



The Cabinet of Ministers of the Republic of Azerbaijan

On approval of the «Procedure for regulation and monitoring of prices on state registered medicines»

Order No. 209

Baku, June 3, 2015

To enforce sub-clause 2.1.3 of the Decree of the President of the Republic of Azerbaijan dated March 18, 2015 No. 493 «On Amendments to the Decree of the President of the Republic of Azerbaijan «On application of the Law of the Republic of Azerbaijan «On Medicines» dated February 6, 2007 No. [528](#) the Cabinet of the Ministers of the Republic of Azerbaijan **orders**:

1. To approve the «Procedure for regulation and monitoring of prices for state registered medicines» (attached).
2. This Order shall enter into force upon signing.

Prime Minister of the Republic of Azerbaijan

Arthur Rasizadeh

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Approved
*by the Cabinet of Ministers
of the Republic of Azerbaijan
dated June 3, 2015
No. 209*

PROCEDURE
for regulation and monitoring of prices on state registered medicines

1. General Provisions

1.1. This Procedure has been prepared in accordance with Article 4.6 of the Law of the Republic of Azerbaijan «On Medicines» and lay down the rules for regulation of prices of medicines in the Republic of Azerbaijan and the implementation of control over these prices.

1.2. This Procedure applies to persons referred to in Articles 1.0.10-1.0.12 of the Law of the Republic of Azerbaijan «On Medicines».

1.3. The price of medicines state registered by the Ministry of Health of the Republic of Azerbaijan and included in the «Register of medicines of the Republic of Azerbaijan», are regulated by the Tariff (price) Council of the Republic of Azerbaijan (hereinafter - the Council).

1.4. Wholesale and retail sale of medicines passed state registration is effected at prices set by the Council.

2. Fixing of basic price for medicines

2.1. Regulation of prices for medicines is based on the basic price. Basic price is a cost of the medicine, inclusive of its specific dosage, trade packaging and its amount in the package based on comparison of official selling prices at the wholesale pharmaceutical enterprises in different countries.

2.2. Basic pricing method for medicines is determined by the Council in accordance with sub-clause 2.1.2 approved by the Decree of the President of the Republic of Azerbaijan dated December 26, 2005 No.341 «Regulations on the Tariff (price) Council of the Republic of Azerbaijan».

2.3. Based on the experience of regulation to establish the basic prices and possibility to access the information sources on the prices of medicines the Tariff (price) Council annually determines five (5) support countries. Amendments to the list of support countries are declared two (2) months before.

2.4. Support countries for the next year are declared by the Council until 31 October of the current year. In the event that new countries will not be announced before the deadline, support country of the current year will remain unchanged for the next year.

2.5. If the information provided by medicine manufacturers or their authorized representatives (hereinafter - the Producers), as well as the sources of information used by the Council Secretariat (hereinafter - Secretariat), do not provide detailed information on the prices of medicines, the used service organizations specializing on the monitoring of medicine prices.

2.6. Information sources used to fix prices of medicines are posted on the official website of the Council.

3. Fixing of wholesale and retail prices for medicines

3.1. Retail price for medicine VAT exclusive is calculated by appropriate premium to the prices of medicines to the conditional sale price provided for wholesale pharmaceutical enterprises in the country in the table to clause 3.4 of this Procedure. Conditional selling price of the medicine for wholesale pharmaceutical enterprise within the country is a price calculated on the basis of the basic price subject to the US dollar rate indicated on the official website of the Central Bank of the Republic of Azerbaijan on the date of submission of price declaration and cost of control mark.

3.2. Retail price for medicine VAT excluded is calculated by appropriate premium to the wholesale prices of medicines VAT excluded, provided for pharmaceutical organizations in the table to clause 3.4 of this Procedure. Conditional selling price of the medicine for wholesale pharmaceutical enterprise within the country is a price calculated on the basis of the basic price subject to the US dollar rate indicated on the official website of the Central Bank of the Republic of Azerbaijan on the date of submission of price declaration and cost of control mark.

3.3. Wholesale pharmaceutical enterprises and pharmacy organizations will determine a level of premiums to the price of medicines in the percentage ratio to portions (amount) of the conditional selling price fixed for the wholesale pharmaceutical enterprises.

3.4. Premiums specified in the table below are applied to fix wholesale and retail prices for medicines:

Conditional selling price of medicines fixed for wholesale pharmaceutical enterprises of the republic	Premium for wholesale pharmaceutical enterprises	Premium for pharmacy organizations
1	2	3
Up to 5 manats (5 manats inclusive)	20 percent of the conditional selling price fixed for the wholesale pharmaceutical enterprises	20 percent of the wholesale price
5-20 manats (20 manats inclusive)	1 manat + 17 percent of the amount of conditional selling price fixed for the wholesale pharmaceutical enterprises exceeding 5 manats	20 percent of the wholesale price
20-50 manats (50 manats inclusive)	3,55 manats + 13 percent of the amount of conditional selling price fixed for the wholesale pharmaceutical enterprises exceeding 20 manats	20 percent of the wholesale price

50-100 manats (100 manats inclusive)	7,45 manats + 7 percent of the amount of conditional selling price fixed for the wholesale pharmaceutical enterprises exceeding 50 manats	11,49 manats +13 percent of the wholesale price exceeding 57,45 manats
more than 100 manats	10,95 manats + 3 percent of the amount of conditional selling price fixed for the wholesale pharmaceutical enterprises exceeding 100 manats	18,45 manats + 11 percent of the wholesale price exceeding 110,95 manats

3.5. Wholesale and retail prices of medicines are approved by the Council VAT inclusive.

4. Form of application and terms of consideration of applications

4.1. Receipt and review of documents to regulate the prices for medicines is implemented by the Secretariat.

4.2. To regulate prices for original and generic medicines manufacturers apply to the Secretariat with a declaration form established by the Tariff (Price) Council. Manufacturers shall ensure an accuracy of submitted data and documents, as well as the transfer of information relating to price reduction in accordance with clause 5.6 of this Procedure to the Secretariat.

4.3. The declaration form is submitted to the Secretariat with the following documents:

4.3.1. copy of the document (registration certificate) on the state registration of medicine in the Republic of Azerbaijan;

4.3.2. financial statement for local production medicines approved by auditor;

4.3.3. pricing documentation indicating the lowest selling price of wholesale pharmaceutical enterprises in the country where the medicine is manufactured, imported or took a pharmaceutical shape which official translation into Azerbaijani language is certified by the diplomatic missions and consulates of Azerbaijan in these countries;

4.3.4. upon availability of GMP (Good Manufacturing Practice) certificate, a notarized copy of the certificate;

4.3.5. if price for the original medicine is fixed for the first time, a notarized copy of the document certifying its originality.

4.4. Regulation of prices for medicine may be rejected in the following cases:

4.4.1. In case of incompleteness of the submitted documents referred to in clause 4.3 of this Procedure;

4.4.2. In case of inaccurate or corrupted data in documents.

4.5. In case of incompleteness of the submitted documents Secretariat will notify the manufacturer of the shortcomings in writing not later than five (5) days.

4.6. The manufacturer is informed in writing of the reasoned refusal to regulate the prices for medicines in accordance with clauses 4.7 and 4.8 of this Procedure.

4.7. Documents of manufacturer first applied for price regulation are reviewed within 30 (thirty) days. This period is calculated from the date of receipt of complete documents submitted for the price regulation.

4.8. Subsequent applications related to regulation of prices for medicines are reviewed within 20 (twenty) days.

4.9. When considering documents by the Secretariat a request is sent to the Ministry of Health of the Republic of Azerbaijan for information about medicines, including information on whether the medicine is original or generic, on medicines that are similar to it by purpose and chemical composition. Information about the medicine is submitted to the Ministry of Health of the Republic of Azerbaijan to the Secretariat within five (5) working days.

4.10. In the absence of grounds for rejection regarding regulation of prices for medicines documents are submitted by the Secretariat to the Council for taking a decision within the period specified in clause 5.2 of this Procedure.

4.11. Council makes an announcement to regulate the prices of medicines. In the event that manufacturer has not applied for prices regulation within the period specified in the announcement of the Council, price regulation is effected by determining basic price along with study based on the data relating support countries, and countries with open sources of information.

4.12. Upon registration of medicines a manufacturer applies to the Council immediately for prices regulation.

5. Regulation of prices for medicines and introduction of changes to this price

5.1. Prices are regulated separately for each dose, and trade package of medicine.

5.2. Regulation of prices for medicines or changes to these prices is reviewed by the Council on a quarterly basis. Council considers on a priority basis prices the issue concerning regulation for medicines on the initiative of the Council itself or in the cases provided for in this Procedure.

5.3. Information relating regulated prices for medicines and their date of use is available on the website of the Council within two (2) working days.

5.4. prices approved by the Council are indicated in the information relating medicines provided by the Ministry of Health of the Republic of Azerbaijan.

5.5. In case of change of the rate of the national currency with reference to the US dollar by more than five (5) percent and if it continues for more than two (2) months, then the prices for medicines on the initiative of the Council will be reviewed on a priority basis in accordance with the requirement of clause 5.2 of this Procedure.

5.6. In the event that in connection with reduction in the basic price or support country reduction in more than 5 (five) percent in the conditional sale price is recorded the manufacturers notify the Secretariat again within three (3) months to make the appropriate changes in price.

5.7. Approved prices for medicines will take effect from the date established by the Council.

5.8. In case of public procurement a lower price than regulated wholesale prices may be offered.

6. Implementation of state control over prices for medicines

6.1. The prices fixed by the state should be clearly marked on the medicines being sold in pharmacy organizations.

6.2. Indication of retail prices on the medicines is ensured by the manufacturers. Approved retail prices including VAT will be indicated on the package of medicines by the manufacturers in printing. In the event that indication of prices in printed form on the package of medicines is not possible, they are indicated by other means set by the Ministry of Economy and Industry of the Republic of Azerbaijan.

6.3. Supervision of pricing discipline in the sale of medicines, including an indication of the prices of medicines in accordance with clause 6.2 of this Procedure by the Ministry of Economy and Industry of the Republic of Azerbaijan.

6.4. The supervisory measures are conducted in accordance with the Law of the Republic of Azerbaijan «On regulation of inspections in entrepreneurship and protection of entrepreneur interests».

7. Final Provisions

7.1. Fixation of basic prices for medicines holding much significance in terms of public health as well as medicines not manufactured in the country or import of which is not profitable, available without prescription, is implemented on special terms determined by the Council.

7.2. Council amends regulated prices due to technical errors based on reasoned appeal by the manufacturers. These amendments are accepted as a re-regulation of price for medicine.