Non-official translation

The Cabinet of Ministers of the Republic of Azerbaijan

On approval of the "Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices"

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 of prices of state registered medicines and implementation of monitoring over these prices" (attached).

2. This Order shall enter into force upon signing.

Prime Minister
of the Republic of Azerbaijan **Arthur RASI-ZADEH**

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

PROCEDURE

for regulation of prices of state registered medicines and implementation of monitoring over these prices

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 monitoring 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 referred to as the "Council").

1.4. Wholesale or retail sale of medicines passed state registration is implemented at prices determined by the Council.

2. Determination of reference prices for medicines

2.1. Regulation of prices for medicines is based on the reference price. Reference 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 to the wholesale pharmaceutical companies in different countries.

2.2. Reference 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 "Statute on the Tariff (price) Council of the Republic of Azerbaijan".

2.3. Based on the experience of regulation and possibility to access the information sources on the prices of medicines in order to determine reference prices the Council annually determines 5 (five) reference countries. Amendments to the list of reference countries are declared 2 (two) months before.

2.4. Reference 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, reference countries 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 referred to as the "producers"), as well as the sources of information used by the Council Secretariat (hereinafter referred to as the "Secretariat"), do not provide detailed information on the prices of medicines, the service of the organizations specializing on the monitoring of medicine prices is used.

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

3. Determination of wholesale and retail prices for medicines

3.1. Wholesale price for medicine excluding VAT is calculated by appropriate mark-up to the conditional selling price to the domestic wholesale pharmaceutical companies provided in the table to clause 3.4 of this Procedure. Conditional selling price of the medicine to the domestic wholesale

pharmaceutical companies is a price calculated on the basis of the reference 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 excluding VAT is calculated by appropriate mark-up to the wholesale prices of medicines excluding VAT, provided for pharmacies in the table to clause 3.4 of this Procedure.

3.3. A level of mark-ups for wholesale pharmaceutical companies and pharmacies will determine in the percentage ratio to portions (amount) of the conditional selling price of medicines to the domestic wholesale pharmaceutical companies.

3.4. Mark-ups specified in the table below are applied to determine wholesale and retail prices for medicines:

Conditional selling price of medicines to the domestic wholesale pharmaceutical companies	**Mark-up for wholesale pharmaceutical companies**	**Mark-up for pharmacies**
1	**2**	**3**
up to 5 manats (5 manats inclusive)	20 percent of the conditional selling price to the wholesale pharmaceutical companies	20 percent of the wholesale price
between 5-20 manats (20 manats inclusive)	1 manat + 17 percent of the amount of conditional selling price to the wholesale pharmaceutical companies exceeding 5 manats	20 percent of the wholesale price
between 20-50 manats (50 manats inclusive)	3.55 manats + 13 percent of the amount of conditional selling price to the wholesale pharmaceutical companies exceeding 20 manats	20 percent of the wholesale price
between 50-100 manats (100 manats inclusive)	7.45 manats + 7 percent of the amount of conditional selling price to the wholesale pharmaceutical companies 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 to the wholesale pharmaceutical companies 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 including VAT.

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 the producers apply to the Secretariat with a declaration form established by the Council. The producers 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 on the state registration of medicine in the Republic of Azerbaijan (registration certificate);

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

4.3.3. pricing documentation indicating the lowest selling price to the wholesale pharmaceutical companies 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 determined 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 producer of the shortcomings in writing not later than 5 (five) working days.

4.6. The producer 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 producer 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 the producers has not applied for price regulation within the period specified in the announcement of the Council, price regulation is effected by determining reference price along with study based on the data relating reference countries, and countries with open sources of information.

4.12. Upon registration of medicines the producers apply to the Council immediately for prices regulation.

5. Regulation of prices for medicines and making changes in these prices

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

5.2. Regulation of prices for medicines or making changes to these prices is reviewed by the Council on a quarterly basis. Council considers in an extraordinary manner to the issue concerning price

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 official website of the Council within 2 (two) 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 5 (five) percent and if it continues for more than 2 (two) months, then the prices for medicines on the initiative of the Council will be reviewed in an extraordinary manner in accordance with the requirement of clause 5.2 of this Procedure.

5.6. In the event that in connection with change in the reference price or reference country reduction in more than 5 (five) percent in the conditional selling price to the wholesale pharmaceutical companies is recorded the producers submit the declaration to the Secretariat again within 3 (three) months to make the appropriate changes in the prices.

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 monitoring over prices for medicines

6.1. The prices regulated by the state should be clearly marked on the medicines being sold in pharmacies.

6.2. Indication of retail prices on the medicines is ensured by the producers. Approved retail prices including VAT will be indicated on the package of medicines in printed form. 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 of the Republic of Azerbaijan.

6.3. Monitoring 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 implemented by the Ministry of Economy of the Republic of Azerbaijan.

6.4. The monitoring 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. Determination of reference 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, over-the-counter medicines, 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 producers. These amendments are not accepted as a re-regulation of price for medicine.