

THE LAW ON DRUGS OF THE REPUBLIC OF ARMENIA

Adopted by the National Assembly
As of 27 October 1998

The present law shall regulate the turnover of drugs in the Republic of Armenia, including their manufacture, dispensation, measurement, packaging, registration, quality control and other activities relevant to the production or destruction thereof, drug acquisition, maintenance, storage, distribution, prescription, trade, export, import, respective information dissemination and promotion as well as determine the powers of the RA state authorities in the above specified fields.

ARTICLE 1

BASIC DEFINITIONS OF THE LAW

In applying the provisions of this Law, the following terms shall have the meanings indicated herein:

a) Drug. Any biologically active measured-out preparation, originated from one or several substances and subsidiary ingredients, consisting of standard components, produced under fixed brand names, in adequate dosage, form and design; intended for human and animal treatment, diagnostics, prevention, anesthesia, contraception, with the aim of effecting the organism functions.

The following preparations shall be considered as drugs:

Antiseptics: means to destroy or eliminate the pathogens of infectious and parasitical diseases as well as the transmitting agents thereof;

Disinfectants : antibacterial active substances used for healthcare products disinfection purpose;

Immunobiological preparations: preparations of bacterial, animal, herbal and other biotechnological origin used for prophylactics, diagnostics and treatment of diseases;

Homeopathic remedies: drugs dispensed and used in appropriate dosage forms in accordance with homeopathic patterns and recorded in specific chapter under State Register for Drugs.

b) Drug substance. Any biologically active substance of natural, synthetic, biotechnological origin used in drug dispensing and manufacture.

c) Drug formulation. Any output form with a definite content, application instructions and complex physical and chemical peculiarities produced as tablets, pills, capsules, drops, vials, injection solutions and other, in a stable aggragate state (solid, viscous, liquid, gaseous).

d) Pharmacography. Drug composition and formulation, where the basic and other pharmaceutical and auxiliary substances, excipients and other ingredients are listed due to the gradual sequence of their target influence as well as due to their respective quantity in the drug composition.

e) Prescription. An approved document, through which a physician instructs the pharmacist on the drug composition, dispensation, dosage form, design and delivery, and the patient - on the drug use with the specification of other relevant data.

The prescriptions may differ in types as they refer to:

narcotic drugs;
psychotropic substances;
ordinary medicine.

The prescription forms shall be established by the Government of the RA.

f) Pharmaceutical products. Drugs, healthcare oriented products, patient care, sanitary and hygienic safety products.

g) Health care products. Items, things, instruments, devices, equipment used for prevention, diagnostics and treatment of diseases and pregnancy contraception.

h) Narcotics. Preparations bringing on drug addiction. The list of narcotics as well as the export-import, manufacture, maintenance, stock-taking, delivery, sale, intake and destruction procedure thereof is subject to the legislation of the RA.

i) National Pharmacopoeia. A guidebook on pharmacological and pharmaceutical peculiarity definitions of basic drugs allowed for medical use in the RA.

j) Pharmaceutical activity. Any activity performed in the areas involving pharmaceutical products manufacture, transportation, maintenance, delivery, consultation, distribution, realization, export-import and destruction.

j(i) Dosage form. The established quantity of a drug assigned for one- time, every day, course, therapeutic administration.

j(ii) Drugs State Register. A document containing information on drugs registered in the RA.

j(iii) Essential Drugs List. A document listing the essential drugs that ensure the health care of the population and should be available at any time in the RA in sufficient amounts and relevant formulations. The Essential Drugs List is subject to approval by the State regulatory body duly authorized by the RA Government (hereinafter: the Drug Authority).

j(iv) Pharmacopoeia. Collection of indices determining drug quality.

j(v) Controlled drugs. Narcotics and psychotropic substances listed in a document subject to verification by the Government of the RA.

j(vi) Pharmacy. An establishment or a subdivision of such engaged in drug dispensing, on-spot control over drugs quality, measurements, packaging, maintenance as well as trade in drugs, healthcare products and other respective items, provides consultation and information on the issues hereof.

j(vii) Drug stall. An establishment or a subdivision of such engaged in on-spot control over drugs quality, measurements, packaging and maintenance as well as trade in drugs, healthcare products and other respective items and provides consultation and information on the issues hereof.

j(viii) Pharmacist. A person having a higher education degree in pharmaceuticals.

j(ix) Pharmacy technician. A person having a secondary education degree in pharmaceuticals.

ARTICLE 2. IMPLEMENTING PHARMACEUTICAL ACTIVITIES

People with higher and secondary vocational education and HOLDING a license shall be entitled to engage in pharmaceutical activities. Responsibility for illegal pharmaceutical activities shall be defined by the law. People engaged in pharmaceutical activities shall be liable for violation of or failure to adequately fulfill their professional obligations in the manner defined by the law.

ARTICLE 3. LICENSING OF PHARMACEUTICAL ACTIVITIES

The license for pharmaceutical activities shall be issued and revoked by the Government Drug Authority.

License for implementing pharmaceutical activities in the Republic of Armenia shall be issued for:

- drug manufacture
- herbs processing
- pharmacy operation
- drug import and export
- trade of narcotics

The procedure for selling veterinarian drugs shall be defined by the Government of the Republic of Armenia.

(Article 3 amended as of 22.02.07, Law No ՀՕ-120-Ն)

ARTICLE 4 THE SUPPLY OF DRUGS

The pharmacies and drug stalls shall supply the population with drugs.

The pharmacies and drug stalls shall be established and run business given the availability of a relevant License.

The pharmacies and drug stalls shall be entitled to acquire and sell the drugs which are registered in the RA.

The lists of OTC (over-the-counter) and controlled drugs shall be approved and issued by the GoA Drug Authority. The Pharmacies and drug stalls shall have the minimal assortment of drugs contained in the Essential Drugs List.

The pharmacies and drug stalls shall be entitled to deliver drugs classified as narcotics and psychotropic substances given the submission of the prescription in the established form.

The prescription shall be written down and approved by a physician on a special prescription form bearing his/her personal seal and signature.

The patient shall reserve the right to obtain precise information on the effect of the drug prescribed, its possible side effects, interaction between different drugs and ways of its administration from a physician or a pharmacist.

Upon the delivery of a drug the pharmacist shall consult the customer on the administration and maintenance of the drug given.

ARTICLE 5 DRUGS MANUFACTURE

Drugs manufacture shall be performed in duly licensed establishments acting in compliance with the norms and procedures determined by the Government Drug Authority.

Drug manufacture shall be subject to professional state control. Any establishment engaged in drug and other pharmaceutical products manufacture shall bear responsibility for its production and shall assure the product quality for the established period of its validation provided that the given product is preserved

under required maintenance conditions.

ARTICLE 6 DRUGS DISPENSATION

Drugs shall be dispensed in pharmacies.

The pharmacies shall dispense drugs from substances authorized for use, based on a prescription and pharmacography.

The drug dispensing license shall be cancelled in case of any technological procedure violations, discrepancy of the dispensed drug with its prescription and other infringements.

ARTICLE 7

RESPONSIBILITY FOR DRUG PREPARATION AND

MANUFACTURE PROCEDURES VIOLATIONS

The establishments engaged in manufacture and dispensing of drugs shall bear responsibility for any infringements to the manufacture arrangement, product maintenance, labeling, design and packaging procedures.

Any person violating the rules for drug manufacture and dispensing, maintenance and transportation shall bear responsibility in the manner prescribed by this law.

ARTICLE 8. DRUG LABELING AND DESIGN

Manufactured and dispensed drugs shall be labeled.

Requirements for labeling shall be defined by the Government Drug Authority.

The label, labeled package, insert, drug instruction shall contain data on compliance of the drug with asserted requirements, warnings on the threats of overdosing and keeping the drug out of reach for children.

The drug shall be put into circulation provided the external or primary package has the readable name and address of producer company, drug name, production date, form of usage, weight and quantity of each unit and the effective substance it contains, date of expiry and storing conditions. Test samples shall have the label "not for sale".

The labels of drugs made by gene engineering methods shall mention the active agents used and transformed microorganisms.

Herbal raw materials shall not contain radioactive substances and shall be labeled "The product underwent radiation testing".

The labels of homeopathic drugs shall be marked as "homeopathic".

ARTICLE 9. PROHIBITION OF DRUG MANUFACTURE SALE AND USAGE

The manufacture, sale and usage of drugs that do not comply with the requirements approved by the Government Drug Authority shall be prohibited.

Drug sale shall be allowed only in pharmacies and drug stalls. Sale of drugs in other places shall be considered implementation of unlicensed activities subject to licensing and shall provide for responsibility defined by the law.

(Article 9 amended as of 22.02.07 Law No ՀՕ-120-Ն)

ARTICLE 10. IMPORT AND EXPORT OF DRUGS

There is a common procedure for the export and import of drugs and drug substances at the territory of the Republic of Armenia, which shall be defined by the Government of the Republic of Armenia.

People arriving in or leaving from Armenia can take drugs of required quantity for their personal use and treatment course.

ARTICLE 11. DRUG INFORMATION DISSEMINATION AND DRUG PROMOTION

The purpose of drug information dissemination shall be to safeguard the population of the Republic of Armenia from counterfeit drugs and the illicit use thereof.

The insert leaflet in the drug package shall contain precise information on the proper administration of the given drug.

The information intended for specialists involved in the drug turnover can be disseminated via monographs, bulletins, scientific articles, various publications, through reports made during scientific conferences and other similar events as well as in the form of indications for physicians having the right to prescribe drugs.

No OTC drugs advertising shall be allowed (on the radio, television, newspapers, magazines, signboards, posters, via illuminated advertising or other advertisement facilities).

No drug promotion shall be allowed if the communication contained therein suggests the consumer that:

using drugs shall not require any consultation from a physician;
drugs are free from side effects;
the certain drug may produce more effect than other drugs;
the intake of the drug might considerably improve the health state and the abstention thereof may cause aggravation;
the drug can be used in food, for cosmetic and other purposes.
The promotion of non-registered drugs in the RA shall be prohibited.

ARTICLE 12. RULES FOR DRUG TRANSPORTATION AND PRESERVATION

The procedure for the transportation, storage and preservation of drugs shall be defined by the Government Drug Authority.

ARTICLE 13. TRANSIT TRANSPORTATION OF DRUGS

The procedure for transit transportation of drugs shall be defined by the Government of the Republic of Armenia.

ARTICLE 14. DESTRUCTION OF DRUGS

Drugs not valid for administration shall be subject to destruction. Drug destruction shall be implemented with consideration of environmental and sanitary norms and codes. The procedure and conditions of drug destruction shall be defined by the Government Drug Authority.

Drug destruction shall be funded by the drug owner organization.

ARTICLE 15 STATE REGISTRATION OF DRUGS

Drug import, manufacture, maintenance, distribution, realization and use in the Republic of Armenia shall be allowed only if the drugs are registered in the RA, other than in the cases determined by the Armenian Government.

Drug registration, registration rejection and cancellation shall be performed in the manner established by the Government of the RA.

Mandatory registration shall apply to:

new drugs and drug forms proposed for treatment;
immunobiological preparations;
new combinations of registered drugs;
registered drugs delivered in new drug formulations and implying new ways of administration or indications;
generic drugs equivalent to the registered ones by name but produced by other manufacturer by means of another technology and involve other supplementary substances.

No registration shall be required for drugs prepared in a pharmacy according to prescriptions.

Drug registration shall be annulated in case of any inconformity thereof to the primary requirements respective to the drug quality, manufacture and safety or in the event of any changes in the drug composition, formulation, indication and manufacturing conditions.

Decisions on drug registration or rejection thereof shall be made on the merits of a relevant expert conclusion following to an examination carried out in compliance with the procedure established by the Government Drug Authority.

The drug registration validity term shall be deemed 5(five) years.

An applicant shall submit the overall documentation package and samples necessary for registration; pay the expert fee and the state tax whilst in the registration proceedings. If only one organization is entitled to perform the expert examination, the registration fee shall be determined by the Government of the RA.

The applicant shall reserve the right and opportunity to view the expert conclusion with the aim of ensuring the elimination of any discrepancies within the defined term.

The Registration Certificate holder shall immediately notify the RA Government Drug Authority on any newly observed data relating to the drug safety, efficacy and pharmacological characteristics.

The Government Drug Authority shall guarantee the confidentiality of the data received.

Any drug formerly authorized for use shall be subject to a new registration, if:

its brand name, composition and manufacturing technology have gone changes;
new observations have emerged relative to its characteristics, ways of administration or other changes occurred;

The applicant shall be entitled to launch an appeal to the relevant judicial bodies against the expert examination results.

(Amendments in Article 15 introduced as of 20.11.02, Law No HO-460-N)

ARTICLE 16. STATE CONTROL OVER DRUG QUALITY

The main objective of the State control over drugs quality is to ensure the introduction of registered

efficient and safe quality drugs in the medical practice.

The State control over the drug quality shall refer to the manufacture and preparation, import and realization of drugs.

Drug quality shall comply with the technical specifications established by the Government of the Republic of Armenia .

The drug quality requirements shall be mandatory for the establishments engaged in pharmaceutical activity.

The State control over the drug quality shall be exercised by the Government Drug Authority.

ARTICLE 17. OBLIGATIONS OF MEDICAL FACILITIES TO PROVIDE INFORMATION ON SIDE EFFECTS OF DRUGS

Medical-preventive facilities, pharmacies, establishments and organizations engaged in the realization and administration of drugs shall immediately inform the Government Drug Authority about all cases of revealed unknown side effects.

ARTICLE 18. STATE GUARANTEES FOR THE SUPPLY OF DRUGS

Guarantees on the availability, affordability of drugs included in the Essential Drugs List as well as protection in case of damages caused to the health by the administration of a drug without a medical indication are provided to the population of the Republic of Armenia.

The list of diseases and social groups entitled to acquisition of drugs free of charge or under privileged conditions shall be approved by the Government of the Republic of Armenia.

The procedure for providing the population with drugs in case of calamities shall be defined by the Government of the Republic of Armenia.

ARTICLE 19. CONTROL OVER PHARMACEUTICAL ACTIVITIES

The control over the adequate pharmaceutical activities shall be carried out by the Government Drug Authority.

ARTICLE 20. LIABILITY FOR VIOLATION OF THE PRESENT LAW

Those violating the requirements of the present law shall be liable in the manner defined by the legislation of the Republic of Armenia.

ARTICLE 21. INTERNATIONAL AGREEMENTS

In case norms other than those in the present law are defined by international agreements of the Republic of Armenia the norms of those international agreements shall be applied.

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ՀՕ-259