

LAW OF THE REPUBLIC OF AZERBAIJAN
“On medicinal products”

This Law defines the legal and organizational principles of handling of medicinal products and medical devices in Azerbaijan Republic, controls the relations arising in this area.

Chapter I

General Provisions

Article 1. Main concepts

1.0. The following definitions are used in this Law:

1.0.1. medicinal products - diagnostics, prophylaxis and treatment of diseases, prevention of pregnancy, rehabilitation of patients, biologically and pharmacologically active medicines of natural (of plant, animal origin, mineral etc.), synthetic and biotechnological origin used for changing the condition and physiological functions of the human body or their mixtures, as well as immune-biological medicinal preparations.

For the objectives of this Law, the medicinal products used for the diagnostics, prophylaxis and treatment of diseases (i.e. medical devices, goods, objects and materials, tools, equipment, medical reagents and optical equipments) are considered to be equal to medicinal products;

1.0.2. drugs (medicinal substances) - biologically active medicines of natural (of plant, animal origin, 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 substance – primary drug used in the production of medicinal products (medicinal substances);

1.0.4. Original medicinal products – medicinal products included in circulation under the name of peculiar patented medicine;

1.0.5. Analogues of original medicinal products (generics) – medicinal products, which are produced by other manufactures with the same composition, dose and form after the expiry of the exclusive patent rights;

1.0.6. Handling of medicinal products - (their substances), scientific research, development, production, packaging, storage, transportation, import and

- export, state registration, certification, control over quality, efficiency and security, sale, use of medicinal products, their destruction when the expiration date finishes or they have become useless, as well as other operations carried out in connection with the medicinal products;
- 1.0.7. pharmaceutical activity - an activity connected with the preparation, manufacturing, wholesale and retail sale of medicinal products;
- 1.0.8. state registration of medicinal products - a system of measures, which envisages an expert assessment of medicinal products 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 production in Azerbaijan Republic by the industrial method, their import and application, and also their registration in the established order;
- 1.0.9. pharmacopeia article - a document that defines quality, packaging, storage conditions and expiration date of medicinal products, as well as requirements to the quality control;
- 1.0.10. wholesale pharmaceutical enterprise - a legal person, who carries out a wholesale of medicinal products in accordance with the requirements of this Law;
- 1.0.11. pharmacy - physical or legal person, who carries out retail sale of medicinal products (including the preparation of medicinal products on the basis of individual orders) taking into account the requirements of this Law;
- 1.0.12. medicine manufacturer - a legal entity, which manufactures medicinal products by the industrial method taking into account the requirements of the relevant standards currently in force in Azerbaijan Republic and this Law;
- 1.0.13. quality certificate of medicinal products - a document, which confirms compliance of medicinal products with the requirements of relevant state quality standards;
- 1.0.14. quality of medicinal products - compliance of medicinal products with the requirements of state standards;
- 1.0.15. Safety of medicinal products - characteristics of medicinal products, which is based on the comparative analysis of the effectiveness of medicinal products and assessment of the probability of harm to health;
- 1.0.16. Effectiveness of medicinal products - the degree of positive impact of medicinal products on the course of treatment of disease.

Article 2. The legislation of Azerbaijan Republic on Medicinal products

- 2.1. The legislation of the Republic of Azerbaijan consists of the Constitution of the Republic of Azerbaijan, the Law of the Republic of Azerbaijan “On protection of the population health”, this Law and other relevant normative-legal acts and international agreements that Azerbaijan Republic has joined.
- 2.2. The characteristics of handling of drugs, psychotropic substances and their precursors, used in medicine as remedy, are 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 medicinal products

- 2.1. The main duties of the state in circulation of medicinal products are as follows:
 - 3.1.1. to guarantee the population right to receive qualitative medicinal products;
 - 3.1.2. to develop and implement state programs in the field of supplying the population with medicinal products;
 - 3.1.3. to prepare and confirm the relevant regulatory and technical documents and standards on production, transportation and storage of medicinal products;
 - 3.1.4. to organize state control over quality and use at all stages of circulation of medicinal products;
 - 3.1.5. to carry out scientific research to identify high-quality, effective and safe medicinal products;
 - 3.1.6. to ensure rendering assistance to the various categories of citizens by supplying them with free or discounted medicinal products in the order established by the legislation;
 - 3.1.7. to preserve and increase the resources, which are raw materials for medicinal products;
 - 3.1.8. to stimulate production of medicinal products, give state orders on production of vital medicinal products;
 - 3.1.9. to carry out provision of immune-biological medicinal products, which are necessary for ensuring treatment, immune-prophylaxis of especially dangerous infections;
 - 3.1.10. implementation of international cooperation in the field of pharmaceutical activity.

Chapter II. State regulation of handling of medicinal products

Article 4. Methods of state regulation of handling of medicinal products

- 4.1. State regulation of handling of medicinal products is implemented by the following methods:
 - 4.1.1. licensing of the pharmaceutical activity;
 - 4.1.2. state registration of medicinal products;
 - 4.1.3. certification of medical devices;
 - 4.1.4. Implementation of state control over quality, effectiveness and safety of medicinal products.
- 4.2. in order to regulate handling of medicinal products, the appropriate executive authority:
 - 4.2.1. carries out state registration of medicinal products;
 - 4.2.2. carries out register of medicinal products and ensures creation of the database on medicinal products;
 - 4.2.3. allows the import of medicinal products;
 - 4.2.4. examines and approves pharmacopeia article for new medicinal products manufactured on the territory of Azerbaijan Republic;
 - 4.2.5. examines new methods of efficient analysis established in the Republic of Azerbaijan to control over quality of existing medicinal products;
 - 4.2.6. develops and publishes the state pharmacopeia;
 - 4.2.7. approves “List of medicinal products used in vital and emergency situations” and “List of medicinal products released without doctor’s prescription”;
 - 4.2.8. Prepares and approves normative-technical documents and state standards on medicinal products within the scope of its authority.
- 4.3. In case side effects of medicinal products and their interaction with other medicinal products are determined, which have not been declared by the manufacturer in the instructions on medicinal products, the relevant executive authority has the right to ban the use of these medicinal products in the Republic of Azerbaijan.
- 4.4. Enterprises and organizations that prepare medicinal products, semi-products 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 of pharmaceutical activity

- 5.1. Pharmaceutical activity is carried out on the basis of special permission (license) in conformity with the relevant legislation of Azerbaijan

Republic, taking into consideration the requirements of this Law. Special permission (license) is given on the following types of pharmaceutical activity:

- 5.1.1. Production of medicinal products;
- 5.1.2. Wholesale of medicinal products;
- 5.1.3. Retail sale of medicinal products;
- 5.2. Physical entities having secondary or higher education on pharmaceutics and legal entities, regardless of property type can deal with pharmaceutical activity in Azerbaijan Republic.
- 5.3. Article 5.1 of this Law is not applicable for state-owned wholesale pharmaceutical enterprises and pharmacy organizations

Article 6. State registration of medicinal products

- 6.1. Except for the cases stipulated in the articles 6.5 and 9.3 of this Law, the import of medicinal products to Azerbaijan Republic, their production, sale and use in the territory of Azerbaijan Republic is permitted only after state registration in the relevant executive authority.
- 6.2. State registration of drugs, psychotropic substances and their precursors, which are used as medicinal products and have been included in the lists approved by the Law “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)” of Azerbaijan Republic 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 medicinal products are state registered:
 - 6.3.1. Original medicinal products
 - 6.3.2. analogues of medicinal products (generics);
 - 6.3.3. new combinations of medicinal products, which have been registered by the state;
 - 6.3.4. medicinal products, the state registration term of which has expired;
 - 6.3.5. Drugs (medicinal substances), used in the manufacture of medicinal products as an active substance.

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

Article 7. Certification of medicinal products

- 7.1. Medicinal products, produced in and imported into the Republic of Azerbaijan, are certified in accordance with legislation by the relevant executive authority.
- 7.2. Certification of medicinal products not registered in the Republic of Azerbaijan is not allowed.

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

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

Article 9. Import and export of medicinal products

- 9.1. The import and export of medicinal products are carried out in conformity with established legislation.
- 9.2. The import of medicinal products into the Republic of Azerbaijan for humanitarian purposes is carried out in the order established by the relevant executive authority. For humanitarian purposes, import of medicinal products that have no guarantees about the quality, by the relevant executive authority into the Republic of Azerbaijan is prohibited.
- 9.3. In cases of epidemics, natural disasters and other emergencies, import of medicinal products, which are not registered in Azerbaijan Republic, is allowed by the decision of the relevant executive authority, if only the documents confirming their registration and use in the manufacturer's country are available.
- 9.4. Individuals, visiting Azerbaijan Republic 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 medicinal products, researches of their quality, safety and effectiveness.

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

- 10.1. Hygiene and sanitary norms in the field of circulation of medicines is regulated by the Law of Azerbaijan Republic "On Sanitary-Epidemiological well-being" and other relevant normative-legal acts.
- 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 on use of medicines

- 11.1. Instructions on use of medicinal products, produced in or imported into the Republic of Azerbaijan, must contain the following information in the Azerbaijani language:

- 11.1.1. trade and unpatented name of the medicinal product;
- 11.1.2. name of country, where the medicinal product was produced;
- 11.1.3. name and legal address of manufacturer of medicinal product;
- 11.1.4. date of preparation and serial number;
- 11.1.5. the rule of appliance of medicinal product, its dosage, form, number of doses per pack;
- 11.1.6. expiry date;
- 11.1.7. storage and dispensing conditions;
- 11.1.8. precautionary measures while taking the medicinal product;
- 11.1.9. information about components within the composition of the medicinal product;
- 11.1.10. the scope of application, contraindications, side effects and interaction with other medicines.
- 11.2. Instructions on the use of medicinal products are confirmed by the relevant executive authority.

Article 12. Storage, transportation and destruction of medicines

- 12.1. Storage and transportation of medicinal products are carried out according to the order established by the relevant executive authority with strict observance of temperature, light regimes, humidity and other requirements.
- 12.2. The medicinal products, 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 medicinal products to the population

- 13.1. Medicinal products are dispensed to the population only by the pharmacy organizations.
- 13.2. It is mandatory for pharmacies to have medicinal products in their stock which are included into “List of medicinal products used in vital and urgent situations”.
- 13.3. Sale of other goods, with the exception of optical equipment, perfumery-cosmetics, baby foods, curative mineral waters, biologically active food-additives and personal hygiene products, is prohibited in pharmacy organizations.
- 13.4. Dispensing of prescribed medicines without a doctor’s prescription is prohibited.

- 13.5. Requirements for pharmacy organizations 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. In pharmacy organizations, first aid may be rendered to the people only in life-threatening situations.

Chapter III. Acquisition and broadcast of information about medicinal products

Article 15. The right of access to information about medicinal products

Each person has the right to be informed on the effectiveness of the medicinal product, its side effects, and its interaction during use together with different medicines, as well as information about use of prescribed medicinal product.

Article 16. Broadcast of information about medicinal product

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

Chapter IV. Final provisions

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

- 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

medicinal products, is paid by the same persons in accordance with legislation.

17.2. The damage, caused to human health as a result of the application of medicinal products, must be covered by the manufacturer, once the following cases are proven:

17.2.1. the medicinal product 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 medicinal products on human health occur as a result of becoming unsuitable due to the violation of storage rules at wholesale pharmaceutical enterprises and pharmacies, then caused damage should be paid by wholesale pharmaceutical enterprises or pharmacy organizations.

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 Azerbaijan Republic.

Article 19. Entry into force of the Law

19.1. This Law comes into effect from the date of publication.

19.2. From the date of entry into force of this Law, the Law of Azerbaijan Republic "On the pharmaceutical activity" dated November 5, 1996 No. 189-IQ (The Collection of Legislation of Azerbaijan Republic, 1997, No 3, article 228; 1999, No. 5, Article 285; 2001, No.11, Article 698; 2004, No. 4, Article 202) is considered invalid.

President of Azerbaijan Republic

Ilham Aliyev

Baku, December 22, 2006

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