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TITLE

Armenian Regulatory Framework of the Cosmetics and Pharmaceutical industries, and its Compliance with International Regulations
Whether the existing regulatory framework of cosmetics and pharmaceutical industries complies with international best practice and ensures product safety and consumer protection

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Introduction

Overall legal and regulatory framework of cosmetics and pharmaceutical markets and their production vary from country to country. Many developed countries, such as the USA, the European Union Member States, Canada and Japan have large markets and, in the meantime, sophisticated regulatory legislation and enforcement mechanisms. Initially, states were differentiated by their relative market power and power was defined as the relative size and diversity of country's internal market; those with largest markets relative to others could decisively shape international market rules and regulations.[1] However, over time the international practice demonstrated that the size of the market on its own does not grant the state a power to shape international market rules. A state can have an international influence if its jurisdiction has capable and powerful domestic regulators with an ability to identify challenges posed by globalization, formulating countervailing strategies and enforcing opposing rules when necessary.[2] Though the market size of Armenia's pharmaceutical and cosmetics industries is not parallel to global market leaders, whether or not and to what extent its legal framework corresponds to international best practice will be discussed in this paper.

The quality of pharmaceuticals has been a considerable concern for many international organizations, one of which is the World Health Organization (WHO). Article 2 of the WHO Constitution emphasizes the setting of global standards and considers one of the organization's main functions to "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products."[3] Regulation of drugs includes variety of

[1] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *Available at* https://www.jstor.org/stable/i25746508 (last accessed March 24,2020)

[2] *Id.*

[3] Quality assurance of pharmaceuticals. a compendium of guidelines and related materials: *Good manufacturing practices and inspection*, World Health Organization, (2007), *available at*

functions. Key functions are licensing, inspection of manufacturing facilities and distribution channels, product assessment and registration, adverse drug reaction (ADR) monitoring, quality control (QC), control of drug promotion and advertising, and control of clinical drug trials. Each of these functions targets a different aspect of pharmaceutical activity. All of these functions must act in concert for effective consumer protection. [4]

As regards the cosmetics industry, consumers' more extensive exposure to cosmetic products in contrast to pharmaceutical products requires more advanced international regulatory framework. Hence, there is a major responsibility on the international regulatory bodies to define rules and laws, which enable manufacturers and importers to develop and trade safe products. As a result of recent rapid growth in the global cosmetics market and innovatory research and development, the border between cosmetics and pharmaceutical industries has been blurred. This engendered new marketing terms such as cosmeceuticals, dermal-cosmetics and functional cosmetics. Different countries have significantly various rules on distinguishing between pharmaceutical and cosmetics products. In the United States, there is a voluntary registration system approach for cosmetics when mandatory approval is required for pharmaceuticals. In EU and Japan, the regulatory systems require mandatory product filings for cosmetics prior to product marketing.[5]

Armenia's pharmaceutical and cosmetics industries' regulatory framework has undergone drastic development during the recent years. However, the overall regulatory framework of cosmetics and pharmaceutical/cosmeceutical products is still weak and requires advancement and further harmonization with international standards.

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https://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf (last accessed March 24, 2020)

[4] Sauwakon Ratanawijitrasin & Eshetu Wondemagegnehu, Effective drug regulation: a multicountry study (World health organization) (2002)

[5] Cosmetic products: an overview of International Regulatory Systems, Eurofins Scientific, (2017) *available at* https://www.eurofins.com/biopharma-services/media/pharma-newsletters/eurofins-biopharma-services-newsletter-16-march-2017/cosmetic-products-an-overview-of-international-regulatory-systems/ (last accessed March 25, 2020)

The safety of pharmaceutical and cosmetic products has always been an issue for manufacturers, consumers and regulators. However, with the radical technological advancements of both industries and the invention of the third industry, which combines both categories in it, regulatory procedures require a more comprehensive and progressive approach by the state and international bodies. Numerous international and regional standards have been set to enhance the quality and safety of cosmetic products, such as the guidance on the safe manufacturing of cosmetic products under a Good Manufacturing Practices (GMP) regime by the International Standardization Organization (ISO).[6] The main trigger is the growing awareness of consumers about the safety of the products they use, their chemical composition and possible health risks of exposure to the harmful chemicals.

Consumers realize the direct correlation between pharmaceutical and cosmetic products they use and their health condition. Hence, the focus of manufacturers and consumers has recently shifted to more "natural, ecological and clean" products.[7] Nevertheless, there is no regulatory framework for mentioned categories thereby they cannot be approved by any state agency or international organization. Consumers tend to trust the products, which label themselves clean, natural or free from harmful chemicals and preservatives, as many pharmaceutical and cosmetic products have been proven to have numerous adverse effects risking consumer's health.[8] However, such labels rarely have any scientific and legal fundaments. Moreover, the absence of some chemicals in a product can lead to its immediate contamination after one use. Thus, more advanced regulatory framework of the industries of cosmetics and drugs and products that fall under both categories is essential and will contribute to reduced health risks for consumers.

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[6] Eize de Boer, Understanding and Implementing the Requirements of the ISO 22716 Good Manufacturing Practices (GMP), Certification Standard for Cosmetic Products, , *available at* https://www.sgs.com/en/white-paper-library/cosmetics-gmp. (last accessed Feb. 9, 2020)

[7] *Natural & Organic Living; Say 'No' To Chemicals For A Healthy Life*, Raconteur (2016), *available at* http://www.eurasiancommission.org/ru/act/dmi/workgroup/materials/Pages/Агропромышленность/Raconteur_В согласии с природой_2016.pdf. (last accessed March 25, 2020)

[8] *Id.*

Being a developing sphere in Armenia, a better regulatory framework of the production of cosmetics and pharmaceuticals can benefit manufacturers as well. Advanced and more detail-oriented national legislation can promote the economic development of the country. Strictly regulated pharmaceuticals and dermal cosmetics will evoke trust towards domestic products and generate a higher number of exports. Meanwhile, manufacturers will have products, which are in compliance with international best practice.

This paper presents a general overview of the international and Armenian regulatory framework of cosmetics and pharmaceutical industries and production. Moreover, it covers the rules and regulations set by some international organizations. In addition, international best practice, requirements for compliance in the international market as well as examples from various developed countries that can be applicable to Armenia's national legislation are discussed. The paper studies the impact of EAEU regulations harmonization with the national regulatory framework and the extent of implementation procedures. It also analyzes the prospects of the advancement of the Armenian regulatory framework based on international best practice and existing EAEU regulations and presents recommendations proceeding from the aforementioned analysis.

The literature of this paper is based on a comprehensive study of the global and Armenian regulatory frameworks of pharmaceutical and cosmetics industries. The paper makes references to numerous research articles, scholarly projects and papers, scientific journals, books, guidelines and studies by world-renowned international organizations specializing in the field of pharmaceutical and cosmetics industries and their legal framework.

Chapter 1: Review of international best practice through the examples of market leaders of pharmaceutical and cosmetics industries: Comparative study of EU and US regulatory frameworks

Within the last few decades, the pharmaceutical and cosmetics industries have gradually transformed into more global market. In order to protect consumers and ensure product safety,

intergovernmental cooperation has come into play as leading market regulators have applied their domestic legal framework extraterritorially and joined forces to harmonize them. [9] The United States and the European Union have long been the dominant players in both industries. While US has dominated the international market regulation of pharmaceuticals for a long period of time, EU has undeniably shaped the international regulatory framework of cosmetics.[10] The global pharmaceutical and cosmetics industries have a worth of close to 1.5 trillion US dollars with firms that worth multi-billion dollars and trade, source and invest worldwide. [11] Hence, despite the fact that these two industries constitute the tremendous part of global economy, they are subject to strict market access regulations and should ensure safety and consumer protection. *Regulatory capacity - the ability of a jurisdiction to define and implement set of market rules and to monitor firms' compliance with them - is largely institutionally determined. It depends on the expertise of staff, the extent of statutory sanctioning authority vested in regulators, and the degree of centralization of regulatory authority over a market.*[12] This regulatory capacity varies from country to country and market to market, therefore, divergence in regulatory capacity among the largest markets is not an anomaly. However, the relative sequential development of largest domestic regulatory capacities can systematically shape international market regulation. Nevertheless, when highly asymmetric distribution of regulatory capacity exists, alternative governance modes are required for international market regulation. Henceforth, extraterritorial application of domestic rules by regulatory dominant markets becomes more than necessary.[13]

EU has become agenda setter not only for pharmaceutical and cosmetics industries but for other numerous sectors as well. The economic might of substantial internal market as well as the development of internal regulatory institutions engendered EU to leverage its market globally.

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[9] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695.,

[10] *Id.*

[11] *Global Pharma & Cosmetics Market Insights, Forecast to 2025*, 360 Market Reports, *available at* https://www.360marketupdates.com/global-pharma-cosmetics-market-13728245 (last accessed Mar 25, 2020).

[12] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695.,

[13] *Id.*

EU regulatory systems for medicines

EU regulatory system of medicines is considered unique, as it is based on a network of medicines regulatory authorities from the 31 European Economic Area (EEA) Member States, the European Commission and the European Medicines Agency (EMA). [14]

The WHO Member States during the World Health Assembly on May 2014 approved the resolution *Regulatory system strengthening for medical products,* which states that "*effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products"* [15]

The followings are some of the actions, which the Member States were obliged to implement during the assembly:

- Strengthening their national regulatory systems;
- Engaging in global, regional, and sub-regional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious, and affordable medical products;
- To support regulatory system strengthening as an essential component of the development or expansion of local or regional production of quality, safe and efficacious medical products;
- Achieving access to and rational use of quality, safe, efficacious, and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious, and affordable medical products.[16]

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[14] *The European regulatory system for medicines and the ...*, European Medicines Agency, *available at* http://apps.who.int/medicinedocs/documents/s22187en/s22187en.pdf (last accessed Mar 26, 2020).

[15] *Regulatory system strengthening for medical products*, World Health Organization, *available at* http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf (last accessed Mar 26, 2020).

[16] *Id.*

These are the principles based on which EU has developed its medicinal product registration process over the years. In 1995, the EMA was established with a mandate to implement scientific evaluation of marketing authorization applications primarily of innovative and high technology medicines developed by pharmaceutical companies for use in the EU. [17] The EMA was set up to ensure the best use of scientific resources across Europe. In order to protect the public health and secure the availability of safe, high quality and effective medicines, the authorization of medicines before entering the market of EU is mandatory.[18]

There are various methods of medicine authorization in the European system. The centralized procedure requires a submission of single marketing-authorization application to the EMA by the pharmaceutical companies. Afterwards, a scientific assessment of the application is carried out by the EMA's Committee for Medicinal Products for Human Use (CHMP) and a recommendation whether or not to grant a marketing authorization is given.[1918] The final decision is made by the European Commission and once it is granted, the centralized marketing authorization becomes valid in all EU Member States. This process gives the opportunity to the marketing-authorization holder to make the medicine available in the market of EU via single marketing authorization. There are certain medicines, for which the use of centralized procedure is mandatory, including the most innovative ones. Nevertheless, the majority of medicines are authorized by the other methods, which are implemented by the national competent authorities (NCAs) in the Member States. [20] The decentralized and the mutual-recognition procedures are used by companies to authorize medicinal products in several Member States. The first method is used in the event the companies apply for simultaneous authorization of a medicine in more than one Member State if it has not yet been authorized in any EU country and it does not fall within the mandatory scope of the centralized procedure. The mutual-recognition procedure can be used to apply for recognition of authorization of a medicine in other EU Member States if it has been

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[17] *The European regulatory system for medicines and the* ..., European Medicines Agency, *available at* http://apps.who.int/medicinedocs/documents/s22187en/s22187en.pdf (last accessed Mar 26, 2020).

[18] *Id.*

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[20] *The European regulatory system for medicines and the* ..., European Medicines Agency, *available at* http://apps.who.int/medicinedocs/documents/s22187en/s22187en.pdf (last accessed Mar 26, 2020).

authorized in one of the Member States. The latter provides the Member States the opportunity to rely on each other scientific assessments.[21]

The mentioned methods of medicine authorization would not be practical and efficient if the legal rules and requirements applicable to pharmaceuticals in the EU were not the same regardless of the authorization method. The rules for monitoring authorized products as well as the requirements and procedures for marketing authorization are mainly laid down in Directive 2001/83/EC and in Regulation (EC) No 726/2004[22]. Harmonized provisions for the manufacture, wholesale or advertising of medicinal products for human use are also included in the mentioned legislation. Moreover, common rules for the conduct of clinical trials (to test the safety and efficacy of medicines under controlled conditions) in the EU is provided by EU legislation as well.[23] EU legislation also includes various rules addressing the peculiarities of certain types of medicinal products and promoting research in those areas.

US regulatory system for medicines

The Food and Drug Administration (FDA) is the body responsible for the approval and regulation of drugs entering the US market.[24] The regulatory agency is within the Department of Health and Human Services (HHS) and is led by the Commissioner of Food and Drugs, who carries out the agency's responsibilities on behalf of the HHS Secretary. These regulatory frameworks complement the process of review of prescription drugs by the FDA. The first process is the premarket approval or preapproval review, where FDA reviews the effectiveness and safety of new drugs applied to the market approval by the manufacturers. In the event the

[21] *Id.*

[22] Pharmaceutical legislation for medicinal products for human use, Public Health - European Commission, *available at* https://ec.europa.eu/health/documents/eudralex/vol-1_en (last accessed Mar 26, 2020).

[23] Raphael DAUE, *Legal framework governing medicinal products for human use in the EU Public Health* - European Commission (2019), *available at* https://ec.europa.eu/health/human-use/legal-framework_en (last accessed Mar 26, 2020).

[24] Agata Dabrowska & Susan Thaul, *How FDA Approves Drugs and Regulates Their Safety and* ...Congressional Research Service(2018), *available at* https://fas.org/sgp//crs/misc/R41983.pdf (last accessed Mar 27, 2020).

drug passes the threshold and is approved by the FDA, the next process called postmarket or postapproval regulatory procedures is being implemented.[25]

With respect to domestic regulatory institutions, pharmaceutical market regulation of US has undergone quite different path compared to EU. Whereas US regulators confronted the period of market globalization with considerable regulatory capacity - manifested by significant expertise, regulatory coherence, and sweeping powers - Europe developed similar capacity much later. [26] The federal government began the regulation of drugs with the Pure Food and Drug Act of 1906, the main aim of which was to prohibit interstate commerce of adulterated misbranded drugs. In 1938 FDA was delegated the authority over the industry by the Congress and built in-house technical expertise quickly and consciously. In order to execute its mandate, the agency got involved in many aspects of pharmaceutical research, development and marketing, including oversight of laboratory conditions, testing methods, human trial protocols, and post-market safety. Nevertheless, FDA's most fundamental task is its function of gatekeeper whereas drugs are required to obtain approval in order to enter the market. Hence, the agency acquired extensive regulatory capacity as the single agency in charge counting on expert staff and sweeping market exclusion power.[27]

Within the period of next half-century, the President and Congress laid down the following two regulatory pieces, which expanded the authority of FDA. In 1938, the Federal Food, Drug, and Cosmetic Act (FFDCA) was enacted, which added the requirement to ensure the safety of drugs before manufacturers may sell them in interstate commerce. [28] It was followed by thalidomide crisis in the Europe, which resulted in deaths and birth defects from the tranquilizer. The latter alerted the FDA to the risk that weak foreign regulation posed a danger to US consumers, and triggered the Kefauver-Harris Drug Amendments to the legislation that

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[25] *Id.*

[26] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *Available at* https://www.jstor.org/stable/i25746508 (last accessed Mar 24,2020)

[27] *Id.*

[28] Agata Dabrowska & Susan Thaul, *How FDA Approves Drugs and Regulates Their Safety and* ...Congressional Research Service(2018), *available at* https://fas.org/sgp//crs/misc/R41983.pdf (last accessed Mar 27, 2020).

ensured increased safety provisions and additional requirement to the manufacturers to prove the effectiveness of their drugs.[29] Thereafter, the amendments of the FFDCA lead to the current mission of FDA, which focuses on the safeness and effectiveness of the pharmaceuticals.

The US has been the most important actor in the globalization of drug regulation. The FDA used its control over market access to extend its de-facto reach far beyond its nominal jurisdiction, for instance, by conducting detailed inspections of overseas research labs and production facilities. Frequently, the international expansion of FDA influence was the by-product of domestic regulatory change. The US as hegemon would introduce a new kind of regulation following domestic regulatory crises, such as Good Manufacturing Practices (GMP) in the early 1970s, continue, and the FDA would subsequently work with the World Health Organization (WHO) to globalize these through mechanisms such as certification of GMP implementation ... To fulfill its mandate of ensuring domestic drug safety amidst a gradually globalizing industry, the FDA began to slowly become a global player, drawing on its unrivalled reputation and authority to push US rules and standards internationally. [30]

In order to enter the market, a manufacturer has to obtain the FDA approval through demonstration of the prescription drug's safety and effectiveness according to the criteria, which are set in the legislation and agency regulations. It also has to ensure that FDA inspection will pass the manufacturing plant and acquire FDA approval for the medicine's labeling. The latter covers all written information about the drug inter alia packaging, prescribing information for physicians and patient brochures.[31]

EU and US regulatory systems for cosmetics

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[29] *Id.*

[30] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *Available at* https://www.jstor.org/stable/i25746508 (last accessed Mar 24,2020).

[31] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *available at* https://www.jstor.org/stable/i25746508 (last accessed March 24,2020).

The regulatory framework of cosmetics corresponds to the case of pharmaceuticals to the extent of focusing on product safety and consumer protection. Nevertheless, there are certain ethical issues such as the reduction and elimination of animal testing that are of significance globally. The EU and US have both been net exporters for a long period of time and are correspondingly largest export markets of each other.[32] The development of global cosmetics regulation reflects the instance of pharmaceuticals, though in the opposite direction. The regulatory framework of US is considered weak as a result of fragmented market and scarce statutory authority. On the other hand, EU has strong and dynamic regulatory state institutions and powerful coordination among the Member States. The roots of this discrepancy come from the establishment of regulatory frameworks of two largest markets with regulatory institutions created and developed in different directions.

As a result of domestic political actions, the US Food, Drugs and Cosmetics Act of 1938 brought cosmetic industry under control of federal legislation for the first time[33] and had the requirement to ensure safe cosmetics, meanwhile, it failed to assign the FDA the power to pre-market authorization.[34] This action of domestic authorities engendered diminishing effect on the US cosmetics regulatory capacity when made an analogy with the case of pharmaceuticals. In 1976, the scenario has changed when the Cosmetics Ingredient Review became voluntary, self-regulatory scheme due to the Cosmetic, Toiletry and Fragrance Association.[35] Nonetheless, FDA still does not have the formal authority to control market access and the industry of cosmetics is relying on industry-led ingredient review, as FDA's expertise in cosmetics is

[32] *Id.*

[33] Tousley, Rayburn D. *"The Federal Food, Drug, and Cosmetic Act of 1938."* Journal of Marketing, vol. 5, no. 3, 1941, pp. 259–269., *available at* www.jstor.org/stable/1246669 (last accessed Apr 20, 2020).

[34] Food, Drug, Cosmetic Act, U.S. Food and Drug Administration, (1938) *available at* https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act (last accessed Apr 20, 2020).

[35] Gerhard J. Nohynek, Eric Antignac & Thomas Re, *Safety assessment of personal care products/cosmetics and their ingredients* (2010), Toxicology and Applied Pharmacology 243 pp. 239–259., *available at* https://www.kudops.org/elearning/course_material/pdf/11.pdf (last accessed Apr 20, 2020).

comparatively little.[36] Such regulatory framework is not exemplary for a state, which is one of the main industry leaders of the world.

EU, in comparison, has adopted binding regulations for the industry with strict rules regarding acceptable, restricted or outright prohibited ingredients with the passage of the *Cosmetics Directive 76/768/EC* in 1976.[37] The main aim of the directive as an early proposal of the Internal Market project was to guarantee the safety of the products meanwhile accelerating the free flow of goods within the EU market. The succeeding three decades followed by a regulatory expertise and control built by the EU over market access. Thereafter, the European Centre for the Validation of Alternative Methods was created in 1991 with the purpose to research the alternative methods of animal testing and approve procedures for EU use.[38] Next, the Scientific Committee on Cosmetic Products was established in 1997, which was renamed as the Scientific Committee on Consumer Products in 2004.[39] The committee's mission, which is composed of experts from the Member States, is to analyze the safety of ingredients and make recommendations to the Commission on the ingredients that should be removed from the approved list and ban them from the EU market.

As regards market access, the following reforms have expanded EU control. In 1993, the 6th Amendment to the Cosmetics Directive prohibited the marketing of cosmetics that contained ingredients that had been tested on animals within EU. In 2003, the 7th Amendment to the Directive was adopted by the EU, according to which European regulatory capacity was further enhanced via extension of the ban on animal testing by including finished products that have been tested on animals in addition to the existing ban on ingredients. As a result of the 7th Amendment, the consumer protection was enhanced dramatically in the Union as the list of

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[36] FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, U.S. Food and Drug Administration, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated (last accessed Apr 22, 2020).

[37] Cosmetics: EU Legislation, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last accessed Mar 27, 2020).

[38] Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *available at* https://www.jstor.org/stable/i25746508 (last accessed Mar 24,2020).

[39] *The SCCS Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation*, European Commission (2018), *available at* https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf (last accessed Apr 23, 2020).

ingredients that were considered prohibited or restricted were broadly expanded.[40] The reform banned substances containing category 1 and 2 carcinogens, which lead to increase in the number of prohibited ingredients to nearly one thousand.

The Directive 76/768/EC is now replaced with *Regulation (EC) N° 1223/2009* on cosmetic products, which is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector, as well as simplifies procedures to facilitate the internal market of cosmetic products.[41] The relatively new directive provides an internationally recognized regime, which emphasizes product safety and takes into account the latest technological developments, including the possible use of nanomaterials. The previous rules on the ban of animal testing were not modified.

The most significant changes introduced by the cosmetics regulation include strengthened safety requirements for cosmetic products, introduction of the notion of 'responsible person' with precise identification of the responsible person and its obligations, centralized notification of all cosmetic products placed on the EU market, introduction of reporting of serious undesirable effects and new rules for the use of nanomaterials in cosmetic products. The latter has a requirement of explicit authorization of colorants, preservatives and UV-filters, as well as products of the mentioned criteria containing nanomaterials.[42] Moreover, the products with nanomaterials that may concern the commission shall pass full safety assessment at EU level. This, combined with the requirement of labelling the nanomaterials with the word ‘nano’ in the ingredients list significantly advances the level of transparency of the product ingredients and its chemical compound provided to the consumer.

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[40] Cosmetics Directive 76/768/EEC Explanatory Brochure, (2004), *available at* https://cosmeticseurope.eu/files/4114/6400/4203/The_European_Union_Cosmetics_Directive_Explanatory_Brochure_2004.pdf (last accessed Apr 25, 2020).

[41] Cosmetics: EU Legislation, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last accessed Mar 27, 2020).

[42] *Id.*

Cosmetics legislation at EU level also

requires that all products to be marketed in the EU must be registered in the cosmetic products notification portal (CPNP) before being placed on the market;

- requires that some cosmetic products are given special attention from regulators due to their scientific complexity or higher potential risk to consumer health;
- ensures that there is a ban on animal testing for cosmetic purposes;
- makes EU countries responsible for market surveillance at national level.[43]

The cosmetic products which deserve special attention from regulators due to their scientific complexity or higher potential risk to consumer health include products containing endocrine disrupters, nanomaterials, carcinogenic, mutagenic, or toxic for reproduction substances (CMR substances), as well as hair dye products, sunscreen products and most importantly borderline products. [44] EU Cosmetics regulation defines cosmetics as *any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.*[45] Meanwhile, Food Drug and Cosmetics Act of US defines cosmetics as a product *to be rubbed, poured, sprinkled or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles, except that such term shall not include soap*.[46] The latter presents relatively narrower definition compared to the definition of EU legislation, though EU's regulatory

[43] Cosmetics: EU Legislation, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last accessed Mar 27, 2020).

[44] *Cosmetic products – specific topics*, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/products_en (last accessed Mar 28, 2020).

[45] Lex Access to European Union law: *Regulation (EC) No 1223/2009 of The European Parliament And of The Council*, Eur-Lex (2009), *available at* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813 (last accessed Apr 26, 2020).

[46] How U.S. Law Defines Cosmetics: Cosmetics & U.S. Law, U.S. Food and Drug Administration, *available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law#U.S._Law (last accessed Apr 27, 2020).

framework of cosmetics as presented is more advanced and maintains a strict control over cosmetic products under its jurisdiction.

Differences in regulatory frameworks can be particularly significant for borderline products. The confusion occurs when it becomes unclear whether a particular product is a cosmetic product under cosmetics legislation or whether it falls under other sectorial legislation. The term borderline products under EU legislation refers to products that may be difficult to classify into a product category, either in the same country or in different countries.[47] Certain products that are considered cosmetics in the EU can be classified as an Over-the-Counter (OTC) drug in the US because of the narrower definition of cosmetics mentioned above.[48] These are mainly borderline products having various active ingredients that may arise safety issues. Even though such products may still be considered cosmetics in the EU, these ingredients require safety approval before entering the market. Therefore, the decision on a product's classification is taken on a case-by-case basis with the support of guidance documents published by the European Commission. The purpose of these documents is to facilitate the application of EU legislation for borderline products. Hence, the scope of the cosmetic products' definition does not imply that the state has more advanced regulatory framework. The decisive factors lie in the extent of details the regulatory framework covers when dealing with borderline products and managing their classification.

Chapter 2: Review of EAEU Regulatory Framework of Pharmaceuticals and Cosmetics

The EAEU, within the five years of its operation, was supposed to established a legal framework for regulating the circulation of medicines and medical devices covering all stages of their life cycle, starting from the development and manufacturing to study and confirmation of

[47] *Borderline products*, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en (last accessed Mar 28, 2020).

[48] Gerhard J. Nohynek, Eric Antignac & Thomas Re, *Safety assessment of personal care products/cosmetics and their ingredients* (2010), Toxicology and Applied Pharmacology 243 pp. 239–259., *available at* https://www.kudops.org/elearning/course_material/pdf/11.pdf (last accessed Apr 20, 2020).

safety, quality, and efficacy.[49] However, there are major gaps left in the regulatory processes of the medical devices industry, particularly, in the stage of their implementation. Common markets of Medicinal Products and Medical Devices started operating in 2018[50] though initially the Member States have agreed to create common market of pharmaceuticals and medicines in 2016. [51] The major obstacles in the creation of common market come across in the process of unification of the governing pharmaceutical operations in the form of regulatory complexities. Hence, the new regulatory framework cannot be without gaps and the Member States should rely and focus on the advancement of national legislation. As regards the pharmaceutical industry, regulations for the production and registration of pharmaceuticals and medical products in the Union are expected to be entirely unified by 2025. The consequences of the unification are supposed to be the reduced administrative costs for manufacturers within the Union as well as better medicinal products for the patients. Total of forty-three legal documents have been adopted for medicines, including all good manufacturing practices on the circulation of medicines — GMP, GCP, GLP, GDP, and GVP, as well as key documents on inspection of manufacturing facilities, confirmation of equivalence of generics, and development and study of biological medicinal products.[52]

The unified approaches to the validation of analytical procedures will enable the recognition of medicines quality control results by all control laboratories of the Union. The unified stability study rules will ensure pharmaceutical products retain their properties throughout their labeled shelf life.[53] The common market of medicines created by the Eurasian Commission promises to provide pragmatic outcomes, one of which is the issuance of marketing

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[49] *EAEU Highlights: Fifth Anniversary of the Eurasian Economic Union*, Eurasian Commission (2019), *available at* http://www.eurasiancommission.org/ru/Documents/3057_ЕЭК_Книга 2019_англ.pdf (last accessed Mar 28, 2020).

[50] *Connecting Paths: 2018 Annual Report*, Eurasian Economic Commission (2018), *available at* http://www.eurasiancommission.org/ru/Documents/2918_1_ЕЭК_ГО2018_англ_08.pdf (last accessed Mar 28, 2020).

[51] E. Vinokurov, *Eurasian Economic Union: Current state and preliminary results,* Russian Journal of Economics (2017), available at https://reader.elsevier.com/reader/sd/pii/S2405473917300041?token=8A293B5763B67BE66CCA5B06CE69BF50D76FA734002F08665112959D2996CC0CB41A7B5DD68AE13C88308C9D1CF366CF (last accessed May 1, 2020).

[52] *Connecting Paths: 2018 Annual Report*, Eurasian Economic Commission (2018), *available at* http://www.eurasiancommission.org/ru/Documents/2918_1_ЕЭК_ГО2018_англ_08.pdf (last accessed Mar 28, 2020).

[53] *Id.*

authorizations of the Eurasian Economic Union for pharmaceuticals and certificates of conformity of production areas of the Union's pharmaceutical enterprises and foreign manufacturers with the Union GMP requirements. The authorized authorities of the Member States have started tight cooperation with registration databases and applications for pharmaceutical inspections in order to comply with Good Pharmaceutical Practices.

Hence, a unified information system combining national regulatory systems for the approval of medicinal products and supervision of safety and quality of medicines was created at the end of 2018.[54] The unified information system is, in fact, the "central nervous system" of the Union's pharmaceutical market and is a basis for transparent registration process. The documents prepared by the Commission reflect the key processes of the common medicines market and contain registers and information databases of the EAEU, such as registers of authorized medicines, medical products, pharmaceutical inspectors and authorized persons of medicines manufacturers, a database of medicines that do not meet the quality requirements, as well as fake and counterfeit medicines.[55]

In 2017, the EAEU Pharmacopoeia was included in the World Health Organization Index of World Pharmacopoeias.[56] First, the establishment of the Union Pharmacopoeia provides formation of mutual requirements for the quality of pharmaceuticals within the EAEU. Additionally, the requirements come to facilitate the procedures of exporting medicines outside the Union customs boundary. The first edition of Union Pharmacopoeia has been completed at the end of 2019.[57] 157 general pharmacopoeia monographs included in the first edition of the Pharmacopoeia cover equipment requirements for analytical research, reagents, description of

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[54] *Union market of medicines: first results and first challenges*, Eurasian Economic Commission (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/23-10-2019-1.aspx (last accessed May 1, 2020).
[55] *Connecting Paths: 2018 Annual Report*, Eurasian Economic Commission (2018), *available at* http://www.eurasiancommission.org/ru/Documents/2918_1_ЕЭК_ГО2018_англ_08.pdf (last accessed Mar 28, 2020).
[56] *EAEU Highlights: Fifth Anniversary of the Eurasian Economic Union*, Eurasian Commission (2019), *available at* http://www.eurasiancommission.org/ru/Documents/3057_ЕЭК_Книга 2019_англ.pdf (last accessed Mar 28, 2020).
[57] *First edition of the EAEU Pharmacopoeia completed;* Eurasian Economic Commission (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/30-12-2019-3.aspx (last accessed May 3, 2020).

physical and physicochemical methods of analysis, pharmaceutical and technological test, as well as general requirements for testing of dosage forms.[58]

In order to have smooth transition into the common pharmaceutical market in the EAEU, the process will be based on a phased method, which will allow the entrepreneurs to have flexibility while adjusting to new conditions.[59] The manufacturers have two options: they can either choose national rules for the registration of the medicine or all-union rules until the end of 2020. However, products that will be registered in accordance with national standards, must be brought into compliance with all-union rules until December 31, 2025.

As regards the cosmetics regulation in EAEU, it is worthy of further consideration that the regulatory system is not as advanced as in EU and requires further development of the sphere. There is one main regulatory document in the sphere, which is in the form of technical regulation. Hence, in order to place cosmetics and perfumes on the market of EAEU Member States, the manufacturers must comply with the applicable requirements of the EAEU Technical Regulations "On Safety of Perfumes and Cosmetics" (EAEU TR009/2011). [60] It contains safety requirements for cosmetic products and perfumery, which are created for consumption and distribution in the EAEU. The main aim of the regulation is to set rules for the protection of consumer's life and health, prevention of misleading actions against the consumer as well as for the protection of the environment. The safety requirements established by the technical regulation cover composition, physical and chemical characteristics, microbiological indicators, content of toxic elements, toxicological indicators, clinical and laboratory indicators, production, consumer packaging, and labeling of products.[61] Hence, the purpose of TR009/2011 is to ensure the uniform application and enforcement of the requirements set in the regulation for cosmetic

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[58] *Id.*

[59] *Connecting Paths: 2018 Annual Report*, Eurasian Economic Commission (2018), *available at* http://www.eurasiancommission.org/ru/Documents/2918_1_ЕЭК_ГО2018_англ_08.pdf (last accessed Mar 28, 2020).

[60] Kristy Zhukovets, EAEU Market Access for Perfumes and Cosmetics (2018), *available at* https://www.gma.trade/single-post/2017/11/23/EAEU-Market-Access-for-Perfumes-and-Cosmetics (last accessed Mar 29, 2020).

[61] *Id.*

products and perfumes within the EAEU territory, including the free movement of the goods as well.

The technical regulation establishes two forms of conformity assessment for the manufacturers to demonstrate their products' compliance with the standards. The first method is EAC Declaration, which is designed for the manufacturer to declare the product's conformity with the minimum requirements set by the technical regulation. It is the manufacturer's responsibility to carry out the declaration and the process is followed by a registration by the notified body of the EAEU. After successful registration, the EAC Declaration becomes legally binding in the territory of EAEU. As the registration of EAC Declaration should be carried out only by a company established in the territory of the EAEU, an authorized representative within the EAEU is required for foreign companies.[62] The next method is the State Registration process, which is required for the products listed in the Annex 12 of the TR009/2011. Annex 12 includes products such as products made with the use of nano-materials, cosmetic products for children, products for hair bleaching, lightening and highlighting, etc. The sanitary-hygienic regulations of the EAEU are used to acknowledge the conformity assessment of the products by the state registration.[63] Notified bodies in the EAEU Member States perform state registration of cosmetic products and perfumes, as a result of which a state registration certificate is issued to the product manufacturer or supplier. The registration procedure consists of analysis of the manufacturer's documents, laboratory tests and in special cases inspection of production as well. All the certificates of state registration are combined in a special register.

In 2019, Board of the Eurasian Economic Commission considered issues in the spheres of customs and technical regulations and introduced number of amendments aimed at harmonizing technical regulation requirements with international standards. Among numerous other amendments, the EEC Board also established the procedure for introducing amendments to the

[62] EEU: Technical regulation on the safety of cosmetics and perfumery *available at* http://www.pravsky.com/eeu-technical-regulation-safety-cosmetics-and-perfumery (last accessed Mar 29, 2020).

[63] EEU: Technical regulation on the safety of cosmetics and perfumery *available at* http://www.pravsky.com/eeu-technical-regulation-safety-cosmetics-and-perfumery (last accessed Mar 29, 2020).

Union's Technical Regulation "On safety of perfume and cosmetic products". [64] Particularly, the validity of documents on conformity assessment of such products to the requirements of Technical Regulation issued or adopted before their entry into force has been determined. The amendments provide the possibility to produce and put into circulation perfumes and cosmetics made within the validity period of these documents, during their shelf life. Moreover, the manufacturers obtain the opportunity to sell such products in the single market of EAEU during their shelf live before the documents' expiry.

The amendments to the Union's Technical Regulation "On safety of perfume and cosmetic products" will enter into force on May 6, 2020. They concern the updating of requirements applied to the ingredient composition of perfume and cosmetic products, specify requirements to pH value, microbiological requirements for perfume and cosmetic products with microbiologically low risk, and requirements to marking; they also establish common validity criteria for statements made in respect of perfume and cosmetic products' consumer properties. [65]

Even though the Technical Regulation establishes basic technical requirements for the EAEU Member States and makes systematic steps towards regulated single market of cosmetics and perfumery, it has a long path to go and genuine efforts to make in order to correspond to the level of regulatory framework that EU has developed over the past few decades. Regulatory system of EAEU has made a fundament for Member States to provide safe and efficient cosmetic products, however, it is the state's responsibility to comply with modern international standards through advanced domestic regulatory system in conformity with international standards such as ISO GMP. Furthermore, the EAEU Technical Regulation does not categorize and cover the supervision of borderline products as EU does and leaves the responsibility of the regulation of developing market of cosmeceuticals on the Member States.

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[64] EAEU harmonizes its Unified veterinary requirements with international standards, EURASIAN COMMISSION (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/09-07-2019-1.aspx (last accessed Mar 29, 2020).
[65] *Id.*

Nevertheless, despite the facts mentioned above, there is a major issue in regards the direct applicability of the technical regulations of EAEU in Armenia, which will be thoroughly discussed in the next chapter.

Chapter 3: Armenia's regulatory framework of pharmaceuticals and cosmetics: analysis of prospects of advancements in domestic regulatory system through international best practice

The regulation of the Armenian pharmaceutical market has been evolving rapidly in the last decade as the new technologies lead to the constant development of the sphere. Armenia's national pharmaceutical policy is proposed by the RA Ministry of Health meanwhile the implementation of this policy is the responsibility of the Scientific Center of Drug and Medical Technologies Expertise (SCDMTE).[66] The main aim of the center is to carry out regulatory activities, which will provide availability of safe, effective and quality pharmaceuticals in Armenia.[67] One of the founding legal bases of the regulation of the pharmaceutical market is the relatively new RA Law on Medicinal Products adopted on 2016.[68] The new law attempts to align the regulatory landscape with international norms, including the harmonization of regulations with the Eurasian Economic Union in order to access the EAEU single medicines market. [69] The law also sets out regulations for the registration of the pharmaceuticals on the market, as well as provision of pharmaceutical manufacturer licenses. There are also several supporting regulations related to pharmaceuticals, its production, inspections, licensing and distribution.

[66] The Scientific Center of Drug and Medical Technologies Expertise, MINISTRY OF HEALTH OF RA, *available at* http://www.moh.am/#1/149 (last accessed Mar 29, 2020).
[67] The Scientific Center of Drug and Medical Technologies Expertise, *available at* http://www.pharm.am/index.php/en/, (last accessed Mar 29, 2020).
[68] Republic of Armenia Law "On Medicines", retrieved 9 February 2020, *available at* http://www.pharm.am/index.php/en/laws/89-on-medicines (last accessed Mar 29, 2020).
[69] Armenia Pharma Market Report, *available at* https://iphexindia.com/events/bsm_in_armenia_belarus_russia_expo_cum_bsm_in_uzbekistan_2019/uploads/Armenia_Report.pdf (last accessed Mar 29, 2020).

The establishment of common markets of medicines and medical devices is considered a significant direction of EAEU. Relevant agreements[70] on common principles and rules for the circulation of medicines and medical devices within the Union were signed on December 23, 2014.[71] In 2016, all the relevant by-laws were also adopted in entirety, which created a regulatory system of medicines and medical products aiming to correspond to international best practice, in particular, having European Union's example as a fundament and building EAEU's own regulatory framework on it. This process thrived as all the restrictions within EAEU in mutual trade in medicines at all stages of a medicine life-cycle (development, manufacturing, safety and efficacy studies, supply and distribution) were eliminated initially. In 2015, number of Protocols on the accession of the Republic of Armenia to the Agreements on Single Principles and Rules of Circulation of Medicines within the Eurasian Economic Union were signed by the Member States, which entered into force on April 2017.[72] Hence, Armenia is now part of a formed legal framework launched common markets of medicines and medical devices and is functioning since May 2017. Currently, the framework is in the transition period, which is provided to ensure smooth transition from domestic to unified regulation. The main aim of the transition period is to allow the Member States, including Armenia to prevent shortages in public health system as well as to provide manufacturers enough timeframe for adapting to new requirements. Moreover, it will give manufacturers the right to register the medicines via two available options, which are national registration and unified registration processes until the end of 2020. If the manufacturer chooses the national method, it will be obliged to pass re-registration in accordance with common market rules until 2025.

Thus, in order to conclude the benefits that EAEU membership provides to Armenia in the sphere of pharmaceuticals, it is worth to mention that common market will result in higher number of registered medicines, as well as in wider circulation of products. A guaranteed control

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[70] Agreement on Common Principles and Rules Of Circulation of Medicinal Products within the Eurasian Economic Union, (2014), *available at* https://docs.eaeunion.org/docs/en-us/01213250/itia_24122014_doc.pdf (last accessed May 2, 2020).

[71] First Results: The Republic Of Armenia In The EAEU, (2018), *available at* http://www.eurasiancommission.org/ru/Documents/Armenia_eng.pdf (last accessed Mar 29, 2020).

[72] Armenia to Accede to Agreements on Common Principles and Rules of Circulation of Medicines and Medical Products in Eurasian Economic Union, Eurasian Economic Commission (2015), http://www.eurasiancommission.org/en/nae/news/Pages/24-11-2015.aspx (last accessed May 2, 2020).

of quality, efficacy and safety of pharmaceuticals is supposed to be ensured as a result of Armenia's integration in the common market of medicines and medical devices.

Meanwhile, the cosmetics industry does not have such an extensive regulatory framework despite its significant growth and development in the last decade. Prior to joining EAEU, there has been one regulation concerning cosmetic products, which is the Order of the Minister of Health of the Republic of Armenia N 2-III-8.2 on Approving of Sanitary Rules and Norms of "Hygiene Requirements of the Production and Safety of Perfume-Cosmetic Products." Since 2015, Armenia has officially unified the national legislation with EAEU regulations, which alleges the direct applicability and enforceability of Technical Regulations of the Customs Union on "Safety of Perfumery and Cosmetics" based on the Treaty on Armenia's accession to the Eurasian Economic Union.[73]

According to this regulation, cosmetic products are classified into two groups: lower-risk products and higher-risk products. Higher-risk products require pre-market State registration, while lower-risk products can be issued with a declaration of conformity (EAC declaration). However, there is still no clear border that distinguishes certain dermal or functional cosmetics from pharmaceuticals and states their regulatory process. In the United States, products, which fall under both cosmetics and pharmaceuticals, must comply with regulations of both industries.

However, a major issue arises when the direct applicability of technical regulations of EAEU in the Republic of Armenia is being examined. In order to assure the economic integration of Member States, the legal framework of the Union for technical regulation issues has been undergoing reforms since 2015.[74] A main part of legislation harmonization of EAEU member states consists the agreement to harmonize policies and regulatory systems in the area of technical regulations. Though the process of harmonization is still ongoing, its goal is to ensure the unification of requirements for the circulation of goods and their free movement within the

[73] Treaty on the Accession of the Republic of Armenia to the Treaty on the Eurasian Economic Union, EAEU Union (2014), *available at* https://docs.eaeunion.org/docs/ru-ru/0027354/itia_11102014 (last accessed Mar 30, 2020).

[74] Emerson & Kofner, Technical Product Standards and Regulations in the EU and EAEU, International Institute for Applied Systems Analysis (2018), *available at* http://pure.iiasa.ac.at/id/eprint/15272/1/2-Technical Product Standards and Regulations in the EU.pdf (last accessed Mar 30, 2020).

EAEU Member States via common technical regulations. Article 51.2 of EAEU Treaty states that Technical Regulations of the EAEU are directly applicable at the territory of the Union.[75] Hence, the technical regulations have a binding power and should to be applied directly in the territory of the member states, without complementary national legislation. Article 51 of the Treaty sets out general principle of technical regulation and states the following:

1. Technical regulation within the EAEU shall be implemented in accordance with the following principles:
1) establishment of mandatory requirements to products or services and product related requirements to design processes (including research), manufacturing, construction, installation, adjustment, operation, storage, transportation, marketing and utilization;
2) establishment of common mandatory requirements in technical regulations of the EAEU or national mandatory requirements in the legislation of the member States in respect to the products included in the common list of products for which established mandatory requirements within the EAEU are established;
3) application and enforcement of technical regulations of the EAEU at the territories of the member States without exceptions;
4) compliance of technical regulations within the EAEU to the level of economic development of member States and the level of scientific and technological development; etc.[76]
The aforementioned provisions come to affirm that exceptions or derogations from the application and enforcement of technical regulations are not permissible for any Member State of the Union.

Nevertheless, a thorough view at the Armenian regulations as regards the applicability of technical regulations of the Union will prove the opposite and question their direct applicability. Even though provision 48 of the Treaty of the Accession of the RA states that *the provisions of the first indent of paragraph 3 of Article 53 of the Treaty on the Eurasian Economic Union of*

[75] Treaty on The Eurasian Economic Union, (2014), *available at* http://www.un.org/en/ga/sixth/70/docs/treaty_on_eeu.pdf (last accessed Mar 30, 2020).
[76]Treaty on the Accession of the Republic of Armenia to the Treaty on the Eurasian Economic Union, EAEU Union (2014), available at https://docs.eaeunion.org/docs/ru-ru/0027354/itia_11102014 (last accessed Mar 30, 2020).

May 29, 2014 shall be applied by the Republic of Armenia 12 months after the date of entry into force of the Treaty, except for the following Technical Regulations of the Customs Union in respect of which different time limits shall be determined for entry into force,[77] the decision of the Constitutional Court on "the Constitutionality of Accession Agreement of Armenia" (hereinafter Decision of CC) does not include technical regulations in the list of documents that have direct applicability. Provision 1 paragraph 8 of the Decision of CC stipulates that *starting from the effective date of this Treaty, all acts of the Bodies of the Eurasian Economic Union, as well as decisions of the Supreme Eurasian Economic Council (the Interstate Council of the Eurasian Economic Community (the Supreme Body of the Customs Union)) and decisions of the Eurasian Economic Commission (Commission of the Customs Union), in effect on the date of entry into force of this Treaty, shall apply on the territory of the Republic of Armenia taking into consideration the provisions specified in Annex 3 to this Treaty.*[78]

On another note, Article 24 of the RA Law on Normative Legal Acts states the following: *after the adoption of normative legal acts by the Commission of Eurasian Economic Union the Government shall come up with a corresponding legislative initiative if the relations regulated by the act are subject to legal regulations in the Republic of Armenia*. Provision 2 adds that in cases not provided by the latter *the Government can give a legal force to a normative legal act of the Eurasian Economic Union's Commission through a national legal act.*[79] However, as the cosmetic industry is subject to legal regulations in RA and the Government has not come up with any legislative initiative, the technical regulation cannot be given legal force on the basis of the 2nd provision of the article. Therefore, it can be inferred from the above mentioned that the non-inclusion of technical regulations in the list of the documents having direct applicability in RA and the impossibility to give the technical regulation legal force through national legal act makes the direct applicability of TR009/2011 even more questionable.

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[77] Treaty on the Accession of the Republic of Armenia to the Treaty on the Eurasian Economic Union, EAEU Union (2014), *available at* https://docs.eaeunion.org/docs/ru-ru/0027354/itia_11102014 (last accessed Mar 30, 2020).

[78] Decision of the Constitutional Court on "the Constitutionality of Accession Agreement of Armenia," Concourt.am (2014), *available at* http://www.concourt.am/armenian/decisions/common/2014/pdf/sdv-1175.pdf (last accessed Mar 30, 2020).

[79] The Republic of Armenia Law on Normative Legal Acts (2018), *available at* https://www.arlis.am/documentview.aspx?docID=120733 (last accessed May 2, 2020).

Conclusion

In order to draw conclusions from the above-mentioned reviews of international best practice and provide recommendations that can be applicable for the Armenian regulatory frameworks of both industries, the vivid and successful example of one of the largest markets of pharmaceutical and cosmetics industries – the EU case shall be considered. One of the major advantages that EU regulatory system has in the pharmaceutical industry is the common legal rules and requirements in all member states. This makes the authorization processes practical and efficient and creates single market, where all the products have equal regulatory requirements. This method can be efficiently applicable in the EAEU Common Market of Medicines and Medical devices. It will create equal environment of regulatory framework in all Member States and facilitate its development. The unified information system of EAEU is in fact a significant step toward a regulatory system similar to EU, which has had its systematic results over the last few decades of its existence. Nevertheless, unified legislation and regulatory framework will enhance the efficacy of the Union's common market.

As regards the cosmetics industry, there are two recommendations based on the EU example as well, which will have significant impact not only on Armenia's but on EAEU's industry's regulatory system as well. EU follows an internationally recognized regime, which reinforces product safety while taking into consideration the latest technological developments. EU's Regulation (EC) N° 1223/2009 on cosmetic products manages to implement entire Union's regulatory role of the industry with strict regulations that protect consumer's safety. A similar regulation shall be developed by the EAEU to enhance consumer protection of cosmetic's industry of the territory. A technical regulation, the direct applicability of which is questionable in one of the Member States is not a sufficient protection of consumer's safety in the Union. However, on the other hand, the technical regulation does propose the method of pre-market registration of higher-risk products. This method resembles EU's method of distinction between the products that require special attention from regulators due to their scientific complexity or

higher potential risk to consumer health, nevertheless, EU requires a prior registration of all the cosmetic products to be marketed in the EU in the cosmetic products notification portal (CPNP). A similar approach would benefit the cosmetics industry of the EAEU as well as each of the Member States. Following already applied method of common market of Medicines and Medical devices of EAEU, the cosmetics industry would flourish rapidly if common market of Cosmetic products would be created. However, the requirement of unified legislation and regulatory framework is also essential in this industry, otherwise, the advancement procedures will not have sufficient outcomes for the Union and Armenia. Moreover, a total ban on animal testing is also extremely necessary as the use of non-cruelty free products in the modern cosmetic world is gradually diminishing.

Another major issue that requires attention from the regulatory bodies of the EAEU and Armenia is the legislation concerning the classification of borderline products. EU's regulations on this issue is exemplary as well. European commission has guidance documents, which come to facilitate the process of product's classification via case-by-case basis decisions. Such guidance documents will help to modernize the regulatory framework of EAEU's and Armenia's cosmetics industries and conform them with international best practice standards.

To summarize, international industries of pharmaceuticals and cosmetics, regardless of the fact of having common features, characteristics and similar extent of significance for human's health, have undergone utterly different paths of development and modernization. The establishment of pharmaceutical industry's regulatory framework was first initiated by the US, while the European Union has made its first steps toward creation of regulatory system after a crisis that resulted in irreversible health consequences. Though both markets do dominate in the global market, their regulatory frameworks dictate the rules of international market of pharmaceuticals and have huge role in the formation of modern global regulatory system of the industry. As regards the cosmetics industry, the development of its regulatory framework does not date back to the beginning of 20th century as pharmaceutical industry's does. However, there is a major change in the role of the largest market that had its impact in regulatory system's formation. EU is considered the market that shaped the rules and regulations of cosmetics

industry's regulatory framework and became the agenda setter in the international market. It also established such strict laws and rules regarding consumer protection and product safety that US, despite its regulatory capacity, fails to accomplish till now. Hence, the cosmetics industry does present more disproportionate distribution of regulatory capacity in comparison with pharmaceuticals industry. The foremost reason behind it is the single market formed in EU, which provides the Union's market expertise and authority in the industry's regulatory framework, leaving US with limited degree of formal regulatory capacity. However, both larger markets do have exemplary characteristics that can be applied to the regulatory framework of EAEU and Armenia. EU has practical and efficient legal rules and requirements applicable to pharmaceuticals in the territory of the Union within the single market of Medicines and Medical devices that guarantee product safety and consumer protection both inside and outside the market. Concerning the industry of cosmetics, EU has adopted binding regulations with strict rules regarding pre-market authorization, acceptable, restricted or prohibited ingredients, animal testing and borderline products. These include regulations that lack in the regulatory framework of EAEU and Armenia and can be applicable for their further advancements. The application of international best practice and harmonization with modern global standards is an essential step for Armenia's and EAEU's cosmetics industries, meanwhile the regulatory framework of pharmaceutical industry is quite developed and can be adjusted to further improvement. However, some issues concerning direct applicability of technical regulations of EAEU in Armenia require immediate attention from regulatory bodies, as it stands as an obstacle for further harmonization of country's legal framework.

Bibliography

1. Eize de Boer, Understanding and Implementing the Requirements of the ISO 22716 Good Manufacturing Practices, Certification Standard for Cosmetic Products, *available at* https://www.sgs.com/en/white-paper-library/cosmetics-gmp (last accessed Mar 23, 2020)

2. Sauwakon Ratanawijitrasin & Eshetu Wondemagegnehu, Effective Drug Regulation: a multicountry study, World health organization (2002), *available at* https://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf (last accessed Mar24, 2020)
3. Quality assurance of pharmaceuticals. a compendium of guidelines and related materials: *Good manufacturing practices and inspection*, World Health Organization, (2007), *available at* https://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf (last accessed Mar 24, 2020)
4. Armenia: Pharmaceutical Country Profile, World Health Organization, (2010), *available at* https://www.who.int/medicines/areas/coordination/armenia_pharmaceutical_profile_18august2010.pdf?ua=1 (last accessed Mar 24, 2020)
5. Legislation on Cosmetics. Internal Market, Industry, Entrepreneurship and SMEs-European Commission, *available at* https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last accessed Mar 24, 2020)
6. Bach, David, and Abraham L. Newman. *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation.* Review of International Political Economy, vol. 17, no. 4, 2010, pp. 665–695., *Available at* https://www.jstor.org/stable/i25746508 (last accessed Mar 24,2020)
7. EU Regulation of CBD in Foods and Cosmetics: Publications and PresentationsArnold & Porter, *Available at* https://www.arnoldporter.com/en/perspectives/publications/2019/04/eu-regulation-of-cannabidiol-in-foods (last accessed Feb. 9, 2020)
8. *Natural & Organic Living; Say 'No' To Chemicals For A Healthy Life* , Raconteur (2016), *available at* http://www.eurasiancommission.org/ru/act/dmi/workgroup/materials/Pages/Агропромышленность/Raconteur_В согласии с природой_2016.pdf. (last accessed Mar 25, 2020)
9. Cosmetic products: an overview of International Regulatory Systems, Eurofins Scientific, *available at*

https://www.eurofins.com/biopharma-services/media/pharma-newsletters/eurofins-biopharma-services-newsletter-16-march-2017/cosmetic-products-an-overview-of-international-regulatory-systems/ (last accessed Mar 25, 2020)

10. Armenia Pharma Market Report, *available at* https://iphexindia.com/events/bsm_in_armenia_belarus_russia_expo_cum_bsm_in_uzbekistan_2019/uploads/Armenia_Report.pdf (last accessed Mar 25, 2020)
11. Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) U.S. Food and Drug Administration, *available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap (last accessed Mar 25, 2020)
12. "Cosmeceutical" Label on Cosmetics U.S. Food and Drug Administration, *available at* https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cosmeceutical (last accessed Mar 25, 2020)
13. *Global Pharma & Cosmetics Market Insights, Forecast to 2025*, 360 Market Reports, *available at* https://www.360marketupdates.com/global-pharma-cosmetics-market-13728245 (last accessed Mar 25, 2020)
14. *The European regulatory system for medicines and the ...*, European Medicines Agency, *available at* http://apps.who.int/medicinedocs/documents/s22187en/s22187en.pdf (last accessed Mar 26, 2020)
15. *Regulatory system strengthening for medical products*, World Health Organization, *available at* http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf (last accessed Mar 26, 2020)
16. Pharmaceutical legislation for medicinal products for human use, Public Health - European Commission, *available at* https://ec.europa.eu/health/documents/eudralex/vol-1_en (last accessed Mar 26, 2020).
17. Raphael DAUE, *Legal framework governing medicinal products for human use in the EU Public Health* - European Commission (2019), *available at* https://ec.europa.eu/health/human-use/legal-framework_en (last accessed Mar 26, 2020).

18. Agata Dabrowska & Susan Thaul, *How FDA Approves Drugs and Regulates Their Safety and* ...Congressional Research Service(2018), *available at* https://fas.org/sgp//crs/misc/R41983.pdf (last accessed Mar 27, 2020).
19. Tousley, Rayburn D. *"The Federal Food, Drug, and Cosmetic Act of 1938."* Journal of Marketing, vol. 5, no. 3, 1941, pp. 259–269., *available at* www.jstor.org/stable/1246669 (last accessed Apr 20, 2020)
20. Food, Drug, Cosmetic Act, U.S. Food and Drug Administration, (1938) *available at* https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act (last accessed Apr 20, 2020)
21. Gerhard J. Nohynek, Eric Antignac & Thomas Re, *Safety assessment of personal care products/cosmetics and their ingredients* (2010), Toxicology and Applied Pharmacology 243 pp. 239–259., *available at* https://www.kudops.org/elearning/course_material/pdf/11.pdf (last accessed Apr 20, 2020)
22. Cosmetics: EU Legislation, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last accessed Mar 27, 2020).
23. *Cosmetic products – specific topics*, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/products_en (last accessed Mar 28, 2020).
24. *The SCCS Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation*, European Commission (2018), *available at* https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf (last accessed Apr 23, 2020)
25. Cosmetics Directive 76/768/EEC Explanatory Brochure, (2004), *available at* https://cosmeticseurope.eu/files/4114/6400/4203/The_European_Union_Cosmetics_Directive_Explanatory_Brochure_2004.pdf (last accessed Apr 25, 2020).

26. Lex Access to European Union law: *Regulation (EC) No 1223/2009 of The European Parliament And of The Council*, Eur-Lex (2009), *available at* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813 (last accessed Apr 26, 2020).
27. How U.S. Law Defines Cosmetics: Cosmetics & U.S. Law, U.S. Food and Drug Administration, *available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law#U.S._Law (last accessed Apr 27, 2020).
28. *Borderline products*, Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2017), *available at* https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en (last accessed Mar 28, 2020).
29. *EAEU Highlights: Fifth Anniversary of the Eurasian Economic Union*, Eurasian Commission (2019), *available at* http://www.eurasiancommission.org/ru/Documents/3057_ЕЭК_Книга 2019_англ.pdf (last accessed Mar 28, 2020).
30. *Connecting Paths: 2018 Annual Report*, Eurasian Economic Commission (2018), *available at* http://www.eurasiancommission.org/ru/Documents/2918_1_ЕЭК_ГО2018_англ_08.pdf (last accessed Mar 28, 2020).
31. E. Vinokurov, *Eurasian Economic Union: Current state and preliminary results,* Russian Journal of Economics (2017), available at https://reader.elsevier.com/reader/sd/pii/S2405473917300041?token=8A293B5763B67BE66CCA5B06CE69BF50D76FA734002F08665112959D2996CC0CB41A7B5DD68AE13C88308C9D1CF366CF (last accessed May 1, 2020).
32. Kristy Zhukovets, EAEU Market Access for Perfumes and Cosmetics (2018), *available at* https://www.gma.trade/single-post/2017/11/23/EAEU-Market-Access-for-Perfumes-and-Cosmetic (last accessed Mar 29, 2020).

33. *Union market of medicines: first results and first challenges*, Eurasian Economic Commission (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/23-10-2019-1.aspx (last accessed May 1, 2020).
34. *First edition of the EAEU Pharmacopoeia completed;* Eurasian Economic Commission (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/30-12-2019-3.aspx (last accessed May 3, 2020).
35. EEU: Technical regulation on the safety of cosmetics and perfumery *available at* http://www.pravsky.com/eeu-technical-regulation-safety-cosmetics-and-perfumery (last accessed Mar 29, 2020).
36. EAEU harmonizes its Unified veterinary requirements with international standards, EURASIAN COMMISSION (2019), *available at* http://www.eurasiancommission.org/en/nae/news/Pages/09-07-2019-1.aspx (last accessed Mar 29, 2020).
37. The Republic of Armenia Law on Normative Legal Acts (2018), *available at* https://www.arlis.am/documentview.aspx?docID=120733 (last accessed May 2, 2020).
38. The Scientific Center of Drug and Medical Technologies Expertise, MINISTRY OF HEALTH OF RA, *available at* http://www.moh.am/#1/149 (last accessed Mar 29, 2020).
39. The Scientific Center of Drug and Medical Technologies Expertise, *available at* http://www.pharm.am/index.php/en/, (last accessed Mar 29, 2020).
40. Republic of Armenia Law "On Medicines", retrieved 9 February 2020, *available at* http://www.pharm.am/index.php/en/laws/89-on-medicines (last accessed Mar 29, 2020).
41. First Results The Republic Of Armenia In The EAEU, (2018), *available at* http://www.eurasiancommission.org/ru/Documents/Armenia_eng.pdf (last accessed Mar 29, 2020).
42. Treaty on the Accession of the Republic of Armenia to the Treaty on the Eurasian Economic Union, EAEU Union (2014), *available at*

https://docs.eaeunion.org/docs/ru-ru/0027354/itia_11102014 (last accessed Mar 30, 2020).

43. Emerson & Kofner, Technical Product Standards and Regulations in the EU and EAEU, International Institute for Applied Systems Analysis (2018), *available at* http://pure.iiasa.ac.at/id/eprint/15272/1/2-Technical%20Product%20Standards%20and%20Regulations%20in%20the%20EU.pdf (last accessed Mar 30, 2020).
44. Agreement on Common Principles and Rules Of Circulation of Medicinal Products within the Eurasian Economic Union, (2014), *available at* https://docs.eaeunion.org/docs/en-us/01213250/itia_24122014_doc.pdf (last accessed May 2, 2020).
45. Armenia to Accede to Agreements on Common Principles and Rules of Circulation of Medicines and Medical Products in Eurasian Economic Union, Eurasian Economic Commission (2015), http://www.eurasiancommission.org/en/nae/news/Pages/24-11-2015.aspx (last accessed May 2, 2020).
46. Treaty on The Eurasian Economic Union, (2014), *available at* http://www.un.org/en/ga/sixth/70/docs/treaty_on_eeu.pdf (last accessed Mar 30, 2020).
47. Treaty on the Accession of the Republic of Armenia to the Treaty on the Eurasian Economic Union, EAEU Union (2014), *available at* https://docs.eaeunion.org/docs/ru-ru/0027354/itia_11102014 (last accessed Mar 30, 2020).
48. Decision of the Constitutional Court on "the Constitutionality of Accession Agreement of Armenia," Concourt.am (2014), *available at* http://www.concourt.am/armenian/decisions/common/2014/pdf/sdv-1175.pdf (last accessed Mar 30, 2020)