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Life Sciences 2024

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Armenia: Law & Practice

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Concern Dialog

ARMENIA

Law and Practice

Contributed by:
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Concern Dialog

Contents

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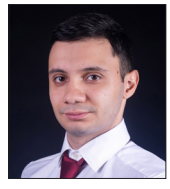

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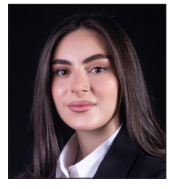

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Within the framework of national legislation, pharmaceuticals are governed by the Law on Medicinal Products of the Republic of Armenia (RA) (the "Law on Medicinal Products"). Medical devices fall under the jurisdiction of the Law on Medical Aid and Service to the Population of the RA and are also regulated by the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Products and Medical Equipment) in the Framework of the Eurasian Economic Union adopted on 23 December 2014 ("the Agreement").

The Law on Medicinal Products oversees the interactions associated with the distribution of drugs, pharmaceuticals, herbal raw materials, and investigational medicinal products.

Furthermore, at subordinate level, various government regulations and decrees of the Minister of Health specify the provisions of the laws.

The Health and Labour Inspection Body of the RA (HLIB) is responsible for implementing and enforcing pharmaceuticals regulations and regulations regarding the marketing of medical devices. The HLIB operates under the authority of the government of the RA.

The Ministry of Health (MoH) oversees the registration, denial, suspension and annulment (declaring void) of medicinal product registrations. Additionally, the MoH handles the registration, denial, suspension and annulment (declaring void) of registration certificates for medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Enforceable decisions by regulatory bodies qualify as administrative acts, which can be challenged by the addressee (or by a third party having legal standing) by lodging an objection with the regulatory body that has issued the administrative act. One also can directly appeal it to the RA Administrative Court, without applying an objection to the regulatory body.

Objections against administrative acts and lawsuits must be lodged in writing and within two months of notification of the decision to be challenged. The aforementioned procedure applies

to pharmaceuticals and medical devices as well as to other regulated products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals may qualify as prescription-only and non-prescription, as well as controlled drugs and pharmaceuticals. "Controlled drugs and pharmaceuticals" refer to medications and substances that require numerical registration in the healthcare system of the RA.

The categorisation of a drug into prescription, non-prescription, and/or controlled groups is established during the state registration process of the medication.

The categorisation of medical devices is ruled by Decision No 173 of the Board of the Eurasian Economic Commission dated 22 December 2015.

Medical devices, depending on the degree of possible risk of their use, are divided into four classes:

- Class 1 includes medical devices with a low degree of potential risk of use;
- Class 2a includes medical devices with an average degree of potential risk of use;
- Class 2b includes medical devices with the highest possible risk of use; and
- Class 3 includes medical devices with a high degree of possible risk of use.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials for pharmaceuticals are conducted in compliance with the guidelines of "Good Clinical Practice" as stipulated by the regulatory authority (Order of the Minister of Health of the RA N25-N of 17 May 2017 "On adopting the rules on Good Clinical Practice", which refers to the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001, Commission Directive 2005/28/EC of 8 April 2005 and the "Rules of Good Clinical Practice of the Eurasian Economic Union" in the Decision No 79 of the Council of the Eurasian Economic Commission dated 3 November 2016).

The MoH is responsible for overseeing and conducting clinical and clinic-laboratory trials (research) of medicinal products. The permission to conduct clinical trials is granted by the MoH after approving the trial plan and attached documents on the basis of a positive expert opinion and a positive opinion from the clinical trial ethics committee.

The expert opinions are given by the Scientific Centre of Drug and Medical Technologies Expertise after Academician Emil Gabrielyan CJSC (hereinafter referred to as "the SCDMTE") and the Ethics Committee for Clinical Trials (the "Ethics Committee").

The conduct of clinical trials for medical devices is regulated by Decision No 29 of the Council of the Eurasian Economic Commission dated 12 February 2016 ("Decision No 29"). While Armenian national law grants authority to the Armenian government to oversee this issue, there are currently no governmental decisions specifically addressing the clinical trials of medical devices.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To obtain authorisation for conducting a pharmaceutical clinical trial, one must submit an application to the MoH. Then the MoH must confirm the receipt of the application within the same

day by sending a return letter to the applicant's email address and, at the same time, inform the SCDMTE by sharing the documents requesting the clinical trial. If the expert opinion from the SCDMTE is positive, the MoH will share a copy of the expert opinion with the Ethics Committee within two working days. After receiving the Ethics Committee's opinion, the Minister of Health will issue an order either granting or denying permission to conduct the clinical trial.

The steps for securing authorisation to undertake a clinical trial of a medical device are described in the Rules dated 9 December 2011 of Decision No 29.

To obtain authorisation for conducting a clinical trial of medical devices, as a general rule the following must be submitted to the MoH:

- statement asserting that the medical device complies with safety and efficacy requirements;
- the Ethics Committee's decision;
- researcher's brochure;
- technical specification of the medical device;
- clinical trials (research) programme; and
- the list of adverse events (incidents).

2.3 Public Availability of the Conduct of a Clinical Trial

Despite the fact that – according to the Law on Medicinal Products – the MoH is required to compile a register of authorised and rejected clinical trials, only a list of medication approved for clinical trials is published. Neither information about rejections nor information about the results of clinical trials are publicly available. As for medical devices, no information about clinical trials of medical devices is publicly available.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Currently, no regulations restricting the use of online tools to support clinical trials have been adopted in Armenia.

2.5 Use of Data Resulting From Clinical Trials

Data resulting from a clinical trial can be qualified under the Data Protection Law of the RA as "biometric data" and "special category data". Biometric data includes information related to the physical, physiological and biological characteristics of an individual, whereas special category data encompasses data concerning race, national origin, political views, religious or philosophical beliefs, association membership, health status, and sexual life. Therefore, data arising from clinical trials on humans is considered both "biometric" and to fall within the "special category of personal data".

As a matter of general rule, the processing of personal data – including its transfer – is subject to explicit consent of data subject.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data would be subject to additional requirements. Regarding the processing of personal data, it is mandatory for the processor to employ encryption keys. This measure aims to safeguard information systems containing personal data from inadvertent loss, unauthorised access, unlawful use, recording, destruction, alteration, blocking, copying, dissemination of personal data, and other forms of interference.

Additionally, Decision No 1175-N dated 15 October 2015, issued by the government of the RA, outlines the specifications for biometric personal

data carriers and the technologies used to store such data beyond information systems. Furthermore, clinical trial participants must receive information about how their data will be used and stored within such a database.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The classification of a specific product as either a pharmaceutical or a medical device is determined by the definitions provided by applicable regulation. Article 45(1) of the Law on Medical Aid and Service to the Population of the RA explicitly references the Agreement.

A pharmaceutical product – as defined by Article 3(1), point 1 of the Law on Medicinal Products – includes substances sourced from human, animal, vegetable, chemical, or biotechnological origins. These substances are formulated in appropriate dosages and forms, accompanied by packaging and labelling. These products are presented with attributes intended for the treatment or prevention of diseases in humans or animals. Additionally, they may be:

- employed to restore, correct or modify physiological functions through pharmacological, immunological or metabolic actions; or
- used for medical diagnostic purposes.

According to Article 2 of the Agreement, "medical devices" refer to any instruments, apparatus, devices, equipment, materials and other products used for medical purposes either independently or in conjunction with one another, including necessary accessories for their intended use (eg, special software). These products – as intended by the manufacturer – are designed for:

- the prevention, diagnosis and treatment of diseases;
- medical rehabilitation; and
- monitoring of the human body's condition.

They are also used for medical research, restoration, replacement, and alteration of anatomical and medical conditions of the human body, as well as for the utilisation of devices, equipment, materials, and other products.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

As with other pharmaceuticals, biologic medicinal products must undergo a registration process in order to be introduced to the market. All medicinal products, including biologics, require research for registration. However, biologic medicinal products must align with the criteria outlined in documents accepted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and/or World Health Organization (WHO) guidelines.

Additionally, in its Decision No 89 dated 3 November 2016, the Council of the Eurasian Economic Commission established rules concerning the approval to conduct research into biological medicines in the Eurasian Economic Union, which – according to the Agreement on the Eurasian Economic Union – is applicable in the RA.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The state registration of pharmaceuticals is valid for five years (see Article 16(18) of the Law on

Medicinal Products, as well as Regulation No 162-N of the Armenian government dated 28 February 2019 ("Decision No 162-N")). However, according to Article 4(6), paragraph 3 of the Agreement, the registration of medical devices is indefinite.

After the initial registration period concludes, re-registration (renewal) for a duration of five years may be conducted, involving the reassessment of the product's safety, efficacy, and quality. Following the expiration of the re-registration term, the maturity of the registration certificate may be prolonged – with the approval of the registration certificate holder – once every five years, based on the outcomes of professional post-registration safety monitoring by the MoH. The maximum timeframe for the re-registration of medicinal products is set at 31 calendar days, which includes the period for expert examination required for registration (a maximum duration of 21 calendar days). The maximum duration for extending the maturity of the medicinal product's registration certificate is 10 calendar days. The re-registration and extension of the registration certificate term should be applied if a favourable expert examination conclusion is granted.

The registration, re-registration, or certificate maturity extension of a medicinal product may be declared void by the MoH in the following circumstances:

- discovery of non-conformity with established requirements, specifications, and new scientific data, where this poses a threat to human life and cannot be corrected;
- receipt of justified and credible negative data about the medicinal product from foreign or international specialised structures and competent authorities regulating medicinal products in other countries;
- negative results from quality testing of three different series after product registration; and
- documentation of serious adverse reactions during post-registration safety monitoring – for example, death, life-threatening situations, hospitalisation, incapacity, or infliction of physical mutilation or congenital defects.

Upon declaring the voidance of medicinal product registration, it becomes prohibited to manufacture, import, distribute, dispense, sell, or apply such medicinal product.

The registration of a medicinal product will be suspended by the MoH if:

- the registration certificate holder has filed a substantiated application;
- non-conformity of safety, efficacy, and quality with the established requirements, specifications or new scientific data has been discovered, where this can be corrected;
- 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
- the registration certificate holder has made changes in the registered medicinal product documents or product packaging, label or marking or to the use and application instructions, where these changes were not agreed upon with the authorised body.

The withdrawal of medicinal products is ruled by Decision No 164-N dated 28 February 2019 of the government of the RA. The HLIB can withdraw (recall) a marketing authorisation for a pharmaceutical or a medical device in the following circumstances:

- if there is a notification indicating a potential issue with the pharmaceutical or the medical device, such as safety concerns or non-compliance;
- if the product is found to be unregistered, non-compliant with quality requirements, or expired, or if its registration has been invalidated or suspended;
- if the pharmaceutical or the medical device is imported in violation of the legislation of the RA; and
- if the withdrawal may apply to drugs, counterfeit drugs, medicinal materials, herbal raw materials, and researched pharmaceutical products.

For medical devices, the MoH performs the registration, rejection of registration, suspension and invalidation of registration certificates, provides duplicates of registration certificates, and processes changes to the registration certificate in accordance with the law. Nevertheless, as of now, there are no existing national regulations that oversee the relevant legal relationships at the subordinate level – for example, government decisions or orders of the Minister of Health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

In the RA, only registered pharmaceuticals are permitted for manufacturing, importation, distribution, dispensation, sale and usage.

Medicinal products (drugs) must undergo registration using either the standard process or a simplified process. The simplified process is applicable to medicinal products registered in a member state of the international professional organisation designated by the Armenian government or those pre-qualified by the WHO.

For the state registration of a pharmaceutical product, application must be submitted with the following attachments:

- a set of documents (dossier) aligned with the ICH universal technical document;
- the evaluation report conducted by the competent authority of another country or obtained during WHO pre-qualification, along with the original specifications and application instructions constituting part of the report (additionally, all relevant materials must be translated into Russian or English if originally in a different language (mandatory for the simplified procedure)); and
- original documents confirming the payment of the state tax and examination fee.

The following changes are not subject to registration:

- alteration of the name and/or location of the rights holder of the registration certificate, provided that the legal entity remains unchanged;
- modification solely to the name of the drug, without any accompanying alterations;
- change in the generic name without any modification to the drug substance;
- adjustment of the manufacturer's name without altering the manufacturer or its location; and
- modification in the form of release (specifically associated with variations in the quantity of units included in the packaging).

The change of other information – for example, the name, ingredient, strength, dosage form, presentation, new indication, manufacturer (including every performer of the production process), and registration certificate holder of a medicinal product – is subject to registration.

Changes in the therapeutic indication, formulation, posology, patient population, packaging, or labelling also need to be appropriately registered.

The process of obtaining marketing authorisation for medical devices involves the state registration of these devices. This registration aims to evaluate whether the devices meet the safety, quality, and efficacy standards established for medical devices. The assessment is conducted by examining the technical and biological impact of the device, as well as reviewing the results of clinical and clinical-laboratory tests or research submitted by the manufacturer.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The registration of a medicinal product is not required when it is imported for the purpose of a curative course or for personal use by individuals. In the RA, the utilisation of novel drugs, methods, forms, and tools – as well as the conduct of biomedical research – is permissible within the framework of delivering medical care and services, following the procedures established by the government.

As of now, however, no corresponding regulation has been issued by the Armenian government. Additionally, explicit guidelines for compassionate use programmes in Armenia are not in place. Nevertheless, when treating patients with new drugs, methods, forms, and tools, or conducting biomedical research, obtaining the explicit written consent of the patient is a necessary requirement. Also, medicinal products or investigational medicinal products undergoing clinical trials in foreign countries can be utilised for treating patients with life-threatening illnesses, provided that approval from the MoH has been obtained following the procedure outlined in this Article.

As regards the use of medical devices on patients, Armenian law refers to the law of the Eurasian Economic Union. Article 4(11) of the Agreement governs exceptions to the registration of medical devices.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance is defined here as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effects of medicines.

Technovigilance is defined here as the science relating to the detection, assessment, understanding and prevention of adverse incidents, particularly long-term and short-term side-effects of medical devices.

The medicinal product registration certificate holder must document the cases of adverse reactions and report them under the procedure established by the MoH.

The holder of the registration certificate is obligated to report instances of serious adverse reactions to the MoH. Such reactions include but are not limited to cases involving death or life-threatening conditions, necessitating inpatient hospitalisation or extension of ongoing hospitalisation, leading to persistent or significant disability or incapacity, or resulting in congenital anomalies or birth defects.

In the context of medical devices, when the SCDMTE uncovers information pertaining to their safety, quality, and efficacy, it promptly

communicates these findings to the manufacturer or its authorised representative. If deemed necessary, the SCDMTE may request supplementary information about the medical devices.

Healthcare professionals have a duty to promptly notify the authorised body in writing regarding any adverse events associated with medical devices.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

If an application for marketing authorisation has been either granted or refused, a third party can access information on the Medicinal Products Register. This information includes details such as the trade name, International Non-proprietary Name (INN), potency, pharmaceutical form, packaging, manufacturer, country of origin, Anatomical Therapeutic Chemical (ATC) code and/or classification, registration certificate number, registration deadline, legal status for supply, manufacturing authorisation holder's name and address, primary and/or secondary packaging, label, mock-ups (including coloured versions), summary of product characteristics (SmPC), and package information leaflet (PIL).

Information on drugs that have been denied registration is also accessible, providing details such as the date, trade name, common name of the active substance, pharmaceutical form, strength and packaging presentation, all manufacturing sites involved in the production process (name and location), country, registration certificate holder's name and location, and legal status for supply.

According to Article 16 (14), the Law on Medicinal Products specifies that the MoH is mandated to safeguard the confidentiality of the data found in the submitted registration documents. This data, protected by the laws of the RA, is not subject to public disclosure. Additionally, the expert responsible for the registration examination is compelled to sign a declaration affirming their commitment to confidentiality and acknowledging any potential conflicts of interest.

It is important to note that confidential information primarily pertains to the documents submitted for the state registration of the drug.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Armenian Administrative Offences Code provides various measures for offences related to pharmaceuticals. Article 47(3) of the Armenian Administrative Offences Code, for instance, stipulates that importing, manufacturing, storing, distributing, or selling medicines not registered in the RA (except for cases defined by Armenian legislation) – or whose registration has been suspended in accordance with the law – is in violation of the law. For each drug the following fines may be imposed:

- for a package of up to five medicines – AMD1 million (which is approximately equal to EUR2,270); and
- for a package of more than five medicines – AMD2 million (which is approximately equal to EUR4,540).

The Armenian Administrative Offences Code establishes a general provision for offences related to medical devices. By way of example, the violation of the requirements outlined in the field of medical device circulation results in a fine ranging from AMD100,000 to AMD1 million.

The Armenian Criminal Code penalises the unlawful trafficking of pharmaceuticals and

medical devices (refer to Articles 408 to 411 of the Criminal Code of the RA). As an illustrative example, Article 408(1) of the Criminal Code of the RA states, in essence:

"Engaging in the sale, production, manufacturing, storage, transportation, shipment, import, export, supply, marketing, or selling of medicine, drugs, herbal raw materials, auxiliary substances, medicinal products, their components, or investigational medicinal products without the state registration mandated by law, or when the registration has been suspended, terminated, or revoked according to the law, and without the required medicine or special permission (licence), is subject to penalties. The penalties may include imprisonment, public works for a duration of 80 to 150 hours, restriction of freedom for a year, suspended imprisonment lasting two months, or imprisonment for a period of two years."

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

In the efforts to combat counterfeit pharmaceuticals and medical devices through border measures, the Anti-Smuggling Department of the State Revenue Committee of the RA serves as an investigative body, actively engaging in operative-investigative activities. The department is vested with several powers, including but not limited to:

- prevention and detection of smuggling and other customs offences;
- implementation of customs control to ensure the integrity of borders;
- implementation of actions within the scope of powers assigned to the investigation body by the Criminal Procedure Code of the RA;
- initiation of administrative proceedings in the event of a violation of customs rules; and
- authority to appoint customs examination when deemed necessary, among other related responsibilities.

These powers enable the Anti-Smuggling Department to play a crucial role in safeguarding against the influx of fake pharmaceuticals and medical devices through comprehensive border control measures.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The production of pharmaceuticals, substances, and investigational medicinal products, as well as the processing of medicinal herb materials, must be conducted by legal entities or sole entrepreneurs possessing a manufacturing licence specifically for medicinal products. Possession of a medicinal product manufacturing licence is mandatory for engaging in any production processes. The licence specifically for medicinal products grants the MoH.

The MoH issues a licence for the manufacturing of medicinal products based on the findings of the expert examination.

The following activities require licensing:

- production of medicines;
- pharmacy activities;
- implementation of medical care and maintenance;
- wholesale of pharmaceuticals;

- production of medical devices; and
- maintenance of medical devices.

In order to obtain a licence for the production of medical devices, the applicant must submit to the MoH an application to obtain a licence together with the state registration certificate demonstrating the applicant's ownership (use) right to the area intended for the licensed activity (along with the plan of the designated area) issued by the competent authority in the name of the applicant, as well as a favourable expert opinion issued by the organisation conducting the expertise (in Armenia, the SCDMTE).

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments engaged in wholesale of pharmaceutical devices are required to acquire a licence (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**). The MoH grants the authorisation.

To obtain the licence, the applicant must submit the same documents as prescribed in **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**. Licences for the wholesale sale of pharmaceuticals are issued and granted for an indefinite period.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified into prescription, non-prescription and controlled medicinal products based on varying regulations and requirements (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and Exportation of Drugs

Within the framework of Armenian legislation, the importation and exportation of drugs are primarily governed by the Law on Medicinal Products and the decision of the government dated 28 February 2019, No 202.

In Armenia, import (compliance) or export certificates are issued for the actual import or export of each pharmaceutical product (drug) group across the customs border.

Pharmaceutical products (drugs) entering the RA require an import (compliance) certificate issued by the MoH. The export of pharmaceutical products from the RA can be conducted with an export certificate issued by the MoH, if desired by the exporter.

In adherence to the Law on Medicinal Products, import (compliance) and export certificates for pharmaceutical products are issued by the MoH. This issuance is based on the expert opinion of the SCDMTE, the organisation appointed by the government decision of 28 February 2019, No 150.

Importation and Exportation of Medical Devices

Separately, the importation and exportation of medical devices fall under the jurisdiction of the Law on Medical Aid and Service to the Population of the RA and the government decision dated 30 March 2023, No 429.

Medical devices are imported to the RA on the basis of the import (compliance) certificate issued by the MoH. The issuance of this certificate is contingent upon the expert opinion provided by the SCDMTE.

The import (compliance) certificate becomes invalid after customs clearance.

The HLIB is authorised to exercise the state control over the field of drug circulation.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

The following are entitled to import drugs, medicinal substances, herbal raw materials, and researched pharmaceutical products into the territory of the RA:

- suppliers holding a licence for the wholesale sale of drugs; and
- entities without a wholesale licence, falling into the following categories:
  - (a) legal entities or individual entrepreneurs engaged in activities related to researching, conducting tests, quality assurance, efficiency assessment, and safety control of drugs, medicinal substances, and herbal raw materials, within the necessary scope for these activities;
  - (b) legal entities or individual entrepreneurs importing drugs within the context of qualified charitable or humanitarian programes;
  - (c) legal entities and individual entrepreneurs possessing a licence to manufacture drugs in the RA, specifically in the case of importing medicinal substances and herbal raw materials for production purposes;
  - (d) representative offices or representatives of foreign manufacturers, when importing or exporting registration and/or test samples (medicines, pharmaceuticals, herbal raw materials, researched pharmaceutical products) and/or exhibition samples;
  - (e) state bodies; and
  - (f) natural persons in instances where an import or export certificate is not required (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**).

As regards medical devices, to secure a certificate of import (compliance) for medical devices entering the RA, the legal entities engaged in importing medicinal products – along with individual entrepreneurs or their authorised representatives – are required to submit an electronic application to the MoH.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Both medical devices and pharmaceuticals imported into the RA need to be accompanied by an import (compliance) certificate issued by the MoH.

Import or export certificates are not required:

- for the treatment of an individual travelling to or from a foreign state, or for medicinal products of personal use, in quantities established by the RA government;
- for medicinal products imported for personal needs by foreign and international organisa-

tions' diplomatic and consular representatives, staff, and family members living with them;
- for medicinal products necessary for the treatment and care of drivers, staff, and passengers of transportation means arriving in the RA; and
- for medicinal products necessary for the treatment and care of participants of international cultural and sports events and international research teams.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

When importing drugs and medical devices, non-tariff regulations and restrictions are established for the import from the Eurasian Economic Union member countries and third countries.

An import (compliance) certificate issued by the MoH (which is issued on the basis of the expert opinion provided by the SCDMTE) is regarded as a form of non-tariff regulation and restriction when importing medicinal products or medical devices from member countries of the Eurasian Economic Union and third countries.

In addition to the above-mentioned non-tariff regulations and restrictions concerning medical devices, once the import compliance certificate is obtained, the importer of medical devices is required to adhere to the following procedures before commencing sales.

- Verification of the alignment between the data presented in the documents accompanying the medical devices and the actual information pertaining to the medical devices, ensuring adherence to the stipulated requirements. This encompasses a thorough examination of compliance with any specified conditions for special storage and transportation.
- For registered medical devices, validation of the existence of a designated circulation mark as endorsed by the decision of the Council of the Eurasian Economic Commission No 26 dated 12 February 2016. Additionally, scrutiny of the compliance of the product's marking with the requirements established by the decision of the Council of the Eurasian Economic Commission No 27 dated 12 February 2016.
- Confirmation of the presence of essential details such as the name, trade mark, and contact information of the manufacturer of the imported medical device, along with the official representative in the RA. This verification extends to the packaging or instructions for the use of unregistered medical devices.

Prior to sale, the importer is responsible for verifying the adherence of storage and transportation conditions for the medical devices under their jurisdiction to the general safety and efficiency requirements established by the decision of the Council of the Eurasian Economic Commission on 12 February 2016, No 27, as well as the conditions specified by the manufacturer (if applicable).

In addition to the aforementioned non-tariff regulations and restrictions, it is noteworthy that under Article (21)8 of the Law on Medicinal Products the import and export of drugs, pharmaceuticals, herbal raw materials, and researched pharmaceutical products in the RA may face rejection due to non-compliance with packaging requirements.

For more on the laws or regulations that list the types of products that are subject to regulations upon importation, see **6.1 Governing Law for the Importation and Exportation of Pharma-**

ceuticals and Medical Devices and Relevant Enforcement Bodies.

6.5 Trade Blocs and Free Trade Agreements

Armenia is a member of the Eurasian Economic Union. Armenia is also a party to the Agreement on the Free Trade Zone (signed on 18 November 2011), which entered into force on 17 October 2012.

Meanwhile, the interim agreement on the establishment of a free trade area between the Eurasian Economic Union and Iran was signed on 17 May 2018 and came into effect on 27 October 2019. Subsequently, a comprehensive free trade agreement was signed on 25 December 2023 (which has not entered into legal force as of 23 February 2024), aiming to supersede the temporary agreement that had been in effect since 2019.

As of 1 January 2022, Armenia is no longer a beneficiary of the Generalised Scheme of Preferences Plus (GSP+) preferential trade regime. Nevertheless, specific developed countries – including the USA, Canada, Switzerland, Japan, and Norway – still offer Armenia the opportunity to avail itself of the Generalised Scheme of Preferences (GSP).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

According to Article 8(1) of the Law on Medicinal Products, the primary principles of state policy regarding the provision of medicinal products and the development of pharmaceuticals include guaranteeing the physical accessibility and affordability of medicinal products. These objectives are implemented, in particular, by the Armenian government defining the lists of social or special groups of the population and the list of illnesses for which medicinal products will be provided to beneficiaries with full or partial reimbursement of their price. Additionally, the government outlines the procedure for reimbursing and supplying such medicinal products.

Armenian law, as well as the law of the Eurasian Economic Union, does not include regulations pertaining to pricing in the production of pharmaceuticals or medical devices. Generally, market control is exercised within the framework of antitrust regulations. However, the State does influence pricing to some extent, as it co-finances the acquisition of specific medications (referred to as “essential medicines” in a list published by the government). This is done to ensure access to medications. Nevertheless, there are no regulations directly addressing specific pricing in the production of pharmaceuticals and medical devices.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Although Armenia is a member of the Eurasian Economic Union, there are currently no regulations for standardising prices of medications or medical devices within the Eurasian single market. Consequently, the prices for the same medications or medical devices may vary across different member countries of the Eurasian Economic Union.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Law on Medicinal Products defines reimbursed medicines as medications that receive full or partial reimbursement of their price through a

government-guaranteed process funded by the state budget of the RA. The Armenian government, through Regulation No 642-N dated 30 May 2019, has outlined the social and special groups and diseases for which the state partially or fully covers the costs.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

For the private sector, there are generally no standardised rules mandating the application of cost-benefit analyses or health technology assessments in determining the pricing of pharmaceuticals or medical devices. Pricing decisions in the private sector are often influenced by factors such as market dynamics, competition, production costs, and business considerations.

The state regulation of prices takes into account the INN of the medicinal product, focusing on products registered in Armenia under the stipulated procedure and considering dosage form and strength. The RA government, with recommendations from a commission dedicated to state regulation of medicinal product prices, establishes the reference price and the maximum wholesale and retail price premiums.

The government defines various aspects related to cost-benefit analyses and health technology assessment, including the methodology for calculating reference prices and premiums, the list of countries used for price comparison, and procedures for determining and revising reference prices and premiums. The transparency of this process is emphasised, as the MoH is required to publish the reference price of reimbursed medicinal products and the maximum wholesale and retail premiums on its website.

It is important to note that specific government regulations pertaining to this matter have not been enacted as of now.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Medicinal products are dispensed with a prescription based on the INN of the product. Pharmacies are required to provide comprehensive information to individuals purchasing medicinal products, including details about all available products containing the same active ingredient, having the same strength and dosage form, and being interchangeable. This information, presented without promotional influence, includes pricing details.

Dispensing a prescription with the trade name of the medicinal product is allowed only when accompanied by a reasoned justification from the prescribing doctor. A copy of this justification is submitted to the pharmacy along with the prescription and another copy is attached to the patient's medical documents. The requirements for justifying the dispensing of prescriptions with the trade name are prescribed by the MoH.

8. Digital Healthcare

8.1 Rules for Medical Apps

Currently, there is only one medical app – named "ArMed E-Health" – designed to provide comprehensive information about episodes of medical care and the services rendered. The usage of the system is regulated by the decree of the Minister of Health No 40-N dated 18 May 2021.

8.2 Rules for Telemedicine

The procedure of telemedicine is governed by the Order No 42-N of the Minister of Health of the RA dated 8 July 2022. Telemedical consul-

tation must take place in an online environment utilising a software application (referred to as "the System") with the capability to record and save the consultation.

The telemedical consultation is conducted under the following circumstances:

- when the patient – and, in the case of a patient under the age of 16 or recognised as legally incapacitated, their legal representative – is physically incapable of personally visiting a medical organisation;
- if the location of the patient (or their legal representative) or the consulting doctor prevents the organisation of an in-person visit; and
- with the consent of the consulting doctor, the treating doctor, and the patient (or their legal representative), even if the above-mentioned conditions mentioned are not applicable.

8.3 Promoting and/or Advertising on an Online Platform

There are specific rules governing the promotion and advertising of medicines in electronic and print mass media, as well as through online portals, company websites, and social networks in the RA. According to the regulations, any advertisement of medicinal products in electronic and print mass media must include specific information. This information comprises the number, day, month, year, and validity term of the state registration certificate of the medicinal product in the RA, along with the number and day, month, and year of the permission for advertising granted by the MoH.

Advertising in the mass media is permitted solely for non-prescription medicinal products that do not include narcotics or psychotropic (psychoactive) substances.

Outdoor advertising of medicinal products is prohibited in the RA.

In accordance with the Law on Advertising of the RA, the following are prohibited:

- advertising medications, medical equipment, and methods of medical treatment without the permission of the Ministry of Health of the RA; and
- advertising medications, medical equipment, and methods of medical treatment requiring a special medical prescription for use.

There are no special rules for the promotion and/or advertising of medical devices.

8.4 Electronic Prescriptions

In the RA, electronic prescriptions have become the standard practice, while paper prescriptions are now the exception. A prescription is defined as the written prescription of a medicinal product, which can be in either paper or electronic form. Authorised doctors have the discretion to issue prescriptions, and this authority extends to both traditional and electronic formats.

8.5 Online Sales of Medicines and Medical Devices

Given that there are no prohibitions on the online sale of medications and medical devices, they are allowed to be sold online.

8.6 Electronic Health Records

The e-health system in Armenia is defined as a set of information and infrastructure that facilitates the entry, processing, storage, archiving, and use of health data about each person in an electronic environment (Article 2(1), paragraph 43 of the Law on Medical Aid and Service to the Population of the RA).

The electronic healthcare system operates based on the following principles.

- Information within the electronic healthcare system is personalised unless otherwise defined under the law for specific cases.
- The database is standardised for all participants in the electronic healthcare system.
- Information is accessible at all times to individuals authorised to use the electronic healthcare system as stipulated by law and within the scope of their authority.
- Information is treated as confidential and safeguarded.

Health-related information falls under the category of "biometric" and "special category data" (see **2.5 Use of Data Resulting From Clinical Trials**).

There are no special requirements for cloud platforms. There is no restriction on the storage of sensitive information on cloud platforms either.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Law on Patents of the RA and the Law on Industrial Design of RA apply to patents in Armenia. Additionally, Armenia is also a party to various international patent treaties such as the Eurasian Patent Convention (EPC), Patent Co-operation Treaty (PCT), the 1883 Paris Convention, and the Trade Related Aspects of Intellectual Property Rights (TRIPS).

There are no specific patentability requirements for pharmaceuticals and medical devices as such. In general, patents are issued for inventions, which may also include pharmaceuticals or medical devices if they meet the patentability requirements for an invention – namely, they should be new, involve an inventive step, and be useful for industrial application (Article 12(2) of the Law on Patents). Meanwhile, a patent can also be granted for the protection of an industrial design as specified in **10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices**.

9.2 Second and Subsequent Medical Uses

None of the international patent treaties to which Armenia is a party explicitly prohibit granting legal protection to second and subsequent medical uses of a known product, new dosage regimes and new or selected patient populations, thereby enabling the regulation of these issues by national laws. Meanwhile, the national laws of the RA do not contain specific provisions to regulate the legal protection of the mentioned categories. Thus, under the RA Law on Patents – given that second and subsequent medical uses of a known product, new dosage regimes, and new or selected patient populations may constitute a method of using an already known product – it is possible for them to be granted protection under a short-term patent, provided they are new, do not directly derive from the state of the art and are useful for industrial application (Articles 12(1) and 12(3) of the Law on Patents).

If second and subsequent medical uses of a known product, new dosage regimes and new or selected patient populations are indeed granted protection as short-term patent inventions, the general provisions on patent infringement as described in **9.4 Pharmaceutical or Medical Device Patent Infringement** should apply to them.

9.3 Patent Term Extension for Pharmaceuticals

In general, the validity period of a patent for an invention is 20 years, whereas for short-term patents it is ten years as from the filing day of the application, which may not be extended (Articles 28(1) and 29(1) of the Law on Patents). However, specifically in the case of pharmaceuticals that require permission from a competent authority to be used, the 20-year validity period of the exclusive right may be extended upon the request of the patent holder for no more than five years, in case granting the first usage permission takes more than five years following the date on which the application to receive a patent was filed (Articles 28(3) and 65(1) of the Law on Patents).

During the entire period of its validity, the patent may be declared invalid in full or in part by a judicial act having entered into legal force upon the request of a third party. The request to declare the Eurasian patent invalid in the territory of the RA must be submitted in accordance with the procedures provided for by the Eurasian Convention and the Patent Instruction attached to it, as well as by the national legislation (Article 65(8) of the Law on Patents).

9.4 Pharmaceutical or Medical Device Patent Infringement

Manufacturing, using, offering for sale, selling, or importing or acquiring the patented product for the purpose of one of the previously mentioned actions without the patent holder's permission constitutes a patent infringement (Article 24(1) of the Law on Patents). Applying for marketing authorisation will not infringe a patent if the patented product has already been legally put into civil circulation by means of sale by the patent holder or with their consent or in any other lawful way, such as compulsory licences (Article 27(1) of the Law on Patents). The threat of infringement, as opposed to actual infringement, is actionable so long as it constitutes acquiring a pharmaceutical or medical device for the purpose of conducting any of the above-mentioned actions that amount to an infringement. Thus, there is a requirement of an "imminent" infringement, which can be understood as a well-founded belief that such intent exists or is likely to occur in the foreseeable future.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

General defences to patent infringement, which equally apply to pharmaceuticals and medical devices, include the usage of these products:

- for personal needs without the purpose of earning income;
- as a subject of scientific experiment or scientific research;
- in the case of one-time preparation of medicines in pharmacies with a doctor's prescription;
- for the performance of necessary studies, tests and experiments for the purpose of testing medical (including phytosanitary) products during the two years preceding the expiration of the patent; and
- in emergency situations, as well as for the purpose of ensuring national security, if the patent holder is informed about such use as soon as possible (Article 25(1) of the Law on Patents).

However, this is only permitted under the condition that it does not cause unjustified harm to the normal use of the patented invention and does not unreasonably violate the legitimate interests of the patent holder, and that the legitimate interests of third parties are taken into account (Article 25(2) of the Law on Patents).

Compulsory licences are available for any person or the RA if the person submitting the request proves that they have made efforts to conclude a licence agreement with the patent holder within a reasonable time limit and on reasonable commercial terms but such efforts have failed to succeed. Compulsory licences are granted upon a judicial act having entered into legal force, where:

- it is so required for the public interest – in particular, the areas of national security, nutrition, health (including lack of availability and access to medicinal products) or other areas of vital importance;
- the patent holder or the licensee does not use the patent rights in good faith – in particular, where the manner of use contradicts the customary business practices by restricting competition; or
- the invention has not been used or has been used insufficiently during a period of four years from the date on which the application was filed or three years from the date on which the patent was granted (Articles 72(1) and 72(3) of the Law on Patents).

9.6 Proceedings for Patent Infringement

The patent holder and the licensee who holds an exclusive licence have legal standing to start patent infringement proceedings. The general rule under the Civil Code is that, in cases of actions mentioned in **9.4 Pharmaceutical or Medical Device Patent Infringement** that infringe a patent, the person who has legal standing can seek the termination of violating actions as well as compensation for the damages caused (Article 1155 of the Civil Code). However, in some cases Armenian legislation limits the patent holder's right to seek remedies – for instance, the defences to patent infringement or compulsory licences as mentioned in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

Additionally, the defendant can claim that the patent that was allegedly infringed is invalid. However, such a claim can be brought only in separate proceedings by filing a claim with a specialised court – namely, the Administrative Court. In this case, Armenian legislation provides for a legal tool, such as the suspension of judicial proceedings until the final decision regarding the validity of the patent enters into legal force (Article 157(1) of the Civil Procedure Code).

9.7 Procedures Available to a Generic Entrant

Armenian legislation does not require a declaratory action for a generic product to enter the market and clearing the way is not a requirement for generic market entry either. According to the Law on Medicinal Products, the generic entrant can be granted marketing authorisation in Armenia ten years after the registration of the original drug (Article 16(15) of the Law on Medicinal Products). Hence, the marketing authorisation procedure for pharmaceuticals and medical devices does not take patent protection into account and does not infringe a patent.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Illegal use of an object of patent right constitutes an offence under the Armenian Administrative Offences Code if the damages do not exceed AMD500,000 (approximately USD1,237), for which a sanction in the form of a fine is foreseen. However, if damages exceed AMD500,000, then the act will constitute a crime under the Criminal Code of the RA. Moreover, the Criminal Code of

the RA also foresees punishment for illegal circulation of pharmaceuticals and medical devices, making and using fake identification documents and the illegal circulation of genuine documents – for which punishments from a fine to imprisonment are foreseen (Articles 228, 409, 410 and 411 of the Criminal Code).

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There are no specific restrictions on trade marks that can be used for pharmaceuticals and medical devices; however, the Law on Trade Marks establishes the absolute and relative grounds for refusal of trade mark registration. These include general restrictions – for example, that the trademark should not contradict public order, principles of humanity or morality, consist of or contain information that is false and/or misleading to consumers, reproduce or contain national emblems, flags or symbols, official names of states or their abbreviated forms, be identical or confusingly similar to an earlier registered trade mark, etc (Articles 9 and 10 of the Law on Trade Marks). Hence, a restriction under the Law on Trade Marks that would restrict the importing or distributing of non-counterfeit genuine pharmaceutical or medical device products is that the trade mark should not be identical or confusingly similar to an earlier registered trade mark or meet any of the other absolute or relative grounds for refusal of trade mark registration.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress or design of pharmaceuticals and medical devices (such as tablets) or their packaging will fall under IP protection if they meet the criteria to qualify as an industrial design – namely, the design characterising the outward appearance of a product should be new and unique. The industrial design will meet the criteria of being new where no identical industrial design has been made available to the public. However, to satisfy the criteria of uniqueness, the overall impression made by an industrial design on the informed consumer should differ from the overall impression produced by any other industrial design.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Under the Law on Medicinal Products, the documents that were submitted for marketing authorisation are protected under data exclusivity for eight years. After eight years data exclusivity is no longer valid and reproduced drugs can be granted marketing authorisation based on the documents that were submitted to receive the marketing authorisation for the genuine product. However, even if the marketing authorisation is granted after eight years, the reproduced pharmaceutical still cannot be put into circulation unless ten years pass from the registration of the genuine drug (Article 16(15) of the Law on Medicinal Products). Hence, to some extent, the data exclusivity is still under protection during the course of the remaining two years.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, a series of measures were implemented to prevent the spread of the virus. To prevent shortages of medicinal products such as face masks, ventilators, disposable medical gloves, and clothing, strict restrictions on the export of medicinal products were imposed. By decree of the Chief Co-ordinator (the Deputy Prime Minister) dated 3

April 2020, the export of various medical devices abroad – including to Eurasian countries – was temporarily prohibited.

Restrictions concerning medicinal products, however, were not implemented.

11.2 Special Measures Relating to Clinical Trials

No special measures were issued in relation to ongoing clinical trials during the COVID-19 pandemic. However, following Decree No 65-N of the Minister of Health dated 20 August 2021, employees in government or self-administration authorities were required to present a PCR test every three days (otherwise entry was denied) or provide evidence of full vaccination.

The order of the Minister of Health No 21 dated 17 August 2020 delineates the rules and norms for implementing vaccinations against communicable diseases in the RA. Although these regulations do not explicitly refer to the COVID-19 disease, they were enacted in response to the pandemic. This directive covers the management of medical contraindications and handling cases of adverse post-vaccination reactions. It further addresses planning to meet the demand for medical immunobiological preparations, encompassing receipt, storage, transportation, accounting, and expenditure. The order also establishes stringent requirements for the utilisation of open vials, with the overarching goal of eradicating manageable infectious diseases. Emphasis is placed on reducing morbidity and mortality rates attributed to such diseases, minimising unjustified contraindications, and achieving timely (95% and more) and comprehensive (90% and more) coverage of vaccinations within target populations. Additionally, the order outlines the process of immunosuppression to ensure the safety and efficacy of the overall vaccination initiative.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

There were no specific regulations concerning emergency approvals for the importation of medicines or medical devices. Armenian law permitted the importation of medicines without registration during a state of emergency, such as the COVID-19 pandemic. Additionally, the requirement for a registered medicinal product to obtain an import certificate is waived in cases of emergencies (or the threat thereof).

Meanwhile, the specific procedures and a list governing the sale, acquisition, and circulation of food, medicine, and essential goods during martial law were established through the government's Decision No 1632-N dated 3 October 2020.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No simplifications or flexibilities (eg, automatic renewal or temporary extensions) were introduced in relation to obtaining required certifications owing to COVID-19, as a state of emergency was declared and registration was not needed for importing medications into Armenia under such circumstances.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

For import/export restrictions or flexibilities introduced in relation to medical devices, please refer to **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**.

There were no restrictions on exporting or importing pharmaceuticals into Armenia. A

flexibility for the import of medications can be observed in the fact that drugs were allowed to be imported into Armenia even if they were not registered, following Decision No 1632-N of 3 October 2020 of the Government of the RA (see **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**).

11.6 Drivers for Digital Health Innovation Due to COVID-19

The regulations for telemedicine were implemented in the Law on Medicinal Products on 6 May 2020 and, as such, during the COVID-19 pandemic. Also, the digital app "ArMed E-Health" launched during the COVID-19 pandemic (see **8.1 Rules for Medical Apps**).

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Armenian government has not announced any intention to issue compulsory licences for treatments or vaccines related to COVID-19. However, under Armenian law, compulsory licences may be granted without the consent of the patentee through a judicial act if the interests of society – including national security, food production, public health (including the unavailability of medicinal products), or other vital areas – necessitate such action (see **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No exemptions from liability have been implemented for treatments or vaccines related to COVID-19. The standard liability regulations for pharmaceuticals remain in effect.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions were not used – nor were new ones introduced – to allow the requisition or conversion of manufacturing sites owing to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There were no changes made to the system of public procurement of medicines and medical devices in response to COVID-19.

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