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TITLE

THE REGULATION OF MEDICAL DEVICES IN THE REPUBLIC OF ARMENIA

WHETHER THE LEGISLATION OF THE REPUBLIC OF ARMENIA COMPLIES WITH
THE STATE'S INTERNATIONAL OBLIGATIONS AND INTERNATIONAL BEST
PRACTICES REGARDING THE REGULATION OF MEDICAL DEVICES AND WHAT ARE
THE POSSIBLE SCENARIOS FOR LEGAL REGULATIONS

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ABSTRACT

The term “medical devices” covers a vast range of equipment, from simple tongue depressors to hemodialysis machines. Like medicines and other health technologies, they are essential for patient care – at the bedside, at the rural health clinic or at the large, specialized hospital. Yet many countries worldwide are lacking access to high quality, safe and effective devices and equipment that are appropriate for their specific needs and for healthcare regulation generally. This refers especially to developing countries where health technology assessments are not widespread and where there are almost no regulatory controls to prevent the import or the circulation (in particular, the usage and the problems emerged resulting from that) of substandard medical devices.

Nowadays, the circulation and sale of counterfeit medical devices, and the misuse and medical errors associated with medical devices especially in healthcare facilities are major concerns in the Republic of Armenia, as in most of the developing countries worldwide. The main reason behind these crucial problems is the absence of supervision in the field of the circulation of medical devices. On the pathway of regulating the market of medical devices in the Republic of Armenia there are a range of legal, social and economic barriers. The current situation of the country in the field of healthcare indicates that national regulatory authorities perform inadequately, focusing mainly on the regulation of medicines and not on medical devices. Historically, the states concentrated on regulating the field of medicines, as it was more or less simple and easy task than the regulation of medical devices (taking into account for example the quantity of medical devices, which is much higher than that of medicines).

There is an incomplete domestic legislation on medical devices and lack of specific mechanisms for the regulation of that field. Although the Eurasian Economic Union tries to conduct some measures with the aim of regulating the circulation of medical devices in the region, they still do not play an important and decision-making role internationally, and it is crucial to have domestic regulations and not depend on the regional organization. In addition, regulatory measures do not comply with the international best practices and the International Medical Device Regulators Forum recommendations (even though it is stipulated by the documents of the Eurasian Economic Union), which in its turn can lead to the purchase of medical devices that may do harm and that do not perform according to their intended purpose.

Through comparing various international practices and models regarding the regulation of medical devices and drawing parallels between the domestic legislation of the Republic of Armenia and the commitments it is legally bound by under international law, this thesis paper advances to making recommendations for a national strategy and legal framework aimed at regulating the circulation of medical devices.

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LIST OF ACRONYMS AND ABBREVIATIONS

RA – Republic of Armenia

MD – medical device

IVD – in vitro diagnostic medical device

GHTF – Global Harmonization Task Force

IMDRF – International Medical Device Regulators Forum

ISO – International Organization for Standardization

NRA – national regulatory authority

QMS – quality management system

GMDN – Global Medical Device Nomenclature

SDG – Sustainable Development Goals

MDG – Millennium Development Goals

UN – United Nations

EU – European Union

EC – European Commission

WHO – World Health Organization

WHA – World Health Assembly

EAEU – Eurasian Economic Union

EEC – Eurasian Economic Commission

HSA – Health Science Authority of Singapore

U.S. FDA – United States Food and Drug Administration

AMAR – Israeli Ministry of Health Medical Devices Regulation Unit

***“It is health that is real wealth,
not pieces of gold and silver.”***

Mahatma Gandhi

INTRODUCTION

“The field of medical devices is large, diverse, competitive, and highly innovative. This is an area of great promise, sometimes spectacular promise, sometimes seductive promise. It is also an area with a number of problems and pitfalls, some familiar, others unique. The medical devices industry produces high-tech high-cost diagnostic and therapeutic equipment, but it also produces the basic supplies and devices that keep any health facility running smoothly on a daily basis. The field also includes devices that aid functional ability, like wheelchairs, hearing aids, eyeglasses, intraocular lenses, and artificial limbs. The vital role of such devices in improving the quality of life is obvious, though often overshadowed by the attention given to more spectacular devices. As many have noted, the field of medical devices requires, and deserves, its own unique agenda. Health officials and hospital managers in all countries, at all levels of development, need guidance.”¹

Medical devices are at the same time different from and similar to other consumer goods or products. They play an important role in, and are an integral part of, healthcare delivery. Therefore, it is important to understand that from a government perspective it is not only accessibility but also quality, safety and efficacy of medical products that counts. Beside these considerations, there are other challenges, such as cultural diversity (languages, literacy levels,

¹ Excerpt from the opening address at the World Health Organization’s First Global Forum on Medical Devices. Dr. Margaret Chan, Director-General. Bangkok, Thailand. 9–11 September 2010. Available at: http://www.who.int/dg/speeches/2010/med_device_20100909/en/index.html (last access: 02 March 2020).

and social and religious customs and traditions) and the attitude of the consumer and healthcare provider towards disease and medication.² The regulation of medical devices according to the principles of good governance and good regulatory practice must also take into account national health plans, existing laws, available resources, and production and importation practices.³ Medical devices are heavily contributing to healthcare delivery universally for the well-being of the people. Continual development and innovation in medical devices is crucial to ensuring quality of life in the world. From sticking plasters to X-ray scanners, syringes to wheelchairs, medical devices are significant in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities.

Medical device's classification depends on the intended use of the device and upon indications for use.⁴ For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned.⁵ The risks associated with each type of device are different; all medical devices may be misused, result in errors and none of them is absolutely safe. Such an example could be the medical gloves. When a doctor uses the gloves during surgery, the risk of causing harm to the patient is much bigger, because the gloves are having connection with an open wound. At the same time, when a doctor uses the gloves while diagnosing a patient's body, the risk of causing harm to the patient decreases, as the gloves are having connection only with the skin.

Many national regulatory authorities (hereinafter also referred to as the "NRAs") consider 3 to 4 different risk classes for medical devices. The Global Harmonization Task Force (hereinafter also referred to as the "GHTF"), which is the predecessor of the International Medical Device Regulators Forum (hereinafter also referred to as the "IMDRF"), gave the 4-level risk classification for different types of medical devices, which reads as follows:

Class I or Low risk (e.g. bandages / tongue depressors);

Class IIa or Low–moderate risk (e.g. hypodermic needles / suction equipment);

Class IIb or Moderate–high risk (e.g. lung ventilator / bone fixation plate);

² *Regulation of Medical Devices. A step-by-step guide. WHO Regional Publications, Eastern Mediterranean Series 38.* World Health Organization. Regional Office for the Eastern Mediterranean (20 November 2016) Available at: https://apps.who.int/iris/bitstream/handle/10665/249571/EMROPUB_2016_EN_18962.pdf?sequence=1&isAllowed=y (last access: 02 March 2020).

³ *Id.*

⁴ *The Official Website of the U.S. Food and Drug Administration. Classify your medical device.* 07 February 2020. Available at: <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device> (last access: 22 March 2020).

⁵ *Id.*

Class III or High risk (e.g. heart valves / implantable defibrillator).⁶

Those classified as “low risk” or “class I” are still capable of killing and injuring patients when misused (e.g. hospital beds, wheelchairs). Some devices, such as those containing software, are subject to endless updates because features are upgraded, resulting in short commercial life cycles.⁷

The primary purpose of implementing regulatory systems for medical devices is to protect public health and ensure safety and performance. Experience shows that countries regulate medicines before they consider introducing similar controls for medical devices. However, the public will likely be outraged if it believes its national regulatory authority has allowed unsafe medical devices to circulate in the market. To do so, not only must the safety and performance of each device be maintained throughout its life span, but also the organizations established in the regulated jurisdiction – such as those responsible for manufacturing, importing, distributing, and representing overseas manufacturers and those using medical devices – must act in an effective and responsible manner. A secondary benefit of introducing regulatory systems is that domestic manufacturers will not only be encouraged to develop and market alternatives to imported devices but will also have an opportunity to grow their business through exporting such products. This is only possible when medical device regulations have been harmonized with regulations already established in major overseas markets.⁸

Many states want to adopt a “single-market” approach to medical devices under one regulatory regime (with mutually accepted regulatory controls within the frames of their region), similar to the European Union. The regulations of the market should be harmonized with each country’s context, with policy-makers of the states determining the extent and complexity of the regulatory controls, which are aimed at regulating the circulation of the medical devices in their country. To regulate medical devices efficiently, regional and global collaboration and harmonization are key elements. Currently, one of the main global harmonization initiatives is the International Medical Device Regulators Forum (IMDRF). The experiences of other countries’ NRAs should be used for drafting new legislation. However, the new legislation

⁶ *Principles of Medical Devices Classification*. Study Group 1, Final Document GHTF/SG1/N77 (2 November 2012) Available at: <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf> (last access: 02 March 2020).

⁷ An industry trade group estimates that medical devices are replaced by improved versions every 18–24 months. *The Advanced Medical Technology Association’s (AdvaMed) Comments on 21st century cures: a call to action*. Submitted to the House Energy and Commerce Committee, 113th Cong. (1 June 2014) Available at: <http://advamed.org/res.download/725> (last access: 12 March 2020).

⁸ *Regulation of Medical Devices. A step-by-step guide*.

should be sufficiently flexible to encourage harmonization and should be tailored to the particular needs of the Republic of Armenia (hereinafter also referred to as the “RA”).

The research problem or subject matter of the present thesis paper is the examination of the international commitments assumed by the Republic of Armenia and the respective domestic legislation regarding the regulation of medical devices. The thesis paper then advances to presenting the best regulatory practices worldwide and making recommendations on possible mechanisms aimed at regulating the circulation of medical devices.

Thesis paper literature is based on a vast array of international documents (charter, treaties, agreements, etc.) research articles, legal journals, scholarly papers, as well as recommendations and guides by reputable international organizations. The paper makes references to expert opinions and reports on the importance and the regulation of the medical devices. Certain legal instruments in terms of Laws and other normative acts (including drafts) of the Republic of Armenia are also cited in the paper. The Agreement on the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union signed by the Member States of the Eurasian Economic Union on 23 December 2014 (which came into force for the Republic of Armenia on 01 January 2016) is one of the core documents to be discussed in this paper. The decisions of the Eurasian Economic Commission’s Council regarding the regulation of medical devices’ circulation are also analyzed in the present paper. That part of the paper mainly stresses whether the mentioned regulations are subject to direct appliance in the Republic of Armenia and the need of having domestic instruments if so. The current standing and the core issues of the main decisions on the registration procedure of medical devices, namely the Decision N 46 on the Rules of the Registration and the Expertise of the Quality, Safety and Efficacy of Medical Devices is discussed. The regulations on medical devices of the European Union, the United States Food and Drug Administration and some other countries’ experience prove a valuable contribution to present research by offering an insight into international best practices. World Health Organization’s documents, especially guides and recommendations prove to be another useful reference point in coming up with best solutions for the regulation of the medical devices’ circulation in the Republic of Armenia. Intended for policy-makers and drafters of the legislation, these specific documents of the World Health Organization are developed with a view to assisting in improving the effectiveness of domestic legislation concerning the regulation process.

The current thesis paper consists of a list of acronyms and abbreviations, an introduction, two chapters, a conclusion and a bibliography. The List of Acronyms and Abbreviations

comprises a number of acronyms and abbreviations, which are widely used in the field of medical devices' regulation. The Introduction presents an overview on general characteristics of medical devices and the importance of their regulation, which will be furtherly discussed therein. Chapter I offers insight on the international commitments assumed by the Republic of Armenia regarding the regulation of medical devices. It will also cover the current standing of the respective domestic legislation of the Republic of Armenia. Chapter II is designed to study the international best practices (international organizations and different countries) with respect to the regulation of medical devices. The Conclusion presents recommendations grounded on the analysis of the issues discussed in the previous two Chapters and will succinctly outline the main findings of the research. Finally, the Bibliography listing all the sources used for the paper will be noted.

CHAPTER I

REVIEW OF THE INTERNATIONAL COMMITMENTS OF THE REPUBLIC OF ARMENIA AND THE RELEVANT DOMESTIC LEGISLATION

Back in March of 1992, the Republic of Armenia joined the United Nations by signing the Declaration of Acceptance of the Obligations Contained in the Charter of the United Nations.⁹ After its membership to the United Nations, the Republic of Armenia signed and ratified a number of international agreements, treaties and conventions, thus committing itself to create

⁹ *Declarations of acceptance of the obligations contained in the Charter of the United Nations (Admission of States to membership in the United Nations in accordance with Article 4 of the Charter)*. Adopted: 24 Oct 1945. Entry into force: 24 Oct 1945. Armenia's participation - Signature: 2 Mar 1992; Registration date: 2 Mar 1992; General Assembly resolution number 46/227; Registration number 28686; UNTS volume 1668; UNTS page 201. Available at: https://treaties.un.org/doc/source/docs/armenia-E_F.pdf (last access: 02 March 2020).

The Declaration was presented to the Secretary-General of the United Nations on 15 January 1992. On 2 March 1992, by resolution A/RES/46/227* adopted by the General Assembly of the United Nations, the Republic of Armenia was admitted to membership in the United Nations.

* United Nations, Official Records of the General Assembly. 46th Session, Supplement N 49A(A/46/49/Add. 1), p. 2.

such conditions, which will provide for the respect towards the obligations proceeding from those international documents. The Charter of the United Nations¹⁰ (hereinafter also referred to as the “Charter”) is an international treaty ratified by the Republic of Armenia, thus, is a constituent part of the legal system of the state.¹¹ Corresponding to the Article 2.2 of the Charter “*All members, in order to ensure to all of them the rights and benefits resulting from membership, shall fulfill in good faith the obligations assumed by them in accordance with the present Charter.*” Additionally, Article 56 of the Charter states the following: “*All Members pledge themselves to take joint and separate action in cooperation with the Organization for the achievement of, inter alia, solutions of health problems.*” The Constitution of the Republic of Armenia states that “*In case of contradiction between the provisions of the ratified international treaties and the Laws of the Republic of Armenia, the provisions of the former must be applied.*”¹² Therefore, having higher authority than the Laws of the state, the obligations under the Charter are subject to execution in the Republic of Armenia.

In 1992, the Republic of Armenia became a member of the United Nations World Health Organization (hereinafter also referred to as the “WHO”) and the Constitution of the World Health Organization¹³ came into force for the Republic of Armenia on 4 May 1992. The WHO Constitution, also being an international treaty ratified by the Republic of Armenia, is a constituent part of the legal system of the state, and thus, it has the same legal effect as the Charter of the United Nations mentioned above. Corresponding to the principles of the WHO Constitution “*Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.*” Under Article 61 of the WHO Constitution, “*Each Member shall report annually to the Organization on the action taken and progress achieved in improving the health of its people.*” Accordingly, Article 62 of the WHO Constitution states that “*Each Member shall report annually on the action taken with respect to recommendations made to it by the Organization and with respect to conventions, agreements and regulations.*” Through ratifying the WHO Constitution, the Republic of Armenia thereby commits itself to protect and ensure the health of its people. Hence, the WHO Constitution implies a positive obligation of the Republic of Armenia to conduct comprehensive

¹⁰ *Charter of the United Nations*. San Francisco (United Nations Conference). Adopted: 26 June 1945. UNTS XVI. Available at: <https://www.un.org/en/sections/un-charter/introductory-note/index.html> (last access: 02 March 2020).

¹¹ *The “Law of the Republic of Armenia on International Treaties” of the Republic of Armenia*. Article 3.2. Available at: www.arlis.am (last access: 22 March 2020).

¹² *Amendments to the Constitution of the Republic of Armenia*. Article 5.3. Adopted: 06 December 2015. Entry into force: 22 December 2015. Available at: www.arlis.am (last access: 22 March 2020).

¹³ *Constitution of the World Health Organization*. New York (International Health Conference). Adopted: 22 Jul 1946. Entry into force: 7 Apr 1948. Armenia's ratification - 4 May 1992. Available at: https://www.who.int/governance/eb/who_constitution_en.pdf (last access: 02 March 2020).

legal reforms in order to solve the issues with regard to healthcare regulation (including, inter alia, the regulation of the medical devices' circulation). Moreover, on 24 May 2014 the 67th World Health Assembly (the decision-making body of the WHO) approved the resolution WHA67.20 "Regulatory system strengthening for medical products."¹⁴ The resolution notes the importance of regulations for medical devices as one of the medical products, with regard to the need of increasing access to safe, effective and quality medical products with the aim of ensuring better public health outcome. The resolutions adopted by the World Health Assembly (hereinafter also referred to as the "WHA") are recommendations made by the WHO to the member states of the organization.

The WHO Constitution created a normative institution with extraordinary powers. It establishes the WHO as the premier global health leader, stating that it should "*act as the directing and coordinating authority on international health work*" and "*generally take all necessary actions to attain the objective of the Organization.*"¹⁵ Article 2 grants the WHO extensive normative powers to carry out its mission, authorizing the WHA to adopt "*conventions, agreements and regulations, and make recommendations with respect to international health matters.*" The Organization principally exercises its normative authority through "soft" power - either constitutionally authorized "recommendations" or more informal action by the Assembly, Board, and/or Secretariat. The Organization rarely exerts its constitutional authority to exercise "hard" power by negotiating binding international law.¹⁶ The WHO's most salient normative activity has been to create "soft" standards underpinned by science, ethics, and human rights. Although not binding, soft norms are influential, particularly at the national level where they can be incorporated into legislation, regulation, or guidelines. The WHO uses a variety of legal and policy tools to set soft norms, with varying levels of institutional support. First, the WHA can pass a resolution, which expresses the will of member states, representing the highest level of commitment. Second, the Secretariat can set a standard on a grant of authority from the Assembly or Board, but without the governing authority's formal approval. The more directly the Assembly approves the normative content, the more likely that member states will support and implement the standard.¹⁷ However, the member states are not

¹⁴ World Health Assembly Resolution WHA67.20 on the "Regulatory system strengthening for medical products". World Health Organization's Sixty-Seventh World Health Assembly. Adopted: 24 May 2014. Available at: <https://apps.who.int/medicinedocs/documents/s21456en/s21456en.pdf> (last access: 02 March 2020).

¹⁵ Constitution of the World Health Organization. Article 2.

¹⁶ L.O. Gostin, D. Sridhar, D. Hougenobler; *The normative authority of the World Health Organization*. PUBLIC HEALTH XXX (2015) 1-10; Published by Elsevier Ltd. (2015). Available at: [http://www.publichealthjrn.com/article/S0033-3506\(15\)00200-0/fulltext](http://www.publichealthjrn.com/article/S0033-3506(15)00200-0/fulltext) (last access: 02 March 2020).

¹⁷ L.O. Gostin, D. Sridhar, D. Hougenobler; *The normative authority of the World Health Organization*.

obliged to comply with the recommendations. Mostly, the WHO has avoided norm-setting, giving preference to scientific and technical solutions to the firmly established problems of global health.¹⁸

On 10 October 2014 the Republic of Armenia signed the Treaty on the Eurasian Economic Union¹⁹ (hereinafter also referred to as the “Treaty”), which came into force on 02 January 2015 and by which the Republic of Armenia officially joined the Eurasian Economic Union (hereinafter also referred to as the “EAEU”). The Republic of Armenia, by signing the Treaty on the Eurasian Economic Union and other treaties and agreements within the framework of the EAEU, commits itself to act in compliance with the obligations proceeding from those international documents. The Treaty stipulates obligations for the EAEU Member States regarding the regulation of, inter alia, medical devices.

The Article 31 of the Treaty states the following:

“Establishment of Common Market of Medical Products (Healthcare Products and Medical Devices).

1. Member States within the framework of the EAEU shall establish the common market of medical products (healthcare products and medical devices) based on the following principles:

1) Harmonization of the legal requirements of the Member States in the field of medical products (healthcare products and medical devices) circulation;

2) Ensuring the unity of the mandatory requirements for the efficacy and safety of medical products (healthcare products and medical devices) in circulation at the territory of the EAEU;

3) Adoption of common rules in the field of medical products (healthcare products and medical devices) circulation;

4) Determination of common approaches for the establishment of system on provision of safety of medical products (healthcare products and medical devices);

5) Harmonization of the legislation of the Member States in the field of control (supervision) of medical products (healthcare products and medical devices) circulation.”²⁰

In addition to this, the Article 100 of the Treaty stipulates the following: *“The common market of medical devices within the EAEU shall function starting from 1 January 2016. It must be in accordance with an international treaty within the EAEU, which will determine the uniform*

¹⁸ Taylor AL. *Making the World Health Organization work: a legal framework for universal access to the conditions for health.* Am J Med Health 1996;18(4):301e46. Fidler D. *The Future of the World Health Organization: What role for international law.* Vanderbilt J Transn Law 1998;31(5):1079- 1126.

¹⁹ *Treaty on the Eurasian Economic Union.* Astana, Kazakhstan (9 October 2014). Available at: https://www.un.org/en/ga/sixth/70/docs/treaty_on_eeu.pdf (last access: 02 March 2020).

²⁰ *Id.* Article 31.

principles and rules for the circulation of medical devices, to be signed by the Member States not later than 01 January 2015.”²¹

The drafters of the EAEU regulations on medical devices most probably assumed there already existed country-specific rules within the Member States, which needed harmonization to be conducted through the Treaty in order to adopt common rules for the whole EAEU on medical devices’ circulation. Considering the fact that the Republic of Armenia lacks complete domestic regulation on medical devices, we can state that the latter should be drafted in the RA and afterwards it should be harmonized with the international instruments ratified by the state.

Further, in accordance with the obligations under the Treaty, on 23 December 2014 the Member States of the EAEU signed the Agreement on the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union²² (hereinafter also referred to as the “Agreement”), which came into force for the Member States on 01 January 2016. Corresponding to the article 1 of the Agreement *“The circulation of medical devices within the frames of the EAEU are regulated according to the Treaty on the Eurasian Economic Union, this agreement, other international agreements forming part of the EAEU legislation, the decisions of the Commission, and also the legislation of the Member States.”*²³

The Article 3 of the Agreement stipulates that the EAEU Member States must conduct the unification of the rules on medical devices in compliance with the international documents. It reads as follows:

“Systematized policy conduction in the field of medical devices circulation.

Member States conduct systematized policy in the field of medical devices circulation by these means:

Taking the steps needed to harmonize the laws of the Member States regulating the circulation of medical devices.

Defining unified rules of medical devices circulation according to the International Medical Devices Regulatory Forum (IMDRF) recommendations.

Harmonizing the Member States’ domestic medical devices nomenclatures with the General Medical Devices Nomenclature (GMDN).

²¹ *Id.* Article 100.

²² *Agreement on the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union.* Moscow, Russia (23 December 2014). Available at: http://www.imeda.ru/netcat_files/32/30/Soglashenie_o_edinyh_printsipah_MI_EAES_Eng.pdf (last access: 25 March 2020).

²³ *Id.* Article 1.

*Harmonizing the laws of the Member States pertaining to control (oversight) of the circulation of medical devices.*²⁴

Even though the Agreement envisages an obligation to stipulate the unified rules of medical devices' circulation in compliance with the IMDRF recommendations, this is still not a reality. The regulating documents of the Eurasian Economic Union regarding medical devices are not harmonized with the recommendations and guidance made by the IMDRF, and there is nothing on the cooperation between the IMDRF and the EAEU in the official documents of IMDRF. A good example for proving the inconsistencies between the EAEU and the IMDRF documents is that there is an absence of harmonization regarding the accreditation mechanism of the manufacturer's Quality Management System (hereinafter also referred to as the "QMS"). According to the IMDRF documents, the compliance of the manufacturer's Quality Management System with the ISO 13485 standard is conducted by independent accreditation bodies, which are members of the International Accreditation Forum.²⁵ However, within the territory of the EAEU, the abovementioned process is conducted by the experts of the EAEU, and there are no independent accreditation bodies, which increases the risk potential and is principally in contradiction with the IMDRF regulations. This means the regulatory documents on medical devices are drafted with major contradictions with the international best practices, although they were supposed to be the basis of such documents. It is also proved by the fact that there are records only about one registered medical device through the EAEU registration procedure over the last 4-5 years.²⁶ The process of harmonization is taking too long, and as far as there is no compliance with the international documents, the field of medical devices' regulation will continue to be out of supervision. In addition, the Article 4 of the Agreement stipulates the following: *"Medical devices cleared for market entry within the framework of the EAEU shall be subject to registration in the manner prescribed by the Eurasian Economic Commission."*²⁷

On 12 February 2016, in accordance with the obligations under Article 31 of the Treaty and Article 4 of the Agreement, the Eurasian Economic Commission (hereinafter also referred to as the "EEC") Council made a Decision N 46 on the Rules of the Registration and the Expertise of the Quality, Safety and Efficacy of Medical Devices (hereinafter referred to as the "Decision N

²⁴ *Id.* Article 3.

²⁵ *The Official Website of the International Accreditation Forum.* Available at: <https://www.iaf.nu/articles/About/2> (last access: 05 May 2020).

²⁶ *The Official Website of the Eurasian Economic Union. Eurasian Economic Commission.* Available at: <http://www.eaeunion.org/?lang=en#info> (last access: 27 March 2020).

²⁷ *Agreement on the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union.* Article 4.

46”).²⁸ According to the Decision N 46, “During the transitional period until 31 December 2021 the registration of the medical devices by the choice of the manufacturer can be done either in accordance with the current Rules or in accordance with the domestic legislation of the Member State. The medical devices, which are registered under the domestic legislation of a Member State, can be circulated within the territory of that Member State. The documents certifying the registration of the medical devices and given by the competent authority of the Member State in accordance with the domestic legislation of that Member State, are in force until the end of its validity period, but not later than 31 December 2021.”²⁹ This provision of the Decision 46 stipulates that after the end of the transitional period (starting from 01 January 2022) the Member States are obliged to conduct the registration of the medical devices only in accordance with the unified rules of the EAEU and the certificates given through domestic registration procedure will lose their validity. Those Member States of the EAEU, which are currently conducting registration in compliance with their domestic legislation, will have to switch to the unified rules of registration after the end of the transitional period. In particular, the Republic of Kazakhstan³⁰, the Republic of Belarus³¹, the Republic of Kyrgyzstan³² and the Russian Federation³³ (four of the EAEU five Member States, excluding the Republic of Armenia) have their domestic legislation regulating the circulation of medical devices and conduct the registration in accordance to that.

The Republic of Armenia is the only Member State of the EAEU, which still does not have complete domestic regulation regarding the circulation of the medical devices.³⁴ Thus, the RA should either adopt domestic acts regulating the circulation of the medical devices and start the registration procedure in accordance to that, or wait until the end of the transitional period (01 January 2022) and conduct the registration in compliance with the EAEU unified legislation. However, it should be noted that after the entry into force of the Decision 46, a more complicated process has started, particularly, the discussion of the amendments’ pack of the document

²⁸ *Decision N 46 on the Rules of the Registration and the Expertise of the Quality, Safety and Efficacy of Medical Devices*. Eurasian Economic Commission Council. Moscow, Russia. Adopted: 12 February 2016. Entry into force: 06 May 2017. Available at: https://docs.eaeunion.org/docs/en-us/01410767/cncd_12072016_46 (last access: 27 March 2020).

²⁹ *Id.*

³⁰ Ministry of Justice of the Republic of Kazakhstan. Institute of Legislation and Legal Information. *Legal Information System of Regulatory Legal Acts of the Republic of Kazakhstan*. Available at: <http://adilet.zan.kz/eng> (last access: 12 March 2020).

³¹ National Center of Legal Information of the Republic of Belarus. *National Legal Internet Portal of the Republic of Belarus*. Available at: <http://law.by/> (last access: 12 March 2020).

³² The Government of the Republic of Kyrgyzstan. *Normative-legal Acts of the Republic of Kyrgyzstan*. Available at: <https://www.gov.kg/ru/npa/c/provisions> (last access: 12 March 2020).

³³ The Governmental System of the Legal Information of the Russian Federation. *Official Internet-Portal of Legal Information of the Russian Federation*. Available at: <http://pravo.gov.ru/index.html> (last access: 12 March 2020).

³⁴ The Ministry of Justice of the Republic of Armenia. *Armenian Legal Information System*. Available at: <https://www.arlis.am/> (last access: 27 March 2020).

(starting from May 2017), which has ended on February 2020 and the amendments' pack is currently undergoing public discussion stage.³⁵ The alterations of the document are connected to that of other related EEC Council decisions. For example, there was a need to make some changes in the Decision 46 because the EEC Council conducted amendments regarding the expertise with the aim of evaluating the biological impact of the medical devices.³⁶ In case those amendments' are adopted, they will enter into force not sooner than 01 May 2021.³⁷ In addition, it is almost impossible for the EAEU Member States to conduct the registration in compliance with only the Decision 46. That is because there are no secondary or related documents adopted after the Decision 46, which are urgent and crucial for the start of the registration. For example, there is no regulation adopted by the EAEU defining the rules for post-market surveillance, which is the main tool for securing safe, high quality and effective medical devices for the people. The rules on the fees for the registration of medical devices and other related procedures are also essential, but still the EAEU and the Republic of Armenia lack such regulations.

The issue of the EEC Council decisions' applicability in the territory of the Republic of Armenia needs to be discussed thoroughly. Particularly, the problem is whether the EEC Council decisions are *per se* applicable in the Republic of Armenia or they should be implemented into the domestic legislation of the country in order for them to be executed. The Constitutional Court of the Republic of Armenia in his decision SDO-1175 regarding the Determination of the Treaty's Compliance with the Constitution of the Republic of Armenia³⁸ (giving reference to the "Law on the Republic of Armenia International Treaties" of the Republic of Armenia in force at that time³⁹) gave an opinion on the issue. It states, "*The decisions of the international organization's body are not considered as international treaties and that decisions are followed by the Republic of Armenia to the extent that such legal authority is given to the decisions by the founding documents of that international organization. If the founding documents of the international organization stipulate that the decisions of its body are mandatory for the member states of that organization, or they undertook an obligation to execute its decisions, then the responsible authority of the member state ensures the execution of the decisions.*" The Treaty on the Eurasian Economic Union in its Annex 1 provides the Regulation on the Eurasian Economic

³⁵ *The Official Website of the Eurasian Economic Union. Public Discussions.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *SDO-1175 Decision of the Constitutional Court of the RA regarding the determination of the compliance with the Constitution of the RA of the Treaty on the Accession of the RA (dated 10 October 2014 and signed in Minsk) to the Treaty on the Eurasian Economic Union (dated 29 May 2014).* Adopted: 14 November 2014. Constitutional Court of the Republic of Armenia. Yerevan, Republic of Armenia. Available at: <https://www.arlis.am/DocumentView.aspx?docID=93758> (last access: 12 March 2020).

³⁹ *The "Law of the Republic of Armenia on International Treaties" of the Republic of Armenia.*

Commission.⁴⁰ Particularly, it states that “*The EEC shall, within its authority, adopt decisions with regulatory and binding effect for the Member States, organizational and administrative dispositions and non-binding recommendations. Decisions of the EEC shall form part of the EAEU law and shall be directly applicable on the territories of the Member States.*” Considering the fact that the Treaty is an international treaty ratified by the RA, and that it grants the EEC Council decisions with an authority to be directly applicable and have regulatory and binding effect for the Member States, we can state that the Decision N 46 is *per se* applicable in the Republic of Armenia. The “Law on the Normative Legal Acts” of the RA envisages the following: “*After the adoption of legal acts with regulatory and binding effect by the EEC, the Government of the RA acts with a legislative initiative if the relations regulated by the act are subject to regulation by the laws of the RA. In all other cases, the Government of the RA through its normative legal act puts into action the EEC legal act with regulatory and binding effect.*”⁴¹

On 07 February 2020, the “Draft Law on the Amendments of the RA Law on Medical Assistance and Service of the Population”⁴² (hereinafter referred to as the “Draft Law”) and other draft amendments related to it were presented to the RA National Assembly by the Government of the RA. The pack of the abovementioned draft amendments was recognized urgent by the RA Government N 1455-U, decision of 24 October 2019.⁴³ On 12 February 2020, the Draft Law was adopted by first reading in the National Assembly of the RA.⁴⁴ Later, after making some amendments, the Draft Law was completely and finally adopted on 06 May 2020.⁴⁵ The 10th Chapter of the Draft Law is dedicated to the regulation of medical devices in the Republic of Armenia. Particularly, it more or less regulates the circulation of medical devices in the Republic of Armenia. However strange it may seem, the Draft Law, which will enter into force after 10 days of its official announcement, does not regulate one of the main fields of medical devices’ circulation: manufacturing. There are no requirements with regard to the manufacturing process, even though the notion “manufacturing” is included in the definition of the “circulation of

⁴⁰ *Treaty on the Eurasian Economic Union*, Annex 1, Regulation on the Eurasian Economic Commission.

⁴¹ The “*Law on the Normative Legal Acts*” of the Republic of Armenia. Article 24. Adopted: 21 March 2018. Entry into force: 07 April 2018. շՕ-180-Ն. National Assembly of the Republic of Armenia. Available at: <https://www.arlis.am/> (last access: 06 May 2020).

⁴² “*Draft Law on the Amendments of the RA Law on Medical Assistance and Service of the Population*”. Presented by the RA Government on 29 October 2019 (amended version: 07 February 2020). Կ-331-29.10.2019,07.02.2020-UU-011/1. Available at: <http://parliament.am/drafts.php?lang=arm> (last access: 06 May 2020).

⁴³ The RA Government N 1455-U, decision of 24 October 2019 on Approving the Draft Amendments of the “*RA Law on Medical Assistance and Service of the Population*”, “*RA Code on Administrative Offences*”, “*RA Criminal Code*”, “*RA Law on Licensing*”, “*RA Law on State Duty*” and Recognizing the Pack as Urgent. Available at: <https://www.e-gov.am/gov-decrees/item/32756/> (last access: 12 March 2020).

⁴⁴ “*Draft Law on the Amendments of the RA Law on Medical Assistance and Service of the Population*”. History of the draft. Available at: http://parliament.am/draft_history.php?id=11320 (last access: 06 May 2020).

⁴⁵ *Id.*

medical devices”.⁴⁶ Nevertheless, the adoption of the Draft Law can be considered as a step forward to design an effective policy framework for the regulation of medical devices’ circulation and for healthcare regulation in general. Despite the existence of the Decision 46, the RA Government presented the Draft Law to the National Assembly of the RA. This means that the RA Government considered the field of medical devices’ circulation to be subject to regulation by the laws of the Republic of Armenia and for that, initiated the abovementioned legislative amendments. In the Justification of the Draft Law, the authors stated that *“The current legislation does not fully regulate the issues related to the circulation, registration and import of the medical devices in the Republic of Armenia, which presents a threat for the security of the public. The absence of the regulation on the circulation, registration and import of the medical devices in the Republic of Armenia raises problems regarding the quality, safety and efficacy of the medical devices imported and/or used within the territory of the RA.”*⁴⁷

Additionally, regarding the notified body (or bodies) of the Member States, the Article 3 of the Agreement envisages that *“For the purposes of implementing this Agreement, a Member State shall establish a notified body (or bodies) authorized to implement and/or coordinate efforts in the field of medical devices’ circulation in the territory of this Member State. The Eurasian Economic Commission shall coordinate the efforts aimed at harmonizing the laws of the Member States pertaining to the circulation of medical devices.”*⁴⁸ Then, the Article 4 stipulates the following: *Medical devices shall be registered by the competent authorities. Expert review of the safety, quality, and efficacy of medical devices for registration purposes shall be performed by the expert organization designated by the government agency of a Member State having jurisdiction over healthcare in the manner prescribed by the Eurasian Economic Commission.”*⁴⁹ Furtherly, the Decision N 46 stipulates that *“Until 31 December 2016 the Member States should determine the notified body (bodies) responsible for the conduct of the registration and other related procedures of medical devices registration, and should apprise the EEC of this competent authority.”*⁵⁰

⁴⁶ “Draft Law on the Amendments of the RA Law on Medical Assistance and Service of the Population”. Article 2, point 51.

⁴⁷ Justification of the draft amendments pack of the “RA Law on Medical Assistance and Service of the Population”, “RA Code on Administrative Offences”, “RA Criminal Code”, “RA Law on Licensing”, “RA Law on State Duty”. Available at: <http://www.parliament.am/drafts.php?sel=showdraft&DraftID=54506> (last access: 12 March 2020).

⁴⁸ Agreement on the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union. Article 3.

⁴⁹ *Id.* Article 4.

⁵⁰ Decision N 46 on the Rules of the Registration and the Expertise of the Quality, Safety and Efficacy of Medical Devices.

The government agency having jurisdiction over healthcare and conducting the policy of the RA Government in this field is the Ministry of Health, which is therefore the competent authority responsible for the registration of medical devices.⁵¹ On 22 November 2017, the Minister of Health of the Republic of Armenia adopted a Decree N 3339-U. on Securing the Execution of the EEC Council's Decision N 46 dated 12 February 2016.⁵² According to the mentioned Decree, "The Scientific Center of Drug and Medical Technologies Expertise after Academician Emil Gabrielyan" Closed Joint Stock Company of the RA Ministry of Health (hereinafter referred to as the "SCDMTE") is obliged to secure the execution of the Decision N 46.⁵³ Afterwards, on 30 November 2017, the Minister of Health of the Republic of Armenia adopted a Decree N 3398-U. on Securing the Execution of the EEC Council's Decisions N 29 and N 42 dated 12 February 2016 and N 38 dated 16 May 2016.⁵⁴ On the same day, Decree N 3399-U. on Securing the Execution of the EEC Board's Decisions N 173 and N 174 dated 22 December 2015 and N 177 dated 29 December 2015 was adopted.⁵⁵ Those decisions concern, inter alia, the rules on the clinical-laboratory expertise of the medical devices, the expertise with the aim of evaluating the biological impact of the medical devices, the classification of medical devices based on their potential risk of usage, the monitoring of the safety, quality and efficacy of the medical devices, the nomenclature of the medical devices. However, those decisions and other documents of the EAEU bodies are lacking some essential regulations (for example, the rules on the post-market surveillance of medical devices).

According to the above discussed decrees, the SCDMTE is the expert organization (notified body) authorized by the competent authority of the Republic of Armenia, which should conduct the expert review of the safety, quality and efficacy of the medical devices for the registration purposes and other related procedures. As discussed above, the "Law on the Normative Legal Acts" of the RA stipulates that "*the Government of the RA either initiates legislative*

⁵¹ *The "Law on the Structure and Functioning of the Government" of the Republic of Armenia*. Annex 1. Adopted: 23 March 2018. Entry into force: 09 April 2018. 20-253-Ն. National Assembly of the Republic of Armenia. Available at: <https://www.arlis.am/> (last access: 12 March 2020).

⁵² *Decree N 3339-U. of the Minister of Health of the Republic of Armenia on Securing the Execution of the EEC Council's Decision N 46 dated 12 February 2016*. Adopted: 22 November 2017. Ministry of Health of the Republic of Armenia. Available at: http://pharm.am/attachments/article/3570/3339_A.PDF (last access: 12 March 2020).

⁵³ *Id.*

⁵⁴ *Decree N 3398-U. of the Minister of Health of the Republic of Armenia on Securing the Execution of the EEC Council's Decisions N 29 and N 42 dated 12 February 2016 and N 38 dated 16 May 2016*. Adopted: 30 November 2017. Ministry of Health of the Republic of Armenia. Available at: http://pharm.am/attachments/article/3661/3398_A.PDF (last access: 12 March 2020).

⁵⁵ *Decree N 3399-U. of the Minister of Health of the Republic of Armenia on Securing the Execution of the EEC Board's Decisions N 173 and N 174 dated 22 December 2015 and N 177 dated 29 December 2015*. Adopted: 30 November 2017. Ministry of Health of the Republic of Armenia. Available at: http://pharm.am/attachments/article/3662/3399_A.PDF (last access: 12 March 2020).

amendments or puts into action the EEC decisions through its normative legal act.”⁵⁶ In the current case, the RA Government initiated draft amendments in the legislation. However, the decrees mentioned above are not normative legal acts, which can put the EEC decisions into action within the territory of the Republic of Armenia. The decrees of a Minister of Health cannot give legal effect to the regulations neither in national nor in international law. Such procedures should be regulated through governmental normative acts (decisions of the RA Government). It needs to be emphasized, that registration of the medical devices in the Republic of Armenia has not started yet, neither in accordance with the EAEU registration procedure nor in the Republic of Armenia domestic level. There are no records in the official website of the SCDMTE⁵⁷ about the medical devices, which are already registered in the Republic of Armenia. There are also a number of decisions, which need to be adopted for the proper legislative basis of the registration procedure. None of the EAEU documents and the RA domestic legal acts with regard to the regulation of medical devices covers the following crucial issues (non-exhaustive list of lacking regulations):

(a) The regulation on the fees for the conduct of expertise.

(b) The regulation on the monitoring of the medical devices’ compliance with the International Organization for Standardization rules.

(c) The regulation on the import and export of medical devices to and from the Republic of Armenia, and the rules on medical devices’ expertise with the aim of its import or export.

(d) The regulation on the notified bodies in charge to conduct the clinical and technical experiments of the medical devices.

The process of starting the registration of medical devices in the Republic of Armenia is taking too much time to be accomplished, which gives no chance to supervise the circulation of medical devices within the territory of the RA. It also puts into risk the future of medical devices’ field in the country, as the international community is going forward with huge steps and the Republic of Armenia is still stuck in this stage of regulations.

⁵⁶ The “Law on the Normative Legal Acts” of the Republic of Armenia. Article 24.

⁵⁷ Official website of the “The Scientific Center of Drug and Medical Technologies Expertise after Academician Emil Gabrielyan” Closed Joint Stock Company of the RA Ministry of Health. Available at: <http://pharm.am/index.php/en/> (last access: 27 March 2020).

CHAPTER II

INTERNATIONAL BEST PRACTICES IN REGULATING THE CIRCULATION OF MEDICAL DEVICES

A good national health system leads to quality health coverage for all people by targeting the population's needs and delivering universal healthcare. The development of national health policy frameworks, which lead to reduced morbidity and mortality, reduced risks and threats to health, are strongly encouraged by the World Health Organization.⁵⁸ Policies are primarily a set of standard protocols that are tailored to the national health needs, conditions and environment, and that serve as directives and guidelines on all levels of the health system. A national health policy framework includes a vision, a situation analysis, policy directions, strategies to overcome challenges, a policy implementation plan, and the leadership and governance required to achieve sustainability. Health technologies are essential for a functioning health system, and medical devices in particular are crucial in the prevention, diagnosis, and treatment of illnesses and diseases as well as in patient rehabilitation. That is the reason why the developed countries of the world and the international organizations are seeking to find systems for the dynamic supervision of the field. The World Health Assembly, in its resolution WHA60.29 acknowledged the need *“to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices, in collaboration with personnel involved in health-technology assessment.”*⁵⁹ Medical devices have an essential role within the health system to deliver better health outcomes. The life of the people nowadays cannot be imagined without the presence of medical devices, as they accompany people starting from the birth date until their death. The medical devices are a cornerstone of every state's healthcare system. Thus, it is crucial to consider the importance of medical devices when designing national health plans, policies, and strategies.

Since 2000, the global health agenda has been focused on achieving the Millennium Development Goals (hereinafter also referred to as the “MDGs”) with firmly defined overall

⁵⁸ *Global atlas of medical devices*. Geneva. World Health Organization. 2017. Available at: https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/ (last access: 17 March 2020).

⁵⁹ *World Health Assembly Resolution WHA60.29 on the “Health Technologies”*. World Health Organization's Sixtieth World Health Assembly. Adopted: 23 May 2007. Available at: https://www.who.int/medical_devices/resolution_wha60_29-en1.pdf?ua=1 (last access: 17 March 2020).

roadmaps and detailed indicators.⁶⁰ The work of achieving equitable access to, and optimal use of, medical devices is a critical component towards achieving the MDGs. Medical devices are particularly important for MDG Goals 4, 5, and 6 (MDG Goal 4: Reduce child mortality; MDG Goal 5: Improve maternal health; MDG Goal 6: Combat HIV/AIDS, malaria, tuberculosis, and other diseases).⁶¹ Based on the Millennium Development Goals, on 2015 a new agenda of Sustainable Development Goals (hereinafter also referred to as the “SDGs”) was established by the United Nations.⁶² SDGs are 17 Goals that all United Nations Member States have agreed to try to achieve by the year 2030.⁶³ The 17 SDGs are broader and more ambitious than the MDGs, presenting an agenda that is relevant to all people in all countries to ensure that “no one is left behind”.⁶⁴ Almost all the SDGs are directly related to health or will contribute to health indirectly. SDG Goal 3 specifically sets out to “*Ensure healthy lives and promote well-being for all at all ages*”⁶⁵ and is underpinned by 13 targets (e.g. by 2030 reduce the global maternal mortality, end preventable deaths of newborns and children under 5 years of age, end the epidemics of AIDS and tuberculosis) which focus on the achievement of universal health coverage. Medical devices offer tangible ways to help achieve the targets set out in the MDGs and SDGs.

The regulation of medical devices is a method for lessening potential health risks as much as could be expected and enabling patient access to high quality, safe and effective medical devices while confining access to those devices that are unsafe or ineffective. Regulating medical devices leads to improved public health outcomes when implemented properly. According to the Global Atlas of Medical Devices, in total, 113 out of 194 Member States of the World Health Organization scored positive on having a legal framework for medical devices, no matter how limited their regulation is.⁶⁶ The existence of a legislation already implies a presence of a regulation system. The latter can always be subject of development and reforms, considering that no matter how good or bad, there are procedures, staff and most importantly a database, which can be established only as a result of long-lasting work and experience. The survey found that 53

⁶⁰ *Development of medical device policies*. Geneva. World Health Organization. 2011. Available at: <https://apps.who.int/medicinedocs/documents/s21559en/s21559en.pdf> (last access: 17 March 2020).

⁶¹ *United Nations Millennium Development Goals*. United Nations Millennium Declaration (Resolution 55/2). New York. 2000. Available at: https://www.who.int/topics/millennium_development_goals/about/en/ (last access: 17 March 2020).

⁶² *United Nations Sustainable Development Goals*. United Nations General Assembly (Resolution 70/1). New York. 2015. Available at: <https://www.un.org/development/desa/disabilities/envision2030.html> (last access: 17 March 2020).

⁶³ *Id.*

⁶⁴ *Report: Health in 2015: from MDGs to SDGs*. Geneva. World Health Organization. December 2015. Available at: <https://www.who.int/gho/publications/mdgs-sdgs/en/> (last access: 17 March 2020).

⁶⁵ *Id.*

⁶⁶ *Global atlas of medical devices*.

countries do not have a regulation for medical devices. For 28 Member States of the World Health Organization, no information was available. Based on the available data, the proportion of countries with a legal framework for medical devices is highest in the European region (91%) and lowest in the African region (32%). This data shows that the European system of supervision is one of the best and well-developed systems worldwide and that it is permanently undergoing dynamic changes. It is a core point that the regulation goes concurrently with the manufacturers and does not stand one-step back from the manufacturers. Firstly, it should be impermissible for the regulation to become an artificial barrier for the development of the field. Secondly, it must take all possible legal measures in order to keep the supervision tools over the field (e.g. when there is a new approach used in medical device manufacturing, the supervision over that can be lost, which, in the end, might result to damages for the life of the people). Of the low-income countries with data available, 45% have a legal framework for medical devices in place; from the high-income countries, 84% have such provisions.⁶⁷ These statistics show that the field of medical devices is mostly regulated in the countries, which have financial stability and proper resources for the control of the field. Countries with low-income should rely on the experience of financially stable ones and use their guidance for the regulation of medical devices' circulation, as the former countries most probably have a lack of needed resources for that.

Regulatory steps should be applied in all stages of a life span of medical devices. Those measures particularly include “Pre-market” regulation, “Placing on the market” regulation and “Post-market” regulation. *Basic legal provisions of “Pre-market” regulation* would include definition of a medical device, risk classification of medical devices and the essential principles of safety and performance. These provide guidance to manufacturers, importers, authorized representatives and health care professionals regarding the scope of the regulated products. *Basic legal provisions of “Placing on the market” regulation* would include registration of establishments, listing of medical devices and import controls. These elements provide an overview of what is available on the domestic market and who are the responsible actors. *Basic legal provisions of “Post-market” regulation* would comprise of adverse events reporting. In clinical use, medical devices may not always perform as expected. Therefore, it is important to analyze the medical devices after they are placed on the market. The supervision system cannot function without the “Post-market” regulation, as it is considered the main measure of getting feedbacks on the medical devices after they are placed on the market. A system whereby users of medical devices may report problems, complaints or adverse events, especially when it concerns

⁶⁷ *Id.*

death or serious injury, may prompt the regulatory authority to take action. The overall picture is that legal provisions and regulatory controls for all elements are regulated to a larger extent in high-income countries, whereas low-income countries include fewer basic elements in their legal framework for medical device regulation.⁶⁸ A proper regulatory framework on medical devices not only controls and supervises the circulation of medical devices, but it also plays a fundamental role for the local manufacturers for reaching the international market of medical devices. Moreover, those regulations ensure the investment flow to the country for the establishment and organization of such manufacturing premises.

Given the wide range of medical devices, it is neither viable nor justifiable in terms of the financial burden it places on manufacturers, NRAs and thereby the public, to subject all medical devices to the highest levels of regulatory control. Therefore, countries with long-established medical device legislation have adopted controls whereby regulatory requirements increase in line with the risk presented by the class of medical device. The challenge for NRAs is to establish and maintain written procedures (normally incorporated within legislation) that provide clear guidance on how to set the requirements for the many different types of medical device.⁶⁹ The development of regulations based on globally harmonized practice is of great benefit, building on the experience of countries with long-established medical device legislation. Countries want to regulate medical devices to ensure that their people have access to high quality, safe and effective medical devices. For this, an assessment must be carried out to determine a medical device's efficacy and quality over its life span. It may be a costly and time-consuming process. However, generally spoken, it is a beneficial process. It not only secures the health of the people, but it also plays a preventive role, which in itself saves the money going to be spent on future treatment of diseases. Moreover, it reduces the risks connected to the damages caused to the health of the people because of medical devices and encourages the establishment of local manufacturing premises in this field.

In order to avoid duplication of effort in the pre-market and post-market assessment of medical devices and to avoid unnecessary spending of money, reliance on other jurisdictions is an option. Reliance must be stipulated by the legislation. It should be noted that the NRA may, at its discretion, rely on regulatory assessments (e.g. certificates, assessment reports) of NRAs or recognized conformity assessment bodies in other jurisdictions to decide, in whole or in part, whether to permit the sale of a medical device in its market. That also gives an opportunity to plan and predict the future developments of the field based on the statistical data received. While

⁶⁸ *Id.*

⁶⁹ *Regulation of Medical Devices. A step-by-step guide.*

relying on other jurisdictions, the NRA of the respective state can concentrate more on their state responsibilities, such as import controls, vigilance, recall and market withdrawal. Reliance may be established between different jurisdictions, but may also be the product of regional collaboration, with work sharing (e.g. collaborative approval) between countries.

World Health Organization's vision is that different national regulatory authorities work together, share experiences and collaborate with international entities to ensure safety and quality of medical products.⁷⁰ This can only be achieved through active collaboration of different well-functioning regulatory authorities. Harmonization of the different national standards and best practices regarding the medical devices is a key element for the regulation of this field. The Global Harmonization Task Force (GHTF), which was formed in 1992, aimed to promote worldwide harmonization of medical device regulatory practices. Membership of the voluntary partnership was initially limited to regulatory officials and industry representatives from five jurisdictions: Australia, Canada, European Union, Japan and United States of America.⁷¹ Over two decades, the GHTF developed and promoted a regulatory model for medical devices based on a series of interlinking guidance documents. Five study groups (Pre-market evaluation, Post-market surveillance/vigilance, Quality systems, Auditing, Clinical safety/performance) were established to prepare the documents.⁷² In February 2011, the study groups were disbanded and the International Medical Device Regulators Forum (IMDRF) replaced the GHTF, although its main purpose – discussion of future directions in medical device regulatory harmonization – remained the same.⁷³ Unlike its predecessor, IMDRF participants are regulators with industry involvement, by invitation only (GHTF founding members plus Brazil, China, South Korea, Singapore and Russia were invited to join).⁷⁴ The IMDRF aims to accelerate international medical device regulatory harmonization and convergence. Currently, the World Health Organization is an official observer to the IMDRF.⁷⁵ The IMDRF is open for all the remained states worldwide in order to cooperate and discuss the issues regarding the medical devices regulation.

The European Union (hereinafter also referred to as the “EU”), which is a founding member of the IMDRF and whose legislation on medical devices' regulation is totally based on and harmonized with the IMDRF recommendations and guidance, has one of the biggest markets of

⁷⁰ *Regulation of Medical Devices. A step-by-step guide.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *The official website of the International Medical Device Regulators Forum (IMDRF).* Available at: <http://imdrf.org/index.asp> (last access: 27 March 2020).

⁷⁴ *Id.*

⁷⁵ *Id.*

medical devices in the world. In addition, the majority of the high quality manufacturing premises and the scientific potential for the development, establishment and usage of innovative technologies with regard to medical devices is concentrated within the territory of the European Union. The circulation of the medical devices in the EU market was initially regulated by three directives: Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD)⁷⁶; Council Directive 93/42/EEC on Medical Devices (MDD)⁷⁷; Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD).⁷⁸⁷⁹ Those Directives were intended to harmonize the legal acts regarding the medical devices within the frames of the European Union. In order for a manufacturer to place a medical device on the EU market legally, the requirements of the abovementioned Directives had to be met.

Since the European Union's rules on the safety and performance of medical devices were laid down in the late 1990s, the EU has therefore decided to revise the legal framework in order to reflect the progress over the last 25 years. The need was raised also following the mass recall in 2012 of faulty PIP breast implants⁸⁰ in the European Union⁸¹ as well as recognition by industry and regulators of the need to update EU medical devices' standards. The PIP scandal made it clear that immediate improvements in the supervision of medical devices were needed. Thus, On 05 April 2017, the European Parliament approved the new regulations for medical devices and in vitro diagnostic medical devices, proposed by the European Commission (hereinafter also referred to as the "EC") back in 2012.⁸² The EU Directive on Medical Devices (93/42/ EEC) and the EU Directive on Active Implantable Medical Devices (90/385/EEC) are replaced by the Regulation (EU) 2017/745⁸³ on Medical Devices. The EU Directive on In Vitro Diagnostic

⁷⁶ Council Directive of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices (90/385/EEC). European Union Council. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011> (last access: 22 March 2020).

⁷⁷ Council Directive of 14 June 1993 concerning medical devices (93/42/EEC). European Union Council. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011> (last access: 22 March 2020).

⁷⁸ Council Directive of 27 October 1998 on in vitro diagnostic medical devices (98/79/EC). European Union Council. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0079-20120111> (last access: 22 March 2020).

⁷⁹ The Official Website of the European Commission. Internal Market, Industry, Entrepreneurship and SMEs. Medical Devices. Available at: https://ec.europa.eu/growth/sectors/medical-devices_en (last access: 22 March 2020).

⁸⁰ Poly Implant Prothese (PIP) was a French company started in 1991 that produced breast implants. PIP went into liquidation in 2011. The company produced circa 100,000 implants per year, during circa 20 years. Approximately 400,000 women worldwide may have been implanted with PIP gel products.

⁸¹ "Restoring confidence in medical devices. Action Plan after the PIP scandal tightened control in Europe." Press release. European Commission. 20 June 2014. Available at: https://ec.europa.eu/commission/presscorner/detail/en/IP_14_699 (last access: 27 March 2020).

⁸² The Official Website of the European Commission.

⁸³ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505> (last access: 27 March 2020).

Medical Devices (98/79/ EC) is also substituted by an up-to-date Regulation (EU) 2017/746⁸⁴ on In Vitro Diagnostic Medical Devices.⁸⁵ The new rules will fully apply only after a transitional period. That period lasts for 3 years after the entry into force of the EU Regulation on Medical Devices (until May 2020), and 5 years after the entry into force of the EU Regulation on In Vitro Diagnostic Medical Devices (until May 2022).⁸⁶

While the European Union's Directives require national implementation in every European Union Member State, the Regulations are directly enforced within the territories of the EU Member States, overcoming issues caused by divergences in the national interpretation of the existing Directives.⁸⁷ The Regulations are considered as new approach for the solutions of a number of issues relating to the field of medical devices. The statistical data and the experience of the last years was taken into account, particularly that the Directives brought some problems with regard to the overall supervision of the field of medical devices. The Directives observed the issues from a local point of view, whereas the field needed general approach to the problems. The Directives were more like standards and not a system for the regulation and most importantly supervision of the field. Since the establishment of the Directives, they were assumed the first phase of the regulation process and now the EU has started the second phase of its regulatory process through adopting the Regulations.

The new rules aim to enhance patient safety through the introduction of numerous changes and improvements, involving both manufacturers and competent authorities. The Regulations significantly tighten the controls to ensure that medical devices are high quality, safe and effective, at the same time foster innovation, and improve the competitiveness of the medical devices' field. Those new rules also better reflect the most recent scientific and technological progress and set the gold standard for medical devices' regulation internationally. The Regulations pave the way to a more patient-friendly environment, where transparency and patients' information and choice are a priority, where patients can benefit from innovative, highly performing devices and new therapies become possible.

The new EU Regulations introduce: (a) Better protection of public health and patient safety. In particular, high-risk devices are going to be subject to stricter pre-market control. Rules on

⁸⁴ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505> (last access: 27 March 2020).

⁸⁵ The Official Website of the European Commission.

⁸⁶ *Id.*

⁸⁷ *Changes to EU Medical Device Legislation: What you need to know.* Claudia Samà, Eurofins Medical Device Testing Italy. 17 June 2017. Official Website of Eurofins Biopharma Services. Available at: <https://www.eurofins.com/biopharma-services/media/pharma-newsletters/eurofins-biopharma-services-newsletter-17-june-2017/changes-to-eu-medical-device-legislation/> (last access: 22 March 2020).

clinical evaluation and clinical investigation (and performance studies for in-vitro diagnostic medical devices) are generally strengthened, and stricter requirements on the use of hazardous substances are introduced. (b) Comprehensive EU database on medical devices (EUDAMED) that will contain a living picture of the lifecycle of all products being available on the EU market. (c) New device identification system based on a unique device identifier (UDI) that will allow easier traceability of medical devices. (d) An “implant card” for patients containing information about implanted medical devices that will make information easily available and accessible to the particular patient. (e) A robust financial mechanism to ensure patients are compensated in case they receive defective products.⁸⁸ The Regulations contain essential changes to the current system to enable the sector to produce safer and more innovative devices and help address future challenges. They contain a number of provisions to increase security and regulatory certainty and take into account the latest developments of the field (medical software, apps, cybersecurity).

The strengthened European governance of the new system is one of the main improvements in the field of medical devices regulation. The new Regulations introduce: (a) A new Medical Device Coordination Group (MDCG), composed of Member State experts and chaired by the European Commission. (b) increased cooperation between the EU Member States in the field of vigilance and market surveillance. (c) A mandatory coordinated assessment of multinational clinical investigations.⁸⁹ As a result, a real European framework for the regulatory control of medical devices will be set in place. It will give an opportunity for more regular exchange of information, so that regulatory decisions by each of the Member States or the EC can be made on a more informed basis. Under this new governance, it will be easier to address safety concerns within the EU and to respond more rapidly whenever necessary.

The medical devices sector is a global leader and a major employer in Europe: it employs more than 500,000 people in over 25,000 companies.⁹⁰ The sector is driven by small and medium-sized companies (SMEs) and the new Regulations will help the EU industry to maintain and further expand its leadership role on the global scale, by making it more competitive and more solid in a complex global environment.⁹¹ This will be the result of three main factors: (a) *Simplified administrative procedures* - under the new framework, registration of medical devices

⁸⁸ *New EU Rules to Ensure Safety of Medical Devices. The Official Website of the European Commission.* 05 April 2017. Available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_17_848 (last access: 22 March 2020).

⁸⁹ *Id.*

⁹⁰ *The Official Website of the European Commission.*

⁹¹ *Id.*

and operators will have to be done only once at the EU level. This is a major change compared to former situation, where in many cases manufacturers might be required to register their products in all Member States of the EU where those products are placed on the market. (b) *Increased legal certainty* - growth and competitiveness build on the existence of a stable set of legal requirements. As mentioned above, contrary to a Directive, a Regulation is directly applicable in all Member States of the EU: this will help to avoid varying conditions for patients and industry in different countries. The new documents also include precise and detailed clarifications of the scope of the new rules, a list of clear obligations of relevant economic operators, as well as an indication of the specific exemption regimes which apply to certain devices or practices such as in-house devices or reprocessing of single-use devices. (c) *Increased credibility and reputation of the overall system* - industry's reputation is highly sensitive to the credibility of the EU medical device system as a whole. Various incidents as well as public reports regarding an alleged “uneven approach” among the bodies responsible for certification and approval of medical devices have damaged the confidence of patients and healthcare professionals in the safety of the devices they use every day. The new Regulations address the shortcomings of the current legislation and aim to increase the overall confidence in the medical device market.⁹² Such benefits would account for the increased costs incurred by companies due to compliance with the higher safety standards and the new specifications included in the new Regulations. Specific needs of small and medium-sized companies have been discussed in the documents, in particular with regard to the new standards for financial compensation for manufacturers, the person responsible for regulatory compliance and fees paid to the competent authorities. It will give small and medium-sized companies operating in this field a future boost.

The European Single Market comprises 28 Member States of the European Union (including the United Kingdom⁹³), the European Economic Area (Iceland, Liechtenstein, and Norway) and, through bilateral treaties, Switzerland and Turkey.⁹⁴ Medical devices can be marketed in European Single Market after obtaining the CE (Conformité Européenne) mark, which guarantees that they are compliant with the essential requirements established by the EU

⁹² *New EU Rules to Ensure Safety of Medical Devices.*

⁹³ There is now a transitional period until the end of 2020 while the UK and EU negotiate additional arrangements. The current rules on trade, travel, and business for the UK and EU will continue to apply during the transitional period. New rules will take effect on 1 January 2021.

The UK has left the EU. The Official Website of the Government of the United Kingdom. Available at: <https://www.gov.uk/transition> (last access: 25 March 2020).

⁹⁴ *The Official Website of the European Commission. Internal Market, Industry, Entrepreneurship and SMEs. The European Single Market.* Available at: https://ec.europa.eu/growth/single-market_en (last access: 25 March 2020).

legislation.⁹⁵ The first and most important thing that manufacturers looking to market their devices within the frames of the European Single Market have to do is to get them CE marked. Class I medical devices are approved after being presented to the competent authority, and the manufacturer himself issues the CE mark. The rest are reviewed by one of the notified bodies accredited by each country's competent authority.⁹⁶ If the notified body of a particular country deems it satisfactory, it grants the CE mark and the manufacturer can then market the device throughout the European Single Market.⁹⁷ Another important thing that manufacturers should look into is picking a Quality Management System. One of the most popular choices in this regard is ISO 13485 (Medical devices; Quality management systems; Requirements for regulatory purposes)⁹⁸ certification, which is the main standard for the supervision of the medical devices' quality and is the core and most important measure of supervision. All International Organization for Standardization (hereinafter referred to as the "ISO") standards typically have a three-year transition period, and, considering that the current ISO 13485 was updated in March 2016, it is mandatory since March 2019.⁹⁹ This fact implies that all manufacturers who elect to demonstrate compliance with the international standards must have switched to ISO 13485:2016 by 1 March 2019. ISO 13485:2016 specifies requirements for a Quality Management System where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.¹⁰⁰ Such organizations can be involved in one or more stages of the life cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including QMS related services to such organizations.¹⁰¹ It is the de facto standard for global Quality Management System compliance for medical devices, and is a prerequisite for access to most major markets worldwide.

⁹⁵ *European CE Marking Strategy for Medical Devices*. EMERGO by UL. 2019. Available at: <https://www.emergobyul.com/services/europe/ce-certification> (last access: 25 March 2020).

⁹⁶ *A full-fledged overhaul is needed for a risk and value-based regulation of medical devices in Europe*. Carlos Campillo-Artero/Health Policy 113 (2013) 38– 44. Available at: www.elsevier.com/locate/healthpol (last access: 25 March 2020).

⁹⁷ Kramer DB, Xu S, Kesselheim AS. *Regulation of medical devices in the United States and European Union*. *New England Journal of Medicine* 2012; 366:848–55. Available at: <https://www.nejm.org/medical-archives/2012> (last access: 25 March 2020).

⁹⁸ This standard was last reviewed and confirmed in 2020. Therefore, this version remains current.

ISO 13485:2016. Medical devices-Quality management systems-Requirements for regulatory purposes. International Standard Organization. Third edition 2016-03-01. Available at: <https://www.iso.org/standard/59752.html> (last access: 25 March 2020).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

Among numerous regulatory practices outside the European Union, the following three countries are considered to have world-acclaimed regulations on medical devices: United States of America, Israel and Singapore. Since 1976, a series of acts have been approved that invest the United States Food and Drug Administration (hereinafter also referred to as the “U.S. FDA”) with the authority to obtain “reasonable assurance of safety and efficacy” before marketing the medical devices in the country. Medical devices are classified into Class I, II, and III.¹⁰² Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.¹⁰³ The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are: Establishment registration; Medical Device Listing; Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA); Investigational Device Exemption (IDE) for clinical studies; Quality System (QS) regulation; Labeling requirements; and Medical Device Reporting (MDR).¹⁰⁴ Besides the General Controls, there can be imposed Special Controls, which can include the following: Adherence to performance standards, guidance documents; Implementation of post-marketing surveillance measures; Special labelling.¹⁰⁵ The U.S. FDA has established classifications for approximately 1,700 different generic types of medical devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and efficacy of the medical device.¹⁰⁶ In the United States, medical devices’ regulation is performed by the Center for Devices and Radiological Health (CDRH).¹⁰⁷ Strict conformity to desired principles is required to obtain marketing authorization. Premarket Notification 510(k) and Premarket Approval are the regulatory pathways in order to obtain marketing authorization in the United States. The choice of the regulatory measure adopted by the organizations depends primarily upon the complexity of design, potential risk to health of user and safety of the medical device. The U.S. has one of the well-developed and experienced

¹⁰² *The Official Website of the U.S. Food and Drug Administration. Overview of Device Regulation.* 31 August 2018. Available at: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance> (last access: 27 March 2020).

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *The Official Website of the U.S. Food and Drug Administration. Center for Devices and Radiological Health.* 12 July 2019. Available at: <https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health> (last access: 27 March 2020).

regulations on medical devices, which is proved by the fact that many countries worldwide are establishing their regulations based on U.S. FDA practices. In addition, a number of developed and developing countries' regulatory bodies require approval for the medical devices from one of the well-known regulatory bodies, including the U.S. FDA.

Gaining access to the Israeli medical device market - one of the largest in the Middle East, requires registering your device with AMAR (the Israeli Ministry of Health's Medical Devices Regulation Unit).¹⁰⁸ Under the new regulation on medical devices, which came into force in 2012, all medical devices manufactured or marketed in Israel must be registered with AMAR.¹⁰⁹ Medical device registration in Israel is based on having prior approval in one of the five founding Global Harmonization Task Force (GHTF) countries: Australia, Canada, European Union, Japan, or the United States.¹¹⁰ Manufacturers that have already obtained approval for their devices in those markets can leverage those registrations to satisfy most of Israel's medical device regulatory approval requirements and the registration is almost automatic. Israel's AMAR regulators require documents to demonstrate approval in the GHTF countries, such as FDA 510(k) or premarket approval letter; CE Marking certificate issued by a European Notified Body; Certificate to Foreign Government (CFG) or Certificate of Free Sale (CFS); Proof of ISO 13485 certification.¹¹¹

Singapore, despite its small geographic size, has one of the largest and most advanced healthcare systems in the world. People throughout Asia rely on Singapore's robust healthcare infrastructure, so there is consistent demand for state-of-the-art medical technologies. Medical devices in Singapore are regulated by the Medical Device Branch of the Health Sciences Authority (hereinafter referred to as the "HSA").¹¹² Singapore is a member of the Association of Southeast Asian Nations (ASEAN)¹¹³ and its regulatory system is based on the Health Products Act 2007¹¹⁴ and Health Products (Medical Devices) Regulations 2010.¹¹⁵ These regulations

¹⁰⁸ *The Official Website of the Ministry of Health of Israel.* Available at: <https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx> (last access: 25 March 2020).

¹⁰⁹ *Medical device registration in Israel.* Thema-med. Italy (2018). Available at: <https://www.thema-med.com/en/medical-device-registration-israel/> (last access: 25 March 2020).

¹¹⁰ *Id.*

¹¹¹ *Medical Device Registration and Approval in Israel.* EMERGO by UL. 2019. Available at: <https://www.emergobyul.com/services/israel/medical-device-registration-israel> (last access: 25 March 2020).

¹¹² *The Official Website Medical Device Branch of the Health Sciences Authority. Singapore Government Agency.* Available at: <https://www.hsa.gov.sg/medical-devices/regulatory-overview> (last access: 25 March 2020).

¹¹³ *The Official Website of the Association of Southeast Asian Nations (ASEAN).* Available at: <https://asean.org/> (last access: 25 March 2020).

¹¹⁴ *Health Products Act (Chapter 122D).* Original Enactment: 15 of 2007. Revised Edition: 31 December 2008. Singapore. Available at: <https://sso.agc.gov.sg/Act/HPA2007> (last access: 25 March 2020).

¹¹⁵ *Health Products Act (Chapter 122D), Health Products (Medical Devices) Regulations 2010.* Singapore. Available at: <https://sso.agc.gov.sg/SL/HPA2007-S436-2010> (last access: 25 March 2020).

dictate how medical devices are classified in Singapore and the registration routes for each class. Device classification in Singapore is based on a four-tier system (Class A, B, C, and D), with Class A assigned to the lowest-risk products and Class D assigned to the highest-risk products.¹¹⁶ All medical devices will require registration with the HSA before they can be marketed in Singapore, except for Class A low risk medical devices, which are exempted from product registration. Medical devices with prior authorization in the U.S., European Union, Canada, Australia, or Japan are eligible for abridged evaluation routes.¹¹⁷ Manufacturers of medium to high risk medical devices may qualify for an abridged product evaluation if the device has been evaluated and approved by one of the following national regulatory bodies: U.S. Food and Drug Administration; EU Notified Body; Health Canada; Australia's Therapeutic Goods Administration (TGA); Japan's Ministry of Health, Labor and Welfare (MHLW).¹¹⁸ Medical devices submitted for product evaluation in Singapore under the abridged evaluation process must be identical to those approved by the reference regulatory body.

Both Israel and Singapore are currently considered as developed countries in the field of medical devices' regulation. Even though these countries' geographical location made it complicated for them to establish a well-developed regulatory system, they managed to do so through relying on the experience of the best systems worldwide. The fact that those states recognize the approvals of U.S. FDA or EU notified bodies shows that reliance to other jurisdictions is a key factor for creating a path to proper regulatory system. By this, the states avoid spending unnecessary resources and efforts for some parts of pre-market assessment of medical devices. Moreover, citizens of those states have the opportunity to be confident about the safety, high quality and efficacy of medical devices being circulated in their country. It is the state's responsibility to ensure the health of its people, so the reliance on international best practices is a proper and justified measure for doing so. Those are just some examples of how the states can solve their regulatory issues relying on international experience. Another key factor for the establishment of good regulatory systems that needs to be highlighted is the harmonization of domestic legislation with the globally accepted documents and recommendations. The developed countries in the world, which succeeded in the establishment of their regulatory systems, have created the international reliance and harmonization best

¹¹⁶ *Id.* Assignment of medical devices into classes. Part I. Classes of medical devices.

¹¹⁷ *Medical Device Registration and Approval in Singapore*. EMERGO by UL. 2019. Available at: <https://www.emergobyul.com/services/singapore/singapore-hsa-registration> (last access: 25 March 2020).

¹¹⁸ *Medical Device Registration in Singapore*. 12 August 2018. Pacific Bridge Global. Available at: <https://www.pacificbridgemedical.com/regulatory-services/medical-device/product-registration/singapore/> (last access: 25 March 2020).

practices. Those can be used by other states of the world, which aim to establish good regulatory systems in their territories. It will give them an opportunity to secure safe, high quality and effective medical devices for their people.

CONCLUSION

Given what has been outlined in the present paper in terms of the regulation of medical devices, it should, however, be highlighted that there exist major gaps in the domestic legislation of the Republic of Armenia. Though the Republic of Armenia has initiated a legislative framework on the regulation of medical devices based on the documents adopted within the frames of the EAEU, the major part of those regulations contradicts internationally acclaimed key values and best practices. Despite the latter, there are crucial regulations missing from the existing documents of the EAEU. Currently, in the Republic of Armenia only the medical devices'

registration procedure is more or less regulated by the Decision 46. However, the latter and other documents of the EAEU on the regulation of medical devices need to be amended, given the need for properly functioning common market. It is worth highlighting that after the entry into force of the Decision 46, it has been permanently undergoing amendments. The alterations of the document are connected to that of other related EEC Council decisions. The differences between the current standing of the EAEU Member States' domestic legislations can also be considered as one of the main reasons for the continuous amendments of the document. The procedure of the registration is very complicated, and the ceaseless changes make it even harder to implement the rules. In case those amendments are adopted, they will enter into force not sooner than 01 May 2021, which, in itself, does not seem likely to be accomplished, taking into account the seriousness and thoroughness of the changes.

Considering that the EAEU Treaty contains an obligation to define the unified rules on medical devices' regulation in accordance with the IMDRF recommendations, it should be noted that the EAEU documents have some major inconsistencies with the IMDRF documents. It would be great to consider the EU Regulations as the basis while drafting or amending EAEU documents, as they are completely based on IMDRF recommendations and can be the best example for the regulations. The Republic of Armenia cannot conduct the registration in compliance with only the Decision 46. That is because there are no secondary or related documents adopted after the Decision 46 in both EAEU and domestic levels, without which it is impossible to start the registration. Apart from this, there are many decisions needed in the domestic level with the aim of fully regulating the circulation of medical devices. Starting the registration of medical devices in current situation will bring more problems than expected. It is not enough for the Republic of Armenia to take the EAEU documents as the only basis for the regulation of medical devices and the state needs to refer to international best regulations and not wait for the EAEU to regulate the medical devices' field especially not in accordance with the best regulatory practices worldwide. The European Union's well-established practice and experience, including their Regulations on medical devices should be a fundament for the regulation of this field in the RA.

In addition, as the global issues on medical devices' regulation are discussed within the IMDRF, it will be beneficial for the state to cooperate with this international organization. As we already know, the IMDRF is open for all the countries, and the medical devices' regulatory authority of the Republic of Armenia can join the organization with the status of invited observer. By that, the regulatory authority will have an insight on international best practices for

the regulation of medical devices and draft or amend its legislation in accordance with that. This will furtherly give a chance to get practical support from the IMDRF and its members or official observers, for instance through organizing trainings and courses for the staff of the regulatory body. The latter in its turn will make the regulatory authority of the Republic of Armenia and the procedures conducted by it compliant with the international standards regarding the regulation systems. Finally, by cooperating with the international bodies in charge of medical devices' regulation, the Republic of Armenia can start the registration with trained staff and procedures that are in accordance with the international standards and best practices.

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