# LAW OF THE REPUBLIC OF ARMENIA ON MEDICINES

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# LAW

## OF THE REPUBLIC OF ARMENIA

Adopted on 17 May 2016

## ON MEDICINES

## CHAPTER 1

## *GENERAL PROVISIONS*

### Article 1. Subject matter of the Law

1. This Law shall regulate the relations pertaining to the circulation of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products in order to provide the population with safe, efficacious, high-quality, affordable medicines and reliable information thereon, as well as shall prescribe the sector-specific powers of competent state bodies of the Republic of Armenia and entities engaged in circulation of medicines.

2. The relations pertaining to the circulation of narcotic drugs or medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products containing psychotropic (psychoactive) substances shall be regulated by this Law, unless otherwise explicitly provided for by the Law of the Republic of Armenia “On narcotic drugs and psychotropic (psychoactive) substances”.

### Article 2. Legal regulation of the circulation of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products

1. The circulation of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products shall be regulated by this Law, other laws and other legal acts.

2. Where ratified international treaties of the Republic of Armenia prescribe norms other than those provided for by this Law, the norms of the international treaties shall apply.

### Article 3. Main concepts used in the Law

1. The following main concepts shall be used in this Law:

(1) **medicine** — a product of human and (or) animal and (or) plant and (or) chemical and (or) biotechnological origin with pharmacological and (or) immunological and (or) metabolic action, in relevant pharmaceutical dosage and form, with necessary packaging and marking, that is designated to be used to treat, prevent diseases of human being and animals and (or) to modify, restore, correct physiological functions of the body or is administered into the body of a human being and animal for the purpose of diagnosis;

(2) **immunological medicine** — any medicine containing vaccines or serums or toxins or globulin or allergen products;

(3) **radioactive medicine** — any medicine containing one or several radionuclides;

(4) **plant-based medicine** — any medicine containing, as an active ingredient, exclusively one or several herbal raw materials and (or) a preparation derived from the processing of the herbal raw material;

(5) **homeopathic medicine** — any medicine derived from homeopathic manufacturing process described in pharmacopoeias included in the list approved as prescribed by this Law;

(6) **pharmaceutical form** — a form of release that has complex characteristic of physical, chemical or pharmacological properties of the medicine, ensures diagnostic or preventive or therapeutic effect, is suitable for use;

(7) **dosage** — approved quantity of medicinal substances (active ingredient(s)) in the medicine expressed per dosage unit for each pharmaceutical form;

(8) **medicinal substance** — a substance of human (human blood, blood preparation, other substances of human origin) and (or) animal (micro-organism, intact animal, parts of organs, animal secretions, toxins, extracts, blood products, other substances of animal origin) and (or) plant (micro-organisms, plants, parts of plants, vegetable secretions, extracts, other substances of plant origin) and (or) chemical origin (elements, naturally occurring chemical materials, chemical products obtained by chemical change or synthesis, other substances of chemical origin) having pharmacological or immunological or metabolic action used to prepare or produce medicines;

(9) **herbal raw material** — whole, fragmented or cut plants, separate parts of plants or algae or fungi or lichen used to prepare or produce medicines in an unprocessed, dried or fresh form;

(10) **excipient** — any component that is not an active ingredient of the medicine or a packaging material;

(11) **investigational pharmaceutical product** — an active ingredient in certain pharmaceutical form or placebo (a product with no active ingredient) being used as a test sample

or reference in a clinical trial, including any registered medicine that is used or produced in a way different from the registered medicine (in a pharmaceutical form or packaging material), or the given instruction for use whereof is not registered or is investigated to obtain additional information on the registered pharmaceutical form;

(12) **new (original) medicine** — any first developed medicine with new active ingredient(s);

(13) **reproduced (generic) medicine** — medicine which is equivalent by its effect to the original medicine, has the same active ingredient (s), the same dosage, the same pharmaceutical form, and the bioequivalence with the original medicine is demonstrated as prescribed by the legislation of the Republic of Armenia;

(14) **bioanalogue** — reproduced medicine of biotechnological and biological origin;

(15) **falsified medicine, falsified medicinal substance** — a product with intentional and (or) fraudulent representation of incorrect information on the identity (including packaging, labelling, name, composition, quantity of separate ingredients) and (or) source (including manufacturer, manufacturing country, country of origin, holder of certificate of registration) and (or) data of distribution chain (including records, supporting documents);

(16) **controlled medicines and medicinal substances** — medicines and medicinal substances subject to record-registration in nominal and quantity expression in the system of healthcare of the Republic of Armenia, and the list of which is established by the state administration body authorised in the field of healthcare;

(17) **essential medicines** — medicines designated by common name, necessary to satisfy the primary healthcare needs of the population of the Republic of Armenia;

(18) **manufacturing** — batch production activity which includes acquisition of starting materials or manufacturing and engineering processes or quality control or packaging or re-packaging or labelling or re-labelling or storage or batch release or related control;

(19) **manufacturer of medicine** — a legal person or an individual entrepreneur having obtained a licence for manufacturing of medicines;

(20) **circulation of medicines** — development or pre-clinical testing or clinical trial or standardisation or manufacturing or preparation of medicine or processing or quality control or registration or import or export or transportation, storage or sales or distribution or use of herbal raw material, or monitoring of efficacy, safety and side effects thereof, or dissemination or destruction of information or advertising;

(21) **entities engaged in circulation of medicines** — legal persons and individual entrepreneurs engaged in any stage of circulation of medicines;

(22) **medicines policy** — an integrated part of the policy implemented in the sector of healthcare, which aims to provide the population with safe, efficacious, high-quality, affordable medicines, as well as ensure their efficient use;

(23) **safety** — absence of any possible unacceptable risk to harm the health;

(24) **efficacy** — characteristic of the degree of producing the expected beneficial effect of the medicine;

(25) **quality** — compliance with the requirements of the pharmacopoeias included in the list approved as prescribed by this Law and (or) quality specifications approved as prescribed by this Law;

(26) **good laboratory practice** — a quality assurance system related to organisational processes of and conditions for planning, conducting, monitoring, recording, archiving and reporting of non-clinical testing in health and environmental safety;

(27) **good clinical practice** — requirements for designing, managing, conducting, monitoring, verifying clinical trials, recording, analysing data, and reporting, that guarantee the reliability and accuracy of data and recorded results, as well as ensure the protection of rights, safety and confidentiality of data of those being tested;

(28) **good manufacturing practice** — a component of the quality assurance system that guarantees that a product is consistently produced and controlled in accordance with quality specifications appropriate to the intended use and registration requirements;

(29) **good distribution practice** — a component of the quality assurance system that guarantees that the quality of a product is maintained by means of adequate control of actions that are carried out in the distribution process, as well as provides a tool to secure the distribution chain from entry of a product containing falsified, non-registered, illegally imported, stolen, substandard, undeclared active ingredients and (or) a misbranded product;

(30) **good agricultural and collection practices for medicinal plants** — a component of the quality assurance system that guarantees the quality of herbal raw materials for consistent production of plant-based medicine;

(31) **good storage practice** — a component of the quality assurance system that guarantees that the quality of a product is maintained by means of adequate control during the storage;

(32) **shelf-life** — a period determined as a result of stability tests, during which the test parameters remain unchanged or change within the proven ranges, provided that they are kept in conditions relevant to the pharmacopoeias included in the list approved as prescribed by this Law and (or) quality specifications;

(33) **pharmacopoeia** — a compendium of pharmacopoeial monographs, methods of analysing, controlling the quality of medicines and their ingredients and other standard requirements. The list

of pharmacopoeias valid in the Republic of Armenia shall be established by the Government of the Republic of Armenia;

(34) **pharmacopoeial monograph** — description of test parameters of and control methods for medicines and their ingredients;

(35) **pre-clinical testing** — physical, chemical, biological, bacteriological, pharmaceutical, pharmacological, toxicological and other testing in the laboratory, without the involvement of a human being, for the purpose of evaluating the safety and efficacy of active pharmaceutical ingredients;

(36) **clinical trials (testing)** — trials (testing) on human being or animals (in case of medicines for animal use) which are designed to identify or confirm clinical, pharmacological and (or) other pharmacodynamic properties of investigational pharmaceutical product(s) and (or) identify its (their) side effects and (or) study the process of absorption, distribution in the body, metabolism and (or) excretion of one or several investigational pharmaceutical products for the purpose of evaluating its (their) safety and (or) efficacy;

(37) **medicinal prescription** — written prescription, in paper-based or electronic form, by a qualified physician of medicine for the purpose of preparing the medicine and (or) releasing the finished medicine;

(38) **formulation** — fixed composition of medicine involving the description of the pharmaceutical form, in which the active and other ingredients are listed by importance of intended effect of the medicine and quantities necessary for preparing the medicine;

(39) **registry** — register of medicines having been granted registration as prescribed by law of the Republic of Armenia;

(40) **certificate of registration** — an official document attesting the fact that the medicine was granted registration in the Republic of Armenia as prescribed by law;

(41) **wholesale of medicines** — a type of activities involving acquisition or import or export of medicines by the supplier from the medicine manufacturer or the holder of certificate of registration or other suppliers, or storage or sales (distribution) thereof, except for sales of medicines to consumers;

(42) **supplier** — a legal person or an individual entrepreneur having obtained a wholesale licence in the manner prescribed;

(43) **retail sales of medicines** — sales or release of medicines to consumers;

(44) **pharmacy activities** — wholesale acquisition, storage and retail sales or release of medicines and other types of goods established by the Government of the Republic of Armenia, provision of information and consultation, promotion of healthy lifestyle in compliance with the requirements of this Law and other legal acts, as well as preparation or delivery of medicines subject to the conditions prescribed by the legislation of the Republic of Armenia;

(45) **pharmacy** — a place where pharmacy activities are carried out;

(46) **pharmacy of a medical institution** — a structural subdivision of a medical institution that carries out pharmacy activities for the needs of the medical institution, except for the sales of medicines. The activities carried out in the pharmacy of a medical institution shall be subject to licensing for relevant type of medical assistance and service;

(47) **therapeutic indications** — indications on treatment of the disease and pharmacological effect;

(48) **parallel import** — import of the authorised medicine (bringing in of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products by crossing the state border of the Republic of Armenia) into the Republic of Armenia not directly from the holder of certificate of registration in the Republic of Armenia or the person properly authorised thereby;

(49) **common name** — international non-patented name given to the active ingredient of the medicine by the World Health Organisation, or in case of absence thereof — commonly used (scientific or chemical) name. Where the medicine contains more than one active ingredient, the common names of all active ingredients shall be listed as a common name of the given medicine;

(50) **list of essential medicines** — the list covering common names, pharmaceutical form, dosage of essential medicines;

(51) **reimbursable medicines** — medicines provided to the beneficiaries prescribed by the legislation of the Republic of Armenia with full or partial reimbursement of the cost of medicines as guaranteed by the State, at the expense of the State Budget of the Republic of Armenia;

(52) **reference price for the reimbursable medicine** — starting price for reimbursable medicine approved as prescribed by this Law for making purchase under the legislation of the Republic of Armenia;

(53) **maximum wholesale mark-up of reimbursable medicine** — the amount of the maximum permissible additional price in percentage, approved under the procedure provided for by this Law against the reference price of the reimbursable medicine in case of wholesale purchase in compliance with the legislation of the Republic of Armenia;

(54) **maximum retail mark-up of reimbursable medicine** — the amount of the maximum permissible additional price in percentage approved under the procedure provided for by this Law against the reference price of the reimbursable medicine in case of retail purchase in compliance with the legislation of the Republic of Armenia;

(55) **price list for reimbursable medicines** — a list approved by the state administration

body authorised in healthcare, which introduces the common name, pharmaceutical form, dosage, reference price, maximum wholesale and retail mark-ups of reimbursable medicines;

(56) **commercial name of medicine** — name of the registered medicine which may or may not conform with the common name of the medicine and may include also the trademark or the name of the holder of certificate of registration or the pharmaceutical form or the dosage thereof.

***(Article 3 amended by HO-43-N of 21 January 2020)***

## CHAPTER 2

## STATE REGULATION OF CIRCULATION OF MEDICINES

### Article 4. State regulation of circulation of medicines

1. In the Republic of Armenia, the state regulation of circulation of medicines shall be carried out in the following directions:

(1) developing and implementing medicines policy in the sector of healthcare;

(2) ensuring circulation of safe, efficient, high-quality medicines;

(3) licensing of types of activities provided for by law, in the field of circulation of medicines;

(4) control and supervision in the field of circulation of medicines;

(5) educating, training specialists;

(6) ensuring accessibility of essential medicines.

### Article 5. Competence of the Government of the Republic of Armenia in the field of state regulation of circulation of medicines

1. For the purpose of state regulation of circulation medicines the Government of the Republic of Armenia shall:

(1) develop and implement state policy in field of circulation of medicines;

(2) adopt legal acts regulating the field of circulation of medicines;

(3) ensure accessibility and affordability of medicines;

(4) offer state guarantees for providing the population with essential medicines;

(5) carry out international co-operation;

(6) perform functions reserved thereto by this Law and other laws.

### Article 6. Competence of the state administration body authorised in healthcare in the field of state regulation of circulation of medicines

***(Title amended by HO-43-N of 21 January 2020)***

1. In the field of state regulation of circulation of medicines the state administration body authorised in healthcare (hereinafter referred to as “the Authorised Body”) shall carry out the following:

(1) the policy of the Government of the Republic of Armenia in the field of circulation of medicines;

(2) regulation of circulation of medicines within the scope of the competence thereof;

(3) licensing of types of activities provided for by law, in the field of circulation of medicines;

(4) state registration of medicines;

(5) organising and conducting expert examinations in the field of state regulation of circulation of medicines;

(6) ensuring other professional monitoring for issuing a certificate of registration of medicine, a certificate for good manufacturing practice, good distribution practice provided for by law;

(7) ensuring the maintenance of the registry of medicines;

(8) ensuring professional monitoring of efficient use of medicines and side effects of medicines and developing relevant guarantees;

(9) international co-operation;

(10) inter-agency co-operation;

(11) developing programmes of the state medicines policy and monitoring their implementation;

(12) functions reserved thereto by this Law and other laws.

***(Article 6 amended by HO-171-N of 21 March 2018, HO-43-N of 21 January 2020)***

### Article 7. Conducting expert examinations in the field of state regulation of circulation of medicines

1. Expert examinations in the field of state regulation of circulation of medicines shall be as follows:

(1) expert examinations conducted for the purpose of issuing an authorisation for clinical trials (testing);

(2) expert examinations conducted for the purpose of registration, re-registration of medicine,

extending the validity period of the certificate;

(3) expert examinations conducted for the purpose of issuing a licence for manufacturing of medicine;

(4) expert examinations conducted for the purpose of issuing an import or export certificate for medicines, medicinal substances, herbal raw material, investigational pharmaceutical products;

(5) other expert examinations required by the law of the Republic of Armenia, conducted in the field of state regulation of circulation of medicines.

2. Expert examinations in the field of state regulation of circulation of medicines shall be conducted on paid basis, except for the cases provided for by law. Fees for expert examinations provided for by this Law shall not be returned, regardless of the results of expert examinations. The fees for expert examinations in the field of state regulation of circulation of medicines shall be determined by the decision of the Government of the Republic of Armenia.

## CHAPTER 3

## MAIN PRINCIPLEES OF THE STATE POLICY FOR PROVIDING THE POPULATION WITH MEDICINES AND DEVELOPING THE PHARMACEUTICS

### Article 8. Main principles of the state policy for providing with medicines and developing the pharmaceutics

1. The main principles of the state policy for providing with medicines and developing the pharmaceutics shall be as follows:

(1) ensuring the availability and affordability of essential medicines;

(2) promoting local manufacturing of medicines;

(3) ensuring social justice in annual state targeted programmes for providing with medicines.

2. The criteria and procedure for selecting the essential medicines shall be established by the Government of the Republic of Armenia, and the list of essential medicines shall be established by the Authorised Body.

### Article 9. State system for ensuring accessibility of medicines

1. The state system for ensuring accessibility of medicines shall include providing beneficiaries prescribed by the legislation of the Republic of Armenia with medicines under the programmes for protecting and improving health, implemented by the State and fully or partially reimbursing the cost of medicines for them, which is financed at the expense of the State Budget, as well as state regulation of and control over the prices for medicines.

### Article 10. Allocating medicines with full or partial reimbursement of their price

1. The Government of the Republic of Armenia shall establish the lists of social and special groups of the population and the diseases, for which the medicines are allocated to beneficiaries with full or partial reimbursement of their cost, as well as the procedure for reimbursement for and allocation of medicines.

### Article 11. State regulation of prices for reimbursable medicines

1. The state regulation of prices for reimbursable medicines shall be carried out in the Republic of Armenia. State regulation of prices shall, pursuant to this Law, be the setting of the maximum price for purchasing reimbursable medicines, which includes the reference price for medicines and the maximum wholesale or retail mark-ups of the medicine.

2. State regulation of prices for reimbursable medicines shall be carried out in conformity with the common name of the medicine, for medicines registered as prescribed by this Law in the Republic of Armenia, in accordance with their pharmaceutical form and dosage.

3. The reference price for, maximum wholesale and retail mark-ups of the reimbursable medicine shall be set by the Government of the Republic of Armenia, based on the opinion of the Commission carrying out activities for the purpose of state regulation of prices for medicines (hereinafter referred to as “the Commission”).

4. The Commission shall be composed of representatives of the state administration bodies, non-governmental organisations engaged in the protection of interests of consumers, patients, economists, pharmacologists. The procedure for setting up the Commission, the maximum number of members and the procedure for the activities thereof shall be established by the Government of the Republic of Armenia.

5. The Government of the Republic of Armenia shall establish the procedure for state regulation of prices for reimbursable medicines, including:

(1) the methodology for calculating the reference price for, maximum wholesale and retail mark-ups for purchasing the reimbursable medicine;

(2) the list of countries, based on the comparison of prices for medicines of which the reference

price, maximum wholesale and retail mark-ups for purchasing medicines are determined;

(3) the procedure for setting the reference price, maximum wholesale and retail mark-ups for purchasing reimbursable medicine;

(4) the procedure for revising the reference price, maximum wholesale and retail mark-ups set for purchasing reimbursable medicine.

6. In a calendar year the reference price for purchasing medicine may be revised not more than once.

7. The Authorised Body shall post reference prices for, maximum wholesale and retail mark-ups of reimbursable medicines on its official Internet website.

8. Decisions for state regulation of prices for medicines provided for by this Law shall enter into force not later than six months after the official promulgation thereof.

## CHAPTER 4

## DEVELOPMENT OF MEDICINES, STATE REGISTRATION OF MEDICINES AND POST-REGISTRATION PROFESSIONAL MONITORING

### Article 12. Development of medicines

1. The development of medicines shall include search for, identification of, pre-clinical tests and clinical trials (testing) on a new medicinal substance, study of side effects, evaluation of safety and efficacy, development of control methods for the composition, technology, quality thereof, standardisation criteria therefor.

2. The rights of medicine developers shall be protected by the legislation regulating the sector of intellectual property.

### Article 13. Pre-clinical testing

1. Pre-clinical testing shall be carried out in compliance with the Rules of Good Laboratory Practice prescribed by the Authorised Body of the Republic of Armenia. The Rules of Good Laboratory Practice shall be posted on the official Internet website of the Authorised Body.

### Article 14. Clinical trials (testing)

1. Clinical trials (testing) (hereinafter referred to as “the clinical trials”) shall be conducted in compliance with the Rules of Good Clinical Practice prescribed by the Authorised Body. The Rules of Good Clinical Practice shall be posted of the official Internet website of the Authorised Body.

2. The authorisation for conducting clinical trials shall be issued by the Authorised Body, while approving the trials programme and attached documents, based on a favourable expert opinion and favourable opinions of the Ethics Commission for Clinical Trials.

3. The Government of the Republic of Armenia shall approve the procedure for issuing an authorisation for clinical trials, as well as for an expert examination conducted to that effect and the lists of required documents. For each clinical trial, the experts conducting expert examination of materials of clinical trials, and the members of the Ethics Commission shall be obliged to sign a declaration of conflict of interests, confidentiality in the form prescribed by the Authorised Body. The powers of a member of the Commission having refused to sign that declaration shall be terminated.

4. An investigational pharmaceutical product subject to clinical trials must be manufactured in compliance with the requirements prescribed by this Law.

5. Participation in clinical trials shall be voluntary. Clinical trials may be conducted upon written consent of the person subject to trial or his or her legal representative where an agreement concluded with the person subject to trial or his or her legal representative is available. The person subject to trial (legal representative) must be informed in written form of the product subject to trial, its safety, expected efficiency, extent of risk, conditions, objective, duration of the trial, in case harm is caused to the health — of the actions of the Contracting Authority, conditions of life and health insurance, guarantees for ensuring confidentiality of his or her participation.

6. The person subject to trial or his or her legal representative shall have the right to refuse, at any stage, to participate in clinical trials.

7. The following persons may not be enrolled in clinical trials:

(1) arrested, detained, and convicted persons;

(2) military servicemen;

(3) minors, except where the pharmaceutical product subject to trial is intended for minors, and where the results of clinical trials of the same pharmaceutical product conducted among minors were positive. The consent to enrol a minor in clinical trials shall be given by the legal representative in written form;

(4) pregnant women and breastfeeding mothers.

8. Granting an authorisation for clinical trials shall be rejected where:

(1) incomplete documents and (or) documents failing to fully contain the required information

are submitted;

(2) the results of pre-clinical and clinical testing are negative or non-satisfactory;

(3) there is (are) adverse opinion(s) of the experts and (or) ethics commission;

(4) substantiated and reliable negative data are obtained from foreign or international professional institutions and competent bodies regulating the field of medicines of other countries;

(5) the requirements of parts 1, 4, 5, 6, 7 of this Article are violated.

9. The Contracting Authority for clinical trials shall be responsible for the accuracy and reliability of submitted data on clinical trials.

10. The Contracting Authority for clinical trials shall be obliged to inform — in the manner and within the time limit prescribed by the Authorised Body — of cases of extremely harmful side effects recorded during the trials (death, posing risk to life, requiring hospitalisation, resulting in incapacity for work, physical mutation or inborn defect), start, termination or end of trials, as well as submit a report in the form prescribed by the Authorised Body.

11. Supervision over the clinical trials shall be exercised as prescribed by law. Professional monitoring thereon shall be organised by the Authorised Body as prescribed by law. The Authorised Body shall be competent to request the Contracting Authority to modify or terminate the clinical trials programme. The procedure for conducting professional monitoring and terminating clinical trials, as well as making modifications or supplements to the clinical trials programme shall be established by the Authorised Body.

12. Clinical trials shall be terminated where the health and (or) life of a person subject to trial is at risk, the requirements for clinical trials prescribed by this Law, medical ethics norms of requirements for Good Clinical Practice adopted by the Authorised Body are violated, as well as the medicine or investigational pharmaceutical product is not sufficiently efficient and safe.

13. The Authorised Body shall maintain the registry of clinical trials authorised and rejected in compliance with the form prescribed by the Authorised Body, including data on the Contracting Authority, the product subject to trial, objective, start and end of the trial, and shall make the registry publicly available on the official website thereof.

14. The decision on refusing to grant or terminating the authorisation for clinical trials may be appealed against as prescribed by the Law of the Republic of Armenia “On fundamentals of administrative action and administrative proceedings”, or through judicial procedure.

15. Violation of requirements for conducting clinical trials prescribed by this Law, falsification or concealment of the results thereof shall be prohibited and shall entail liability prescribed by law.

16. The harm caused to the person subject to trial as a result of clinical trials shall be compensated as prescribed by the law of the Republic of Armenia.

17. Medicines in the stage of clinical trials in other countries or investigational pharmaceutical products may be used for treatment of those patients that suffer from life-threatening diseases where the authorisation of the Authorised Body is available under the procedure prescribed by this Article.

18. The powers of the expert conducting expert examination of the materials of clinical trials shall be terminated where undeclared data on conflict of interests in relation to the given clinical trials become known to the Authorised Body following the signature of the declaration in the form provided for by part 3 of Article 14 of this Law. The powers of the expert conducting expert examination of the materials of clinical trials shall be terminated within three working days after such data become known to the Authorised Body.

### Article 15. Objectives and functions of the Ethics Commission for Clinical Trials

1. The Ethics Commission for Clinical Trials shall be a body operating on a voluntary basis.

2. The Ethics Commission for Clinical Trials shall be comprised of at least 5 persons. The Ethics Commission for Clinical Trials shall include a physician, a pharmacologist, a lawyer, a representative of non-governmental organisations engaged in the protection of rights of patients. The procedure for selection of members, individual composition and the rules of procedure of the Ethics Commission for Clinical Trials shall be established by the Authorised Body.

3. The term of office of a member of the Ethics Commission for Clinical Trials shall be five years. A member of the Ethics Commission for Clinical Trials may hold office for only one consecutive term. When exercising his or her powers, a member of the Ethics Commission for Clinical Trials shall be independent and comply with only the Constitution and laws of the Republic of Armenia.

4. The Authorised Body shall terminate the powers of a member of the Ethics Commission for Clinical Trials where non-declared data on conflict of interests in relation to the given clinical trials become known to the Authorised Body following the signing of the declaration in the form prescribed by part 3 of Article 14 of this Law. The powers of a member of the Ethics Commission for Clinical Trials shall be terminated within three working days after such data become known to the Authorised Body.

5. Where a member of the Ethics Commission for Clinical Trials signs a declaration in the form prescribed by part 3 of Article 14 of this Law, the member of the Commission shall not participate in the delivery of an opinion with respect to the given clinical trial.

6. The objectives of the activities of the Ethics Commission for Clinical Trials shall be as follows:

(1) maximum protection of the rights of all stakeholders during the clinical trials on medicines

and investigational pharmaceutical products in the Republic of Armenia;

(2) ensuring of voluntary participation in clinical trials on medicines, guarantees for the safety of participants.

7. Based on the provisions of part 5 of Article 14 of this Law, the Ethics Commission for Clinical Trials shall perform the following functions:

(1) assessing the conduct of clinical trials on medicines and investigational pharmaceutical products from the point of ethics, according to the requirements of Good Clinical Practice adopted by the Authorised Body, and delivering favourable or adverse opinions as a result thereof;

(2) assessing the modifications and supplements to the clinical trials programme and other documents from the point of ethics, according to the requirements of Good Clinical Practice adopted by the Authorised Body, and delivering favourable or adverse opinions as a result thereof.

**Article 16. State registration of medicines**

1. The Republic of Armenia shall permit the manufacturing, import, distribution, release, sales and use of the medicines registered in the Republic of Armenia, except for the cases prescribed by this Law.

2. Registration, or refusing, suspending and revoking the registration of medicine upon an expert opinion shall be carried out by the Authorised Body as prescribed by the Government of the Republic of Armenia, except for veterinary vaccines, serums and diagnostic agents, the state registration, or refusing, suspending and revoking the registration of which is carried out by the state Authorised Body operating in the sector of agriculture as prescribed by the Government of the Republic of Armenia.

3. In the Republic of Armenia medicines shall be registered under general procedure and simplified procedures. The simplified procedure shall be applied to medicines registered in a member country of international professional organisations established by the decision of the Government of the Republic of Armenia, or to pre-qualified medicines of the World Health Organisation.

4. The registration of medicine shall be based on scientifically justified criteria for safety, efficiency and quality of products adopted as prescribed by the legislation of the Republic of Armenia and documents adopted by international professional organisations established by the Government of the Republic of Armenia, taking into consideration also the possible risk factors of undesirable effect on the environment.

5. Each name, composition, pharmaceutical form, dosage, release form, new indication, manufacturer (including those conducting each manufacturing process), holder of the certificate of registration of medicines shall be subject to registration.

6. The primary and (or) outer packaging, label, make (including in the form of colourful illustrations) of the medicine, instruction for medical use (general description of the medicine), instruction for use (leaflet) and quality specifications thereof shall be approved during the registration.

7. The quality of the product, active ingredients and excipients, the container and sealing materials subject to registration in the Republic of Armenia must comply with the requirements of pharmacopoeias included in the list approved as prescribed by this Law. The studies of quality, safety and efficiency of medicines registered in the Republic of Armenia must be conducted in compliance with the documents of the international professional organisation established by the Government of the Republic of Armenia.

8. The registration of medicines containing different medicinal substances but having the same or confusingly similar names shall be prohibited. The requirements to the names of medicines shall be established by the Authorised Body.

9. For the purpose of registration the manufacturer or other individual entrepreneur or a legal person responsible for the product may act as an applicant considered as holder of the certificate of registration following the registration of the medicine. The documents of registration may be submitted also by a person authorised by the applicant as prescribed by the legislation of the Republic of Armenia. The applicant shall be responsible for the accuracy and reliability of submitted data.

10. The Government of the Republic of Armenia shall approve the procedure for expert examination conducted for registration, re-registration, extending the validity period of the certificate of the medicine, by introducing the form of opinion of the expert examination conducted for registration, re-registration, extending the validity period of the certificate of new, reproduced medicines, bioanalogues, combination medicines, homeopathic, biological medicines, including medicines derived from blood or blood plasma, immunological, radioactive, veterinary medicines (including forage containing medicinal substances), plant-based medicines (including herbal raw materials packed in consumer packages and labelled), antiseptics and anti-parasitic drugs destroying infecting agents for diseases of skin, mucosa, hair, nails, as well as insects transmitting them and parasites, the list of documents required for conducting an expert examination in compliance with the requirements of the document of the international professional organisation established by the Government of the Republic of Armenia.

11. For the purpose of registration of low-demand but vital medicines the expert examination

may be conducted under state funding. The list of low-demand but vital medicines shall be approved by the Authorised Body.

12. Reports of pre-clinical testing and (or) clinical trials shall be required for the registration of new combinations of medicines or medicines reproduced in a new dosage or new pharmaceutical form or under a new indication, different from the original.

13. The total maximum term for registration of medicine shall be 150 calendar days which includes the term of the expert examination for the purpose of registration, the maximum duration of which shall be 140 calendar days, except for medicines registered in the member country of the international professional organisation established by the decision of the Government of the Republic of Armenia. In this case, the maximum term of registration shall be 31 calendar days which includes the term of the expert examination for the purpose of registration, the maximum duration of which shall be 21 calendar days. Where the applicant makes supplements to the documents during the expert examination, the expert examination shall be extended for 10 calendar days.

14. The authorised body shall be obliged to ensure the confidentiality of the data in the documents submitted for registration that are considered information protected by law of the Republic of Armenia and are not subject to publication. The expert conducting an expert examination for the purpose of registration shall be obliged to sign a declaration of conflict of interests and confidentiality in the form prescribed by the Authorised Body.

15. During the registration of a reproduced medicine, the applicant shall not be required to submit data on pre-clinical testing and (or) clinical trials in case the applicant submits documents which demonstrate that the medicine is reproduced from the original medicine that was registered in the Republic of Armenia or in the member country of the international professional organisation established by the decision of the Government of the Republic of Armenia for not less than eight years. That reproduced medicine may be circulated in the Republic of Armenia for ten years after the registration of the original medicine. Where the holder of the certificate of registration registers one or more new indications within a ten-year period, the term shall be extended for another one year at large. The applicant shall not submit data on bioequivalence studies for the reproduced medicine where the documents submitted thereby prove that that medicine was used in the Republic of Armenia or in the member country of the international professional organisation established by the decision of the Government of the Republic of Armenia for more than ten years. In such cases the applicant shall submit only relevant data on the academic literature.

16. The applicant shall have the right to refuse the registration at any stage of the expert examination. In case of failure to submit additional or missing materials required at the expert examination following the expiry of six months from being duly notified of the need for submission thereof, the expert examination shall be terminated, and the application shall be rejected.

17. The authorised body may conduct pre-registration professional monitoring which is conducted with a view of assessing the compliance of the product or manufacturing processes with the documents submitted during the expert examination for registration of medicines. The professional monitoring provided for by this part shall be conducted instantly on the manufacturing site, as well as in the venues of pre-clinical testing, clinical trials and bioequivalence studies (including those carrying out activities on a contractual basis). The procedure for recognising the reports of the professional monitoring and reports of the monitoring by the competent bodies of other countries shall be established by the Government of the Republic of Armenia. The expenses for pre-registration professional monitoring shall be compensated by the applicant, based on the agreement concluded between the parties as prescribed by law. For the purpose of regular risk-benefit evaluation the Authorised Body may, during the monitoring, request from the holder of the certificate of registration to submit data relevant to the registration of relevant medicine or related thereto.

18. The term for registration of the medicine shall be 5 years, which is calculated from the date of entry into force of the order of the Authorised Body on registration of the medicine. As a result of registration a certificate of registration shall be issued, and the registered medicine shall be entered into the registry. The Authorised Body shall approve the form of the certificate of registration, the form of the registry and the procedure for maintaining it. The certificate of registration shall include attached primary and (or) outer packaging of the medicine, label, instruction for medical use in Armenian (general description of the medicine) and the instruction for use (leaflet) thereof, which shall serve as a ground for identification of medicines, quality control and (or) provision of official information at all stages of circulation of medicines in the Republic of Armenia. The Authorised Body shall ensure the publicity of the registry, the primary and (or) outer packaging of the medicine, label, instruction for medical use in Armenian (general description of the medicine) and the instruction for use (leaflet) thereof attached to the certificate of registration and shall post them on the official website of the Authorised Body.

19. After the expiry of the term of registration, re-registration may be made for a period of 5 years as prescribed by the Government of the Republic of Armenia, while re-evaluating the safety, efficacy and quality of the product. After the expiry of the term of re-registration, upon the consent of the holder of the certificate of registration, the term of the certificate of registration may be extended every 5 years, based on the results of post-registration professional monitoring of safety by the Authorised Body. The maximum term of re-registration of the medicine shall be 31 calendar

days, which includes the term of expert examination for the purpose of registration, the maximum duration of which is 21 calendar days. The maximum term for the extension of the term of the certificate of registration of the medicine shall be 10 calendar days. The re-registration of the medicine, extension of the validity period of the certificate of registration shall be carried out by the Authorised Body based on the favourable expert opinion.

20. The Government of the Republic of Armenia shall introduce the list of modifications concerning the registered medicines, where no new registration is required and the certificate of registration of the medicine is re-issued.

21. A state duty shall be levied for the registration, re-registration, re-issuance of the certificate and extension of the term thereof in the manner and in the amount prescribed by the Law of the Republic of Armenia “On state duty”.

22. The holder of the certificate of registration of the medicine shall be responsible, as prescribed by law, for the safety, efficacy, quality of the registered product, and shall be obliged to promptly notify the Authorised Body in writing of each new data thereon and (or) modification thereof being identified and (or) made in the post-registration period, including the data of the competent body of any country on prohibition or restriction on the use of the product. The Government of the Republic of Armenia shall establish the procedure for expert examination for these modifications and data and for their submission, as well as the list of necessary documents. The modifications of the medicine registered under the simplified procedure must be approved by the competent body of the member country of the international professional organisation established upon the decision of the Government of the Republic of Armenia.

23. Registration shall not be required for the following:

(1) medicines prepared in the pharmacy;

(2) medicines exported from the Republic of Armenia;

(3) medicines manufactured in the Republic of Armenia only for the purpose of export;

(4) scientific, pre-clinical testing and clinical trials, medicines used by the special authorisation of the Authorised Body, investigational pharmaceutical products, as well as samples of veterinary medicines for trials on animals;

(5) samples for registration in the Republic of Armenia;

(6) medicines imported for placing on exhibitions. Moreover, the samples imported for placing on exhibitions shall not be fit for use and shall be subject to export or destruction in compliance with the requirements prescribed by the legislation and other legal acts of the Republic of Armenia;

(7) medicines imported in the name of physical persons for treatment plan or for personal use.

24. The fact of whether or not the medicine falls under the groups of medicines sold on prescription or with no prescription and (or) controlled medicines shall be determined during the registration. The medicine shall refer to the prescription medicines where:

(1) it may directly or indirectly harm the health of the patient in case of use thereof in compliance with the instruction for medical use but without the supervision of the physician;

(2) it may harm the health of patients due to use by the majority of them not in compliance with the prescription;

(3) it contains medicinal substances, the further studies of the pharmacological activity whereof and (or) side effect whereof are necessary;

(4) it is administered into the body parenterally;

(5) it contains narcotic drugs or psychotropic (psychoactive) substances in quantities higher than those set by the Authorised Body;

(6) it is highly dangerous from the point of abuse, addiction or use for illegal purposes;

(7) it contains substances that, based on the pharmacological characteristics, are equal to the medicines referred to in point 6;

(8) it is intended for use only in hospitals;

(9) it is used for treatment of diseases, the diagnosis of which is made in a medical institution, although the drug treatment and further supervision by a physician may be conducted on an outpatient basis;

(10) it is intended for outpatient treatment, but the use of the medicine may be accompanied by serious side effects that require supervision by the physician during the entire course of treatment.

25. The Authorised Body shall establish the procedure for determining the fact of whether or not the medicine falls under the groups of prescription medicines, over-the-counter medicines, and that for revising it. The Authorised Body shall ensure the publicity of the lists of prescription medicines, over-the-counter medicines and controlled medicines and shall post them on the official website of the Authorised Body.

26. For the purpose of ensuring the accessibility of medicines, agreements concluded with member countries of the international professional organisation established by the decision of the Government of the Republic of Armenia may envisage cases of recognising the registrations of certain medicines in these States and of entering these medicines into the registry. For the purpose of registering the medicines in the Republic of Armenia, the Authorised Body may apply to applicant on their own initiative and at their own expense.

27. The registration, re-registration, extension of the validity period of the certificate of the medicine shall be rejected where the expert examination has established that:

(1) the data certifying the safety and (or) efficacy are missing or insufficiently substantiated and (or) the risk posed to the health exceeds the benefit resulting from the use;

(2) the quality does not comply with the requirements prescribed by the legislation and other legal acts, or the actual qualitative and quantitative composition is not such as presented in the registration documents;

(3) the manufacturing does not comply with the rules of Goods Manufacturing Practice approved by the Authorised Body;

(4) name, general description, packaging, labelling, marking, leaflet of the product do not comply with the requirements prescribed by the legislation and other legal acts of the Republic of Armenia;

(5) there are substantiated and reliable negative data on the medicine available at foreign or international professional institutions and competent bodies regulating the sector of medicines of other countries;

(6) the medicine contains chlorofluorocarbons (freons), except for the cases where the pharmaceutical form not containing freons yet is not developed;

(7) incomplete or obviously false or distorted data or documents were submitted;

(8) the product is not registered in the country of the applicant, except for medicines registered in the countries that are members of the international professional organisation established by the decision of the Government of the Republic of Armenia;

(9) there are unsubstantiated deviations from the documents adopted by the international professional organisation established by the decision of the Government of the Republic of Armenia;

(10) residual quantities of the veterinary medicine in the food of animal origin exceed the maximum portions prescribed by the legislation and other legal acts of the Republic of Armenia;

(11) the name of the medicine coincides with the name of the medicine already registered, but the active ingredients or their quantities are different;

(12) the leaflet and general description of the medicine registered under the simplified procedure does not comply with the leaflet and the general description of the medicine registered in the member country of the international professional organisation established by the decision of the Government of the Republic of Armenia;

(13) the medicine contains excipient(s) prohibited in the composition of medicines circulated in the Republic of Armenia, the list of which is approved by the Authorised Body.

28. In case of refusing the registration, re-registration, extension of the validity period of the certificate of the medicine, as well as terminating the expert examination in the cases prescribed by this Law, the documents, samples submitted for the purpose of registration shall not be returned.

29. The registration, re-registration, extension of the validity period of the certificate of the medicine shall be revoked where:

(1) the safety, efficacy, quality is found to be non-compliant with the prescribed requirements, specifications, new scientific data, that pose risk to human life and are impossible to remedy;

(2) substantiated and reliable negative data on the medicine were obtained from foreign or international professional institutions and competent bodies regulating the sector of medicines of other countries;

(3) following the registration of the product the results of inspection of the quality of three different series were negative;

(4) during the post-registration safety monitoring, cases of extremely harmful side effects (death, posing a risk to the life, requiring hospitalisation, resulting in incapacity for work, physical mutation and inborn defects) were registered.

30. In case of revoking the registration of the medicine, the manufacturing, import, distribution, release, sales and use of the medicine shall be prohibited.

31. The registration of the medicine shall be suspended where:

(1) there is a substantiated application of the holder of the certificate of registration;

(2) remediable non-compliance of safety, efficacy, quality with the prescribed requirements, specifications, new scientific data was identified;

(3) the holder of the certificate of registration failed to provide the new data regarding the quality, safety or efficacy of the product or failed to make modifications to the registration documents in line with the new data;

(4) the holder of the certificate of registration made modifications to the documents of the registered medicine and the package, label, marking, instructions for medical use and use of the product that were not agreed with the Authorised Body.

32. The suspension of the registration of the medicine shall be the temporary termination of the registration of the medicine within the territory of the Republic of Armenia. In case of suspending the registration of the medicine, the manufacture, import, distribution, release, sales and use of the medicine shall be temporarily prohibited. In the cases provided for by point 1 of part 31 of this Article the registration of the medicine shall be suspended for a term offered by the holder of the certificate of registration and in the cases provided for by points 2-4, until the violations or inconsistencies are eliminated.

33. Where the holder of the certificate of registration of the medicine has notified the Authorised

Body, in writing, of the intention to terminate the obligations of the holder of the certificate of registration of the medicine in the Republic of Armenia, the medicine shall still be considered as registered in the Republic of Armenia until the expiry of the term of registration, and the obligations of the holder of the certificate of registration shall be assigned to the entity importing the given medicine as prescribed by the legislation of the Republic of Armenia.

34. The decisions on refusing the registration, re-registration, extension of the validity period of the certificate of the medicine, revoking, suspending the registration of the medicine may be appealed against as prescribed by the Law of the Republic of Armenia “On fundamentals of administrative action and administrative proceedings” or through judicial procedure.

***(Article 16 supplemented by HO-279-N of 1 June 2020)***

### Article 17. Submitting information on side effects and falsified products

1. Side effect shall be the emergence of harmful and undesirable phenomena in case of use of the product in compliance with the instruction for medical use. The absence of efficacy of the medicine or the consequences of overdose shall not be considered as side effects.

2. The holder of the certificate of registration shall be obliged to record the cases of side effects and notify thereof as prescribed by the Authorised Body.

3. The holder of the certificate of registration may not provide the public with the information collected with regard to the side effect of the registered product without prior notice to the Authorised Body.

4. The healthcare specialists, entities engaged in the circulation of medicines shall inform the Authorised Body of the suspicious side effects as prescribed by the Authorised Body.

5. Any person may notify the Authorised Body, healthcare specialists, entities engaged in the circulation of medicines of the side effects of medicines as prescribed by the Authorised Body.

6. The Authorised Body shall maintain a registry of side effects of medicines and organise the professional monitoring of side effects and analysis of data. The form of the registry maintained in relation to the side effects of medicines shall be approved by the Authorised Body. Based on the expert opinion, the Authorised Body shall adopt relevant decision on suspending or revoking the registration or making modifications to the instruction for medical use and use and shall inform the holder of the certificate of registration thereof.

7. The Authorised Body shall post on its official Internet website confirmed information on extremely harmful side effects (death, posing risk to life, requiring hospitalisation, resulting in incapacity for work, physical mutation or inborn defects), without disclosing the data on individual natural persons, and shall notify the relevant international professional institutions thereof.

8. The holder of the certificate of registration shall inform the Authorised Body of the cases of extremely harmful side effects (death, posing risk to life, requiring hospitalisation, resulting in incapacity for work, physical mutation or inborn defect) as prescribed by the Authorised Body. In case of extremely harmful side effects (death, posing risk to life, requiring hospitalisation, resulting in incapacity for work, physical mutation or inborn defect) the circulation of the medicine shall be terminated and it shall be withdrawn from circulation as prescribed by part 2 of Article 23 of this Law.

9. The procedure for collection, informing, monitoring, reporting of side effects and data analysis shall be established by the Authorised Body.

10. The healthcare specialists, entities engaged in the circulation of medicines, consumers, holder of the certificate of registration shall also notify the Authorised Body, as prescribed by the Authorised Body, of the suspicion of lack of efficacy, misuse, falsification of medicine.

## CHAPTER 5

## MANUFACTURING OF MEDICINES, MEDICINAL SUBSTANCES, INVESTIGATIONAL PHARMACEUTICAL PRODUCTS, PROCESSING OF HERBAL RAW MATERIALS AND PREPARATION OF MEDICINES

### Article 18. Manufacturing of medicines

1. The manufacturing of medicines, as well as medicinal substances, investigational pharmaceutical products and processing of herbal raw materials shall be carried out by legal persons or individual entrepreneurs having a licence for manufacturing of medicines. The availability of a licence for manufacturing of medicines is obligatory for conducting out any manufacturing process. A licence for manufacturing of medicines shall not be required only for acquisition of starting materials and conducting storage procedures.

2. A licence for manufacturing of medicines shall be issued by the Authorised Body based on an expert opinion, as prescribed by the Government of the Republic of Armenia, except for the licence for manufacturing of medicines containing narcotic drugs and psychotropic (psychoactive) substances that is issued by the Government of the Republic of Armenia. A licence for manufacturing of medicines shall have a leaflet, the list of requirements and conditions included wherein shall be defined by the procedure for licensing the manufacturing of medicines which is

approved as prescribed by law.

3. The manufacturing of medicines, medicinal substances, investigational pharmaceutical product must be carried out according to the rules of Good Manufacturing Practices approved by the Authorised Body. The rules of Good Manufacturing Practice adopted by the Authorised Body shall be posted on the official Internet website of the Authorised Body.

4. The Authorised Body shall issue a certificate for Good Manufacturing Practice to the manufacturer having obtained a licence for manufacturing of medicines based on the general professional monitoring report. The professional monitoring provided for by this part shall be the process of assessment of compliance with the rules of Good Manufacturing Practice on the medicines manufacturing site (including outsourced) for the purpose of assuring the quality of medicines circulated in the Republic of Armenia, and it shall also include the assessment of activities of the quality control laboratory (including the laboratory control activities carried out on a contractual basis). The expenses for professional monitoring, except for special monitoring, shall be compensated by the applicant based on an agreement concluded between the parties as prescribed by law.

5. Types of professional monitoring provided for by this Article shall be the following:

(1) general monitoring which includes assessment of compliance with the general principles of rules of Good Manufacturing Practice and is carried out before the issuance of a licence for manufacturing of medicines and a certificate for Good Manufacturing Practice, based on the application of the manufacturer of the medicine;

(2) current (scheduled, regular) monitoring which includes assessment of compliance with all the components of the Goods Manufacturing Practice and is conducted under the annual observation plan, based on the application of the manufacturer of the medicine;

(3) pre-registration monitoring which is conducted to assess the compliance of the product or manufacturing process with the documents submitted during the expert examination for registration of medicines;

(4) special monitoring which is conducted in the cases where it is necessary to establish circumstances (including valid alerts in relation to the quality and the safety), for the identification of which the manufacturer is not priorly informed of the monitoring.

6. In the manufacturing facilities of legal persons and individual entrepreneurs holding a licence for manufacturing of medicines the current professional monitoring shall be conducted annually, then once in 2 years within the first 3 years after obtaining a licence for manufacturing of medicines.

7. State duty shall be levied for granting a certificate for Good Manufacturing Practice in the manner and amount prescribed by the Law of the Republic of Armenia “On state duty”.

8. The licence for manufacturing of medicines, except for the cases provided for by the Law of the Republic of Armenia “On licensing”, shall be suspended also in the following cases:

(1) in case of violations of the rules of Good Manufacturing Practice detected during the monitoring of compliance of the manufacturing of medicines with the rules of Good Manufacturing Practice (except for the case provided for by point 1 of part 5 of this Article), of which the legal person or the individual entrepreneur holding a licence for manufacturing of medicines was properly notified but failed to eliminate them within a reasonable time limit set by the licensing body;

(2) in case of failure to submit an application for ensuring the professional monitoring provided for by point 2 of part 5 of this Article and the frequency provided for by part 6 of this Article.

9. In cases provided for by points 1 and 2 of part 8 of this Article the licence shall be suspended until the reasons for violations are eliminated.

10 The Government of the Republic of Armenia shall establish the procedures for monitoring of compliance of the manufacturing of medicines and medicinal substances with the rules of good manufacturing practice, and for issuing a certificate for Good Manufacturing Practice, as well as the procedure for conducting an expert examination for licensing the manufacturing of medicines, and the list of necessary documents.

11. The manufacturer shall guarantee the quality of the product where the necessary conditions are ensured during the defined shelf life.

12. Each manufacturer must have at least one qualified person, the requirements for whom shall be set down by the Authorised Body.

13. The quality of medicinal substances, herbal raw materials, excipients, container and sealing materials used in the manufacturing must comply with the requirements of pharmacopoeial monographs of pharmacopoeias included in the list approved as prescribed by this Law and (or) in quality specifications.

14. The Manufacturer shall guarantee the use of medicinal substances manufactured in compliance with the rules of Good Manufacturing Practice, while conducting assessment of compliance of Good Manufacturing Practice on its own or on a contractual basis.

15. The manufacturer shall ensure that the information on the product thereof is reliable, up-to-date and complies with the requirements prescribed by this Law.

16. In the Republic of Armenia the herbal raw materials shall be processed in compliance with the rules of Good Processing and Collection Practices for Medicinal Plants prescribed by the Authorised Body. The Rules of Good Processing and Collection Practices for Medicinal Plants shall

be posted on the official Internet website of the Authorised Body.

17. It shall be prohibited to:

(1) manufacture falsified medicines and medicinal substances;

(2) manufacture non-registered medicine, except for the cases provided for by points 2-5 of part 23 of Article 16 of this Law;

(3) manufacture medicines, medicinal substances, herbal raw material and investigational pharmaceutical products in violation of the requirements prescribed by this Law.

### Article 19. Preparation of medicines

1. Medicines may be prepared only in pharmacies that comply with the requirements of the decision of the Government adopted under part 1 of Article 25 of this Law, and the licence for which contains an indication on preparing medicines. Medicines shall be prepared in pharmacies according to the prescription or formulations approved by the Authorised Body.

2. Preparing solutions for infusion in pharmacies shall be prohibited, except for pharmacies constituting structural subdivisions of a medical institution, where the preparation of solutions for infusion not circulated in the Republic of Armenia as prescribed by law shall be permitted as prescribed by this Law.

3. Licensed legal persons and individual entrepreneurs engaged in pharmacy activities shall be responsible as prescribed by law for the quality and accuracy of shaping, packaging, labelling of medicines prepared in the pharmacy, as well as for proper storage and release thereof.

4. Medicines prepared and dispensed in the pharmacy shall be sold in the given pharmacy only.

5. Preparing falsified medicines shall be prohibited and shall entail liability provided for by law.

### Article 20. Packaging, labelling and marking of medicines

1. Medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products must be packaged, labelled and marked.

2. The requirements for packaging, labelling and marking of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products, including the leaflet of medicines, as well as the general description thereof shall be prescribed by the Authorised Body.

3. Medicines sold by retail must come with a leaflet in Armenian as prescribed by the Authorised Body; moreover, selling medicines with a leaflet in Armenian in pharmacies shall be mandatory where the buyer makes such request.

4. The package of the medicine may bear symbols or pictograms conveying the information listed in the requirements prescribed by the Authorised Body, as well as other information that complies with the general description of the medicine, is important for raising awareness in medicine and contains no advertising. It shall be prohibited to introduce the name of the supplier of the medicine in the Republic of Armenia or the trademark thereof in the marking, general description and leaflet of the medicine.

5. It shall be prohibited to introduce therapeutic indications on the packaging and (or) in the instruction for use of any product not considered medicine (including beauty (cosmetic) products, bioactive additives).

## CHAPTER 6

## IMPORT, EXPORT, STORAGE, TRANSPORTATION OF MEDICINES, INVESTIGATIONAL PHARMACEUTICAL PRODUCTS, MEDICINAL SUBSTANCES AND HERBAL RAW MATERIALS

### Article 21. Import and export of medicines, medicinal substances, investigational pharmaceutical products and herbal raw materials

1. Medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products shall be imported into the territory of the Republic of Armenia (bringing in medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products by crossing the state border of the Republic of Armenia (hereinafter referred to as “the import”)) and they shall be exported from the territory of the Republic of Armenia (bringing out medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products by crossing the state border of the Republic of Armenia (hereinafter referred to as “the export”)) as prescribed by the Government of the Republic of Armenia.

2. The following shall have the right to import medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products into the territory of the Republic of Armenia:

(1) suppliers — where a licence for wholesale of medicines is available;

(2) without a licence for wholesale provided for by this Law:

a. legal persons or individual entrepreneurs, the activities whereof relates to investigation of medicines, medicinal substances, herbal raw materials, conduct of trials, control of quality, efficacy, safety thereof, to the extent of the volumes and stocks required for these activities;

b. legal persons or individual entrepreneurs importing medicines within the framework of

programmes qualified as charitable or humanitarian as prescribed by the legislation;

c. legal persons and individual entrepreneurs holding a licence of manufacturing of medicines in the Republic of Armenia where medicinal substances and herbal raw materials are imported for manufacturing purposes;

d. representations or representatives of foreign manufacturers when importing or exporting samples for registration and (or) trials (medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products) and (or) exhibition samples;

e. state bodies;

f. natural persons in compliance with point 1 of part 7 of Article 21 of this Law.

3. The medicinal substances and herbal raw materials, the data on which are presented in the registration document of the finished product, shall be permitted to import for manufacturing purposes, except for medicinal substances and herbal raw materials imported for developing the pharmaceutical form and for medicines manufactured only for the purpose of export. In case of import of medicinal substances or herbal raw materials by a medicine developer no laboratory examination shall be conducted when issuing an import certificate.

4. It shall be permitted to import medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products based on the import certificate, except for the cases provided for by this Article. In case of export a certificate shall be issued if the exporter desires so. Import or export certificates shall be issued based on the relevant expert opinion, under the procedure established by the Government of the Republic of Armenia. The Government of the Republic of Armenia shall establish the procedure for expert examination conducted for import or export of medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products, and the list of necessary documents.

5. Medicines registered in the Republic of Armenia may be imported into the territory of the Republic of Armenia, except for the cases prescribed by law. Medicines registered in the Republic of Armenia may, pursuant to this Law, be imported into the Republic of Armenia by any entity holding a licence for wholesale of medicines.

6. The fact as to the medicine being registered shall not be mandatory for issuing an import certificate:

(1) where there are emergency situations or risk of their emergence;

(2) for medicines imported within the framework of charitable and humanitarian programmes — where there is a document certifying the registration in the member country of the international professional organisation established by the decision of the Government of the Republic of Armenia, or the pre-qualification by the World Health Organisation, after agreeing with the Authorised Body under the procedure for processing, agreeing the order for, receiving, record-keeping and distributing the medicines under the procedure for humanitarian aid established by the Government of the Republic of Armenia;

(3) in the cases provided for by points 4-6 of part 23 of Article 16 of this Law;

(4) where there is a written decision of the Authorised Body, in case of importing medicines for state needs or for the purpose of medical assistance and service to individual patients;

(5) for bulk semi-finished products of medicine that underwent all the stages of manufacturing, except for the final packaging and marking, and the finished product of which is registered or imported in the Republic of Armenia for the purpose of registration;

(6) in case of import of medicines designated for animals of zoological gardens.

7. An import or export certificate shall not be required:

(1) for medicines for treatment plan of a natural person departing to a foreign State and arriving from a foreign State or for personal use, as well as for medicines for personal use imported by a carrier or by international postal deliveries in the name of a physical person under the procedure established by the Government of the Republic of Armenia;

(2) for medicines imported by international organisations, foreign diplomatic and consular representatives, their staff and family members living therewith for satisfying their own needs;

(3) for medicines necessary for medical assistance and service to drivers, staff members and passengers of vehicles arriving in the Republic of Armenia;

(4) for medicines necessary for medical assistance and service to participants of international cultural and sport events, international research groups.

8. The import and export of medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products into the Republic of Armenia shall be rejected where:

(1) the submitted data or documents are incomplete or obviously false or distorted, or any of the documents required by the legislation or other legal acts of the Republic of Armenia is missing, and where the shortcomings were not eliminated within the prescribed time limit;

(2) the imported medicines have no state registration in the Republic of Armenia, except for cases prescribed by this Law;

(3) the qualitative indicators of imported medicines or medicinal substances or herbal raw materials or investigational pharmaceutical products (hereinafter referred to as “ the imported products”) do not comply with the requirements of the pharmacopeias included in the list approved as prescribed by this Law and quality specifications;

(4) the imported product is expired;

(5) the remaining shelf-life of the imported product does not comply with the requirements set

down by the Government of the Republic of Armenia;

(6) the product and the data of the documents accompanying it contravene each other;

(7) the records of the packaging of the imported medicine do not contain the indicators characterising the medicine that are reflected in the registry, or they do not comply with the sample for registration;

(8) the records of the packaging or the leaflet of the imported product do not contain the excipients used in the composition thereof and to be mandatorily indicated on the packaging prescribed by the Authorised Body, and for medicines for injection, local use and used in ophthalmology — do not contain an indication on any excipients, or it does not comply with the sample for registration;

(9) the records of the packaging of the imported product do not contain an indication on the shelf-life of the medicine, or it does not comply with the sample for registration;

(10) the records of the packaging of the imported product do not contain indications on the special conditions for storage of medicine, or they do not comply with the sample for registration;

(11) the records of the packaging of the imported product do not contain an indication of the manufacturing batch;

(12) the records of the packaging of the imported product do not contain special warning, or they do not comply with the sample for registration;

(13) after opening the primary package, the records of the packaging of the imported product do not contain the permissible date for use thereof, or it does not comply with the sample for registration;

(14) the temperature regime for transportation and storage of the medicine and (or) medicinal substance (“cold chain”) is disrupted;

(15) the language of the records of the packaging of the imported medicines does not comply with any of the languages recognised for the packaging of medicines by the legislation of the Republic of Armenia.

9. The absence of the leaflet in Armenian of the registered medicine being imported shall not constitute a ground for refusing the import of the medicine. Where the medicine does not come with a leaflet in Armenian when importing into the Republic of Armenia, the leaflet in Armenian shall be made available under part 3 of Article 20 of this Law after the import as prescribed by the legislation of the Republic of Armenia.

10. The procedure for and special aspects of granting an authorisation for parallel import of medicines shall be established by the Government of the Republic of Armenia.

11. Granting of an authorisation for parallel import of medicines shall be rejected where:

(1) the country of manufacturing or the manufacturer of the medicine does not comply with the country of manufacturing or the manufacturer of the medicine registered in the Republic of Armenia;

(2) the pharmaceutical form or dosage does not comply with the pharmaceutical form or dosage of the medicine registered in the Republic of Armenia;

(3) the shelf-life of the medicine does not comply with the shelf-life of the medicine registered in the Republic of Armenia;

(4) the active ingredient of the medicine is other than the active ingredient of the medicine registered in the Republic of Armenia;

(5) the anatomical, therapeutic, chemical classification of the medicine introduced by the World Health Organisation does not comply with the anatomical, therapeutic, chemical classification of the medicine registered in the Republic of Armenia;

(6) the commercial name of the medicine does not comply with the commercial name of the medicine registered in the Republic of Armenia;

(7) the indications or contraindications for administration of the medicine do not comply with the indications or contraindications for administration of the medicine registered in the Republic of Armenia;

(8) the medicine is not registered in the country, wherefrom it was acquired and imported into the Republic of Armenia;

(9) the circulation of the given medicine was terminated in the Republic of Armenia or the country, wherefrom the medicine is imported, for the purposes of safety, efficacy and quality of the medicine.

12. Where the language of the packaging or labelling of the medicine imported in parallel is different from the language of packaging or labelling of the medicine registered in the Republic of Armenia, the supplier having obtained a licence for wholesale of medicines shall carry out the repackaging and relabelling before the sales.

13. The supplier having obtained a licence for wholesale of medicines must make available a leaflet for the medicine imported in parallel, registered in the Republic of Armenia, by including in the records its name, location, data for ensuring communication with consumers.

14. In case of parallel import, the supplier having obtained a licence for wholesale of medicines shall be responsible in compliance with part 22 of Article 16 of this Law.

15. The person holding a licence for manufacturing of medicines in the Republic of Armenia shall — before 31 January of each year — submit to the Authorised Body a report on the product exported in the previous year, by including data on the name, dosage, pharmaceutical form,

manufacturer, batch number, exported quantity, country of export of the product. The form of the report and the procedure for submission thereof shall be established by the Authorised Body.

16. The persons holding a licence for wholesale of medicines may not — within the validity period of the licence (including within the period of suspension of the validity of the licence) — carry out pharmacy activities provided for by law, except for the cases where a separate legal person is established that holds a relevant licence for wholesale.

17. A state duty shall be levied for issuing an import or export certificate for medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products in the amount and in the manner prescribed by the Law of the Republic of Armenia “On state duty”.

***(Article 21 amended by HO-43-N of 21 January 2020, supplemented, edited by HO-279-N of 1 June 2020, amended by HO-290-N of 7 July 2022)***

### Article 22. Transportation and storage of medicines

1. Medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products shall be stored according to the rules of Good Storage practice approved by the Authorised Body. The rules of Good Storage Practice approved by the Authorised Body shall be posted on the official website of the Authorised Body. The requirements of the rules of Good Storage Practice shall apply to the storage of medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products in customs warehouses.

2. Medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products shall be transported according to the rules of Good Distribution Practice approved by the Authorised Body. The rules of Good Distribution Practice approved by the Authorised Body shall be posted on the official website of the Authorised Body.

3. The relations pertaining to the transit transportation of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products shall be regulated by the customs legislation of the Republic of Armenia.

## CHAPTER 7

## SALES OF MEDICINES, MEDICINAL SUBSTANCES, HERBAL RAW MATERIALS

### Article 23. General requirements for sales of medicines, medicinal substances, herbal raw materials

1. The sales of medicines, medicinal substances, herbal raw materials may be carried out, as prescribed by this Law, by persons licensed for pharmacy activities or wholesale of medicines that submit to the Authorised Body a report on volumes of sales as prescribed by the Authorised Body.

2. It shall be prohibited to sell medicines, falsified medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products that are not registered in the Republic of Armenia or fail to comply with the quality requirements, or are expired, or have their registration revoked or suspended or circulation terminated (recalled), or are imported in violation of the legislation of the Republic of Armenia. The procedure for notifying the alert concerning the product referred to in this part, terminating their circulation or withholding them from circulation (recalling) shall be established by the Government of the Republic of Armenia. The expenses for termination of circulation and recall shall be incurred by the holder of the certificate of registration or the supplier.

3. After the expiry of the term of registration, it shall be permitted — until the expiry of the shelf-life — to sell the medicines, that — as of the day of issuing an import certificate, and for products manufactured in the Republic of Armenia — as of the day of issuing an invoice for sales by the manufacturer, were registered in the Republic of Armenia as prescribed by law.

### Article 24. Wholesale of medicines, medicinal substances, herbal raw materials

1. The wholesale of medicines, medicinal substances, herbal raw materials shall be carried out by suppliers according to the rules of Good Distribution Practice approved by the Authorised Body.

2. The Authorised Body shall issue a licence for wholesale of medicines to the supplier based on the expert opinion, under the procedure established by the Government of the Republic of Armenia. Along with the licence for wholesale of medicines, a leaflet shall be issued which must mandatorily contain an indication on medicines subject to wholesale by the supplier and satisfying the general conditions for storage, or medicines containing narcotic drugs, psychotropic (psychoactive) substances, or medicines containing blood components and deriving therefrom, or immunological medicines, or radioactive medicines, or medicinal gases, or medicines requiring cold chain.

3. The procedure for licensing the wholesale approved as prescribed by law shall define other requirements and conditions included in the leaflet of the licence.

4. Persons holding a licence for manufacturing of medicines in the Republic of Armenia shall have the right to carry out the wholesale of products of own manufacturing without a licence for

wholesale of medicines.

5. Medicines prepared and dispensed in the pharmacy shall not be subject to wholesale.

6. The Authorised Body shall issue a certificate for Goods Distribution Practice to the supplier having obtained a licence for wholesale of medicines based on the general professional monitoring report. The professional monitoring provided for by this part shall be the process of assessment of compliance with the rules of Good Distribution Practice on the site of the supplier (including outsourced) for the purpose of assuring the quality of medicines circulated in the Republic of Armenia. The costs for professional monitoring (except for special monitoring) shall be compensated by the applicant based on the agreement concluded between the parties as prescribed by law. The Government of the Republic of Armenia shall establish the procedure for conducting professional monitoring and issuing a certificate for certification of the supplier, as well as the procedure for expert examination for licensing of the wholesale, and the list of necessary documents.

7. Types of professional monitoring provided for by this Article shall be the following:

(1) general monitoring, which includes assessment of compliance with the general principles of the rules of Good Distribution Practice and is conducted before the issuance of a licence for wholesale of medicines and a certificate for Good Distribution Practice, based on the application submitted by the supplier;

(2) current (scheduled, regular) monitoring which includes assessment of compliance with all the components of the Good Distribution Practice and is conducted under the annual observation plan, based on the application submitted by the supplier;

(3) special monitoring which is conducted in the cases where it is necessary to establish circumstances (including valid alerts in relation to the quality and the safety), for the identification of which the supplier was not informed of the monitoring in advance.

8. The professional monitoring for legal persons and individual entrepreneurs holding a licence for wholesale of medicines shall be conducted annually, then once in 2 years within the first 3 years after obtaining a licence.

9. The licence for wholesale of medicines, except for the cases provided for by the Law of the Republic of Armenia “On licensing”, shall also be suspended in the following cases:

(1) in case of violations of the rules of Good Manufacturing Practice approved by the Authorised Body, detected during the professional monitoring of compliance of the wholesale of medicines with the rules of Good Distribution Practice approved by the Authorised Body (except for the case provided for by point 1 of part 7 of this Article), of which the legal person or individual entrepreneur holding a licence for wholesale of medicines was properly notified but failed to eliminate them within a reasonable time limit set by the licensing body;

(2) in case of failure to submit an application for ensuring the frequency prescribed by part 8 of the monitoring provided for by point 2 of part 7 of this Article.

10. Legal persons and individual entrepreneurs holding a licence for wholesale of medicines shall be designated as persons responsible for good distribution practice, the requirements for which shall be set down by the Authorised Body.

11. State duty shall be levied for granting a certificate for goods distribution practice in the manner and amount prescribed by the Law of the Republic of Armenia “On state duty”.

12. Legal persons and individual entrepreneurs holding a licence for wholesale of medicines shall, until 31 January of each year, submit to the Authorised Body a report on medicines sold by wholesale. The form of the report and the procedure for submission thereof shall be established by the Authorised Body.

13. An official Internet website on legal persons and individual entrepreneurs holding a licence for wholesale of medicines shall be maintained as prescribed by the Authorised Body, and it shall provide exhaustive information on the availability of medicines included in the list of essential medicines, including the commercial name of the medicine, their maximum wholesale mark-up, quantities available at the given moment (on-line).

14. Within the meaning of this Law, wholesale of medicines shall not be the return — as prescribed by the legislation of the Republic of Armenia — of medicines not sold by the pharmacy to the same supplier holding a licence for wholesale of medicines. This provision shall apply also to the return — as prescribed by the legislation of the Republic of Armenia — of medicines not sold by the person holding a licence for pharmacy activities, undergoing liquidation process, to the same supplier holding a licence for wholesale of medicines. In these cases the responsibility for the quality, safety and efficacy of the medicine shall be borne by the supplier holding a licence for wholesale of medicines.

### Article 25. Retail sales of medicines

1. The retail sales of medicines, where a relevant licence is available, shall be carried out only in pharmacies in compliance with the requirements prescribed by the legislation of the Republic of Armenia. The licence for pharmacy activities shall contain a leaflet, the list of requirements and conditions covered thereby shall be defined by the procedure for licensing pharmacy activities approved as prescribed by law.

2. The requirements for the structure (preparing or not preparing medicines), subdivisions,

technical equipment, education of employees (secondary vocational, graduate, postgraduate, extended), operating mode of pharmacies, as well as the peculiarities of pharmacy activities and pharmacies in settlements of a certain category shall be set down by the Government of the Republic of Armenia. The Government of the Republic of Armenia shall set down the requirements for pharmacy activities and the list of goods sold in pharmacies.

3. Legal persons or individual entrepreneurs holding a licence for pharmacy activities may carry out delivery of medicines in compliance with the technical and professional requirements for the delivery of medicines prescribed by the legislation of the Republic of Armenia. The technical and professional requirements for the delivery of medicines shall be set down by the Government of the Republic of Armenia.

4. The retail sales of medicines in pharmacies shall be carried out on prescription and without a prescription. The forms of prescriptions, the procedure for writing prescriptions, releasing medicines (including electronically), as well as the procedure for record-keeping of medicines and medicinal substances shall be established by the Government of the Republic of Armenia. An entry on the procedure for releasing medicine on prescription or without a prescription shall be made in the registry.

5. Legal persons and individual entrepreneurs engaged in pharmacy activities must ensure a minimum stock in compliance with the list of essential medicines subject to sales in pharmacies or release therefrom; moreover, the list of minimum stocks shall be different depending on the fact whether the pharmacy operates in a rural or urban settlement. The list of minimum stocks in compliance with the list of essential medicines subject to sales in pharmacies of rural or urban settlements or release therefrom shall be established by the Authorised Body.

6. In case of absence of medicine included in the minimum stock provided for by part 5 of this Article the pharmacy shall be obliged to provide the requested medicine within 24 hours after the buyer submits a request.

7. The medicine sold in the pharmacy that complies with the quality, efficacy, safety, prescription (proper quality) prescribed by the legislation of the Republic of Armenia shall not be replaced or accepted back. The violation of this norm shall entail administrative liability provided for by law.

8. The sales of prescription medicines without a prescription shall be prohibited.

9. It shall be prohibited to fill, write out and provide prescriptions of prescription medicines on forms not prescribed by the legislation of the Republic of Armenia.

10. Medicines shall be made available on prescription by the common name of the medicine. The pharmacy shall be obliged to present to the person acquiring medicine exhaustive information on all interchangeable medicines containing the same ingredients, the same dosage and in the same pharmaceutical form that are available in the pharmacy, including on prices, without guidance. Writing out a prescription by the commercial name of the medicine shall be possible only in case of reasoned substantiation by the physician, one copy of which, along with the prescription, shall be presented to the pharmacy, and the other copy shall be attached to the medical documents of the patient. The requirements for substantiation for writing out a prescription by the commercial name of the medicine shall be set down by the Authorised Body.

11. It shall be prohibited to provide non-pharmacological professional consultation at the pharmacy.

12. The persons holding a licence for pharmacy activities may not carry out wholesale of medicines within the validity period of the licence for pharmacy activities (including within the period of suspension of the validity period of the licence).

13. Veterinary medicines shall be sold at veterinary pharmacies, the requirements for activities of which shall be set down by the Government of the Republic of Armenia.

14. The requirements for pharmacies constituting a structural subdivision of a medical institution and their activities shall be set down by the Government of the Republic of Armenia.

### Article 26. Destruction of medicines, medicinal substances, herbal raw materials, investigational pharmaceutical products

1. Medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products that have expired, are not registered, as well as falsified and not fit for use, which have been acquired illegally, contain low-quality, undeclared ingredients shall be destructed by the licensed legal person or individual entrepreneur in compliance with the requirements for destruction of hazardous wastes prescribed by the legislation and other legal acts of the Republic of Armenia.

2. The destruction of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products shall be financed at the expense of the entity engaged in the circulation, under whose ownership they fall, or from other sources not prohibited by the legislation of the Republic of Armenia.

## CHAPTER 8

## *INFORMATION ON AND ADVERTISING OF MEDICINES*

**Article 27. Information on medicines**

1. The objective of providing information on medicines shall be ensuring their intended and efficient use by way of providing reliable information thereon.

2. The information on medicines must be complete, impartial and reliable, substantiated by scientific studies and (or) data approved during the registration. The information on medicines must comply with the requirements prescribed by the Authorised Body.

3. Information on over-the-counter medicines may be published in specialised and general publications in the form of scientific and informative articles, instructions for use (leaflet), unless the information contains elements of advertising.

4. Information on prescription medicines may be introduced only in professional publications, reference books in the form of scientific and informative articles, in the monographs, reports presented in scientific conferences and other similar events, as well as in the instructions for use and medical use of medicines. The requirements for professional publications shall be approved by the Government of the Republic of Armenia.

5. Dissemination of information on prescription medicines via mass media shall be prohibited.

6. The official information on medicines shall published only by the Authorised Body.

7. Reference books containing information on essential medicines, i.e. the National Catalogue of Medicines, shall be published by the Authorised Body once in two years, under the procedure established by the Government of the Republic of Armenia.

**Article 28. Advertising of medicine**

1. The advertising of the medicine for the purpose of promoting its prescription, supply, sales, administration and consumption shall be the dissemination of information intended to arouse or maintain the interest in it, and shall include:

(1) advertising of the medicine among consumers;

(2) advertising of the medicine among persons carrying out activities in the medical and pharmaceutical system and in medical institutions;

(3) visit of representatives of medicine sellers to persons carrying out activities in the medical and pharmaceutical system, including to medical institutions;

(4) free-of-charge provision of a sample of the medicine;

(5) any other type of advertising of the medicine.

2. The authorisation for advertising of the medicine shall be issued by the Authorised Body under the procedure established by the Government of the Republic of Armenia. The authorisation for advertising of veterinary vaccines, serums and diagnostic agents shall be issued by the state body authorised in the sector of agriculture, as prescribed by the Government of the Republic of Armenia. When advertising medicines in electronic and print mass media, the number and date of the state registration certificate in the Republic of Armenia, the number and date of the authorisation of the Ministry of Health of the Republic of Armenia for medicines shall be indicated in the advertising. The external advertising of medicines shall be prohibited in the Republic of Armenia.

3. The advertising text must comply with the data of general description approved during the registration.

4. The advertising of the medicine not registered in the Republic of Armenia or controlled in the Republic of Armenia or prepared in the pharmacy by prescription or formulations shall be prohibited.

5. The advertising, as a curative agent, of any product not constituting as medicine (bioactive additives, beauty products) shall be prohibited.

6. Mass media may advertise the medicine that falls under the group of over-the-counter medicines and contains no narcotic drugs and psychotropic (psychoactive) substances.

7. The advertising of the medicine on mass media may not contain the materials that:

(1) create an impression that the consultation by the physician or the medical intervention is unnecessary;

(2) assure that the absolute efficacy of the medicine is guaranteed, taking the medicine is not accompanied by side effects, or its effect exceeds or is equivalent to other treatment methods or other medicine;

(3) assure that when a human being takes the medicine, he or she will become perfectly healthy;

(4) assure that if the medicine is not administered, the state of health of the human being will deteriorate, except for advertising within the framework of universal vaccination programmes;

(5) target children;

(6) contain references to guarantees of scientists, medical workers or other popular persons or non-governmental organisations, that may boost the use of the medicine;

(7) suggest that the medicine be used in the food or for beauty (cosmetic) purposes;

(8) assure that the safety and efficacy of the medicine result from its natural origin;

(9) may result in erroneous self-diagnosis by way of describing or presenting in detail the

medical record;

(10) contain statements on improving the state of health that are accompanied by incorrect, alarming or confusing phrases;

(11) contain unreliable concepts that are not related to the administration of the medicine.

8. It shall be prohibited to name the following diseases when advertising medicines on the mass media:

(1) diseases posing risk to the surroundings;

(3) tumours;

(4) persistent insomnia;

(5) diabetes and other metabolic diseases;

(6) cardiovascular diseases.

9. Providing the medicine directly to the consumer or persons carrying out activities in the medical and pharmaceutical system for advertising purposes shall be prohibited.

10. The medicines registered in the Republic of Armenia may be advertised among persons carrying out activities in the medical and pharmaceutical system only where an authorisation of the Authorised Body is available, by excluding the use of the mass media.

11. The authorisation for advertising of medicines shall be rejected where:

(1) the documents for obtaining an authorisation for advertising are incomplete or obviously false or distorted, or any of the documents required by the legislation of the Republic of Armenia for issuing an authorisation for advertising is missing, and unless the shortcomings are eliminated within the prescribed time limit;

(2) the text of advertising of medicines contradicts this Law or the Laws of the Republic of Armenia “On advertising” or “On licensing” or “On ensuring sanitary and epidemiological safety of the population of the Republic of Armenia” or “On medical assistance and service to the population” or “On transplantation of organs and (or) tissues to human being” or “On donation of human blood and its components and transfusion medical assistance” or “On psychiatric care” or regulatory legal acts adopted based thereon.

12. The Authorised Body shall establish the list of data to be mandatorily indicated in any documents provided to consumers, persons carrying out activities in the medical and pharmaceutical system and relating to the medicine.

13. When advertising medicines among persons carrying out activities in the medical and pharmaceutical system it shall be prohibited to offer, provide or promise free samples of medicines, gift, profit or remuneration in cash or in kind. Persons carrying out activities in the medical and pharmaceutical system shall be prohibited to request or accept any incentive, except for price discounts and benefits, as well as contribution to professional and scientific events.

14. The advertiser of medicines shall keep, for at least two years, the advertising materials and data in compliance with the list established by the Authorised Body, in order to submit for the purpose of surveillance over advertising.

15. The relations pertaining to advertising of medicines shall be regulated by the Law of the Republic of Armenia “On advertising” unless this Law prescribes special aspects regulating these relations.

## CHAPTER 9

## *SUPERVISION IN THE SECTOR OF MEDICINES AND LIABILITY FOR VIOLATING THIS LAW*

### Article 29. State supervision in the sector of circulation of medicines

1. State supervision in the sector of circulation of medicines shall be carried out by the inspection body exercising supervision that is authorised by the Government of the Republic of Armenia, as prescribed by law of the Republic of Armenia.

2. The quality of medicines, medicinal substances, herbal raw materials and investigational pharmaceutical products circulated in the Republic of Armenia must comply with the requirements of this Law.

***(Article 29 edited by HO-171-N of 21 March 2018)***

### Article 30. Liability for violating this Law

1. Persons violating the requirements of this Law shall be held liable as prescribed by the legislation of the Republic of Armenia.

## CHAPTER 10

## *FINAL AND TRANSITIONAL PROVISIONS*

### Article 31. Entry into force of this Law

1. This Law shall enter into force six months following its official promulgation, except for:

(1) Article 11, which shall enter into force:

a. one and a half year following its official promulgation, with respect to state regulation of prices for reimbursable medicines purchased by the Authorised Body (centralised procedure);

b. with respect to state regulation of prices for reimbursable medicines by medical institutions, including through pharmacies starting from 1 January 2025;

(2) part 16 of Article 18 which shall enter into force five years following the official promulgation of this Law;

(3) parts 1 and 2 of Article 22 which shall enter into force three years following the official promulgation of this Law.

2. Before the entry into force of this Law, persons having obtained a licence for manufacturing of medicines but holding no certificate for good manufacturing practice for medicines shall be obliged to obtain a certificate for good manufacturing practice for medicines as prescribed by law within three years after the entry into force of this Law.

3. Legal persons and individual entrepreneurs carrying out activities related to the wholesale of medicines shall be obliged to undergo licensing within a period of seven months after the entry into force of the procedure for licensing of wholesale of medicines. Persons having obtained a licence for wholesale of medicines shall be obliged to obtain, in the manner prescribed, a certificate for good distribution practice for medicines within a period of four years after the entry into fore of this Law.

4. In case of failure to obtain a certificate for good manufacturing practice or a certificate for good distribution practice for medicines within the time limit and under the procedure prescribed by parts 2 and 3 of this Article the Authorised Body shall terminate the licence for manufacturing of medicines or the licence of wholesale of medicines.

5. Persons holding a licence for manufacturing of medicines or a licence for pharmacy activities shall be obliged, within a period of six months after the entry into force of this Law, to bring the requirements and conditions for activities subject to licensing in line with the requirements of this Law.

6. Persons holding a licence shall be obliged, within a period of six months after the entry into force of this Law, to re-issue the valid licence for manufacturing of medicines and the licence for carrying out pharmacy activities, for which new conditions and requirements arise under this Law. In case of failure to re-issue the licences within the mentioned time limit, they shall be subject to termination by the state administration body authorised in the sector of healthcare.

7. It shall be defined that licences for pharmacy activities carried out in the form of pharmacy stores shall not be subject to re-issuance where the form of pharmacy activities underwent transitions from pharmacy store to pharmacy that does not prepare medicines.

8. In case of re-issuance of licences within the time limit referred to in part 6 of this Article, no state duty for re-issuance of a licence prescribed by the Law of the Republic of Armenia “On state duty” shall be levied.

9. Law of the Republic of Armenia HO-259 of 27 October 1998 “On medicines” shall be repealed upon entry into force of this Law.

***(Article 31 edited by HO-268-N of 4 December 2019, amended by HO-195-N of 13 April 2020)***

**President**
**of the Republic of Armenia** **S. Sargsyan**

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