Pharma & Medical Device Regulation 2022

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Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the third edition of *Pharma & Medical Device Regulation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Armenia.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

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Getting The Deal Through

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Armenia

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HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

The bodies concerned with the delivery of healthcare and appropriate products for treatment are the following:

- the Ministry of Health of the Republic of Armenia (the authorised body);
- the Clinical Trials Ethics Committee (non-governmental body);
- the health and labour Inspection body of the Republic of Armenia; and
- public and private hospitals, pharmacies, medical professionals.

The authorised body's responsibilities are as follows:

- licensing the types of activities in the sphere of circulation of medicinal products;
- state registration of medicines;
- organising and carrying out expert examinations in the sphere of state regulation of the circulation of medicinal products;
- ensuring the issuing of a certificate for the registration of medicines, good manufacturing practices (GMP) and good distribution practices (GDP);
- ensuring the maintenance of the medicines register; and
- ensuring the rational use of medicines, the pharmacovigilance, and development of appropriate recommendations.

The Clinical Trials Ethics Committee is responsible for evaluation of the clinical trials of medicinal products and researched investigational products from an ethics standpoint and, as a result, issues a positive or negative conclusion. This committee also evaluates amendments to the clinical trials programme and other documents from an ethics standpoint and, as a result, issues a positive or negative conclusion.

In the sphere of circulation of medicinal products and in the sphere of medical aid and population services, the health and labour inspection body of the Republic of Armenia, among other responsibilities, carries out the function of state supervision over the circulation of medical products.

Competent authorities for authorisation

2 Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The Ministry of Health of the Republic of Armenia approves the marketing (ie, import, export, wholesale distribution and storage) of medicinal products in Armenia. Armenian law does not require licences for manufacturing, importing, exporting, conducting wholesale distribution or storage of medical devices. In the Republic of Armenia it is allowed to produce, import, distribute, release, sell and use the medical devices registered in the Republic of Armenia. The state registration of medical devices carries out the Ministry of Health of the Republic of Armenia. The approval for drug, medical equipment and medical methods advertisement is issued by the Ministry of Health of the Republic of Armenia.

Republic of Armenia Law 'On Medicines' (2016), Republic of Armenia Law 'On medical aid and population services'(1996) and Decree of the Government of the Republic of Armenia No. 867 of 29 June 2002 govern approvals and decide whether a product is categorised as a drug or any other category.

According to the definition given under the law, 'medicinal product' stands for any substance of human, animal, vegetable, chemical or biotechnological origin in an appropriate dosage and dosage form, and the requisite packaging and labelling, which is 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, immunological or metabolic action, or to making a medical diagnosis.

The law also provides the following definitions:

- 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.
- Strength of the medicinal product: the content of the active substances expressed quantitatively in the measurement units established for each dosage form.
- Substance: material of human origin (human blood, blood products, other materials of human origin); material of animal origin (microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; and other materials of animal origin); material of vegetable origin (microorganisms, plants, parts of plants, vegetable secretions, extracts; and other materials of vegetable origin); 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.

The Law On Medical Aid and Population Services defines the medical devices as follows: any instrument, apparatus, equipment, materials and other products used for medicinal purposes separately or in combination, as well as the specified products, with the necessary accessories (including special software) provided by the manufacturer for the prevention of diseases, for diagnosis, treatment, medical rehabilitation and observation of the human body, conducting medical examinations, restoration, replacement, modification, prevention or termination of physiological functions or anatomical structure of the body, the functional purpose of which is not mediated by pharmacological, immunological, genetic or metabolic effects on the human body, but may be accompanied by drugs or medications.

Everything that falls into the above-mentioned definitions (including dosage form, the strength of the medicinal product, substance) is a medicinal product or medical device.

Approval framework

3 Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

The rules on the granting marketing authorisations are set out in the Decree of the Government of the Republic of Armenia No. 867 of 29 June 2002. A marketing authorisation of medicinal products is issued by the Ministry of Health of the Republic of Armenia. The marketing authorisation can be granted if:

- the applicant provides the application for obtaining a licence;
- the applicant provides copies of the state registration certificate of the applicant's ownership (use) right to the area subject to licensing activity and Copies of the plan of the area intended for the activity issued on behalf of the applicant by the competent body;
- a legal entity has the right to engage in the activities subject to licensing;
- the area meets the requirements for the structure and property saturation; and
- the necessary thermal regime for the storage of medicines by technical means is provided.

For medical devices, the EEU rules (Agreement on common principles and rules of circulation of medicinal products (medical products and medical equipment) within the Eurasian Economic Union (2014)) for market access apply. The circulation of medical devices shall be prohibited if:

- the circulation of the medicinal product has been suspended or that it has been withdrawn from circulation or recalled by the manufacturer;
- the expiry date of the medical product has passed; or
- the medicinal product is not properly registered.

Order of Ministry of Health of the Republic of Armenia N02-N of 21 January 2020 (the Order) contains special rules for the labelling of products. The Order states that the labelling of medicines must comply with the requirements approved by Decision No. 76 of the Council of the Eurasian Economic Commission of 3 November 2016. Drug instructions for use and general descriptions must comply with the requirements approved by Decision No. 88 of the Council of the Eurasian Economic Commission Council of 3 November 2016.

CLINICAL PRACTICE

Applicable rules

4 What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Clinical trials are regulated by:

- Republic of Armenia Law 'On Medicines' (2016);
- Republic of Armenia Law 'On medical aid and population services';
- Decree of the Government of the Republic of Armenia No. 168-N of 28 February 2019 'On adopting the rules of issuance a permission of clinical trials in the Republic of Armenia, assessment for this purpose, the lists of necessary documents and on repeal of the Decree of the Government of the Republic of Armenia No. 63 of 24 January 2002'.

Permission to conduct clinical trials is given by the Ministry of Health (the authorised body). It is given on the basis of a positive conclusion of the expert organisation and on the basis of a positive conclusion of the Clinical Trials Ethics Committee.

After receiving the positive expert opinion, the authorised body shall provide a copy of the expert opinion to the Ethics Committee within two working days, to which the organisation shall also transfer the package of documents on the same day. Within two working days after receiving the conclusion of the Ethics Committee, the authorised body shall issue an order on granting or denying the clinical trial permit.

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 authorised body on the absence of conflicts of interest and on confidentiality. The powers of committee members refusing to sign such a statement shall be terminated.

The Clinical Trials Ethics Committee protects the rights of all stakeholders in the clinical trials of medicinal products and investigational medicinal products in Armenia; ensures the voluntary nature of participation in clinical trials of medicinal product; and ensures the security of the participants. The Clinical Trials Ethics Committee evaluates the clinical trials of medicinal products and researched investigational products from an ethics standpoint and, as a result, issues a positive or negative conclusion, evaluates amendments to the clinical trials programme and other documents from an ethics standpoint and, as a result, issues a positive or negative conclusion.

Reporting requirements

5 What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

RA Law 'On Medicines' prescribes that the client that requested the clinical trials shall inform the authorised body about cases of serious adverse reactions that occur during the trials (eg, death, life-threatening situation, situation requiring hospitalisation, incapacity, infliction of physical mutilation or congenital defects), as well as about starting or ending the trials, and submits a report. Additionally, Decree of the Government of the Republic of Armenia No. 168-N of 28 February 2019 prescribes that the results of the clinical trials are summarised and an expert opinion is drawn up, which is submitted to the Ministry of Health of the Republic of Armenia, also notifying the applicant in writing about the results of the trial.

Consent and insurance

6 Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

RA Law 'On Medicines' and RA Law 'On medical aid and population services' mandate that, in all clinical trials, informed and written consent must be obtained from each study subject in the prescribed informed consent form (participation in clinical trials shall be voluntary). The tried person 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 regarding confidentiality of his or her participation. The tried person has the right to refuse, at any stage, to participate in the clinical trials.

The RA Law on 'Insurance and insurance activities' defines health insurance that does not have compulsory nature. Decree of the Government of the Republic of Armenia No. 168-N of 28 February 2019 prescribes that the copy of the document certifying the insurance of the subject (minimum insurance premium in the amount of 500,000 Armenian dram) is included in the list of documents required for providing permission for clinical trials. Additionally, the RA Law 'On Medicines' provides that damage inflicted upon a tried person as a result of clinical trials shall be compensated.

MARKETING AUTHORISATION

Time frame

7 How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

Medical devices

Armenian law does not require licences for the manufacturing, importing, exporting, conducting wholesale distribution or storage of medical devices.

Medicinal products

Republic of Armenia Law 'On licensing' and Decree of the Government of the Republic of Armenia No. 867 of 29 June 2002 prescribe that, in general, it takes 23 working days from submitting all the documents to grant to obtain an authorisation. The authorisation is issued termless.

Republic of Armenia Law 'On state duty' sets the amount of state fees for issuing licences as follows:

- for manufacturing medicines – annually Armenian dram;
- for pharmacy activities – annually 50,000 Armenian dram;
- for the wholesale of medicines – annually 100,000 Armenian dram;
- for state registration of medical products – 40,000 Armenian dram; and
- for medical product trial – 20,000 Armenian dram.

Protecting research data

8 What protection or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

The following protections apply to the data submitted by originators:

- licensing authorities are obliged to keep the information of applicants or licensees, which is a trade secret or other secret defined by the law;
- the authorised 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 authorised body on the absence of conflicts of interest and on confidentiality; and
- a person who has received, disseminated or used undisclosed information on an illegal basis is obliged to compensate the rightful owner of that information for the damages caused by its illegal use.

Freedom of information

9 To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

As a general rule, every person has the right to get acquainted with the information he or she seeks and to request information from the information holder and to receive that information. This is publicly accessible information (such as the state registration number of legal entities). The interested person can receive this kind of information by asking the authorised body and also, for example, by making a request on certain websites (eg, e-register.am).

Research data submitted by applicants for authorisation to market medicinal products or medical devices does not contain personal data but may contain trade secrets (such as the recipe of the medicine). Information is a trade secret if it has real or possible commercial value due to the virtue of being unknown to third parties, there is no possibility to obtain it freely on legal grounds; the holder of the information takes measures to maintain its confidentiality. In general, this kind of information is confidential; the holder of the information refuses to provide the information but still, in some cases, state bodies have access to this information.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

Armenian law does not give a definition of traditional herbal products, biologicals and biosimilars as a medicinal product. Armenian law does not contain specific rules for approval, and rewards or incentives for approval for homeopathic products, orphan drugs and those for paediatric use.

There are specific rules for controlled drugs (narcotics and psychotropic substances). Republic of Armenia Law 'On narcotics and psychotropic substances' prescribes that licences for activities related to narcotics and psychotropic substances are issued for a period of up to three years. A commission may be established by the decision of the government of Armenia to issue an advisory opinion to the licensing body on the issuance of licences in the field of activities related to the circulation of psychotropic (psychoactive) substances drugs. The legal persons possessing a licence for the activities relating to the traffic of the narcotic drugs and psychotropic substances shall be obliged on a quarterly basis to conduct an inventory registration of the narcotic drugs and psychotropic substances under the possession of these persons and design a balance sheet containing the costs of the substances and commodities.

There is a regime with relatively special regulations for the approval of industrial hemp. In particular, licences for industrial hemp activities are issued for a period of up to 10 years. The licensing of the

above activities is based on a quoting system, which differs depending on the type of the chosen activity subject to licensing. Only legal entities, with the charter capital of at least 20 million Armenian dram, whose employees are at least 18 years old and have not been criminally or administratively liable for drug or psychotropic substance offences may engage in licensed activities. To apply for a licence, the applicant must, in particular, submit a business plan for the exercise of the licensed activity; ensure the availability of the property rights to land, where the licence may be exercised; and later ensure that special conditions for the turnover of the industrial cannabis are met.

Post-marketing surveillance of safety

11 What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

In the post-marketing phase, the holder of a relevant authorisation is obliged to:

- document the cases of adverse reactions;
- report the cases of adverse reactions under the procedure established by the authorised body;
- destroy 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; and
- submit to the authorised 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.

This rule is applicable to medicinal products. Armenian law does not require licences for manufacturing, importing, exporting, conducting wholesale distribution or storage of medical devices.

Other authorisations

12 What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

Medicinal products

A person who intends to manufacture, import, export or conduct wholesale distribution and storage of medicinal products in Armenia must obtain a licence from the licensing authority.

The manufacturer of medicinal products must provide the following information to the licensing authority with an application to obtain the manufacture licence:

- the application for obtaining a licence (the application may contain the following information: the name of the legal entity, name and surname of the sole proprietor; place of business, telephone number, e-mail address, official website address (if available); state registration number of a legal entity (registration number of a sole proprietor) or taxpayer registration number (VAT number));
- the list of information that is mandatory represented in the regulation of drug production;
- a positive expert opinion issued by the expert organisation on the goods, items, equipment intended for the declared activity;
- copies of the state registration certificate of the applicant's ownership (use) right to the area subject to licensing activity and copies of the plan of the area intended for the activity issued on behalf of the applicant by the competent body; and
- receipt of annual state fee payment.

The fee to obtain a licence for manufacturing medical products is 200,000 Armenian dram annually. The licence is issued termless.

To obtain an import, export, wholesale distribution and storage licence of medicinal products, the following information must be provided to the licensing authority with an application:

- application for obtaining a licence may contain the following information: the name of the legal entity, name and surname of the sole proprietor; place of business; state registration number of a legal entity or registration number of a sole proprietor; email address, official website address (if available); telephone number of the legal entity; and the scope of wholesale activities of medicines (eg, import, export, wholesale distribution and storage);
- receipt of state fee payment;
- copies of the state registration certificate of the applicant's ownership (use) right to the area subject to licensing activity and the plan of the area intended for the activity issued on behalf of the applicant by the competent body; and
- a positive expert opinion issued by the expert organisation.

The fee to obtain a licence for the importing, exporting, distributing and storing of medical products is 100,000 Armenian dram annually. The issued licence is termless.

Medical devices

Armenian law does not require licences for manufacturing, importing, exporting, conducting wholesale distribution or storage of medical devices.

Sanctions

13 What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

The Criminal Code of the Republic of Armenia provides criminal sanctions for violations of its provisions. The Code provides that only a sane physical person is subject to criminal liability, but there is a new Criminal Code of the Republic of Armenia (entering into force on 1 July 2022), which provides the criminal liability of not only a sane physical person, but also legal entities.

Engaging in private medical or pharmaceutical activities without state registration, registration or special permit (licence) will be punished with fine of maximum 300,000 Armenian dram or with imprisonment of maximum three years.

Manufacture or sale of counterfeit medicines will be punished with imprisonment of maximum three years.

Falsifying or concealing the results of clinical trials of medicines will be punished with fine from 1 million Armenian dram to 1.5 million Armenian dram.

Manufacture of medical products without state registration, registration or special permit (licence) will be punished with fine of maximum 200,000 Armenian dram or with imprisonment of a maximum of one year.

Manufacture or sale or use of counterfeit medical products will be punished with imprisonment of maximum two years.

The administrative sanctions for breach of the requirements concerning controlled activities are notice and fine (from 5,000 Armenian dram to 1 million Armenian dram). The administrative responsibility comes if the violations in character do not involve criminal liability.

Exemptions

14 What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

RA Law 'On Medicines' prescribes that, in the Republic of Armenia, it shall be permitted to manufacture, import, distribute, dispense, sell and use medicinal products that are registered in Armenia. Registration shall not be required for:

- medicinal products prepared in a pharmacy;
- medicinal products exported from Armenia;
- medicinal products manufactured in Armenia only for the purpose of exports;
- medicinal products used for scientific and preclinical research and clinical trials, as well as medicinal products used with a special permission of the authorised body, investigational medicinal products, and samples of veterinary medicinal products intended for trials on animals;
- samples intended for registration in Armenia;
- 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; and
- for medicines imported in the name of individuals for the course of treatment or for personal use.

What refers to authorisation, RA Law 'On Medicines' prescribes that only acquiring and keeping inputs materials is exempt from the requirement to obtain a marketing authorisation.

Parallel trade

15 Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

In Armenia, imports of finished products already authorised in another jurisdiction are not allowed, without the importer having to provide the full particulars normally required to obtain an authorisation to market. A drug imported in parallel shall be imported to the Republic of Armenia on the basis of an import (compliance) certificate issued by the authorised body.

Granting permission for parallel imports of medicinal products shall be rejected if:

- the medicinal product manufacturer or production country does not correspond to the medicinal product manufacturer or production country registered in Armenia;
- the dosage form or strength does not correspond to the dosage form or strength registered in Armenia;
- the medicinal product expiry date does not correspond to the medicinal product expiry date registered in Armenia;
- the medicinal product active ingredient is different from the medicinal product active ingredient registered in Armenia;
- 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 Armenia;
- the medicinal product commercial name does not correspond to the medicinal product commercial name registered in Armenia;
- the medicinal product use indications or counter-indications do not correspond to the medicinal product use indications or counter-indications registered in Armenia;
- the medicinal product is not registered in the country from which it was procured and is being imported into Armenia; or
- in 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.

If the language of the packaging or labelling of medicinal product imported in parallel differ from the language of the packaging or labelling of medicinal product registered in Armenia, the supplier that received the wholesale distribution licence for such medicinal product shall, prior to selling, carry out re-packaging and re-labelling. The supplier that received the wholesale distribution licence for medicinal product imported in parallel shall secure such medicinal product with the medicinal product insert registered in Armenia, adding to the notes its name, business address and contact details for consumers.

AMENDING AUTHORISATIONS

Variation

16 What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

In case of reorganisation of a legal person holding a licence or in case of any changes in its name or registered office, the licensee shall be obliged to file an application for conversion of a licence within 15 days after such changes enter into force, attaching documents verifying the relevant information. In case of any changes in the name or place of residence of an individual entrepreneur or a natural person, the licensee shall be obliged to file an application for conversion of a licence within 15 days after such changes enter into force, attaching documents verifying the relevant information. Where a legal person is reorganised through spin-off, the licence shall be issued to the successor (successors) spin-off of the legal person only in accordance with the procedure provided for obtaining the licence concerned. Where a legal person is reorganised through division, the licence shall be issued to the divided legal persons only in accordance with the procedure provided for obtaining the licence concerned. When converting the licence, the licensing authority shall make the corresponding modifications in the licence register.

The variation of authorisations shall be rejected when:

- the documents submitted by the applicant are incomplete, obviously false or distorted;
- the submitted documents do not correspond to the requirements of the legislation of the Republic of Armenia;
- the applying legal person is not entitled pursuant to law or its statute to carry out the type of activity subject to licensing;
- the applying natural person has no right to carry out the activities subject to licensing applied for.

These rules are applicable for medicinal products. Armenian law does not require licences for manufacturing, importing, exporting, conducting wholesale distribution or storage of medical devices.

Renewal

17 What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

The licensee has the right to file an application to the licensor before the validity of the licence is expired to extend the licence issued for a definite period. The validity of the licence shall be extended for the same

period as the previous licence. The application to extend the validity of the licence shall state the requested period. The validity of the licence shall be extended by a corresponding note on the licence.

The application for renewal of a licence shall be rejected when:

- the documents submitted by the applicant are incomplete, obviously false or distorted;
- the submitted documents do not correspond to the requirements of the legislation of the Republic of Armenia;
- the applying legal person has been deprived, pursuant to law or to its statute, of the right to carry out the type of activity claimed;
- the applying natural person or individual entrepreneur has been deprived, pursuant to law, of the right to carry out the type of activity requested; or
- licensing requirements have been changed within the period following the acquisition of the licence.

These rules are applicable to medicinal products. Armenian law does not require licences for manufacturing, importing, exporting or conducting wholesale distribution or storage of medical devices.

Transfer

18 How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Under Armenian law, the licence may not be issued, alienated or pledged for the use of other persons. This rule is applicable to medicinal products. Armenian law does not require licences for manufacturing, importing, exporting or conducting wholesale distribution or storage of medical devices.

RECALL

Defective and unsafe products

19 What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

Decree of the government of the Republic of Armenia No. 164-N of 28 February 2019 'On adopting the procedures in the Republic of Armenia related to rapid alert, termination of circulation and recall of non-registered, non-conforming quality requirements, expired, registration withdrawal or suspended medicinal products, counterfeit medicinal products, active substance, herbal substances, investigational medicinal products and medicinal products imported in violation of the legislation of the Republic of Armenia' (the Decree) contains provisions relating to drug recall.

The Decree classifies drug recall into three categories:

- Class I – defects that pose a threat to the life and health of humans and animals;
- Class II – defects that endanger health or cause incomplete treatment, the degree of risk of which is lower than the first group; and
- Class III – defects that do not cause significant damage to health, but there is a need to recall the product for other reasons.

The order of product recall is issued by the Health and Labour Inspection Body of the Republic of Armenia (Inspection Body) on the basis of the conclusion of the expert organisation established by the decision of the government of the Republic of Armenia (expert organisation).

In case of receiving or detecting a defect signal, the expert organisation carries out a defect assessment within 24 hours and draws a conclusion. In case of confirmation of the defect by the conclusion, the order of the Inspection Body on the recall is issued within three days after receiving the conclusion.

PROMOTION

Regulation

20 Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

The goal of information on medicinal products is the safeguarding of their purposeful and effective use by means of providing credible information about them. Information on medicinal products shall be complete, impartial, and credible, justified with scientific research or data confirmed upon registration. 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. 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. Disseminating information on medicinal products sold with a prescription in the mass media shall be prohibited. Official information on medicinal products shall be published only by the authorised body.

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. Permission to advertise medicinal product shall be issued by the authorised body. Advertisement text shall correspond to the summary of product characteristics (SmPC) information approved upon registration. It is prohibited to advertise medicinal product not registered in the Republic of Armenia or medicinal products controlled in the Republic of Armenia or medicinal product prepared in a pharmacy according to a prescription or pharmacopeia. It is prohibited to advertise any non-medicinal product (bioactive supplements, cosmetics, and the like) as means of treatment. If it is the mass media, it is allowed to advertise only such medicinal products that are dispensed without a prescription and do not contain narcotics or psychotropic (psychoactive) materials.

Therapeutic methods by which it is proposed to achieve unsubstantiated results in medicine or to completely cure diseases that cannot be completely cured on the basis of medical data may not be advertised. The advertisements of medical methods may not reflect or broadcast the claims or opinions of the persons treated by the given medical method about the course or effectiveness or results of the treatment.

Inducement

21 What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The regulations to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product are the following:

- the advertisement of medicinal products in the mass media may not contain materials that contain citations of endorsement by scientists, medical professionals or other well-known individuals or non-governmental organisations that can stimulate the use of the medicinal product;

- 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; and
- 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.

Reporting transfers of value

22 What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

Armenian law does not contain requirements for recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The Health and Labour Inspection body of the Republic of Armenia monitors and ensures compliance with advertising controls for medicinal products and medical devices.

The Inspection Body exercises control and other functions and applies sanctions in the fields of healthcare and workers' health and safety, acting on behalf of the Republic of Armenia.

Sanctions

24 What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

There are administrative (fines) and criminal sanctions for breach of advertising and promotional controls for medicinal products or medical devices.

For failing to implement the requirements of its orders on the infringement of the advertising legislation or implementing them irregularly, the advertisers, advertisement producers and advertisement transmitters can be punished with a maximum fine of 100,000 Armenian dram.

Deliberate misleading of advertising consumers by an advertiser, advertisement producers or advertisement transmitters will be punished with fines ranging from 200,000 Armenian dram to 400,000 Armenian dram or with maximum imprisonment of two months.

PRICING AND REIMBURSEMENT

Pricing

25 What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

Armenian law does not contain special provisions that control the pricing of medicines and medical devices. The Republic of Armenia Law on Protection of Economic Competiton, along with other products, is applicable for medicines and medical devices.

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OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

No Armenian law prescribes, governs or uses 'off-label' drugs.

RA Law on 'Medicines' prescribes that medicinal products, substances, medicinal herb material and investigational medicinal products shall be packaged and labelled. Medicinal product registration, re-registration and certificate maturity extension shall be rejected if the expert examination finds that the product name, SmPC, packaging, labelling, marking or insert do not correspond to the requirements defined by the Republic of Armenia legislation and other legal acts. It follows from this rule that the use of 'off-label' products is forbidden.

Unlicensed products

27 What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

Medicines

RA Law on 'Medicines' prohibits the manufacture, importation and supply of unregistered medicines.

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

- in case of emergencies or threat of their emergence;
- 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 organisation defined by a decree of the Republic of Armenia government or the prequalification by the World Health Organization, after obtaining the consent of the authorised body under the established procedure;
- if there is a written decision of the authorised body, and the medicinal products are imported for the state's needs or for the health care and treatment of specific patients;

- 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; or
- in the case of importing medicinal products designated for the animals of zoological parks.

Engaging in private medical or pharmaceutical activities without state registration, registration or special permit (licence) will be punished with a maximum fine of 300,000 Armenian dram or with maximum imprisonment of three years.

Medical devices

Armenian law does not require licences for the manufacturing, importing, exporting or conducting wholesale distribution or storage of medical devices.

Compassionate use

28 What rules apply to the establishment of compassionate use programmes for unlicensed products?

The medicinal product being registered shall not be required for issuing an import certificate 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 organisation defined by a decree of the government of Armenia or the prequalification by the World Health Organization, after obtaining the consent of the authorised body under the established procedure.

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 authorised body has been received.

SALE AND SUPPLY

Regulation

29 Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

For certain types of medicinal products, narcotic medicinal products, there are special rules governing the dispensing or sale. These rules provide that licences for activities related to narcotics and psychotropic substances are issued for a period of up to three years. The rules, among others, also provide that the quota is needed for the production, storage, import and export of psychotropic (psychoactive) drugs. The export and import of narcotic drugs (psychoactive) substances included in the lists of psychotropic substances (psychotropic substances) and their preparations shall be carried out on the basis of a sample approved by the UN Commission on Narcotic Drugs issued by the government of Armenia.

Online supply

30 What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

Armenian law does not contain special rules for the online dispensing, sale and supply of medicinal products and medical devices. So, the general regulations are equally applicable for the online dispensing, sale and supply of medicinal products and medical devices.

UPDATE AND TRENDS

Forthcoming legislation and regulation

31 Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

Forthcoming legislation includes:

- RA Draft Law on Making Amendments to the Law on Medicines and on Making Amendments to RA Code of Administrative Offences provides a ban for the storage of medicines or herbal raw materials or examined pharmaceutical products that are not registered in Armenia or have been suspended in accordance with the law or imported in violation of the law and regulates the relations related to the implementation of the recall.
- RA Draft Law on Making Amendments and Supplements to the Decree of the Government of the Republic of Armenia No. 867 of 29 June 2002. Licence application forms will be simplified.
- RA Draft Law on Making Amendments and Supplements to the Decree of the Government of the Republic of Armenia N. 162 of 28 February 2019.

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