THE REPUBLIC OF ARMENIA

LAW

Adopted on 17 May 2016

ON MEDICINAL PRODUCTS

CHAPTER 1

GENERAL PROVISIONS

Article 1. Regulatory Scope

1. This Law regulates the circulation of medicines, substances, herbal substances and preparations, and investigational medicinal products with the aim of securing safe, effective, quality, and affordable medicinal product and reliable information thereon to the population. This Law also defines the powers of the competent state authorities of the Republic of Armenia and the powers of entities involved in the circulation of medicinal products in this sphere.

2. The circulation of medicinal products, substances, medicinal herb materials, and Investigational medicinal products containing narcotics or psychotropic (psychoactive) substances shall be regulated by this Law unless the Republic of Armenia Law on Narcotics and Psychotropic (Psychoactive) substances directly provides otherwise.

Article 2. Legal Regulation of the Circulation of Medicinal products, Substances, Medicinal Herb Material, and Investigational medicinal products

1. The circulation of medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be regulated by this Law, other laws, and other legal acts.

2. If the international treaties ratified by the Republic of Armenia prescribe provisions that differ from the provisions of this Law, the international treaty provisions shall apply.

Article 3. Key Terms Used in the Law

1. The following key terms are used in this Law:

1) Medicinal product: any substance of human and/or animal and/or vegetable and/or chemical and/or biotechnological origin in an appropriate dosage and dosage form, and the requisite packaging and labeling, which presented as having properties for treating or preventing disease in human beings or animals or may be used in or administrated either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological and/or immunological and/or metabolic action, or to making a medical diagnosis.

2) Immunological medicinal products: any medicinal product consisting of vaccines, toxins, serums, globulins or allergen products;

3) Radioactive medicinal products: medicinal product containing one or more radionuclides;

4) Herbal medicinal products: any medicinal product, exclusively containing as active ingredients one or more herbal substances or (and) one or more herbal preparations;

5) Homeopathic medicinal products: medicinal product received through the homeopathic production process described in the pharmacopeias recognized under the procedure defined by this Law;

6) Dosage form: a form that has the complex profile of physical, chemical, and pharmaceutical features of the medicinal product, ensuring a diagnostic or preventive or treatment outcome, and issued suitably for use;

7) Strength of the medicinal product: the content of the active substances expressed quantitatively in the measurement units established for each dosage form.

8) Substance: material of human origin (human blood, blood products, other materials of human origin), and/or material of animal origin (microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; and other materials of animal origin), and/or material of vegetable origin (microorganisms, plants, parts of plants, vegetable secretions,

extracts; and other materials of vegetable origin), and/or material of chemical origin (elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis, and other materials of chemical origin); when used for preparing or manufacturing medicinal products, and having pharmaceutical or immunological or metabolic activity;

9) Herbal substances: whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh used for the purpose of preparing or manufacturing of medicinal products;

10) Excipients: any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients;

11) Investigational medicinal products: an active ingredient or placebo (a product not containing an active ingredient) of a certain form, used in clinical trials as a testing sample or comparison sample, or a registered medicinal product the route of administration or production of which differs from a registered medicinal product (in terms of form or packaging), or when a particular indication for use is not registered or is being researched with a view to receiving additional information on a registered dosage form;

12) New (original) medicinal product: a medicinal product with a new active ingredient/-s discovered for the first time;

13) Generic medicinal product: a reproduced medicinal product equivalent to an original medicine in terms of effect, containing the same active ingredient/-s, with the same strength and in the same dosage form, the bioequivalence of which to the original has been demonstrated under the procedure defined by the legislation of the Republic of Armenia;

14) Biosimilar: a reproduced medicinal product of biotechnological and biological origin;

15) Counterfeit medicine/counterfeit substance: a product which is deliberately and fraudulently mislabelled with respect to identity (including the packaging, labeling, name, composition, and quantities of individual ingredients) and/or source (including the manufacturer, the production country, the country of origin, and the registration certificate holder) and/or distribution chain (including protocols and accompanying documents);

16) Controlled medicinal products and substances: medicinal product and substance subject to name-quantity recording in the health system of the Republic of Armenia, the list of which is defined by the Authorized Body of state government in the health sector;

17) Essential medicine: those medicinal products that satisfy the health care needs of the majority of the population of the population of the Republic of Armenia marked under INN;

18) Manufacture: all operations of purchase of materials and products, Production, Quality Control, packaging, repackaging, labeling, re-labeling, storage, release of medicinal products and the related controls;

19) Manufacturer: a legal entity or sole entrepreneur, which is holder of a manufacturing authorization (License);

20) Circulation of medicinal products: discovery, nonclinical testing, clinical trials, standardization, manufacture, preparation, processing of medicinal herb material, quality control, registration, imports or exports, transportation, storage, sale, distribution, use, monitoring of efficacy, safety, and adverse reactions , information, advertisement dissemination or disposal of medicinal products;

21) Entities performing the circulation of medicinal products: legal entities and sole entrepreneurs performing any stage of the circulation of medicinal products;

22) Medicine policy: an element of the policy carried out in the health sector, which is aimed at providing safe, effective, quality, and affordable medicines to the population, as well as ensuring their rational use;

23) Safety: absence of unacceptable potential health risk;

24) Efficacy: description of the degree of anticipated positive impact of medicine;

25) Quality: conformity to the requirements of pharmacopeias included in the list approved under the procedure defined by this Law and/or the quality specifications approved under the procedure defined by this Law;

26) Good laboratory practices (GLP): a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported;

27) Good clinical practices (GCP): a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected;

28) Good manufacturing practices (GMP): a part of quality assurance which ensures that medicinal products are consistently manufactured and controlled to the quality standards (specifications) appropriate to their intended use and as required by the marketing authorization (registration).

29) Good distribution practices (GDP): a part of quality assurance that ensures that the quality of medicinal product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as

providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products;

30) Good agricultural and collection practices (GACP): a part of quality assurance that ensures quality of medicinal plant materials for the sustainable production of herbal product classified as medicines;

31) Good storage practice (GSP): a part of quality assurance that ensures that the quality of medicinal products is maintained by means of adequate control throughout the storage thereof;

32) Shelf life: a certain time period determined as a result of stability tests, during which the medicinal product quality indicators remain unchanged or change within defined limits when kept in conditions conforming to the quality specifications or the pharmacopeias included in the list approved under the procedure defined by this Law;

33) Pharmacopeia: a compilation of monographs, methods and other criteria for analyzing and controlling the quality of medicinal products, and their ingredients; the list of acting pharmacopeias in the Republic of Armenia shall be approved by the Government of the Republic of Armenia;

34) Monographs: description of the quality specifications and control methods of medicinal product and their ingredients;

35) Nonclinical study: for the purpose of evaluating the safety and efficacy of an active ingredient, physical, chemical, biological, microbial, pharmacological, pharmaceutical, toxicological, and other testing in laboratory conditions, without human involvement;

36) Clinical trials: trials performed on humans or animals (in case of veterinary medicine) with a view to discovering or confirming the clinical, pharmacological, and/or other pharmacodynamic features of the tested investigational product/-s and/or discovering its/their adverse reactions and/or studying the process of absorption, distribution, metabolism, and/or excretion from the body of one or more tested investigational products, with the purpose of evaluating their safety and/or efficacy;

37) Prescription: the written prescription of medicinal product on paper or in electronic form by a doctor having such authority, for the purpose of preparing such medicine and/or releasing the ready medicine;

38) Official formulation: the fixed composition of the medicinal product, with a description of the dosage form, in which the active and other ingredients are described in the sequence order of importance of their impact, and in the quantities necessary for preparing the medicine;

39) Register: list of medicines that have been registered in the Republic of Armenia in accordance with the procedure stipulated by law;

40) Registration certificate: an official document confirming the fact that a medicine has been registered in the Republic of Armenia in accordance with the procedure stipulated by law;

41) Wholesale distribution of medicinal product: a type of activity that involves a supplier purchasing medicinal product from the medicinal product registration certificate holder or another supplier, import or export of medicinal product, storage or sale/distribution, except for sale of medicinal product to consumers;

42) Supplier: a legal entity or sole entrepreneur, which has received a wholesale distribution license under the established procedure;

43) Retail sale of medicinal product: the sale or dispensing of medicinal product to consumers;

44) Pharmacy activities: the procurement, storage, and retail sale, dispensing of medicinal product and other products defined by the Government of the Republic of Armenia in accordance with the requirements of this Law and other legal acts, as well as information, advice, advocating for a healthy lifestyle, and preparing or delivering medicinal product —when the conditions defined by the legislation of the Republic of Armenia are present;

45) Pharmacy: a place where pharmacy activities are carried out;

46) Health facility pharmacy: a structural subdivision of a health facility, which carries out pharmacy activities for the needs of the medical institution, save for selling of medicinal products; the activities carried out in the frameworks of the pharmacy of a health facility shall be subject to licensing under the respective type of medical care and service activities;

47) Treatment indication: an indication on illness treatment and the pharmacological effect;

48) Parallel importation: the importation of registered medicinal product (bringing medicinal product, substances, medicinal herb material, into the Republic of Armenia by means of crossing the state border) into the Republic of Armenia not directly from the holder of a certificate of registration in the Republic of Armenia or a person who has been duly authorized by such holder;

49) Common name: an international nonpropriety name given to the active ingredient of a medicinal product by the World Health Organization (INN) or, in its absence, a common used (scientific or chemical) name. If the medicinal product contains

more than one active ingredient, the INN of all such active ingredients shall be listed as the common name of the medicinal product;

50) List of essential medicines: a list containing the INN (common name), dosage form, and strength of the essential medicinal products;

51) Reimbursed medicines: medicines provided with full or partial reimbursement of the medicinal product price under the government-guaranteed procedure from the state budget of the Republic of Armenia to beneficiaries defined by the Republic of Armenia legislation;

52) Reference price of reimbursed medicines: reference price approved under the procedure stipulated by this Law for purchasing reimbursed medicinal product in accordance with the Republic of Armenia legislation;

53) Maximum wholesale price premium of reimbursed medicinal product: the maximum permissible price premium (in percent) approved under the procedure stipulated by this Law in relation to the reference price of the reimbursed medicinal product in case of making wholesale procurement in accordance with the Republic of Armenia legislation;

54) Maximum retail price premium of reimbursed medicinal product: the maximum permissible price premium (in percent) approved under the procedure stipulated by this Law in relation to the reference price of the reimbursed medicinal product in case of making retail procurement in accordance with the Republic of Armenia legislation;

55) Reimbursed medicinal product price list: a list approved by the Authorized Body of state government in the health sector, which sets out the INN of reimbursed medicinal product, the dosage forms, strength, reference price, and maximum retail and wholesale price premiums; and

56) Trade name of medicine: the name of the registered medicine, which may be the same as or differ from the INN and may contain also a trademark or the registration certificate holders name or the dosage form or strength.

CHAPTER 2

STATE REGULATION OF THE CIRCULATION OF MEDICINAL PRODUCTS

Article 4. State Regulation of the Circulation of Medicinal products

1. State regulation of the circulation of medicinal products in the Republic of Armenia shall be performed in the following areas:

1) Development and implementation of medicine policy in the field of healthcare;

2) Ensuring the circulation of safe, effective, and high quality medicines;

3) Licensing the types of activities stipulated by law in the sphere of circulation of medicinal products;

4) Control and oversight in the sphere of circulation of medicines;

5) Education and training of specialists; and

6) Safeguarding the accessibility of essential medicines.

Article 5. Powers of the Republic of Armenia Government in the Field of State Regulation of the Circulation of Medicinal products

1. For the purpose of state regulation of the circulation of medicinal products, the Government of the Republic of Armenia shall:

1) Develop and implement the state policy in the sphere of circulation of medicinal products;

2) Adopt legal acts regulating the sphere of circulation of medicinal products;

3) ensure the physical accessibility and affordability of medicines;

4) Provide state safeguards for securing the essential medicines to the population;

5) Carry out international cooperation; and

6) Carry out functions reserved for it by this Law and other laws.

Article 6. Powers of the Authorized Body of State Government in the Health Sector in the Field of State Regulation of the Circulation of Medicinal products

1. The Authorized Body of state government in the health sector (hereinafter, "the Authorized Body") shall carry out the following in the sphere of state regulation of the circulation of medicinal products:

1) The policy of the Republic of Armenia Government in the sphere of circulation of medicinal products;

2) Regulation of the circulation of medicinal products within the framework of its competence;

3) Licensing the types of activities stipulated by law in the sphere of circulation of medicinal products, and oversight stipulated by law;

4) State registration of medicines;

5) Organizing and carrying out expert examinations in the sphere of state regulation of the circulation of medicinal products;

6) Issuing a certificate for the registration of medicines, GMP, and GDP, and ensuring other inspections stipulated by this Law;

7) Ensuring the maintenance of the medicines register;

8) Ensuring the rational use of medicines, the pharmacovigilance, and development of appropriate recommendations;

9) International cooperation;

10) Inter-agency cooperation;

11) Development of state medicine policy programs and monitoring their implementation; and

12) Functions reserved for it by this Law and other laws.

Article 7. Expert Examinations in the Sphere of State Regulation of the Circulation of Medicinal products

1. The following are the expert examinations in the sphere of state regulation of the circulation of medicinal products:

1) Expert examinations carried out for issuing clinical trials authorization;

2) Expert examinations carried out for medicinal product registration, re-registration, and extension of the certificate term;

3) Expert examinations carried out for issuing a manufacturing license;

4) Expert examinations carried out for issuing an import or export authorization; and

5) Other expert examinations required by the Republic of Armenia law in the sphere of state regulation of the circulation of medicinal products.

2. Expert examinations in the sphere of state regulation of the circulation of medicinal products shall be paid, except for cases provided by law. The fees for expert examinations stipulated by this Law shall not be refunded irrespective of the outcome of such examinations. The fees for expert examinations in the sphere of state regulation of the circulation of medicinal products shall be set by decree of the Republic of Armenia Government.

CHAPTER 3

KEY PRINCIPLES OF THE STATE POLICY FOR PROVIDING MEDICINES TO THE POPULATION AND DEVELOPING PHARMACEUTICS

Article 8. Key Principles of State Policy of Providing Medicines and Developing Pharmaceutics

1. The following are the key principles of state policy for providing medicinal products and developing pharmaceutics:

1) Ensure the physical accessibility and affordability of medicinal products;

2) Promote the local production of medicinal products; and

3) Ensuring social fairness in annual state programs of providing medicinal products.

2. The criteria and procedure of selecting the essential medicinal products shall be defined by the Republic of Armenia Government. The list of essential medicinal products shall be defined by the Authorized Body.

Article 9. State System of Ensuring the Accessibility of Medicinal products

1. The state system of ensuring the accessibility of medicinal products includes the provision of medicinal products to beneficiaries stipulated by the Republic of Armenia legislation in the framework of programs implemented by the state to maintain and improve health, as well as the full or partial reimbursement of the price of medicinal products for such beneficiaries, when their implementation is funded from the state budget, as well as the state regulation and oversight of medicinal products prices.

Article 10. Provision of Medicinal products with Full or Partial Reimbursement of Their Price

1. The Republic of Armenia Government shall define the lists of social or special groups of the population and the list of illnesses, for which the medicinal products shall be provided to beneficiaries with full or partial reimbursement of their price, as well as the procedure of reimbursing and providing such medicinal products.

Article 11. State Regulation of Prices of Reimbursed Medicinal products

1. State regulation of the prices of reimbursed medicinal products shall be carried out in the Republic of Armenia. State regulation of prices is the setting of the maximum price of purchasing medicinal products reimbursed under this Law, which shall include the reference price of the medicinal product and the maximum wholesale and retail price premiums of reimbursed medicinal product.

2. State regulation of the prices of reimbursed medicinal products shall be carried out in accordance with the INN of the medicinal product, for medicinal products registered in the Republic of Armenia under the procedure stipulated by this law, as per their dosage form and strength.

3. The reference price of the reimbursed medicinal product and the maximum wholesale and retail price premiums of reimbursed medicinal product shall be set by the Republic of Armenia Government based on an opinion of the commission working towards state regulation of medicinal products prices (hereinafter, “the Commission”).

4. The Commission membership shall include representatives of public administration bodies and non-governmental organizations engaged in the protection of interests of consumers and patients, as well as economists and pharmacists. The Commission composition procedure, the maximum number of members, and the procedure of operation shall be defined by the Republic of Armenia Government.

5. The Republic of Armenia Government shall define the procedure of state regulation of the prices of reimbursed medicinal products, including:

1) The methodology of calculating the reference price of the medicinal product and the maximum wholesale and retail price premiums of reimbursed medicinal product;

2) The list of countries, the prices of which are used as a reference for comparison to determine the medicinal products procurement reference price and the maximum wholesale and retail price premiums;

3) The procedure of defining the reference price and the maximum wholesale and retail price premiums for purchasing reimbursed medicinal product; and

4) The procedure of revising the reference price and the maximum wholesale and retail price premiums for purchasing reimbursed medicinal product.

6. During a calendar year, the medicinal product procurement reference price may be revised no more than once.

7. The Authorized Body shall post on its website the reference price of reimbursed medicinal products and the maximum wholesale and retail premiums.

8. Decisions stipulated by this Article for state regulation of medicinal products prices shall enter into force no later than six months after their official publication.

CHAPTER 4

THE DISCOVERY OF MEDICINAL PRODUCTS: STATE REGISTRATION OF MEDICINAL PRODUCTS AND POST-REGISTRATION PHARMACOVIGILANCE

Article 12. The discovery of Medicinal products

1. The discovery of medicinal products includes the searching and discovery of new medicinal material, preclinical study, and clinical trials, the study of adverse reactions, the assessment of safety and efficacy, and the development of the composition, technology, quality control methods, and standardization criteria.

2. The rights of creators of medicinal products shall be protected by the legislation regulating intellectual property.

Article 13. Preclinical study

1. Preclinical research shall be carried out in accordance with the GLP Rules defined by the Authorized Body of the Republic of Armenia. The GLP Rules shall be posted on the official website of the Authorized Body.

Article 14. Clinical Trials

1. Clinical trials shall be carried out in accordance with the GCP Rules defined by the Authorized Body. The GCP Rules shall be posted on the official website of the Authorized Body.

2. The permit to carry out clinical trials shall be issued by the Authorized Body, which shall also approve the trials program and attached documents based on the positive expert examination conclusion and the positive conclusion of the ethics Committee for clinical trials.

3. The Republic of Armenia Government shall approve the procedure of issuing permits for clinical trials, the procedure of carrying out clinical trials, and the lists of required documents. Experts carrying out the expert examination of the trials materials

and the ethics Committee members shall sign, for each clinical trial, a statement in the form approved by the Authorized Body on the absence of conflicts of interest and on confidentiality. The powers of Committee member refusing to sign such statement shall be terminated.

4. The investigational medicinal product undergoing clinical trial shall be manufactured in accordance with the requirements defined by this Law.

5. Participation in clinical trials shall be voluntary. Clinical trials may be carried out with the written consent of the tried person or his legal representative, provided there is a concluded contract with the tried person or his legal representative. The tried person (or legal representative) shall be informed in writing about the tried product, its safety, expected efficacy, hazard, trial conditions, goal, and duration, client actions in case of inflicting health damage, life and health insurance conditions, and safeguards of the confidentiality of his participation.

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

7. The following may not be engaged in clinical trials:

1) Arrested persons, detained persons, and persons convicted to imprisonment;

2) Military servicemen;

3) Minors, unless the tried investigational medicinal product is intended for minors, and if the results of clinical trials of the same product among adults were positive. The written consent of the legal representative of the minor shall be required for participation of the minor in clinical trials; and

4) Pregnant women and breastfeeding mothers.

8. Issuance of the permit to carry out clinical trials shall be rejected if:

1) The documents presented are incomplete and/or do not contain all of the required information;

2) The results of the preclinical research and clinical trials were negative or insufficient;

3) The expert examination and/or ethics Committee conclusions is/are negative;

4) Justified and credible negative data has been received from foreign or international specialized structures and the competent authorities regulating the medicinal products sphere in other countries; or

5) The requirements of Paragraphs 1, 4, 5, 6, or 7 of this Article have been violated.

9. The client that requested the clinical trials shall be responsible for the accuracy and correctness of the presented data on clinical trials.

10. The client that requested the clinical trials shall inform the Authorized Body, in the procedure and time periods set by the Authorized Body, about cases of serious adverse reactions that occur during the trials (death, life-threatening situation, situation requiring hospitalization, incapacity, or infliction of physical mutilation or congenital defects), as well as about starting, terminating, or ending the trials, and submit a report in a form established by the Authorized Body.

11. Oversight of clinical trials shall be carried out in the procedure stipulated by law. Inspection thereof shall be organized by the Authorized Body under the procedure stipulated by law. The Authorized Body may request the client to change the clinical trials program or to terminate it. The procedure of carrying out inspection and terminating clinical trials, as well as amending or supplementing the program of clinical trials shall be defined by the Authorized Body.

12. A clinical trial shall be terminated if the life and/or health of the tried person are endangered, or if the requirements of this Law on clinical trials have been breached, or if the GCP rules of medical ethics adopted by the Authorized Body have been breached, or the medicinal product or the researched investigational medicinal product is not sufficiently effective or safe.

13. The Authorized Body shall compile a register of authorized and rejected clinical trials in accordance with the form approved by the authorized body. Such register shall contain data on clients, tried products, the trial objective, start, and end, and shall ensure the publicity of such register on its official website.

14. A decision to refuse issuing a permit for a clinical trial or a decision to terminate a clinical trial may be appealed in court or under the procedure stipulated by the Republic of Armenia Law on the Foundations of Administration and Administrative Proceedings.

15. It shall be prohibited to violate the clinical trial requirements stipulated by this Law, or to falsify or conceal the results. Failure to comply shall give rise to liability stipulated by law.

16. Damage inflicted upon a tried person as a result of clinical trials shall be compensated under the procedure stipulated by the Republic of Armenia laws.

17. Medicinal products or investigational medicinal products undergoing clinical trials in other countries may be used to treat patients that suffer from a life-threatening illness, provided that the permission of the Authorized Body has been received in accordance with the procedure stipulated by this Article.

18. The powers of an expert performing the expert examination of clinical trials materials shall be terminated if, after signing a statement of the form stipulated by Paragraph 3 of Article 14 of this Law, the Authorized Body has become aware of undisclosed information on the existence of a conflict of interests with respect to such clinical trial. The powers of an expert performing the expert examination of clinical trials materials shall be terminated within three working days of the Authorized Body becoming aware of such information.

Article 15. Objectives and Functions of the Clinical Trials Ethics Committee

1. The clinical trials Ethics Committee shall be a non-governmental body.

2. The clinical trials Ethics Committee shall consist of at least five members. The composition of the clinical trials Ethics Committee shall include a doctor, a pharmacist, a lawyer, and a representative of a non-governmental organization engaged in patient rights protection. The clinical trials Ethics Committee members' selection procedure, composition, and operating procedure shall be defined by the Authorized Body.

3. The clinical trials Ethics Committee member term in office shall be five years. A member of the clinical trials Ethics Committee may serve for only one consecutive term. A member of the clinical trials Ethics Committee shall, in the exercise of his powers, be independent and shall abide only by the Republic of Armenia Constitution and laws.

4. The Authorized Body shall terminate the powers of a member of the clinical trials Ethics Committee if, after signing a statement of the form stipulated by Paragraph 3 of Article 14 of this Law, the Authorized Body has become aware of undisclosed information on the existence of a conflict of interests with respect to such clinical trial. The powers of a member of the clinical trials Ethics Committee shall be terminated within three working days of the Authorized Body becoming aware of such information.

5. If a member of the clinical trials Ethics Committee has signed a statement of the form stipulated by Paragraph 3 of Article 14 of this Law, such Committee member shall not participate in the issuance of a conclusion on the respective clinical trial.

6. The objectives of the activities of the clinical trials Ethics Committee shall be:

1) Utmost protection of the rights of all stakeholders in the clinical trials of medicinal products and investigational medicinal products in the Republic of Armenia; and

2) Safeguarding the voluntary nature of participation in clinical trials of medicinal product and safeguarding the security of the participants.

7. The clinical trials Ethics Committee shall, based on the provisions of Paragraph 5 of Article 14 of this Law, carry out the following functions:

1) Evaluation of the clinical trials of medicinal products and researched investigational products from an ethics standpoint in accordance with the requirements on GCP adopted by the Authorized Body and, as a result, issuing a positive or negative conclusion; and

2) Evaluation of amendments to the clinical trials program and other documents from an ethics standpoint in accordance with the requirements on GCP adopted by the Authorized Body and, as a result, issuing a positive or negative conclusion.

Article 16. State Registration of Medicinal products

1. In the Republic of Armenia, it shall be permitted to manufacture, import, distribute, dispense, sell, and use medicinal products that are registered in the Republic of Armenia, except for medicinal products stipulated by this Law.

2. The registration of medicinal product, refusal to register, and suspension and voiding of the registration of medicinal product shall, on the basis of an expect conclusion, be performed by the Authorized Body in accordance with the procedure established by the Republic of Armenia Government, save for veterinary vaccines, plasmas, and diagnostic materials, for which state registration, refusal to register, suspension, and voiding shall be reserved for the authorized state body in the field of agriculture under the procedure established by the Republic of Armenia Government.

3. In the Republic of Armenia, medicinal products shall be registered under the general procedure and under simplified procedures. A simplified procedure shall be applied for medicinal products registered in a member state of the international professional organization defined by a decree of the Republic of Armenia Government or medicinal products prequalified by the World Health Organization.

4. Medicinal products registration shall be based on the scientifically-justified criteria of product safety, efficacy, and quality, which are adopted under the procedure stipulated by the Republic of Armenia legislation, as well as on documents adopted by the international professional organization defined by a decree of the Republic of Armenia Government, taking into consideration also the factors of potential harm to the environment.

5. Registration shall be required for every name, ingredient, strength, dosage form, presentation, new indication, manufacturer (including every performer of the production process), and registration certificate holder of a medicinal product.

6. The primary and/or external package, label, color mock-ups of packages, Summary of products characteristics (SmPC), instruction for use (PIL), and quality specifications of the medicinal product shall be approved during registration.

7. The quality of products, substances, excipients, container, and closure material of medicinal product subject to registration in the Republic of Armenia shall correspond to the requirements of pharmacopeias included in the list approved under the procedure defined by this Law. Studies of quality, safety, and efficacy of medicinal products registered in the Republic of Armenia shall be performed in accordance with the documents of the international professional organization defined by a decree of the Republic of Armenia Government.

8. It shall be prohibited to register medicinal products with the same substances with a name that is the same or similar to a confusing extent. The requirements on medicinal products names shall be defined by the Authorized Body.

9. For purposes of registration, the applicant may be the manufacturer or another sole entrepreneur or legal entity responsible for the product, which shall, after registration, be deemed the registration certificate holder. Registration documents may also be presented by a person authorized by the applicant under the procedure stipulated by the Republic of Armenia legislation. The applicant shall be responsible for the accuracy and correctness of the presented data.

10. The Republic of Armenia Government shall approve the procedure of expert examinations performed for medicinal product registration, re-registration, and certificate maturity extension, defining the form of the conclusion issued on the basis of

expert examination performed for registration, re-registration, and certificate maturity extension for new medicinal products, reproduced medicinal products, biosimilars, combinations of medicinal products, homeopathic medicinal products, biological medicinal products, including those derived from blood or plasma, immunological medicinal products, radioactive medicinal products, veterinary medicinal products (including animal fodder containing substances), herbal medicinal products (including those packaged in consumer packaging and labeled medicinal herb materials), and antiseptic and anti-parasitic medicinal products destroying disease agents for skin, mucous membrane, hair, and nails, as well as the insects carrying them and parasites. The Republic of Armenia Government shall also approve the lists of documents required for performing expert examinations in accordance with the documents of the international professional organization defined by a decree of the Republic of Armenia Government.

11. The expert examination for registration of medicinal products for which demand is low, but which are of major therapeutic and public health interest intended for the treatment of serious or life threatening diseases or condition, may be performed in the framework of the government order. The list of medicinal products for which demand is low, but which are vitally necessary shall be approved by the Authorized Body.

12. Reports of preclinical research and/or clinical trials shall be required for registration of bioanalogues, as well as for new combinations of medicinal products or medicinal products reproduced in a new strength different from the original or a new dosage form or medicinal products reproduced with a new indication.

13. The maximum total duration of registration of medicinal products shall be 150 calendar days, which shall include the time of the expert examination performed for registration, the maximum duration of which shall be 140 calendar days, except for medicinal products registered in a country that is a member of the international professional organization defined by a decree of the Republic of Armenia Government, for which the maximum duration of medicinal product registration shall be 31 calendar days, which shall include the time of the expert examination performed for registration, the maximum duration of which shall be 21 calendar days. In case the applicant supplements the documents during the expert examination, the expert examination shall be extended by 10 calendar days.

14. The Authorized Body shall ensure the confidentiality of such data in the documents submitted for registration, which comprises information protected by laws of the Republic of Armenia and is not subject to disclosure. The expert performing the

expert examination for the purpose of registration shall sign a statement in the form approved by the Authorized Body on the absence of conflicts of interest and on confidentiality.

15. For the registration of generics, the applicant shall not be required to present preclinical research and/or clinical trials data, if the applicant submits documents proving that the medicinal product is reproduced from the original medicinal product that has been registered in the Republic of Armenia or a country that is a member of the international professional organization defined by a decree of the Republic of Armenia Government for at least eight years. Such reproduced medicinal product may circulate in the Republic of Armenia for 10 years after the registration of the original medicinal product. If the registration certificate holder registers one or more new indications during the 10-year period, such time period shall be extended by a maximum of 10 more years. The applicant shall not present bioequivalence studies data for generic medicinal product, if the documents submitted by the applicant confirm that this medicinal product was applied in the Republic of Armenia or a country that is a member of the international professional organization defined by a decree of the Republic of Armenia Government for more than 10 years. In such case, the applicant shall submit only appropriate data from the scientific literature.

16. An applicant may refuse registration at any stage of the expert examination. Six months after being duly notified of the need to submit supplementary or missing materials required during the expert examination, if they are not submitted, the expert examination shall be terminated, and the application shall be rejected.

17. The Authorized Body may carry out pre-registration inspection for the purpose of evaluating the conformity of the product or the production process with the documents submitted during the expert examination for the registration of medicinal products. The inspection stipulated by this Paragraph shall be carried out directly at the production premises, as well as in places where preclinical research, clinical trials, and bioequivalence studies are performed (including those performed by contractors). The procedure of inspection and the procedure of recognizing the inspection reports of the competent authorities of other countries shall be defined by the Republic of Armenia Government. Expenses related to pre-registration inspection shall be compensated by the applicant on the basis of a contract concluded between the parties under the procedure provided by law. For continuous evaluation of the risk-benefit ratio during the inspection, the Authorized Body may demand the registration certificate holder to present data related to the registration of the respective medicine or other related data.

18. The medicinal product registration term shall be five years, calculated from the date on which the order of the Authorized Body on the medicinal product registration enters into effect. As a result of the registration, a registration certificate shall be issued, and the registered medicinal product shall be included in the register. The Authorized Body shall approve the registration certificate form, register form, and register compilation procedure. The medicinal product primary and/or external package, label, SmPC and PIL in Armenian, shall be attached to the registration certificate, and shall be the basis for identification of the medicinal products, quality control, and/or official information on the medicinal product during all stages of the circulation of medicinal products in the Republic of Armenia. The Authorized Body shall ensure publicity of the register, the medicinal product primary and/or external package, label, SmPC and PIL attached to the registration certificate, as well as their posting on the official website of the Authorized Body.

19. After the registration time period expires, reregistration for a term of five years may be performed under the procedure established by the Republic of Armenia Government based on reassessment of the product safety, efficacy, and quality. After the reregistration term expires, the registration certificate maturity may be extended with the consent of the registration certificate holder, once every five years, based on the results of professional post-registration monitoring of safety by the Authorized Body. The maximum time period of medicinal product reregistration shall be 31 calendar days, which shall include the time of the expert examination performed for registration, the maximum duration of which shall be 21 calendar days. The maximum time period for medicinal product registration certificate maturity extension shall be 10 calendar days. The medicinal product reregistration and extension of the registration certificate term shall, based on a positive conclusion of the expert examination, be performed by the Authorized Body.

20. The Republic of Armenia Government shall define the list of variations related to registered medicinal products, for which new registration shall not be required, and for which the medicinal product registration certificate shall be restated.

21. State tax shall be collected for registration, reregistration, restating the certificate, and extension of the maturity in the amount and procedure stipulated by the Republic of Armenia Law on State Tax.

22. The medicinal product registration certificate holder shall bear liability stipulated by law for the safety, efficacy, and quality of the registered product, and shall immediately communicate to the Authorized Body in writing any new data concerning them and/or any change that was found and/or made during the post-registration period, including data from the

competent authority on product application prohibitions or limitations. The Republic of Armenia Government shall define the procedure of submission and expert examination of such changes and data, as well as the list of required documents. Changes to medicinal product registered under the simplified procedure shall be approved by the competent body of a country that is a member of the international professional organization defined by a decree of the Republic of Armenia Government

23. Registration shall not be required for:

1) Medicinal products prepared in a pharmacy;

2) Medicinal products exported from the Republic of Armenia;

3) Medicinal products manufactured in the Republic of Armenia only for the purpose of exports;

4) Medicinal products used for scientific and preclinical research and clinical trials, as well as medicinal products used with a special permission of the Authorized Body, investigational medicinal products, and samples of veterinary medicinal products intended for trials on animals;

5) Samples intended for registration in the Republic of Armenia; and

6) Medicinal products imported for presentation in exhibitions: samples imported for presentation in exhibitions shall not be usable and shall be exported or destroyed in accordance with the requirements defined by the Republic of Armenia legislation and other legal acts.

24. At the time of registration, it shall be determined whether the medicinal product shall be sold with or without prescription, and whether or not it shall be a controlled medicinal product. The medicinal product shall be classified as a medicinal product dispensed with a prescription if:

1) The medicinal product may directly or indirectly harm patient health in case of use according to the instruction, but outside the supervision of a doctor;

2) The medicinal product may harm patient health as a result of the majority of patients using it not in accordance with the prescription;

3) The medicinal product contains substances the pharmaceutical activity and/or adverse reactions of which require further studies;

4) The medicinal product is introduced into the body in parenteral way;

5) The medicinal product contains narcotics or psychotropic (psychoactive) substances in excess of the quantities set by the Authorized Body;

6) The medicinal product poses a significant threat of abuse, creation of addiction, or use for unlawful purposes;

7) The medicinal product contains substances that, in view of pharmaceutical peculiarities, are equated to the medicinal products specified in sub-paragraph (6) above;

8) The medicinal product is intended only for use in a hospital setting;

9) The medicinal product is used to treat illnesses that are diagnosed in a medical institution, although medicinal product treatment and subsequent supervision by a doctor may be performed in a non-hospital setting; or

10) The medicinal product is intended for non-hospital treatment, but the use of the medicinal product may be accompanied with serious adverse reactions that require supervision by a doctor throughout the treatment.

25. The Authorized Body shall define the procedure of determining whether a medicinal product belongs to the category that is with or without prescription, as well as the procedure of revising such categories. The Authorized Body shall ensure the publicity of lists of prescription medicinal products, non-prescription medicinal products, and controlled medicinal products, as well as their posting on the official website of the Authorized Body.

26. To ensure the accessibility of medicinal products, agreements concluded with member states of the international professional organization defined by a decree of the Republic of Armenia Government may contemplate cases in which the registrations of certain medicinal products in such countries shall be recognized under the procedure defined by the Republic of Armenia Government and of including such medicinal products in the register. For the purpose of registration of medicinal products in the Republic of Armenia, the Authorized Body may address applicants at its initiative and with its own resources.

27. Medicinal product registration, reregistration, and certificate maturity extension shall be rejected if the expert examination finds that:

1) Data confirming safety and/or efficacy is missing or is not sufficiently justified, and/or the threat to health exceeds the reported benefit from use;

2) The quality does not correspond to the requirements defined by the legislation and other legal acts, or the actual quality and quantity composition does not match what was presented in the registration documents;

3) The production does not correspond to the GMP rules approved by the Authorized Body;

4) The product name, SmPC, packaging, labeling, marking, or insert do not correspond to the requirements defined by the Republic of Armenia legislation and other legal acts;

5) Foreign or international structures or the competent bodies of other countries, which regulate the sphere of medicinal products, have provided justified and credible negative information on the medicinal product;

6) The medicinal product contains chlorofluorocarbons (freons), except when the dosage forms not containing Freon has not been developed yet;

7) Incomplete or obviously false or distorted data or documents have been presented;

8) The product is not registered in the applicant's country, except for medicinal products registered in a member state of the international professional organization defined by a decree of the Republic of Armenia Government;

9) There are unfounded deviations from the documents adopted by the international professional organization defined by a decree of the Republic of Armenia Government;

10) The residual quantities of veterinary medicinal product in foodstuff of animal origin exceed the maximum limits set by the Republic of Armenia legislation and other legal acts;

11) The medicinal product name coincides with a medicinal product name that is already registered, but the active ingredients or their quantities are different;

12) The PIL and SmPC of medicinal product registered under the simplified procedure do not correspond to the PIL and SmPC of the medicinal product registered in a member state of the international professional organization defined by a decree of the Republic of Armenia Government; or

13) The medicinal product contains excipients prohibited in medicinal product content, the list of which shall be approved by the Authorized Body.

28. In case of rejecting medicinal product registration, reregistration, or certificate maturity extension, or when the expert examination is terminated in cases stipulated by this Law, the documents and samples submitted for registration shall not be returned.

29. The medicinal product registration, reregistration, or certificate maturity extension shall be declared void if:

1) Non-conformity of safety, efficacy, and quality with the established requirements, specifications, and new scientific data has been discovered, which poses a threat to human life and cannot be corrected;

2) Justified and credible negative data about the medicinal product has been received from foreign or international specialized structures and the competent authorities regulating the medicinal products in other countries;

3) The results of quality testing of three different series after product registration were negative; or

4) During the post-registration safety monitoring, cases of serious adverse reactions were documented (death, life threat, requiring hospitalization, incapacity, or inflicting physical mutilation or congenital defects).

30. In case of declaring medicinal product registration as void, it shall be prohibited to manufacture, import, distribute, dispense, sell, or apply such medicinal product.

31. The registration of medicinal product shall be suspended if:

1) The registration certificate holder has filed a substantiated application;

2) Non-conformity of safety, efficacy, and quality with the established requirements, specifications, or new scientific data has been discovered, which can be corrected;

3) The registration certificate holder has not communicated new data on product quality, safety, or efficacy, or has not made changes in the registration documents in accordance with the new data; or

4) The registration certificate holder has made changes in the registered medicinal product documents or product packaging, label, or marking, or the use and application instructions, which were not agreed upon with the Authorized Body.

32. The suspension of medicinal product registration is the temporary ceasing of medicinal product registration in the territory of the Republic of Armenia. In case of suspending medicinal product registration, it shall be temporarily prohibited to manufacture, import, distribute, dispense, sell, or apply such medicinal product. In the cases provided by Paragraph 31(1) of this Article, the medicinal product registration shall be suspended for a term submitted by the registration certificate holder. In the cases provided by Paragraph 31(2)-31(4) of this Article, the medicinal product registration shall be suspended until the violations or the non-conformities of the registration certificate holder are rectified.

33. If the medicinal product registration certificate holder informed the Authorized Body in writing about it intention to cease bearing the obligations of the medicinal product registration certificate holder in the Republic of Armenia territory, the

medicinal product shall continue to be deemed registered in the Republic of Armenia until the end of its registration term, and the obligations of the medicinal product registration certificate holder shall be transferred to the entity importing such medicinal product under the procedure stipulated by the Republic of Armenia legislation.

34. A decision on rejecting registration, reregistration, or certificate maturity extension, or a decision on voiding the registration of medicinal product may be appealed in court or under the procedure stipulated by the Republic of Armenia Law on the Foundations of Administration and Administrative Proceedings.

Article 17. Presenting Information on adverse reaction and Counterfeit Products

1. An adverse reaction is the response to a medicinal product which is noxious and unintended and which occurs at doses normally used in accordance with the instructions for use. The absence of drug efficacy or the consequences of overdosing shall not be deemed adverse reactions.

2. The medicinal product registration certificate holder shall document the cases of adverse reactions and report them under the procedure established by the Authorized Body.

3. The medicinal product registration certificate holder may not communicate to the public the information collected about the adverse reactions of registered products without first communicating them to the Authorized Body.

4. Health sector specialists and entities involved in the circulation of medicinal products shall inform the Authorized Body, under the procedure established by the Authorized Body, about suspected adverse reactions.

5. Anyone may inform the Authorized Body, health sector specialists, and entities involved in the circulation of medicinal products about adverse reactions of medicinal product under the procedure established by the Authorized Body.

6. The Authorized Body shall compile a register of adverse reactions of medicinal products and shall organize professional monitoring of adverse reactions and data analysis. The Authorized Body shall approve the form of a register of adverse reactions of medicinal products. Based on an expert conclusion, the Authorized Body shall adopt an appropriate decision on suspending or voiding registration or on amending the SmPC and PIL, and shall inform the registration certificate holder thereof.

7. The Authorized Body shall publish on its official website the confirmed information about serious adverse reactions (death, life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or congenital anomaly/birth defect.) without disclosing information about individuals, and shall inform the relevant international professional organizations about them.

8. The registration certificate holder shall inform the Authorized Body about cases of serious adverse reactions (death, life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or congenital anomaly/birth defect) under the procedure established by the Authorized Body. In case of a serious adverse reaction (death, life-threatening situation, situation requiring hospitalization, incapacity, or infliction of physical mutilation or congenital defects), the circulation of the medicinal product shall be terminated, and it shall be removed from circulation under the procedure defined by Paragraph 2 of Article 23 of this Law.

9. The Authorized Body shall define the procedure of collecting information on adverse reactions, communicating, monitoring, reporting, and data analysis

10. Health sector specialists, entities involved in the circulation of medicinal products, consumers, and the registration certificate holder shall, under the procedure established by the Authorized Body, also inform the Authorized Body about the lack of efficacy of medicinal products, about wrong use, and about suspected counterfeiting.

CHAPTER 5

THE PRODUCTION OF MEDICINAL PRODUCTS, SUBSTANCES, AND INVESTIGATIONAL MEDICINAL PRODUCTS; PROCESSING OF MEDICINAL HERB MATERIAL AND PREPARATION OF MEDICINES

Article 18. The Manufacture of Medicinal products

1. The manufacture of medicinal products, substances, and investigational medicinal products, and the processing of medicinal herb material shall be carried out by legal entities or sole entrepreneurs that have manufacturing license for medicinal products. The existence of a license to manufacture medicinal products is mandatory for carrying out any production process. A license to manufacture medicinal products shall not be required only for acquiring and keeping inputs materials.

2. A license to manufacture medicinal products shall be issued by the Authorized Body on the basis of a conclusion of the expert examination, under the procedure established by the Republic of Armenia Government, except for a license to manufacture medicinal products containing narcotics and psychotropic (psychoactive) substances, which shall be issued by the Republic of Armenia Government. A license to manufacture medicinal products shall have an insert that shall contain requirements and conditions, the list of which shall be approved under the procedure of licensing the production of medicinal products approved in accordance with law.

3. The manufacture of medicinal products, substances, and Investigational medicinal products shall be carried out in accordance with the GMP rules approved by the Authorized Body. The GMP rules approved by the Authorized Body shall be posted on the official website of the Authorized Body.

4. The Authorized Body shall issue to a licensed manufacturer a certificate of GMP compliance on the basis of the inspection report. Such inspection is a process of evaluating the conformity of medicinal products production (including subcontracted production) with the GMP rules with a view to safeguarding the quality of medicinal products circulating in the Republic of Armenia, which includes, among other things, an evaluation of the performance of a quality control laboratory (including the laboratory control performed on the basis of a contract). Expenses related to inspection, except for special

inspection, shall be reimbursed by the applicant on the basis of a contract concluded between the parties under the procedure stipulated by law.

5. The following are the types of inspections stipulated by this Article:

1) General inspection, which includes the evaluation of conformity to the general principles of the GMP rules and is carried out prior to issuing the medicinal products manufacturing license and the GMP certificate, on the basis of the medicinal product manufacturer's request;

2) Current (planned/recurrent) inspection, which includes the evaluation of conformity to all the components of the GMP and is carried out as part of the annual inspection plan, on the basis of the medicinal product manufacturer's request;

3) Pre-registration inspection, which is carried out for evaluating the conformity of the product or the production process to the documents submitted during the expert examination performed for the registration of the medicinal product; and

4) Special inspection, which is carried out when it is necessary to reveal circumstances (including grounded reports of issues related to quality and safety), for the discovery of which the manufacturer is not given advance notice of the inspection.

6. In production facilities of legal entities and sole entrepreneurs holding a license to manufacture medicinal products, in the first three years after receiving such license, recurrent inspection shall be carried out every year, after which they shall be carried out once every two years.

7. State tax shall be collected for issuing the GMP certificate, in the amount and procedure stipulated by the Republic of Armenia Law on State Tax.

8. The license to manufacture medicinal products shall, in addition to cases stipulated by the Republic of Armenia Law on Licensing, be suspended in the following cases:

1) In case of violation of the GMP rules discovered during the inspection of the medicinal products manufacturing for conformity to the GMP rules (except for the case stipulated by Paragraph 5(1) of this Article), about which a legal entity or sole entrepreneur holding a license to manufacture medicinal products was duly notified, but failed to rectify them during the reasonable time set by the licensing authority; or

2) In case of not submitting an application for inspection stipulated by Paragraph 5(2) of this Article or for ensuring the frequency specified in Paragraph 6 of this Article.

9. In the cases stipulated by Paragraphs 8(1) and 8(2) of this Article, the license shall be suspended until such time when the causes of the violation are eliminated.

10. The Republic of Armenia Government shall define the procedure of inspection conformity of the production of medicinal products and substances to the GMP rules and the procedure of issuing the GMP certificate, as well as the procedure of carrying out the expert examination for licensing the production of medicinal products and the list of the necessary documents.

11. The manufacturer shall guarantee product quality during the established expiry period, subject to ensuring the required conditions of storage.

12. Every manufacturer shall have at least one qualified person meeting the requirements defined by the Authorized Body.

13. The quality of substances, medicinal herb material, excipients, containers, and closure materials used in production shall correspond to the requirements of monographs and/or quality specifications of pharmacopeias included in the list approved under the procedure defined by this Law.

14. The manufacturer shall guarantee the use in production of substances manufactured in accordance with the GMP rules, and carry out evaluation of conformity to the GMP on its own or based on a contract.

15. The manufacturer shall ensure the credibility, timeliness, and conformity of information about its product with the requirements defined by this Law.

16. In the Republic of Armenia, medicinal herb material shall be processed in accordance with the GACP Rules approved by the Authorized Body. The GACP Rules shall be posted on the official website of the Authorized Body.

17. It shall be prohibited:

1) To manufacture counterfeit medicinal products and substances;

2) To manufacture unregistered medicinal products, except for the cases stipulated by sub-paragraphs 23(2) to 23(5) of Article 16 of this Law; or

3) To manufacture medicinal products, substances, medicinal herb material, and Investigational medicinal products in violation of the requirements defined by this Law.

Article 19. The Preparation of Medicinal products

1. Medicinal products may be prepared only by pharmacies that correspond to the requirements of the Government decree adopted in accordance with Paragraph 1 of Article 25 of this Law, and the license of which contains a reference to the preparation of medicinal products. Medicinal products shall be prepared in pharmacies according to prescriptions or official formulations approved by the Authorized Body.

2. It shall be prohibited to prepare capillary-injection solutions in pharmacies, except for pharmacies that are a structural subdivision of a medical institution, in which it shall be permitted to prepare capillary-injection solutions under the procedure stipulated by this Law, if such solutions do not circulate in the Republic of Armenia under the procedure stipulated by law.

3. Licensed legal entities and sole entrepreneurs carrying out pharmacy activities shall bear liability defined by law for the quality and design, packaging, labeling accuracy, and proper storage and dispensing of medicinal products prepared in the pharmacy.

4. Medicinal products prepared and retail-weighed in the pharmacy shall be sold only from such pharmacy.

5. The preparation of counterfeit medicinal products shall be prohibited and shall give rise to liability defined by law.

Article 20. Packaging and Labeling of Medicinal products

1. Medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be packaged and labeled.

2. The requirements on the packaging and labeling of medicinal products, substances, medicinal herb material, and Investigational medicinal products, including the requirements on the PIL, as well as the requirements on the SmPC shall be defined by the Authorized Body.

3. Medicinal products sold retail shall have an insert in the Armenian language under the procedure defined by the Authorized Body. The sale of medicinal products from pharmacies with a PIL in the Armenian language shall be mandatory if a buyer so demands.

4. The medicinal product package may contain symbols or a sign expressing the information listed in the requirements defined by the Authorized Body, as well as other information that corresponds to the SmPC of the medicinal product, is important for medical awareness, and does not contain advertisement. In the medicinal product marking, SmPC, and PIL, it shall be prohibited to include the name or trademark of the medicinal product supplier in the Republic of Armenia.

5. It shall be prohibited to specify medical indications in the use instructions and/or on the package of any product that is not deemed medicinal product (including cosmetic supplies and dietary supplements).

CHAPTER 6

IMPORTS, EXPORTS, STORAGE, AND TRANSPORTATION OF MEDICINAL PRODUCTS, SUBSTANCES, INVESTIGATIONAL MEDICINAL PRODUCTS, AND MEDICINAL HERB MATERIAL

Article 21. Imports and Exports of Medicinal products, Substances, Investigational medicinal products, and Medicinal Herb Material

1. Medicinal products, substances, Investigational medicinal products, and medicinal herb material shall be imported to the territory of the Republic of Armenia (brought into the Republic of Armenia by crossing the state border of the Republic of Armenia) and exported from the Republic of Armenia (taken out of the Republic of Armenia by crossing the state border of the Republic of Armenia) in accordance with the procedure approved by the Republic of Armenia Government.

2. The following shall have the right to import medicinal products, substances, Investigational medicinal products, and medicinal herb material into the Republic of Armenia territory:

1) Suppliers, provided they have a license for wholesale distribution of medicinal products;

2) The following, without having a license stipulated by this Law for wholesale distribution of medicinal products;

a. Legal entities or sole entrepreneurs the activities of which are related to research and trials of medicinal products, substances, and investigational medicinal product, or quality, efficacy, or safety controls—within the limits of the volume and assortment required for such activities;

b. Legal entities or sole entrepreneurs importing medicinal products in the framework of projects recognized as charitable or donation under the procedure stipulated by the legislation;

c. Legal entities or sole entrepreneurs that have a license to manufacture medicinal products in the Republic of Armenia—in case of importing substances and herbal materials for production purposes;

d. Representations or representatives of foreign manufacturers—when importing or exporting registration and/or trial samples (medicinal products, substances, investigational medicinal product and/or exhibition samples); and

e. Public administration institutions.

3. It shall be permitted to import for production purposes such substances and herbal substances, information about which is presented in the registration documents of the final product, except for substances and herbal substances imported for developing the dosage form and for medicinal products manufactured only for the purpose of exporting. In case the substances or herbal substances are imported by the medicinal product manufacturer, laboratory expert examination shall not be performed when issuing an import certificate.

4. It shall be permitted to import medicinal products, substances, Investigational medicinal products, and herbal substances on the basis of an import certificate, except for the cases stipulated by this Article. In case of export, a certificate shall be issued if the exporter so wishes. Import or export certificates shall be issued on the basis of the relevant expert examination conclusion under the procedure defined by the Republic of Armenia Government. The Republic of Armenia Government shall define the procedure of carrying out the expert examination for importing or exporting medicinal products, substances, Investigational medicinal products, and herbal substances, as well as the list of required documents.

5. Medicinal products registered in the Republic of Armenia may be imported into the Republic of Armenia territory, except for cases provided by law. Medicinal products registered in the Republic of Armenia may be imported into the Republic of Armenia in accordance with this Law by any entity having a license for wholesale distribution of medicinal products.

6. The medicinal product being registered shall not be required for issuing an import certificate:

1) In case of emergencies or threat of their emergence;

2) For medicinal products imported in the framework of charitable or philanthropic projects, provided there is a document confirming registration in a member state of the international professional organization defined by a decree of the Republic of Armenia Government or the prequalification by the World Health Organization, after obtaining the consent of the Authorized Body under the established procedure;

3) In the cases stipulated by Paragraphs 23(4) to 23(6) of Article 16 of this Law;

4) If there is a written decision of the Authorized Body, and the medicinal products are imported for the state's needs or for the health care and treatment of specific patients;

5) For bulk semi-finished products of medicinal products, which have passed all the stages of production, except for final packaging and marking, when their final product is registered in the Republic of Armenia, or when they are imported for such registration; and

6) In case of importing medicinal products designated for the animals of zoological parks.

7. Import or export certificates shall not be required:

1) For the treatment of an individual traveling to or from a foreign state, or for medicinal products of personal use, in quantities established by the Republic of Armenia Government;

2) For medicinal products imported for personal needs by the foreign and international organizations' diplomatic and consular representatives, staff, and family members living with them;

3) For medicinal products necessary for the treatment and care of drivers, staff, and passengers of transportation means arriving in the Republic of Armenia; and

4) For medicinal products necessary for the treatment and care of participants of international cultural and sports events and international research teams.

8. Importing and exporting medicinal products, substances, Investigational medicinal products, and medicinal herb material in the Republic of Armenia shall be rejected if:

1) The presented data or documents are incomplete or obviously false or distorted, or one of the documents required by the Republic of Armenia legislation or other legal acts is missing, and if the deficiencies have not been rectified during the established time period;

2) The imported medicinal products do not have state registration in the Republic of Armenia, except for cases provided by this Law;

3) The qualitative features of the imported medicinal products, substances, Investigational medicinal products, and medicinal herb material (hereinafter, "imported products") do not correspond to the requirements of pharmacopeias included in the list approved under the procedure defined by this Law or the quality specifications;

4) The imported product is expired;

5) The remaining expiry period on the imported product does not meet the requirements defined by the Republic of Armenia Government;

6) The product and the data in the accompanying documents are not consistent;

7) The indicators characterizing the medicinal product, which are reflected in the register, are missing in the packaging notes of the imported medicinal product or do not correspond to the registered sample;

8) The labeling or PIL of the imported medicinal product does not contain the excipients used in the medicinal product and subject to mandatory marking on the package as specified by the Authorized Body, and in case of medicinal products used by injection, locally, or eye treatment, the marking of any excipients is missing or does not correspond to the registered sample;

9) The expiry date information in the packaging notes of the imported product is missing or does not correspond to the registered sample;

10) Information on special conditions of medicinal product storage is missing in the packaging notes of the imported product or does not correspond to the registered sample;

11) The production series information is missing from the packaging notes of the imported product;

12) Special warnings are missing from the packaging notes of the imported product or do not correspond to the registered sample;

13) The permitted time of use after opening the primary package is missing from the packaging notes of the imported product or do not correspond to the registered sample;

14) The medicinal product and/or substances transportation and storage cold chain has been breached; or

15) The language of the packaging of imported medicinal product does not correspond to any of the languages accepted for packaging of medicinal products under the Republic of Armenia legislation.

9. The absence of the imported registration medicinal product insert in Armenian is not a basis for denying imports of the medicinal product. If the medicinal product does not have the insert in Armenian at the time of importation into the Republic of Armenia, its insert in Armenian shall be ensured after importation under the procedure stipulated by the Republic of Armenia legislation in accordance with Paragraph 3 of Article 20 of this Law.

10. The Republic of Armenia Government shall define the procedure and peculiarities of granting permission for parallel imports of medicinal products.

11. Grating permission for parallel imports of medicinal products shall be rejected if:

1) The medicinal product manufacturer or production country does not correspond to the medicinal product manufacturer or production country registered in the Republic of Armenia;

2) The dosage form or strength does not correspond to the dosage form or strength registered in the Republic of Armenia;

3) The medicinal product expiry date does not correspond to the medicinal product expiry date registered in the Republic of Armenia;

4) The medicinal product active ingredient is different from the medicinal product active ingredient registered in the Republic of Armenia;

5) The medicinal product anatomical, treatment, or chemical classification defined by the World Health Organization does not correspond to the medicinal product anatomical, treatment, or chemical classification registered in the Republic of Armenia;

6) The medicinal product commercial name does not correspond to the medicinal product commercial name registered in the Republic of Armenia;

7) The medicinal product use indications or counter-indications do not correspond to the medicinal product use indications or counter-indications registered in the Republic of Armenia;

8) The medicinal product is not registered in the country from which it was procured and is being imported into the Republic of Armenia; or

9) In the Republic of Armenia or in the country from which the medicinal product is being imported, the circulation of such medicinal product has been ceased in view of considerations of medicinal product safety, efficacy, and quality.

12. If the language of the packaging or labeling of medicinal product imported in parallel differ from the language of the packaging or labeling of medicinal product registered in the Republic of Armenia, the supplier that received the wholesale distribution license for such medicinal product shall, prior to selling, carry out re-packaging and re-labeling.

13. The supplier that received the wholesale distribution license for medicinal product imported in parallel shall secure such medicinal product with the medicinal product insert registered in the Republic of Armenia, adding to the notes its name, business address, and contact details for consumers.

14. In case of parallel imports, the supplier that received the wholesale distribution license for such medicinal product shall bear liability under Paragraph 22 of Article 16 of this Law.

15. A person holding a license to manufacture medicinal products in the Republic of Armenia shall, by 31 January of each year, submit to the Authorized Body a report on products exported in the preceding year, which shall contain information on the product name, strength, dosage form, manufacturer, series number, exported quantity, and country of exports. The report form and submission procedure shall be defined by the Authorized Body.

16. A person that has wholesale distribution license for medicinal product may not, during the term of such license (including the license suspension period), carry out pharmacy activities stipulated by law, except when it creates a separate legal entity that has an appropriate license for retail sale.

17. State tax shall be collected for issuing a certificate to import or export medicinal products, substances, medicinal herb material, and Investigational medicinal products, in the amount and procedure stipulated by the Republic of Armenia Law on State Tax.

Article 22. Medicinal product Transportation and Storage

1. Medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be stored in accordance with the GSP rules approved by the Authorized Body. The GSP rules approved by the Authorized Body shall be posted on the official website of the Authorized Body. The requirements of the GSP rules shall apply to the storage of medicinal products, substances, medicinal herb material, and Investigational medicinal products in customs warehouses.

2. Medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be transported in accordance with the GDP rules approved by the Authorized Body. The GDP rules approved by the Authorized Body shall be posted on the official website of the Authorized Body.

3. The transit transportation of medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be regulated by the customs regulation of the Republic of Armenia.

CHAPTER 7

SALE OF MEDICINAL PRODUCTS, SUBSTANCES, AND MEDICINAL HERB MATERIAL

Article 23. General Requirements on the Sale of Medicinal products, Substances, and Medicinal Herb Material

1. The sale of medicinal products, substances, and medicinal herb material in accordance with the procedure stipulated by this Law may be carried out by persons licensed to carry out pharmacy activities or wholesale distribution of medicinal products, about the sale volumes of which an annual report shall be submitted to the Authorized Body in the procedure established by the Authorized Body.

2. It shall be prohibited to sell medicinal products, counterfeit medicinal products, substances, medicinal herb material, or Investigational medicinal products that are not registered in the Republic of Armenia, or do not meet the quality requirements, or have expired, or have had their registration voided or suspended, or have had their circulation ceased (have been recalled), or

were imported in violation of the Republic of Armenia legislation. The Republic of Armenia Government shall define the procedure of reporting product issues under this Paragraph and ceasing circulation or removing from circulation (recall). The expenses of ceasing circulation and recall shall be born by the registration certificate holder or by the supplier.

3. After the end of the registration period, it shall be permitted to sell, up to the expiry date, such medicinal products that were, in accordance with the procedure stipulated by law, registered in the Republic of Armenia on the day of issuing the import certificate, or medicinal products manufactured in the Republic of Armenia, which were registered in the Republic of Armenia on the day of the manufacturer issuing the sale invoice.

Article 24. Wholesale Distribution of Medicinal products, Substances, and Herbal substances

1. The wholesale distribution of medicinal products, substances, and medicinal herbal substances shall be carried out by suppliers in accordance with the GDP rules approved by the Authorized Body.

2. A license for wholesale distribution of medicinal product shall be issued to a supplier by the Authorized Body on the basis of the conclusion of the expert examination, under the procedure defined by the Republic of Armenia Government. Together with the license for wholesale distribution of medicinal product, an insert shall be issued, which shall contain information on the following, which will be sold wholesale by the supplier and corresponds to the general conditions of storage: medicinal products or narcotics, medicinal products containing psychotropic (psychoactive) substances, blood components or medicinal products made from them, immunological medicinal products, radioactive medicinal products, medical gas, or medicinal products requiring cold chain.

3. Other requirements and conditions included in the license insert shall be defined under the wholesale distribution licensing procedure approved under the procedure defined by law.

4. Persons holding a manufacturing license of medicinal products in the Republic of Armenia may carry out wholesale distribution of their own products without a license for wholesale distribution of medicinal products.

5. Medicinal products prepared in the pharmacy and retail-weighed shall not be subject to wholesale distribution.

6. Based on the report of the general inspection, the Authorized Body shall issue a GDP certificate to a supplier that received the wholesale distribution license for medicinal products. Such inspection is a process of evaluating the supplier's (including in case of outsource) conformity to the GDP rules for the purpose of ensuring the quality of medicinal products circulating in the Republic of Armenia. The expenses of inspection (except for those related to special inspection) shall be compensated by the applicant on the basis of a contract concluded between the parties under the procedure stipulated by law. The Republic of Armenia Government shall define the procedure of inspection for the purpose of supplier certification and the procedure of issuing such certificates, as well as the procedure of expert examinations carried out for the purpose of licensing wholesale distribution activities, and the list of the required documents.

7. The following are the types of inspection stipulated by this Article:

1) General inspection, which includes the evaluation of conformity to the general principles of the GDP rules and is carried out prior to issuing the medicinal products wholesale distribution license and the GDP certificate, on the basis of the supplier's request;

2) Current (planned/recurrent) inspection, which includes the evaluation of conformity to all the components of the GDP and is carried out as part of the annual inspection plan, on the basis of the supplier's request; and

3) Special inspection, which is carried out when it is necessary to reveal circumstances (including grounded reports of issues related to quality and safety), for the discovery of which the supplier is not given advance notice of the inspection.

8. For legal entities and sole entrepreneurs holding a license for wholesale distribution of medicinal products, in the first three years after receiving such license, inspection shall be carried out every year, after which they shall be carried out once every two years.

9. The medicinal product wholesale distribution license shall, in addition to cases stipulated by the Republic of Armenia Law on Licensing, be suspended in the following cases:

1) In case of violation of the GDP rules discovered during the inspection of the medicinal products wholesale distribution for conformity to the GDP rules (except for the case stipulated by Paragraph 7(1) of this Article), about which a legal entity or sole entrepreneur holding a license to carry out wholesale distribution of medicinal products was duly notified, but failed to rectify them during the reasonable time set by the licensing authority; or

2) In case of not submitting an application for inspection stipulated by Paragraph 7(2) of this Article or for ensuring the frequency specified in Paragraph 8 of this Article.

10. Legal entities and sole entrepreneurs having a license for wholesale distribution of medicinal products shall designate a person responsible for the appropriate distribution activities, which shall comply with the requirements defined by the Authorized Body.

11. State tax shall be collected issuing a GDP certificate in the amount and procedure stipulated by the Republic of Armenia Law on State Tax.

12. Legal entities and sole entrepreneurs having a license for wholesale distribution of medicinal products shall, by 31 January of each year, submit to the Authorized Body a report on medicinal products sold wholesale by them. The report form and submission procedure shall be defined by the Authorized Body.

13. An official website shall be maintained, in the procedure defined by the Authorized Body, about legal entities and sole entrepreneurs having a license for wholesale distribution of medicinal products. The website shall provide comprehensive information on the availability of medicinal products included in the List of Essential Medicinal products, including the medicinal product commercial name, the maximum wholesale price premium, and the currently available (online) quantities.

14. The return, by a pharmacy to the same supplier holding the wholesale distribution license, and in accordance with the procedure stipulated by the Republic of Armenia legislation, of medicinal products not sold by the pharmacy shall not be deemed wholesale distribution of medicinal products for purposes of this Law. This provision shall also apply to the return, by a pharmacy to the same supplier holding the wholesale distribution license, and in accordance with the procedure stipulated by the Republic of Armenia legislation, of medicinal products not sold by the pharmacy when such pharmacy is undergoing liquidation. In such cases, the supplier holding the wholesale distribution license for such medicinal products shall bear liability for the medicinal product quality, safety, and efficacy.

Article 25. Retail Selling of Medicinal products

1. Retail selling of medicinal products shall be performed only in pharmacies, subject to having an appropriate license, and in accordance with the requirements defined by the Republic of Armenia legislation. A license for pharmacy activities shall have an insert that shall contain requirements and conditions in accordance with a list defined under the procedure of licensing pharmacy activities, which shall be approved under the procedure defined by law.

2. The requirements on the structure of pharmacies (those preparing medicinal products and those not preparing medicinal products), their subdivisions, technical and technological capacity, the education of employees (vocational, university, postgraduate, or additional), and work schedule, as well as the peculiarities of pharmacies and pharmacy activities in specific categories of settlements shall be defined by the Republic of Armenia Government. The Republic of Armenia Government shall define the requirements on pharmacy activities and the list of product types sold from pharmacies.

3. Legal entities or sole entrepreneurs holding a license for pharmacy activities may carry out delivery of medicinal products in accordance with the technical and professional requirements on delivery of medicinal products stipulated by the Republic of Armenia legislation. The technical and professional requirements on delivery of medicinal products shall be defined by the Republic of Armenia Government.

4. Retail sale of medicinal products from pharmacies shall be carried out with and without a prescription. The prescription forms, the procedure of filling prescriptions, the procedure of dispensing medicinal products (including electronically), and the procedure of recording medicinal products and substances shall be defined by the Republic of Armenia Government. The legal status of medicinal product with or without prescription shall be noted in the register.

5. Legal entities or sole entrepreneurs holding a license for pharmacy activities shall secure a minimum assortment in line with the List of Essential Medicinal products subject to sale or dispensing from pharmacies, provided that the List of Essential Medicinal products shall differ depending on whether a pharmacy operates in a rural or urban settlement. The minimum assortment in accordance with the List of Essential Medicinal products subject to sale or dispensing from pharmacies of urban or rural settlements shall be defined by the Authorized Body.

6. If a medicinal product included in the minimum assortment specified in Paragraph 5 of this Article is missing, the pharmacy shall be obliged, within 24 hours of a buyer presenting such requirement, to provide the required medicinal product to such buyer.

7. Medicinal product sole from a pharmacy in accordance with the medicinal product quality, efficacy, safety, and prescription (due quality) stipulated by the Republic of Armenia legislation may not be exchanged or returned. A violation of this provision shall give rise to administrative liability stipulated by law.

8. It shall be prohibited to sell medicinal products, which are dispensed with a prescription, without a prescription.

9. It shall be prohibited to fill prescriptions for or dispense or sell medicinal products, which are dispensed with a prescription, on a form that is not stipulated by the Republic of Armenia legislation.

10. Medicinal products shall be dispensed with a prescription according to the INN of the medicinal product. A pharmacy shall present to a person purchasing medicinal product comprehensive information about all medicinal products available in the pharmacy, which contain the same active ingredient, have the same strength and dosage form, and are interchangeable, including information about prices, without guiding. Dispensing a prescription with the trade name of the medicinal product shall be possible only if there is a reasoned justification of the doctor, one copy of which shall be presented to the pharmacy with the prescription, while the other shall be attached to the patient's medical documents. The Authorized Body shall prescribe the requirements on the justification for dispensing a prescription with the trade name of a medicinal product.

11. It shall be prohibited to provide non-pharmaceutical professional advice in a pharmacy.

12. A person holding a license for pharmacy activities may not carry out wholesale distribution of medicinal products during the validity term of such license (including when such license is suspended).

13. Veterinary medicinal products shall be sold at veterinary pharmacies, the requirements on the activities of which shall be defined by the Republic of Armenia Government.

14. The Republic of Armenia Government shall define the requirements on pharmacies that are structural subdivisions of a medical institution, as well as the requirements on the activities of such pharmacies.

Article 26. Destroying Medicinal products, Substances, Medicinal Herb Material, and Investigational medicinal products

1. Medicinal products, substances, medicinal herb material, and Investigational medicinal products, which have expired, are not registered, are counterfeit, are not fit for use, were acquired unlawfully, are of poor quality, or contain undisclosed ingredients shall be destroyed by a licensed legal entity or sole entrepreneur in accordance with the requirements on the disposal of hazardous waste under the Republic of Armenia legislation and other legal acts.

2. The disposal of medicinal products, substances, medicinal herb material, and Investigational medicinal products shall be paid for by such entity involved in the circulation, which owns them, or from other sources not prohibited by the Republic of Armenia legislation.

CHAPTER 8

INFORMATION ON MEDICINAL PRODUCTS; ADVERTISEMENT

Article 27. Information on Medicinal products

1. The goal of information on medicinal products is the safeguarding of their purposeful and effective use by means of providing credible information about them.

2. Information on medicinal products shall be complete, impartial, and credible, justified with scientific research and/or data confirmed upon registration. Information on medicinal products shall correspond to the requirements defined by the Authorized Body.

3. Information on medicinal products provided without a prescription may be published in professional and general publications in the form of scientific and information articles or use instructions (inserts), provided that the information does not contain elements of advertisement.

4. Information on medicinal products sold with a prescription may be presented only in professional publications and bulletins, in the form of scientific and information articles, monographs, reports presented in conferences and similar events, as well as the medicinal product use and application instructions. The Republic of Armenia Government shall approve the requirements on professional publications.

5. Disseminating information on medicinal products sold with a prescription in the mass media shall be prohibited.

6. Official information on medicinal products shall be published only by the Authorized Body.

7. The bulletin containing information on the essential medicinal products—the National Pharmacopeia—shall be published by the Authorized Body once every two years under the procedure defined by the Republic of Armenia Government.

Article 28. Medicinal product Advertisement

1. The advertisement of medicinal product is the dissemination of information for stimulating its prescription, supply, sale, application, and consumption, which is intended to create or maintain interest in the medicinal product and includes:

1) Advertisement of the medicinal product among consumers;

2) Advertisement of the medicinal product among persons working in the medical and pharmaceutical system, as well as in medical institutions;

3) Visits of representatives of sellers of medicinal products to persons working in the medical and pharmaceutical system, as well as visits to medical institutions;

4) Providing free samples of the medicinal product; and

5) Any other type of advertisement of the medicinal product.

2. Permission to advertise medicinal product shall be issued by the Authorized Body under the procedure defined by the Republic of Armenia Government. Permission to advertise veterinary vaccines, plasmas, and diagnostic materials shall be issued by the authorized state body in the field of agriculture under the procedure established by the Republic of Armenia Government. In case of advertising medicinal products in electronic and print mass media, the advertisement shall specify the number, day, month, year, and validity term of the state registration certificate of the medicinal product in the Republic of Armenia, as well as

the number and day, month, and year of the permission by the Ministry of Health of the Republic of Armenia. Outdoor advertisement of medicinal products shall be prohibited in the Republic of Armenia.

3. Advertisement text shall correspond to the SmPC information approved upon registration.

4. It shall be prohibited to advertise medicinal product not registered in the Republic of Armenia or medicinal product controlled in the Republic of Armenia or medicinal product prepared in a pharmacy according to a prescription or pharmacopeias.

5. It shall be prohibited to advertise any non-medicinal product (bioactive supplements, cosmetics, and the like) as means of treatment.

6. It the mass media, it is allowed to advertise only such medicinal product which is dispensed without a prescription and does not contain narcotics or psychotropic (psychoactive) materials.

7. The advertisement of medicinal products in the mass media may not contain materials that:

1) Create the impression that a doctor's advice or medical intervention is unnecessary;

2) Assure that the absolute efficacy of the medicinal product is guaranteed, that taking the medicinal product shall not cause adverse reactions, or that its effect exceeds or is equal to other treatment methods or other medicinal products;

3) assure that the person shall be completely healthy in case of taking the medicinal product;

4) Assure that in case of not taking the medicinal product; the person's health condition will deteriorate, except for advertisement carried out in the framework of the national immunization programs;

5) Aimed at children;

6) Contain citations of endorsement by scientists, medical professionals, or other well-known individuals or non-governmental organizations, which can stimulate the use of the medicinal product;

7) Propose using the medicinal product in food or for cosmetic purposes;

8) Assure that the medicinal product safety and efficacy are due to its natural origin;

9) May lead to wrong self-diagnosis by describing the history of the illness or through a detailed presentation;

10) Contain statements about health improvement, which are accompanied with incorrect, alarming, or misleading wording; or

11) Contain notions that are not related to the use of the medicinal product or are not credible.

8. When advertising medicinal products in the mass media, it shall be prohibited to mention the following illnesses:

1) Illnesses posing a threat to the environment;

3) Oncological illnesses;

4) Lasting insomnia;

5) Diabetes and other metabolic disease; or

6) Cardiovascular disease.

9. It shall be prohibited to provide medicinal product directly to a consumer or to persons working in the medical and pharmaceutical system for advertisement purposes.

10. Medicinal products registered in the Republic of Armenia among persons working in the medical and pharmaceutical system may be advertised only with the permission of the Authorized Body, precluding the use of the mass media.

11. Permission to advertise medicinal product shall be rejected if:

1) The documents for receiving advertisement permission are incomplete or obviously false or distorted, or any of the documents required by the Republic of Armenia legislation for issuing advertisement permission is missing, and the deficiencies have not been rectified during the established time period;

2) The medicinal products advertisement text contradicts this Law or the Republic of Armenia Law on Advertisement or the Republic of Armenia Law on Licensing or the Republic of Armenia Law on the Sanitary-Epidemiological Safety of the Population or the Republic of Armenia Law on Medical Care and Services for the Population or the Republic of Armenia Law on Transplanting Organs and/or Tissue to Humans or the Republic of Armenia Law on Donorship of Human Blood and Blood Elements and Transfusion Medical Care or the Republic of Armenia Law on Psychiatric Care, or normative legal acts adopted on the basis of such laws.

12. The Authorized Body shall define the list of data, which is provided to consumers and persons working in the medical and pharmaceutical system, and is specified in every document related to the medicinal product.

13. When advertising medicinal products among persons working in the medical and pharmaceutical system, it shall be prohibited to offer, provide, or promise free samples of the medicinal products, gifts, profit, or remuneration in money or in

kind. Persons working in the medical and pharmaceutical system shall be prohibited from demanding or accepting any encouragement, save for price discounts and privileges, as well as support to professional and scientific events.

14. An advertiser of medicinal product shall retain the advertisement materials and information, as per the list approved by the Authorized Body, for a minimum term of two years for the purpose of presenting for advertisement controls.

15. Medicinal product advertisement shall be regulated by the Republic of Armenia Law on Advertisement, unless this Law prescribes regulatory peculiarities thereof.

CHAPTER 9

SUPERVISION IN THE SPHERE OF MEDICINAL PRODUCTS; LIABILITY FOR VIOLATING THIS LAW

Article 29. State Supervision over the Circulation of Medicinal products

1. In the sphere of circulation of medicinal products, state supervision stipulated by law shall be carried out by the relevant body of state government authorized by law.

2. The quality of medicinal products, substances, medicinal plant material, and Investigational medicinal products circulating in the Republic of Armenia shall correspond to the requirements defined by this Law.

Article 30. Liability for Violating This Law

1. Persons violating the requirements of this Law shall bear liability under the procedure stipulated by the laws of the Republic of Armenia.

CHAPTER 10

FINAL AND TRANSITIONAL PROVISIONS

Article 31. Entry into Force

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

1) Article 11, which shall enter into force:

A. One and a half year after official publication, with respect to the state regulation of prices of reimbursed medicinal products purchased (in a centralized manner) by the Authorized Body;

B. From 1 January 2025, with respect to the state regulation of prices of reimbursed medicinal products purchased by medical institutions, including through pharmacies;

2) Paragraph 16 of Article 18, which shall enter into force five years after the official publication of this Law; and

3) Paragraphs 1 and 2 of Article 22, which shall enter into force three years after the official publication of this Law.

2. Persons that received a medicinal products production license prior to the entry into force of this Law, but do not have a certificate for GMP of medicinal products, shall be obliged, within three years of the entry into force of this Law, to receive such certificate.

3. Persons that received a license for wholesale distribution of medicinal products under the procedure stipulated by this Law shall be obliged, within three years of the entry into force of this Law, to receive a certificate for GDP under the procedure stipulated by this Law.

4. In case of failure to receive certificates for GMP or GDP in the time periods and procedure stipulated by Paragraphs 2 and 3 of this Article, the manufacturing or wholesale licensees shall be terminated by the licensing authority.

5. Persons holding a license for manufacturing or for pharmacy activities shall be obliged, within six months of the entry into force of this Law, to align the requirements and conditions of the licensed activity to the requirements of this Law.

6. For manufacturing and pharmacy activities licenses, for which this Law creates new conditions and requirements, the licensees shall be obliged, within six months of the entry into force of this Law, to restate their existing licenses. In case of failure

to restate the licenses during such period, the licenses shall be terminated by the Authorized Body of state government in the health sector.

7. Licenses for pharmacy activities carried out in the form of a pharmacy kiosk shall not be restated if the form in which the pharmacy activities are carried out is changed from a pharmacy kiosk to a pharmacy not preparing medicinal products.

8. In case of restating the licenses during the time period specified in Paragraph 6 of this Article, the state tax stipulated by the Republic of Armenia Law on State Tax for restating a license shall not be collected.

9. From the moment this Law enters into force, the Republic of Armenia Law on Medicinal products dated 27 October 1998 (Law HO-259) shall be repealed.

Republic of Armenia President S. Sargsyan

13 June 2016
Yerevan
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