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LEGAL FRAMEWORK FOR THE PHARMACEUTICAL SECTOR IN ARMENIA

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ENTERPRISE DEVELOPMENT AND MARKET COMPETITIVENESS PROJECT

LEGAL FRAMEWORK FOR THE PHARMACEUTICAL SECTOR IN ARMENIA

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List of Acronyms

GoA	Government of the Republic of Armenia
GMP	Good Manufacturing Practice
MoH	Ministry of Health of the Republic of Armenia
RA	Republic of Armenia
SCDMTE	Scientific Center for Drug and Medical Technology Expertise
USA	United States of America
WHO	World Health Organization

1. Legal Background

General Overview

The Law “On Medicines”¹ regulates the circulation of medicines in the Republic of Armenia (RA), including manufacture, dispensing, measurement, packaging, registration, quality control of medicines and other activities related to medicine preparation or destruction, acquisition, maintenance, storage, distribution, prescription, sale, export, import, drug information dissemination and promotion. The law also defines competences of state authorities of the RA in these fields.

In particular, the Law “On Medicines” regulates the following aspects of medicine circulation:

- right to engage in pharmaceutical activity,
- licensing of pharmaceutical activity,
- supply of medicines to the population,
- manufacture of medicines,
- preparation of medicines,
- sanctions for violation of rules for medicine preparation and manufacture,
- medicine labeling and design,
- prohibition of manufacture, sale and use of medicines,
- rules for medicine transportation and storage,
- transit transportation of medicines,
- destruction of medicines,
- state registration of medicines,
- state control over medicine quality,
- duties of medical facilities to provide information on side effects of medicines,
- state guarantees for supply of medicines to the population,
- control over pharmaceutical activity,
- sanctions for violation of the law.

Article 1 of the “Law on Medicines” defines medicines as biologically active products measured out in doses, made from one or several substances and subsidiary ingredients. They have a standard composition, unchangeable brand names, necessary medicine form, dosage form and design.

¹ Law of the Republic of Armenia on Medicines, No. 259, Oct. 27, 1998, Official Gazette [O.G.] Dec. 22, 1998, No. 31(64).

Medicines are intended for human and animal treatment, diagnostics, prophylactics, anesthesia, contraception; they have an influence on the functions of the organism.

The following products are also considered as medicines:

- Antiseptics - means for destroying or eliminating pathogens of infectious and parasitical diseases as well as their transmitting agents;
- Disinfectants - antibacterial active substances used for disinfecting healthcare products;
- Immuno-biological preparations - preparations of bacterial, animal, herbal and other biotechnological origin used for prophylactics, diagnostics and treatment of diseases;
- Homeopathic means - medicines dispensed and used in appropriate dosage forms according to homeopathic patterns.

Article 8 of the Law “On Medicines” requires manufactured and dispensed medicines to be labeled. Although the law provides for the Ministry of Health (MoH) to issue requirements for labeling, such requirements have not yet been put in place. The law itself contains the following rules:

- The label, labeled package, leaflet-insert, and instruction for use of a medicine must contain data on compliance of the medicine with mandatory requirements, warnings on danger of medicine overdose and necessity of keeping the medicine out of the reach of children.
- A medicine can be put in circulation if its outer or primary package legibly indicates the medicine manufacturer’s name and address, medicine name, manufacturing date, way of administration, weight (volume) and quantity of each unit and the active ingredient it contains, expiration date, and storing conditions. Samples must be labeled “not for sale”.

Importation, exportation, manufacture, storage, distribution, realization and use of medicines in the RA is allowed only if the medicines are registered in the Republic of Armenia.² Trade in medicines is allowed only in pharmacies and drugstores.³ Activities of pharmacies or drugstores are considered pharmaceutical activities and are subject to licensing.⁴

Licensing in the Pharmaceutical Sector

The Law “On Licensing”⁵ specifies the activities subject to licensing and regulates the licensing process. Licensing is defined as a procedure for the issuance or reformulation of a license, or its extension, suspension and termination.

In accordance with article 43 of the Law “On Licensing,” the following activities in the pharmaceutical (healthcare) sector are subject to licensing:

- Manufacturing of medicines;
- Pharmaceutical activities (pharmacy or drugstore).

The procedure for licensing of activities in the healthcare sector specified in paragraph 2 of article 43 of the Law “On Licensing” has been adopted by Resolution No. 867 of the GoA.⁶

² *Id.*, art. 15.

³ *Id.*, art. 9.

⁴ Art. 43, Law of the Republic of Armenia on Licensing, No. 193, May 30, 2001, O.G. Aug. 8, 2001, No. 26(158).

⁵ *Id.*

The MoH issues licenses for manufacturing of medicines or for pharmaceutical activities (pharmacy or drugstore) for an indefinite term. In order to obtain a license organizations or individual entrepreneurs must pay a state duty, the rate of which is defined by the Law “On State Duty”.⁷

License		State duty in Armenian drams
1.	Manufacturing of medicines	200,000
2.	Pharmaceutical activities	50,000

Licenses are issued by compound procedures specified in regulations within 30 days after the submission of required documents, in accordance with the Law “On Licensing” and governmental Resolution No. 867.

Pharmacies and drugstores are entitled to trade in medicines, healthcare products and other related goods and to provide consultancy and information on them. However, only pharmacies are authorized to prepare medicines according to prescriptions and pharmacographies from substances authorized for use.

The regulations stipulate the following minimum space requirements for pharmacies and drugstores:

- Pharmacies - 104 m²;
- Drugstores -28 m².

Activities of pharmacies and drugstores must comply with sanitary rules and norms set forth in

Decree No. 574 of the Minister of Health of the RA.⁸ Control over compliance with sanitary rules is exercised by chief sanitary doctors of hygienic and sanitary-epidemiological centers of Yerevan city, regions (marzes) and intraregional stations.

By January 1, 2013, entities licensed for production of pharmaceuticals must ensure compliance with the GMP (Good Manufacturing Practice) requirements of Resolution No. 734⁹ of the GoA.

Registration of Medicines

The procedure for registration of medicines has been established by Resolution of the GoA No. 347¹⁰ in accordance with article 15 of the Law “On Medicines” and applies to the registration of medicines, rejection and withdrawal of registration.

⁶ Resolution of the Government of the Republic of Armenia “On approving procedures for licensing of medicine manufacturing, pharmaceutical activities, medical assistance and service, implementation of programs of higher and vocational medical education in the Republic of Armenia and forms of licenses for mentioned activities” No. 867, Jun. 29, 2002, O.G. Jul. 17, 2002, No. 25 (200).

⁷ Para. 2, art. 19, Law of the Republic of Armenia on State Duty, No. 186, Dec. 27, 1997, O.G. Jan. 11, 1998, No. 1.

⁸ Decree of the Minister of Health of the Republic of Armenia “On approving sanitary rules N 2-III-2.2.7. “For pharmacies and drugstores,” No. 574, Sep. 4, 2002, O.G. Nov. 15, 2002, No. 28 (114).

⁹ Resolution of the Government of the Republic of Armenia “On implementation in the Republic of Armenia of rules for appropriate medicine manufacturing activities and approving the schedule of implementation of reforms in the area of medicine circulation,” No. 734, May 28, 2011, O.G. Jun. 8, 2011, No. 34 (837).

Registration of medicines is possible after an expert examination of their safety, efficacy and quality according to scientifically justified criteria. Expert examination of medicinal products for purposes of registration is performed by the Scientific Center for Drug and Medical Technology Expertise (SCDMTE).

Registration of medicines is performed for each manufacturer and for each country of origin, if the medicine is produced by the same manufacturer in different countries. The quality of medicines registered in the RA must comply with the requirements of current pharmacopoeias officially used in the RA: the XI State Pharmacopoeia of the former Union of Soviet Socialist Republics, the European Pharmacopoeia (Ph Eur), the International Pharmacopoeia (Ph Int), the American Pharmacopoeia (USP), the British Pharmacopoeia (BP), the German Pharmacopoeia (DAP), the German Homeopathic Pharmacopoeia (HAB), the French Pharmacopoeia (PhF) and, in some cases, with temporary pharmacopoeial monographs approved by the MoH.

The registration of medicines in the RA is valid for five years. When the registration expires the medicines are subject to a new registration.

In order to register a medicine, the manufacturer or its authorized representative (the applicant) submits the required documents and samples of the medicine to the SCDMTE and pays a state duty for registration.¹¹

Type of application for registration		State duty in Armenian drams
1.	First and additional pharmaceutical form and dosage strength of medicines containing new active substances	70,000
2.	New combination of known medicines	40,000
3.	First and additional pharmaceutical form and dosage strength of generic medicines	40,000
4.	New indications	10,000
5.	Herbal preparations and other preparations from natural substances	10,000
6.	Homeopathic medicines	2,000
7.	Dietary supplements	20,000
8.	Reformulation of registration certificates due to changes in the name of the product and/or the manufacturing company, packaging and other minor changes which do not affect the certified quality, safety and efficacy of the product.	5,000

¹⁰ Resolution of the Government of the Republic of Armenia "On approving the procedure for state registration of medicines in the Republic of Armenia and expert examination fees for state registration of medicines," No. 347, Apr. 25, 2001, O.G. May 18, 2001, No. 14 (146).

¹¹ Para. 35, art. 16, Law on State Duty, *supra* note 7.

The SCDMTE performs a preliminary examination of submitted documents and samples within 10 days, and notifies the applicant in writing of its results and the expert examination fee.¹²

Type of application for registration		Expert examination fee (including VAT) in Armenian drams
1.	First dosage form and dosage strength of generic medicinal products	900,000
	- each additional pharmaceutical form	450,000
	- each additional dosage strength	240,000
	- each new indication	450,000
2.	New combination of known medicinal products	1,200,000
3.	First pharmaceutical form and dosage strength of medicinal products containing new active substances	2,250,000
	- each additional pharmaceutical form and dosage strength	1,200,000
4.	First pharmaceutical form and dosage strength of homeopathic medicinal products	240,000
	- each additional pharmaceutical form, dosage strength and new indication	60,000
5.	Herbal preparations and other preparations from natural substances and dietary supplements	240,000
6.	Reformulation of registration certificates due to changes in the name of the product and/or the manufacturing company, packaging and other minor changes which do not affect the certified quality, safety and efficacy of the product.	24,000

If a medicine has already been registered in the RA expert examination fees for the registration of the same medicine manufactured by the same producer in other countries are reduced by half.

Expert examination for registration starts after an advance payment of the expertise fee. The payment date is considered to be the starting date of the expert examination. The maximum duration of the expert examination is 180 days, except for medicines registered in one of the full member states of the European Union, the USA or Japan. In the latter case the expert examination of medicines is performed within 30 days in a simplified order without any laboratory examination. If a simplified order is applicable the following documents must be submitted either in English or in Armenian:

¹² Resolution of the Government of the Republic of Armenia No. 347, *supra* note 10.

- Certified copy of the registration certificate of the medicinal product issued within the last 2 years in one of the member states of the European Union, the USA, Japan, or the Certificate of Pharmaceutical Products in a form approved by the World Health Organization (WHO).
- Summary of product characteristics approved by a competent body of the country that has registered the medicinal product.
- Data on qualitative and quantitative composition of the medicinal product (including excipients).
- Pharmacopoeial monographs or control methods, specifications of the medicinal product.
- The medicinal product's label and packages, their colored mock-ups, a leaflet-insert or instruction for medical use for specialists and patients, as well as their electronic versions for all output forms indicated in the application in English or in Armenian.
- Reference standards specified in documents on the quality control.
- Periodic Safety Update Report.

Within 15 days after receiving the results of the expert examination, the Pharmacological Council of the MoH issues a recommendation for registering or refusing to register the medicine in the RA and a conclusion on including the medicine in the list of controlled medicines, non-prescription medicines or essential medicines¹³.

The decision on registration of the medicine is made by a decree of the Minister of Health on the basis of the minutes of the Pharmacological Council meeting. Information on registered medicines is included in the register of medicines state registered in the RA.¹⁴

In accordance with Resolution No. 347 of the GoA, the Minister of Health of the RA has approved by Decree No. 12 "The order of conducting expert examination of medicines for purposes of state registration in the Republic of Armenia, the table of minimum quantity of samples of medicines submitted with the application, the form of the conclusion of the examination of a medicine for purposes of registration, the form and description of the state registration certificate, the list of changes to medicines registered in the Republic of Armenia which do not require a new registration".

The expert examination of medicines of major therapeutic and public health interest, intended for treatment of serious or life threatening diseases or conditions, may be performed at the expense of the state budget upon an order of the GoA. A list of these low-demand but vital medicines is approved by the MoH¹⁵.

¹³ Decree of the Minister of Health of the Republic of Armenia "On approving the list of essential medicines," No. 854, May 12, 2007, O.G. Jun. 20, 2007, No. 18 (258) and Decree of the Minister of Health of the Republic of Armenia "On approving the list of medicines released without prescription in the Republic of Armenia," No. 204, Feb. 8, 2007, O.G. Mar. 15, 2007, No. 8 (248).

¹⁴ Decree of the Minister of Health of the Republic of Armenia "On approving the state register (list) of medicines registered in the Republic of Armenia," No. 07, Apr. 3, 2012, O.G. Apr. 28, 2012, No. 11 (424).1.

¹⁵ Decree of the Minister of Health of the Republic of Armenia "On approving the list of low-demand but vitally necessary medicines," No. 22, Nov. 20, 2008, O.G. Jan. 8, 2009, No. 1 (319).

Clinical Trials of New Medicines

The procedure¹⁶ for conducting clinical trials of new medicines in the RA has been established in accordance with article 21 of the Law of “On Medical Assistance and Service to Population.”

After submission by the applicant of required documents to the MoH and a preliminary examination of documents¹⁷ the program of clinical trials is examined within a period of 60 days. A permit to conduct clinical trials is issued by the MoH upon a conclusion of the Ethics Committee¹⁸.

Importation and Exportation of Medicines

The procedure of importation and exportation of medicines and substances in the RA was established by resolution No. 581 of the GoA¹⁹ in accordance with article 10 of the Law “On Medicines.” The purposes of the procedure are:

- To facilitate the importation of effective, safe and quality medicines and substances for the healthcare of the population and for the protection of consumers' rights,
- To prevent the importation in the RA of non-registered, expired, falsified and inefficient medicines and substances,
- To control the export of medicines and substances from the RA.

A permit for importation and exportation of medicines and substances is issued by the MoH. Permit forms (importation certificate or exportation certificate) were approved as appendices to the resolution of the GoA.

The right to import and/or export medicines and substances is reserved to:

- Business entities licensed for importation or exportation of medicines and/or substances²⁰,
- Entities licensed for manufacturing of medicines and/or substances, if necessary for their own manufacturing,
- Business entities not licensed for importation or exportation, the activities of which are related to research, expert examination, quality control, efficiency and safety of medicines and substances.

A permit for importation can be issued only for medicines having a state registration in the RA, provided that changes to packaging do not affect product safety, efficacy and quality, and the applicant submits an original copy of the quality certificate issued by the manufacturer or a certified copy of the certificate issued by the manufacturer and stamped by the exporter, except for importation of the following medicines:

¹⁶ Resolution of the Government of the Republic of Armenia “On approving the procedure for conducting clinical trials of new medicines in the Republic of Armenia,” No. 63, Jan. 24, 2002, O.G. Feb. 14, 2002, No. 7 (182).

¹⁷ The period for the preliminary examination has not been defined.

¹⁸ Decree of the Minister of Health of the Republic of Armenia “On approving the list of documents required for obtaining a permit for conducting clinical trials of medicines and the statute of the Committee on Ethical Issues,” No. 05, May 17, 2011, O.G. Jul. 15, 2011, No. 17 (400).

¹⁹ Resolution of the Government of the Republic of Armenia “On approving the procedure for importing and exporting medicines and medical substances in the Republic of Armenia,” No. 581, Sep. 20, 2000, O.G. Oct. 10, 2000, No. 23 (121).

²⁰ However, the Law “On Licensing” does not provide for such a license.

- Samples for preclinical and clinical research,
- Samples for state registration of medicines in the RA,
- Samples imported for exhibitions, conferences or other similar events, without a right to sell,
- Medicines imported in the RA at the time of disasters, epidemics and other emergency situations and as humanitarian aid,
- Medicines imported for purposes of packaging provided that they have undergone all stages of manufacturing, except packaging and labeling, and the final product is registered in the RA.

If there are substantial differences between the leaflet-insert of the imported medicine and the leaflet-insert of the medicine registered in the RA, the importer must ensure that the medicine is sold with a leaflet-insert registered in the RA and, if there are language differences, must provide a leaflet-insert in Armenian. Changes to the leaflet-insert are not allowed if it is technically impossible to open the box without damaging the medicine or violating its sterility.

The time remaining before the expiration date of medicines and substances imported to the RA must not be less than one year, except if there is permission of the MoH and the possibility of consumption before the expiry date is justified. If a medicine or a substance has a period of validity of less than a year, two thirds of this period must remain at the time of importation.

Importation and exportation of medicines and/or substances in the RA are prohibited if:

- Submitted documents contain incorrect information,
- Imported medicine does not have a state registration in the RA,
- Quality indicators of medicines and/or substances do not meet the accepted standards of the RA,
- Medicines and/or substances are expired,
- Medicines and/or substances do not meet the requirements on remaining validity period,
- Medicines, substances and information in cover documents are not consistent with each other,
- Changes to packaging of medicines affect product safety, efficacy and quality²¹, or the original copy of the quality certificate issued by the manufacturer or the certified copy of the certificate issued by the manufacturer and stamped by the exporter is missing.

A permit (importation or exportation certificate) for each importation or exportation is issued by the MoH within 10 working days after submitting the application (within 30 days if a full laboratory examination is required) on the basis of results of an expert examination of the SCDMTE.

²¹ An eight-point list of discrepancies of packaging of the medicine has been approved by Decree of the Minister of Health of the Republic of Armenia "The list of discrepancies of packaging of medicines imported into the Republic of Armenia with their registration samples affecting the safety, efficacy and quality of the medicines," No. 2006, Oct. 10, 2011. This decree was issued as an individual act and was not published in the Official Gazette.

Documents submitted to the MoH for obtaining an importation or exportation certificate (permit) include a contract between the buyer and the seller, an air way bill (AWB), an invoice, and a quality certificate for each imported or exported medicine.²²

Withdrawal and Destruction of Medicines

The procedure for withdrawal, suspension and recalling of medicines, medical substances, medical devices and dietary active supplements provides for a rapid alert and a rapid alert follow up notification, in accordance with recommendations of the WHO and guidelines of the European Union. Grounds for withdrawal are specified in the procedure²³.

Medicines must be destroyed in accordance with sanitary rules and norms²⁴. The purpose of current sanitary rules and norms is to prevent and fight against infectious diseases and protect the healthcare interests of the population. Pharmaceutical wastes, *i.e.* expired medicines and medicines unfit for usage are considered medical wastes. Medical and pharmaceutical entities are required to maintain a register of medical waste and ensure their destruction by organizations having an appropriate license.

Control over compliance with sanitary requirements is exercised by chief sanitary doctors of hygienic and sanitary-epidemiological centers of Yerevan city, regions (marzes) and intraregional stations.

Advertisement of Medicines

The Law “On Advertising”²⁵ defines “advertisement” as the spread of information in an indefinite circle of persons, through various mass media, on legal and physical entities, merchandise, ideas and projects, intended to form and maintain interest in those physical and legal entities, merchandise and projects.

A permit for advertising a medicine is issued only to entities licensed for manufacturing medicines, trading in medicines²⁶ or pharmaceutical activities. Advertisement of medicines must comply with requirements of the Law “On Advertising,” the Law “On Medicines” and Decree No. 1608 of the GoA. An advertisement of a medicine must specify the name of the applicant and information on its license, the number and date of the registration certificate of the medicine, and the number and date of the permit issued by the MoH. It is forbidden to advertise a medicine if the purpose of the advertisement is to persuade the consumer that the medicine in question:

- Does not require a doctor’s advice,
- Does not have side effects,
- Is the most effective medicine,

²² Decree of the Minister of Health of the Republic of Armenia “On approving the list of documents required for obtaining a certificate for importing or exporting medicines and (or) medical substances to the Republic of Armenia,” No. 662, Oct. 10, 2002, O.G. Nov. 15, 2002, No. 28 (114).

²³ Decree of the Minister of Health of the Republic of Armenia “On approving the procedure for withdrawal, suspension and recalling of medicines, medical substances, medical devices and dietary active supplements, rapid alert and rapid alert follow-up notification,” No. 303, Feb. 24, 2012. This decree was issued as an individual act and was not published in the Official Gazette.

²⁴ Decree of the Minister of Health of the Republic of Armenia “On approving sanitary rules and norms N 2.1.3-3 “Hygienic and anti-epidemic requirements for treatment of medical wastes,” No. 03, Mar. 4, 2008, O.G. Nov. 24, 2008, No. 40 (314).

²⁵ Law of the Republic of Armenia on Advertising, No. 55, Apr. 30, 1996, O.G. 1996/10.

²⁶ However, the Law “On Licensing” does not provide for licensing of trade in medicines.

- Will significantly improve the health, and failure to use it will worsen the health,
- Can be used in food, for cosmetic and other purposes.²⁷

It is prohibited to advertise a medicine not registered in the RA.

A permit to advertise medicines, medical equipment and methods of treatment is issued by the MoH within 5 working days after submitting an application²⁸.

Supply of Medicines

The list of diseases and social groups of population entitled to a free or privileged purchase of medicines has been approved by Resolution No. 1717 of the GoA of November 23, 2006, in accordance with article 18 of the Law “On Medicines.” Tuberculosis, diabetes, and mental diseases have been included in this list. Disabled people in the first two groups of disability are entitled to free provision of medicines, while those in the third group are entitled to a 50% reduction of the purchase price. Free or privileged provision of medicines is implemented in accordance with Decree No. 74 of the Minister of Health of the RA of January 27, 2005. Medical facilities were required by governmental Resolution No. 1717 to organize the free and privileged provision of medicines in a more complete and efficient way.

In accordance with article 1 of the Law “On Medicines,” the GoA enacted Resolution No. 759 of August 14, 2001, defining the following types of prescriptions are applicable in the Republic of Armenia:

- Prescriptions for narcotic drugs;
- Prescriptions for psychotropic substances;
- Ordinary prescriptions.

In accordance with paragraph 4 of the above-mentioned governmental resolution the Minister of Health of the RA issued Decree No. 100 of February 26, 2002, establishing a procedure for writing prescriptions, dispensing medicines and maintaining a register of written prescriptions.

Violations of Rules of Pharmaceutical Activity

The following violations²⁹ of the rules of pharmaceutical activity are punishable under the laws of the RA:

- Failure to have in stock a minimum range of medicines included in the list of essential medicines,
- Failure to comply with the procedure for clinical research of new medicines,

²⁷ The Law “On Medicines” contains similar provisions in its article 11.

²⁸ Resolution of the Government of the Republic of Armenia “On approving the procedure for granting a permit for advertising medicines, medical equipment and methods of treatment and requirements for such advertising,” No. 1608, Nov. 2, 2006, O.G. Dec. 6, 2006, No. 62 (517).

²⁹ Articles 47.3, 47.4, 47.5, 47.6, Code of the Republic of Armenia on Administrative Violations, O.G. 1985/23.

- Importing, manufacturing, storing, distributing or realizing medicines not registered in the RA,
- Failure to comply with legal provisions requiring works in pharmacies and drugstores to be performed only by specialists,
- Storing by pharmacies and drugstores of expired medicines in premises for trading,
- The use of expired medicines by providers of medical assistance and services,
- Employing, or permitting to work, persons which have not passed a mandatory medical examination or have medical contra-indications
- Failure to notify in writing the Hygiene and Sanitary-Epidemiological Inspection of obtaining a license by simple procedures.

2. Institutional Set-Up

The Law “On Medicines” designated the MoH as the authorized state body for healthcare issues. The MoH is also the regulatory authority in the pharmaceutical sector, according to the Law “On Medicines” and Resolution No. 487 of the GoA of July 31, 1999, “On designating an authorized state body of the Government of the Republic of Armenia for the pharmaceutical activities sector and destruction of medicines.” Competences of the MoH include the following:

- Approving the list of essential medicines necessary to ensure public health,
- Licensing of activities in the healthcare area,
- Approving the list of medicines released without prescription,
- Establishing norms and procedures for production of medicines,
- Approving procedures for transportation, storage and safety of medicines,
- Issuing requirements for labeling of medicines,
- Issuing requirements for sale and use of medicines.

Responsibilities of the MoH are the following:

- Developing pharmaceutical policy and submitting it for approval to the GoA,
- Regulating circulation of medicines,
- Licensing and supervising activities in the pharmaceutical area,
- Ensuring international and inter-agency cooperation,
- Performing other functions provided by law.

The structure³⁰ of the MoH comprises the following separate units involved in the supervision of pharmaceutical activities:

- The Scientific Center for Drug and Medical Technology Expertise (SCDMTE) Closed Joint-Stock Company,
- The Licensing Agency,
- The Hygiene and Sanitary-Epidemiological Inspection.

The MoH has the authority to issue certain licenses, permits and certificates, including the following:

- Licenses for activities in the healthcare sector (Licensing Agency),
- Permits for advertising medicines, medical equipment and methods of treatment (Licensing Agency),
- Permits for importation and exportation of medicines (MoH Pharmaceutical Policy Division),
- Registration of medicines (SCDMTE),
- Permits for clinical trials (Ethics Committee).³¹

³⁰ The organizational chart of the MoH is shown in the Annex.

³¹ Decree No. 05 of the Minister of Health of the Republic of Armenia, *supra* note 18.

The SCDMTE

The SCDMTE was founded in 1992 as an organization accountable to the MoH, invested with managerial, financial and technical independence, in accordance with recommendations of the WHO, and is fully owned by the state.

The mission of the SCDMTE is to implement the national policy in the area of medicines, to ensure the safety, efficacy and quality of medicinal products in the RA. The responsibilities of the SCDMTE are as follows:

- Performing expert examinations of medicines, bio-active additives and medical products,
- Participating in drafting documents related to pharmaceutical policy, implementation of policy and monitoring,
- Conducting all types of professional monitoring of pharmaceutical activities,
- Monitoring effective use of medicines and side effects,
- Creating and managing an accurate database of medicines and bio-active additives,
- Organizing professional training for the MoH staff,
- Assisting the MoH in implementing state regulation functions in the pharmaceutical area,
- Providing expert services to the MoH,
- Performing other functions provided by laws and other legal acts,
- Conducting inspections and observations of pharmaceutical entities with a view to detecting non-registered and falsified medicines.

Inspections and observations are initiated only by order of the Minister of Health.

The Licensing Agency

The Licensing Agency is charged with the following functions:

- Licensing activities in the healthcare sector,
- Conducting all types of professional monitoring of licensed entities,
- Maintaining a register of licensed entities,
- Inspecting and observing licensed entities with a view to ensuring their compliance with licensing terms and conditions.

The Hygiene and Sanitary-Epidemiological Inspection

The Hygiene and Sanitary-Epidemiological Inspection is responsible for conducting inspections and observations of pharmaceutical entities (medicine importers, pharmacies, drugstores) to ensure that:

- Destruction of medicines is carried out in accordance with sanitary rules and norms³².
- Activities of pharmacies and drugstores comply with sanitary rules and norms established by order N574 of the Minister of Health of the Republic of Armenia.³³

Control over compliance of pharmacies and drugstores with sanitary rules is exercised by chief sanitary doctors of hygienic and sanitary-epidemiological centers of Yerevan city, regions (marzes) and intraregional stations.

³² Decree No. 03 of the Minister of Health of the Republic of Armenia, *supra* note 24.

³³ Decree No. 574 of the Minister of Health of the Republic of Armenia, *supra* note 8.

3. Recommendations

The Law “On Medicines” covers biologically active preparations intended for human and animal treatment. The scope of the law appears to be excessively broad, and it appears that some biologically active preparations and means for animal treatment could be exempt from the procedure for registration of medicines.

Recommendation: Redefine the scope of the law and provide for less strict requirements for preparation intended for animal treatment and bioactive food additives.

The law also applies to narcotic drugs and psychotropic substances. International best practices show that registration requirements for narcotic drugs and psychotropic substances are not the same as those for ordinary medicines.

Recommendation: Provide rules for registration of narcotic drugs and psychotropic substances in a separate legal act.

Under the legislation in force³⁴ the state registration certificate of a medicine must specify addresses (places) where medicines are manufactured, including addresses of the bulk manufacturer, dosage manufacturer, packager, and batch releaser. This information is made public.

By contrast, regulations of the European Union³⁵ provide that the product license, which is the equivalent of the registration certificate in the RA, is given to the marketing authorization holder. At the same time the WHO instructs³⁶ drug regulatory authorities to publish lists of newly authorized products, including at least the following information:

- Generic name, dosage form and strength;
- Trade name;
- Marketing authorization holder;
- Product marketing authorization number.

Thus, commercially sensitive confidential details of the marketing authorization are not published, except under exceptional circumstances.

Recommendation: Eliminate the requirement for publication of the manufacturing site addresses.

Under current rules for conducting clinical trials documents submitted for obtaining a clinical trial permit must undergo a preliminary examination before a conclusion is issued by the Ethics Committee. However, the duration of this preliminary examination has not been fixed by any legal act and remains unclear.

Recommendation: Provide for a maximum duration of preliminary examinations of documents submitted for obtaining a clinical trial permit.

³⁴ Decree of the Minister of Health of the Republic of Armenia “On approving the procedure for expert examination of medicines for state registration in the Republic of Armenia, tables of minimum quantities of sample medicines submitted with the application, form of conclusion of the expert examination for purposes of state registration, form and description of the state registration certificate, and the list of changes to medicines registered in the Republic of Armenia, which do not require a new registration,” No. 123, Feb. 7, 2006, O.G. Apr. 3, 2006, No. 10 (219).

³⁵ Art. 8, Directive 2001/83/EC of the European Parliament and of the Council of 6 Nov. 2001 on the community code relating to medicinal products for human use.

³⁶ Marketing authorization of pharmaceutical products with special reference to multisource (generic) products: a manual for drug regulatory authorities (WHO/DMP/RGS/98.5).

Governmental resolution No. 581 on importation and exportation of medicines³⁷ provides that importation and exportation can be carried out by licensed entities, including holders of licenses for importation or exportation of medicines. However, the Law “On Licensing,” which contains an exhaustive list of business activities subject to licensing does not provide for such a license.

Recommendation: Remove from the text of the governmental resolution provisions regarding entities licensed for importation and exportation of medicines.

Regulations on advertisement of medicines provide for permits for advertisement to be issued only to entities licensed for manufacturing medicines, trading in medicines or pharmaceutical activities. However, the Law “On Licensing” does not provide for a separate license to trade in medicines.

Recommendation: Remove from the text of the regulation provisions regarding entities licensed for trade in medicines.

Several legal acts, including Decree No. 2006 of the Minister of Health of the RA on medicine packaging³⁸ and Decree No. 303 on withdrawal of medicines³⁹ clearly contain regulations applicable to an indefinite circle of persons but have been enacted as individual acts and, consequently, have not been registered at the Ministry of Justice or published in the official gazette.

Recommendation: Reenact the regulations on medicine packaging and withdrawal as normative acts and made them public in accordance with the Law on Legal Acts.

(Article 8), as well as in “Directive 2001/83/EC of the European Parliament” (Article 54) the mentioning of the legal status of medicines is not considered as mandatory requirement.

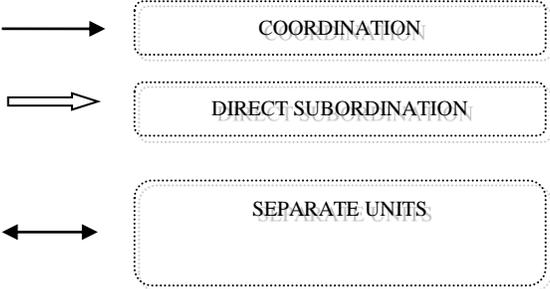
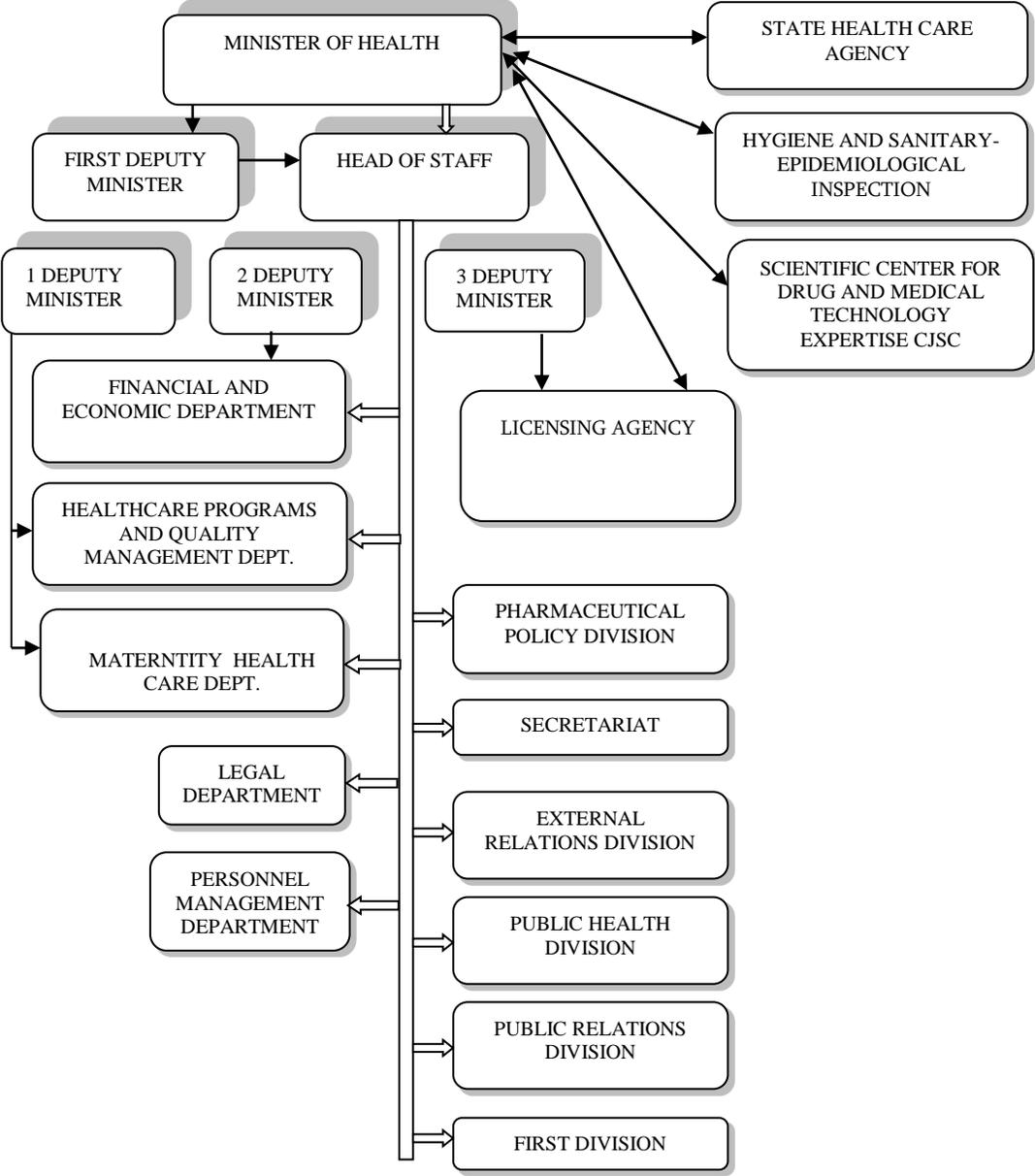
Recommendation: To exclude the suggested statement and remain as it mentioned.

³⁷ Resolution No. 581 of the Government of the Republic of Armenia, *supra* note 19.

³⁸ Decree No. 2006 of the Minister of Health of the Republic of Armenia, *supra* note 21.

³⁹ Decree No. 303 of the Minister of Health of the Republic of Armenia, *supra* note 23.

Annex: Structure of the Ministry of Health of the Republic of Armenia



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