THE LAW OF THE REPUBLIC OF ARMENIA

Adopted by the National Assembly
27 October 1998

A B O U T D R U G S

The present law regulates drug circulation in the Republic of Armenia. It includes drug manufacture, dispensing, measurement, packaging, registration, quality control and other activities connected with drug preparation or utilization, acquisition, maintenance, storage, distribution, prescribing, sale, export, import, drug information and promotion. It also determines the rights of state authorities of the RA in those fields.

Article 1
Definitions and terms used in the law

The following definitions and main terms are used in given law:

a) **Drugs.** Drugs are biologically active products measured out in doses made from one or several substances and subsidiary ingredients. They have a standard composition, unchangeable brand names, necessary drug form, dosage form and design. Drugs are intended for human and animal treatment, diagnostics, prophylactics, anesthesia, contraception; they have an influence on the functions of the organism.

The following are considered as drugs:

- **Antiseptics:** the means destroying or eliminating the pathogens of infectious and parasitical diseases as well as their transmitting agents;
- **Disinfectants**: substances displaying antibacterial activity, which are used for Health Care products' disinfecting;
- **Immunobiological preparations:** preparations of bacterial, animal, herbal and other biotechnological origin used for prophylactics, diagnostics and treatment of diseases;
- **Homeopathic means:** drugs dispensing and using in appropriate dosage forms according to the homeopathic patterns, and included in special part of State Register of Drugs.

b) **Drug substance.** Any biologically active matters of natural, synthetic, biotechnological origin which are used for drug dispensing and manufacture.

c) **Drug form.** An output form having a definite composition, complex physical and chemical peculiarities as tablets, pills, capsules, drops, vials, solutions for injection and others in a stable aggregate state (solid, viscous, liquid, gaseous).

d) **Pharmacography.** Drug composition and form, in which the basic and other substances, auxiliary matters, excipients and other ingredients are listed according to the gradual sequence of target influence and in the quantity necessary for drug preparation.

e) **Prescription.** An approved document, by which a physician appeals to a pharmacist about drug composition, dispensing, dosage form, design and delivery, and to a patient - about indication of drug use.

The types of prescriptions are:

- for narcotic drugs;
- for psychotropic substances;
- ordinary

The types of prescriptions are determined by the Government of the RA.

f) **Pharmacy products.** Drugs, Health Care products, patient care, safety products, sanitary and hygienic products.

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

h) **National Pharmacopoeia.** Collection of definitions of pharmacological and pharmaceutical peculiarities of basic drugs allowed for medical use in the RA.

i) **Narcotics.** Drugs bringing drug addiction, the list of which as well as export-import, manufacturing, maintenance, stock-taking, delivery, sale, use and utilization order are set by the legislation of the RA.

j) **Pharmaceutical activity.** Any activity performed in such fields as pharmaceutical products manufacturing, transportation, maintenance, delivery, consultation, distribution, use, export-import and utilization.

1) **Dosage form.** The amount of drug assigned for one-time, every day, course, therapeutic administration.
2) **Drug State Register.** A document that includes an information about drugs registered in the RA.
3) **Essential Drug List.** A document that includes drugs provided health care of the population and which should be available in sufficient amounts in the RA.

Essential Drug List is approved by the State Regulatory body authorized by the RA Government (henceforth: drug authorities).

4) **Pharmacopoeia.** A collection of indices determining drug quality.
5) **Controlled drugs.** Narcotic drugs and psychotropic substances the list of which is approved by the Government of the RA.
6) **Pharmacy.** An establishment or a subdivision of an establishment engaged in drug dispensing, drug quality control performance on the spot, measurements, packaging, maintenance. It performs a trade of drugs, Health Care products and other related goods and provides any consultation and information about them as well.
7) **Pharmacy kiosk.** An establishment or a subdivision of an establishment engaged in drug dispensing, drug quality control performance on the spot, measurements, packaging, maintenance. It performs a trade of drugs, Health Care products and other related goods and provides any consultation and information about them as well.
8) **Pharmacist.** A person having a higher education degree in pharmaceutics.
9) **Pharmacy technician.** A person having a secondary education degree in pharmaceutics.

Article 2
The right of pharmaceutical activity

Any person having higher and secondary education degree and holding a License reserves the right to perform a pharmaceutical activity.

Amenability for those engaged in an illegal performance of a pharmaceutical activity is determined by the law.

Any person engaged in pharmaceutical activity in case of breach of professional duties or their improper performance bears a responsibility according to the order determined by the given law.

Article 3
Licensing of pharmaceutical activity

The License for pharmaceutical activity is given or deprived by the drug authorities.

The License for the engagement in pharmaceutical activity in the RA is given for:

- drug manufacture
- culture and sale of herbs
- pharmacy activity
- drug trade
- drug export and import
- narcotics trade

The order of the veterinary drugs realization is determined by the Government of the RA.

Article 4
Supply of the population with drugs

Pharmacies and pharmacy kiosks supply the population with drugs. Pharmacies and pharmacy kiosks can be established and run only in case of availability of the corresponding License.

Pharmacies and pharmacy kiosks reserve the right to acquire and sell only the drugs which are registered in the RA.

The lists of OTC-drugs and controlled drugs are approved and published by the drug authority. Pharmacies and pharmacy kiosks should have a minimal assortment corresponding to the Essential Drug List.

Drugs classified as narcotic drugs and psychotropic substances can be delivered only upon the presentation of the established type of the prescription.

The prescription should be written down on a special prescription form by the physician and approved by the personal seal and signature.

Patient reserves the right to obtain complete information about the prescribed drug effect, possible side effects, different drugs' interaction and ways of administration from the physician or the pharmacist.

Upon the delivery of a drug pharmacist should explain to a client the ways of administration and maintenance of this drug.

Article 5
Drug manufacture

Drug manufacture is performed in the licensed establishments according to the norms and order determined by the drug authorities.

Drug manufacture is subject to professional state control. Establishments manufacturing drugs and other pharmaceutical production bear responsibility for their production and should provide the guarantees for drug quality within the established period of drug validation under the required maintenance conditions.

Article 6
Drug dispensing

Drugs are dispensed in pharmacies according to a prescription and a pharmacography from the substances authorized for their use.

An authorization for drug dispensing is considered invalid in case of the breach of the technological process, the discrepancy of a dispensed drug and its prescription and other infringements .

Article 7
Responsibility for the violation of drug preparation and manufacture order

Any establishment manufacturing and dispensing drugs bears responsibility for the infringements in the order of the organization of manufacture, good maintenance of production, labeling, design and packaging.

Any person breached the rules of drug manufacture and dispensing, maintenance and transportation, bears a responsibility according to the order determined by the given law.

Article 8
Drug labeling and design

Manufactured and dispensed drugs should be labeled. The requirements for the labeling are determined by the drug authority.

Label, labeled package, insert leaflet, instruction for medical use of a drug should contain data on the compliance of a drug with the approved requirements; warnings

concerning the danger of drug overdose and the necessity of keeping the drug out of the reach of children.

A drug can be put into the turnover if the drug manufacturer's name and address, drug name, date of issue, way of administration, the volume of each ingredient, as well as the active ingredient volume and quantity in each unit, expiration date, maintenance conditions on the outer or primary package are legibly indicated. Samples should be marked by "not for sale".

The drugs obtained by the methods of genetic engineering should bear the indications concerning the active ingredients and modified microorganisms used for their manufacture.

The herbal raw materials should not contain radioactive substances. They should bear the label "Production is radiation tested".

Homeopathic drugs should be labeled "Homeopathic".

Article 9
Prohibition of drug manufacture, sale and use

The manufacture, sale and use of the drugs not complying with the requirements approved by the drug authority are prohibited.

Article 10
Drug export and import

The unified system of drugs and drug substances export-import which was established by the Government of the RA runs on the territory of the RA.

Any person arriving from and departing abroad can carry on a certain quantity of drugs necessary for their personal use or the treatment course.

Article 11
Drug information and promotion

The purpose of drug information is to protect of the population of the RA from counterfeit drugs and illegal use of drugs.

The insert leaflet should contain necessary data on proper administration of the given drug.

Drug information for the specialists involved in drug turnover can be presented in the manner of monographs, bulletins, scientific articles, various publications, reports made during scientific conferences and other similar performances presented reports, as well as in the manner of indications intended for physicians having the right to prescribe drugs.

Promotion of prescription drugs by the radio, television, newspapers, performances, signboards, posters and other means of light and advertisement. is prohibited.

Drug promotion is prohibited if the information included persuades a consumer that:

- the use of the drug does not require any consultation of the physician;

- the drug is free from side effects;
- the drug is more efficient than the others;
- the use of the drug can considerably improve health state and the abstention from its use can lead to the aggravation of symptoms;
- the drug can be used in food, with cosmetic and other purposes.

The promotion of drugs which are not registered in the RA is prohibited.

Article 12
Rules of drug transportation and maintenance

The order of drug transportation, storage and maintenance is established by the drug authority.

Article 13
Transit transportation of drugs

The order of transit transportation of drugs is established by the Government of the RA.

Article 14
Drug disposal

Drugs unfit for use are subject to disposal. The norms and rules of the conservation of the environment and sanitary state should be taken into account during the drug disposal. The order and conditions of drug utilization are established by the drug authority.

The drug disposal is financed by the organization which is in charge of the drugs.

Article 15
State registration of drugs

The permission to import, export, manufacture, maintenance, distribution, realization and use in the RA is given only to the drugs which are registered in the RA.

Drug registration, refusal of registration and invalidation of registration are performed according to the order established by the Government of the RA.

The following is the subject of registration:

- new drugs and drug forms proposed for treatment;
- immunobiological preparations;
- new combinations of registered drugs;
- registered drugs delivered in the new drug forms and for which the new ways of administration and new indications are proposed;
- generic drugs which are equivalent to the registered ones but produced by the other manufacturer.

Registration for the drugs prepared in a pharmacy according to prescriptions is not required.

Drug registration is invalidated when the inconformity with primary requirements for drug quality, manufacture and safety is found out, or when any change of their composition, form, indications and manufacturing conditions has taken place.

Decision about drug registration or refusal is made on the basis of the conclusion of expert examination performed according to the established order by the body authorized by the RA Government.

Registration of a drug is valid for 5 years.

An applicant should submit for the registration all necessary documentation and samples; pay registration Fee, and upon the registration – the State tax as well. If only one organization reserves the right to perform the expert examination, then the registration Fee is determined by the Government of the RA.

Applicant reserves the right and opportunity to get acquainted with the conclusion of expert examination to eliminate any discrepancy within a defined period of time.

The holder of registration Certificate should immediately inform the body authorized by the RA Government about any new data found concerning drug safety and efficacy, and its pharmacological characteristics as well.

The body authorized by the RA Government guarantees the confidentiality of data obtained.

A drug formerly authorized allowed to use is subject of a new registration, if:

- its brand name, composition and manufacture technology have been changed;
- its new characteristics, new ways of administration have been found, or other changes have been done;

Applicant reserves the right to appeal in legal form to the results of expert examination.

Article 16
State control of drug quality assurance

The task of State control of drug quality assurance is the implementation of registered and safe drugs of good quality in medical practice.

State control of drug quality assurance includes drug manufacturing and preparation, import and realization.

Drug quality should comply with the requirements of the technical conditions determined by the Government of the RA.

The requirements for drug quality are obligatory for the establishments engaged in pharmaceutical activity.

State control of drug quality assurance is performed by the body authorized by the Government.

Article 17
Duties of medical establishments in presenting the data concerning side effects of drugs

Prophylactic establishments, pharmacies and establishments and organizations engaged in drug realization and use should immediately notify the body authorized by the Government about all cases of unknown side effects of drugs.

Article 18
The guarantees of State for supply the population with drugs

The availability of drugs included in Essential Drug List is guaranteed for the population of the RA, as well as their affordability, and on case of harm – protection against the harm of the health caused by the drugs taken without a physician's prescription.

The Government of the RA ratifies the list of those diseases and social groups by which the right to acquire drugs free of charge or with discounts is given.

The order of drug supply in case of "force major" circumstances is determined by the Government of the RA.

Article 19
Control of pharmaceutical activity

The control of proper pharmaceutical activity is performed by the body authorized by the Government.

Article 20
Responsibility for a infringement of the given law

Persons infringed the requirements of the given law bear the responsibility according to the order established by the legislation of the RA.

Article 21
International agreements

If norms other than those stipulated in the present law are established by the international agreements of the RA, then the norms of international agreements are adopted.

The President of the Republic of Armenia — Robert Khocharyan

Yerevan, November 26, 1998