
This law defines the legal and organizational principles of dealing with medicines and medical facilities in the Republic of Azerbaijan, regulates the relations arising in this area.

CHAPTER I. General Provisions

Article 1. Definitions

1.0. The following definitions are used in this law:

1.0.1. Medicines - diagnostics, prophylaxis and treatment of diseases, prevention of pregnancy, rehabilitation of patients, biologically and pharmacologically active medicines of natural (plant, animal, mineral etc.), synthetic and biotechnological origin, which are used for changing the condition and physiological functions of the human body or the mixtures thereof, including also immune-biological medicines.

For the purposes of this law, the medical facilities used for the diagnostics, prophylaxis and treatment of diseases (i.e. medical devices, articles, objects and materials, tools, equipment, medical reagents and optical equipment) are considered to be equal to medicines;

1.0.2. Drugs (medicinal substances) - biologically active medicines of natural (plant, animal, mineral etc.), synthetic and biotechnological origin, which can change the condition and physiological functions of the human body, and are used in the manufacture of medicines;

1.0.3. Active substances - drugs used in the manufacture of medicines (medicinal substances);

1.0.4. Original medicines - medicines, which have been included in circulation under the name of peculiar patented medicine;

1.0.5. Analogues of original medicines (generics) - medicines, which are being produced by other manufactures with the same composition, dosage and form after the expiry of the exclusive patent rights;

1.0.6. Dealing with medicines - scientific research on medicines (their substances), their development, manufacture, packaging, storage, transportation, import and export, registration, certification, quality, efficiency and safety control, sale, use, their
destruction when the expiration date comes or they have become useless, as well as other operations carried out in connection with the medicines;

1.0.7. Pharmaceutical activity - an activity connected with the preparation, manufacturing, wholesale and retail sale of medicines;

1.0.8. State registration of medicines - a system of measures, which envisages an expert assessment of medicines with the purpose of their use in medical practice on the basis of relevant documents and (or) according to the results of tests licensing their manufacture in the Republic of Azerbaijan by the industrial method, their import and application, and also registering them in the established order;

1.0.9. Pharmacopeia article - a document that defines quality, packaging, storage conditions and expiration date of medicines, as well as requirements to the quality control;

1.0.10. Wholesale pharmaceutical enterprise - a legal person, who carries out a wholesale of medicines in accordance with the requirements of this law;

1.0.11. Pharmacy - a physical or a legal person, who carries out retail sale of medicines (including the preparation of medicines on the basis of individual orders) taking into account the requirements of this law;

1.0.12. Medicine manufacturer - a legal entity, which manufactures medicines by the industrial method taking into account the requirements of the relevant standards currently in force in the Republic of Azerbaijan and this Law;

1.0.13. Quality certificate of medicines - a document, which confirms compliance of medicines with the requirements of relevant state quality standards;

1.0.14. Quality of medicines - compliance of medicines with the requirements of state standards;

1.0.15. Safety of medicines - characteristics of medicines, which is based on the comparative analysis of the effectiveness of medicines and assessment of the probability of harm to health;

1.0.16. Effectiveness of medicines - the degree of positive impact of medicines on the course of treatment of disease.

Article 2. The legislation of the Republic of Azerbaijan on Medicines

population health,” this Law and other relevant normative-legal acts and international agreements, which the Republic of Azerbaijan has joined.

2.2. The characteristics of dealing with drugs, psychotropic substances and their precursors, used in medicine as remedy, is regulated by the law of the Republic of Azerbaijan "On the turnover of narcotic drugs, psychotropic substances and their precursors " and other relevant legislative acts.

Article 3. The main duties of the state in circulation of medicines

3.0. The main duties of the state in circulation of medicines consist of the following:

3.0.1. to guarantee the population right to receive qualitative medicines;
3.0.2. to develop and implement state programs in the field of supplying the population with medicines;
3.0.3. to prepare and approve the relevant regulatory and technical documents and standards on production, transportation and storage of medicines;
3.0.4. to organize state control over quality and use at all stages of circulation of medicines;
3.0.5. to carry out scientific research to identify high-quality, effective and safe medicines;
3.0.6. to ensure rendering assistance to the different categories of citizens by supplying them with free or discounted medicines in the order established by the legislation;
3.0.7. to preserve and increase the resources, which are raw materials for medicines;
3.0.8. to stimulate production of medicines, place state orders for production of vital medicines;
3.0.9. to carry out purchase of immune-biological medicines, which are necessary for ensuring treatment, immune-prophylaxis of especially dangerous infections;
3.0.10. implementation of international cooperation in the field of pharmaceutical activity.

Chapter II. State regulation of dealing with medicines

Article 4. Methods of state regulation of dealing with medicines

4.1. State regulation of dealing with medicines is carried out by using the following methods:

4.1.1. licensing of the pharmaceutical activity;
4.1.2. state registration of medicines;
4.1.3. certification of medical devices;
4.1.4. implementation of state control over quality, effectiveness and safety of medicines.

4.2. To regulate dealing with medicines, the relevant executive authority:

4.2.1. carries out state registration of medicines;
4.2.2. carries out register of medicines and ensures creation of the database on medicines;
4.2.3. allows the import of medicines;
4.2.4. examines and approves pharmacopeia article for medicines manufactured on the territory of the Republic of Azerbaijan;
4.2.5. examines new methods of rational analysis established in the Republic of Azerbaijan to control over quality of existing medicines;
4.2.6. develops and publishes the state pharmacopeia;
4.2.7. approves "List of medicines used in vital and urgent cases" and "List of medicines released with a doctor’s prescription’’;
4.2.8. prepares and approves normative-technical documents and state standards on medicines within its competence.

4.3. In case of revealing additional impacts and interaction with other medicines, which were not declared by the manufacturer in the guidelines related to the medicines, the relevant executive authority has the right to prohibit use of this medicine in the Republic of Azerbaijan.

4.4. Enterprises and organizations that prepare medicines, semi-product for their production on the basis of the state order cannot stop their production or withdraw them from production without the relevant executive authority’s approval and substitute of the product earlier put out.

Article 5. Licensing the pharmaceutical activity

Taking into account the requirements of this law, the pharmaceutical activities are carried out on the basis of a special permission (license) in accordance with the relevant legislation of the Republic of Azerbaijan. The special license is for the following types of the pharmaceutical activities:

5.1.1. manufacture of medicines;
5.1.2. whole sale of medicines;
5.1.3. retail sale of medicines.
5.2. In the Republic of Azerbaijan, persons who have higher education or secondary special education in pharmacy and legal persons, regardless of their form of ownership may be engaged in the pharmaceutical activities.

5.3. Article 5.1 of this law is not applied to the state-owned wholesale pharmaceutical enterprises and pharmacy organizations.

**Article 6. State registration of medicines**

6.1. With the exception of cases stipulated in Articles 6.5 and 9.3 of this law, the import of medicines to the Republic of Azerbaijan, their production, sale and use on the territory of the Republic of Azerbaijan is permitted only after the registration with the relevant executive authority.

6.2. State registration of drugs, psychotropic substances and their precursors , which are used as medicines and have been included in the lists approved by the law of the Republic of Azerbaijan “On approval of lists of narcotic drugs, psychotropic substances and precursors, turnover of which on the territory of the Republic of Azerbaijan is prohibited, restricted and controlled, as well as precursors the import, export, transit transportation and production of which on the territory of the Republic of Azerbaijan requires a license (special permission)” is carried out in accordance with requirements of the law of the Republic of Azerbaijan “On circulation of drugs, psychotropic substances and their precursors” and other relevant legislative acts.

6.3. The following medicines are registered:

6.3. original medicines;
6.3.2. analogues of medicines (generics);
6.3.3. new combinations of medicines, which have been registered by the state;
6.3.4. medicines, the state registration term of which has expired;
6.3.5. drugs (medicinal substances), used in the manufacture of medicines as an active substance.

6.4. If any change is made to the information contained in registration documents of the state registration of medicines, those changes are registered with the state.

6.5. The following medicines are not included in the State Register:

6.5.1. medicines and medical devices intended for demonstration at exhibitions (the exhibition samples);
6.5.2. medicines, prepared at the pharmacies on a doctor’s prescription on the basis of medicines, which have been included in the State Register;
6.5.3. medicines imported with the purpose to be used during epidemics, natural
disasters and other emergency situations;
6.5.4. medicines, which are intended to carry out scientific research, prior-to-clinic researches and clinical tests. The use of these medicines is allowed only under the decision of the relevant executive authority.
6.6. State registration of different medicines under the same trade name is not allowed.
6.7. Medicines, registered with the state in the Republic of Azerbaijan, are included in the "Register of medicines of the Republic of Azerbaijan”.
6.8. Rules of state registration of medicines and filling out their register are determined by the relevant executive authority.

Article 7. Certification of medicines

7.1. Medicines, produced in the Republic of Azerbaijan and imported into the country, are certified by the relevant executive authority in the order established by the legislation.

7.2. Certification of medicines not registered in the Republic of Azerbaijan is not allowed.

Article 8. State control over quality, effectiveness and safety of medicines

At all stages of circulation of medicines in the Republic of Azerbaijan (purchase of raw materials for medicines, production of medicines, their storage, transportation, sale, etc.) control over their quality, effectiveness and safety is realized by the relevant executive authorities.

Article 9. The import and export of medicines

9.1. The import and export of medicines are carried out in the order established by the legislation.

9.2. The import of medicines into the Republic of Azerbaijan for humanitarian purposes is carried out in the order established by the relevant executive authority. The medicines, about the quality of which no guarantees are given by the relevant executive authority, are prohibited for import into the Republic of Azerbaijan for humanitarian purposes.

9.3. In cases of epidemics, natural disasters and other emergency situations, medicines, which are not registered in the Republic of Azerbaijan, are allowed for import by the decision of the relevant executive authority only if the documents confirming their registration and use in the manufacturer’s country are available.
9.4. Persons, visiting the Republic of Azerbaijan or traveling abroad, may bring for personal use sufficient number of medicines, including medicines, not registered in the Republic of Azerbaijan, without any problems.

9.5. The import of medicines into the Republic of Azerbaijan is carried out by their manufacturers, wholesale pharmaceutical enterprises. Scientific-research institutions can also carry out their import in the quantity and order established by the relevant executive authority for the purposes of preparation of medicines, researches of their quality, safety and effectiveness.

Article 10. Hygiene and sanitary control in the field of circulation of medicines


10.2. Control over compliance with hygiene and sanitary norms in the field of circulation of medicines are carried out by the relevant executive authority.

Article 11. Requirements for instructions about use of medicines

11.1. Instructions about use of medicines produced in or imported into the Republic of Azerbaijan must contain the following information in the Azerbaijani language:

11.1.1. trade and not patented name of the medicine;
11.1.2. name of country, where the medicine was produced;
11.1.3. name and legal address of medicine manufacturer;
11.1.4. date of preparation and serial number;
11.1.5. way to take medicine, its dosage, form, number of doses per pack;
11.1.6. expiration date;
11.1.7. storage and dispensing conditions;
11.1.8. precautionary measures while taking the medicine;
11.1.9. information about components of the medicine;
11.1.10. the scope of application, contraindications, additional effects and interaction with other medicines.

11.2. Instructions on the use of medicines are approved by the relevant executive authority.

Article 12. Storage, transportation and destruction of medicines
12.1. Storage and transportation of medicines are carried out in the order established by the relevant executive authority with strict observance of temperature, light regimes, humidity and other requirements.

12.2. The medicines, which are required by this law to be registered, but have not been registered, which do not meet requirements of normative-technical documents, the origin of which is unknown, counterfeit, defective, the expiry date of which has passed or became unfit, are withdrawn in the order established by the legislation and destroyed in accordance with sanitary norms.

**Article 13 Dispensing of medicines to the population**

13.1. Medicines are dispensed to the population only by the pharmacies.

13.2. It is mandatory for pharmacies to have in their stock medicines, which are included in “List of medicines used in vital and urgent situations”.

13.3. Pharmacies are prohibited to sell other goods, except optical equipment, perfumery-cosmetics, baby foods, curative mineral waters, biologically active food-additives and personal hygiene products.

13.4. Dispensing of prescribed medicines without a doctor’s prescription is prohibited.

13.5. Requirements for pharmacies and the norms for dispensing medicines from the pharmacies are determined by the relevant executive authority.

**Article 14 Medical care in pharmacies**

Pharmacies are prohibited to receive patients. Only in life-threatening situations, first aid may be rendered to the people in pharmacies.

**Chapter III. Acquisition and dissemination of information about medicines**

**Article 15. The right of access to information about medicines**

Every person has the right to be informed about the effectiveness of the medicine, its additional effects, its interaction during use together with different medicines, as well as information about use of prescribed medicine.

**Article 16. Dissemination of information about medicines**

16.1. Information about medicines, which are dispensed without a doctor’s prescription, may be disseminated in mass media, specialized and general publications, instructions on taking medicines.
16.2. Information about medicines, which are dispensed with a doctor’s prescription, and information about medical facilities, which are applied only in specialized medical institutions, may be disseminated by medical personnel and in specialized publications intended for pharmacists. Information about medicines may be presented in the form of monographs, reference books, scientific articles, as reports at congresses, conferences, symposia, scientific councils and other gatherings of that kind, as well as in the form of instructions intended for doctors.

16.3. Medicine manufacturers are obliged to inform the medical staff about all properties of their application.

16.4. The advertisement of medicines is prohibited in the Republic of Azerbaijan.

Chapter IV. Final provisions

Article 17. Compensation for damage caused to human health as a result of use of medicines

17.1. Compensation for damage to human health as a result of illegal actions of physical and legal persons engaged in application and circulation of medicines is paid by the same persons in the order established by the legislation.

17.2. Should the below-listed situations be proven, then the damage, caused to human health as a result of the application of medicines, must be covered by the manufacturer:

17.2.1. The medicine was applied as per prescription, in accordance with the instructions on how to use it, and its harmful effects on human health have occurred as a result of errors committed during the production;

17.2.2. The harmful effect on human health has occurred as a result of errors in the instructions about its use, published by the manufacturer.

17.3. If harmful effects of medicines on human health occur as a result of becoming unfit due to the violation of storage rules at wholesale pharmaceutical enterprises and pharmacies, then caused damage should be paid by wholesale pharmaceutical enterprises or pharmacies.

Article 18. Responsibility for violation of the law

The physical and legal persons, who are guilty of violating this law, are brought to the civil, administrative and criminal responsibility in the order and cases established by the legislation of the Republic of Azerbaijan.

Article 19. Entry into force of the law
19.1. This Law comes into force from the date of publication.

19.2. Paragraphs 6.1 and 7.2 of this Law, come into force from March 1, 2008.


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