adding the price of the control mark to reference price determined in accordance with sub-clauses 2.5.2, 2.5.4 or 2.5.5 of the Instructions the conditional selling price to the domestic WPC is calculated.

3.2.2. in the event that medicine is made in Germany, Austria, United Kingdom of Great Britain and Northern Ireland, Belgium and Switzerland:

3.2.2.1. by adding the price of the control mark to the lowest reference price of the medicine made in the above mentioned five countries determined in accordance with sub-clauses 2.5.1-2.5.5 of the Instruction;

3.2.2.2. in the event that the reference price is not indicated by the producer in the price declaration in accordance with sub-clause 3.2.2.1 of this Instructions, without taking into account the sub-clause 2.5.3 of this Instructions:

3.2.2.2.1. by adding the price of control mark to the arithmetic mean of the reference prices determined in accordance with sub-clause 2.5.1 of these Instructions, in the event that from two to five reference prices are determined to the result obtained by multiplying of arithmetic mean of these prices with coefficient 1.1, in the event that only one reference price is determined to the result obtained by multiplying of this reference price with coefficient 1.2;

3.2.2.2.2. by adding the price of the control mark to reference price determined in accordance with sub-clauses 2.5.2, 2.5.4 or 2.5.5 of these Instructions the conditional selling price to the domestic WPC is calculated.

3.2.3. in the event that medicine is made in the countries not specified in sub-clauses 3.2.1 and 3.2.2 of these Instructions the conditional selling price to the domestic WPC is calculated by adding the price of the control mark to the lowest reference price determined in accordance with sub-clauses 2.5.1-2.5.5 of these Instructions.

3.3. In the event that retail price of the medicine of which price is adjusted for the first time, is determined on the basis of the conditional selling price to the domestic WPC calculated in accordance with clause 3.2 of these Instructions, is above current domestic average retail price of the respective medicine manufactured in the specified country groups (with respect to the countries not specified in sub-clauses 3.2.1 and 3.2.2 of these Instructions in that country) conditional selling price to the domestic WPC is calculated with VAT and relevant additions provided for in table section of the clause 3.4 of the "Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices" approved by the Order of the Cabinet of Ministers of the Republic of Azerbaijan No. 209 dated June 3, 2015, deducted from the current average retail price. In calculating conditional selling price to the domestic WPC for equivalent medicine the conditional selling prices to the domestic WPC of other equivalent medicines with less unit amount in the package are taken into consideration.

3.4. In the event that conditional selling price to the domestic WPC is calculated in accordance with clause 3.3 of these Instructions, the conditional selling price to the domestic WPC of the medicine manufactured in the countries specified in the sub-clause 3.2.3 is determined provided that it will not exceed 90 percent of the conditional selling price to the domestic WPC of the medicine manufactured in the countries specified in the sub-clause 3.2.1, in turn the conditional selling price to the domestic WPC of the medicine manufactured in the countries specified in the sub-clause 3.2.1 will not exceed 90 percent of the conditional selling price to the domestic WPC of the medicine manufactured in the countries specified in the sub-clause 3.2.2.

3.5. In the event that the reference price of generic medicine exceeds the one determined for the original by 80 percent, the conditional selling price to the domestic WPC is calculated on the basis of 80 percent of the reference price of original medicine (by adding the price of control mark).

3.6. The reference price of the medicine intended solely for the use at the medical facilities subject to packaging form is determined based on the price of the medicine in same packaging. In case of no sales of medicine with the same packaging form, from among other packaging forms of this medicine being on sale the one with lowest price of medicine unit is selected, and the reference price is determined multiplying its unit price by the amount of packaging. The conditional selling price to the domestic WPC of this medicine is calculated based on 90 percent of the reference price (by adding the price of control mark).

3.7. The producer may apply for approval of the price which is lower than the price calculated in accordance with the requirements of sub-clauses 3.2-3.5 of these Instructions.

4. Medicines with prices regulated on special conditions

4.1. For the following medicines that are of significant importance in terms of population's health and not produced domestically or have inefficient import conditions, the conditional selling price to the domestic WPC exceeding the price calculated in accordance with the requirements of clauses 3.2-3.5 of this Instruction may be fixed, by obtaining by the Council of a relevant opinion from the Health Ministry of the Republic of Azerbaijan concerning the mentioned medicines. The Council shall review prices of such medicines in the last quarter of each year:

- 4.1.1. original medicines officially registered in the country, with no generic;
- 4.1.2. medicines officially registered in the country, with no original and other generic;
- 4.1.3. certain equivalent or similar medicines in order to ensure reliable supply.

4.2. The conditional selling price to the domestic WPC for medicines included in the "List of medicines sold without physician's prescription" shall be determined by adding 10 percent to the reference price and control mark price.

5. Calculation of prices for medicines

5.1. The lowest official selling price to WPC, taking into account the unit amount in the packaging for equivalent medicines - with the same active ingredient(s), pharmaceutical form and amount of unit raw substance (dosage) shall be taken as a reference price.

5.2. The lowest official selling price to WPC, taking into account the amount of raw substance for a similar medicines - with the same active ingredient(s), different pharmaceutical form, amount of unit raw substance (dosage) and/or unit amount in the packaging shall be taken as a reference price.

5.3. Reference price shall be determined based on the official selling price to WPC of medicine in the country referred to in accordance with the requirements of these Instructions and the samples shown in the tables below:

| Sample | Medicine | The official selling price to WPC | Reference price | Note |
|--------|---|---|--|---|
| 1. | 5 mg 5 capsules | Medicine 1: 5 mg 1 capsules = 1 US Dollars Medicine 2: 5 mg 5 capsules = 6 US Dollars Medicine 3: 5 mg 8 capsules = 7 US Dollars | 5 mg 5 capsules ≤ 5 US Dollars | The reference price is calculated based on the price of equivalent medicine 1. |
| 2. | 5 mg 5 capsules | Medicine 1: 5 mg 5 capsules = 6 US Dollars Medicine 2: 5 mg 8 capsules = 7 US Dollars | 5 mg 5 capsules = 6 US Dollars | The price of equivalent medicine 1 is taken as a reference price. |
| 3. | 5 mg 5 capsules | Medicine 1: 5 mg 5 capsules = 6 US Dollars Medicine 2: 5 mg 6 capsules = 5 US Dollars | 5 mg 5 capsules = 5 US Dollars | The price of equivalent medicine 2 is taken as a reference price. |
| 4. | 5 mg 5 capsules 5 mg 10 capsules 5 mg 15 capsules | Medicine 1: 5 mg 5 capsules = 5 US Dollars Medicine 2: 5 mg 10 capsules = 11 US Dollars Medicine 3: 5 mg 15 capsules = 13 US Dollars | 5 mg 5 capsules = 5 US Dollars 5 mg 10 capsules ≤ 10 US Dollars 5 mg 15 capsules = 13 US Dollars | The reference price is calculated based on the price of the medicines 1 and 3. |
| 5. | 10 mg 10 capsules | Medicine 1: 5 mg 5 capsules = 5 US Dollars Medicine 2: 5 mg 10 capsules = 11 US Dollars Medicine 3: 10 mg 25 capsules = 25 US Dollars Medicine 4: 20 mg 5 capsules = 18 US Dollars | 10 mg 10 capsules ≤ 20 US Dollars | In the event that no price is found in either reference country with 1-4 samples of this table applied, selection is made between similar medicines with less amount of unit raw substance, and the reference price is calculated based on the price of medicine 1. |

| Sample | Medicine | The official selling price to WPC | Reference price | Note |
|--------|-------------------|--|-----------------------------------|--|
| 6. | 10 mg 10 capsules | Medicine 1: 10 mg 15 capsules = 30 US Dollars Medicine 2: 10 mg 20 capsules = 35 US Dollars Medicine 3: 10 mg 24 capsules = 40 US Dollars | 10 mg 10 capsules = 20 US Dollars | In the event that no price is found in either reference country with 1-5 samples of this table applied, the reference price is calculated based on the price of the closest equivalent medicine 1 with the amount in the packaging not exceeding 100%. |
| 7. | 10 mg 10 capsules | Medicine 1: 15 mg 2 capsules = 6 US Dollars Medicine 2: 30 mg 1 capsules = 5 US Dollars | 10 mg 10 capsules ≤ 20 US Dollars | In the event that no price is found in either reference country with 1-6 samples of this table applied, the reference price is calculated based on the price of the closest similar medicine 1 with the amount of unit raw substance not exceeding 100%. |
| 8. | 10 mg 10 capsules | Medicine 1: 25 mg 6 capsules = 15 US Dollars Medicine 2: 25 mg 10 capsules = 20 US Dollars | 10 mg 10 capsules = 10 US Dollars | In the event that no price is found in either reference country with 1-7 samples of this table applied, the reference price is calculated based on the price of the closest similar medicine 1 with the amount of raw substance not exceeding 100%. |

5.4. The conditional selling price of medicine to the domestic WPC shall be determined based on the reference price of medicine, complying with the requirements of these Instructions.

5.5. Wholesale price of the medicine to the pharmacy organization and retail price thereof by the pharmacy organization shall be determined by applying relevant additions provided in the table to clause 3.4 of the “Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices” approved by Order No. 209 of the Cabinet of Ministers of the Republic of Azerbaijan dated June 3, 2015.

5.6. Wholesale and retail prices of medicine shall be calculated using the following functions on the Microsoft Excel:

| No. | Price of medicine | Function |
|-----|------------------------------|---|
| 1. | Conditional selling to a WPC | Conditional selling price to the domestic WPC shall be entered in the box A1 |
| 2. | Wholesale (excluding VAT) | The following function should be entered in the box B1: =IF(A1<=5,A1*1.2,IF(A1<=20,A1+1+(A1-5)*0.17,IF(A1<=50,A1+3.55+(A1-20)*0.13,IF(A1<=100,A1+7.45+(A1-50)*0.07,A1+10.95+(A1-100)*0.03))) |
| 3. | Wholesale (including VAT) | The following function should be entered in the box C1: =B1*1.18 |
| 4. | Retail (excluding VAT) | The following function should be entered on box D1: =IF(A1<=50,B1*1.2,IF(A1<=100,B1+11.49+(B1-57.45)*0.13,B1+18.45+(B1-110.95)*0.11)) |
| 5. | Retail (including VAT) | The following function should be entered in the box E1: =D1*1.18 |

5.7. Lower price may be determined to any form of medicine based on the producer’s request. In this case, such lower price shall not be applied to other forms of the medicine without the producer’s request.

5.8. In the event that medicine of which price is regulated based on the information on other countries due to not being on sale in reference countries, as well as in the countries where it is manufactured or imported to, or acquired in a pharmaceutical form, is later put on sale in such countries with the selling price to WPC lower than the reference price, such case shall be reported by the producer and the reference price shall be re-determined. Should such case be discovered during the monitoring conducted by the Secretariat in accordance with clause 2.10 hereof, the reference price shall be re-determined, by requesting for a new price declaration.

5.9. In the event that the original medicine is registered in Azerbaijan for the first time in the world, financial documents approved by an auditor, pharmacoeconomics information based on an expert opinion, as well as cost of treatment methods used for diseases for which such medicine is prescribed should be taken into account in price regulation.

5.10. Announcements shall be made by the Council to regulate the prices of medicines. In the event that no application was filed by producers during the term defined by the Council for price regulation, price regulation shall be effected by conducting examination based on information on reference countries, as well as the countries with open information sources.