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Standards for safe use of medicinal products following the pattern of the distribution system for medicinal products in Japan

Standardy bezpieczeństwa stosowania produktów leczniczych na przykładzie systemu dystrybucji produktów leczniczych w Japonii

Streszczenie

Standardy bezpieczeństwa stosowania produktów leczniczych są dostosowane do systemu ochrony zdrowia, który ze względu na ograniczenia finansowe jest efektem kompromisów. Jedną z możliwości realizacji konstytucyjnego prawa do ochrony zdrowia jest określenie zasad dystrybucji produktów leczniczych. Model funkcjonowania aptek ogólnodostępnych powinien uwzględniać poziom rozwoju technicznego, kulturowego i wiedzy pacjentów/konsumentów o produktach leczniczych. Publikacja jest próbą odnalezienia elementów możliwych do implementacji w celu podwyższenia standardów dla procesu dystrybucji produktów leczniczych w Polsce.

Słowa kluczowe: prawo farmaceutyczne, pharmacovigilance, prawo medyczne

Abstract

Safety standards for medicinal products are adapted to health care systems, which, due to financial constraints, is a result of compromises. One way to influence the constitutional right to health care is to define the rules for the distribution of medicinal products. The model of operation of general pharmacies should take into account the level of technical and cultural developments and patient/consumer knowledge about medicinal products. The article is an attempt to find possible elements for implementation, in order to raise standards for the process of distribution of medicinal products in Poland.

Key words: pharmaceutical law, pharmacovigilance, medical law

Introduction

The article will present legal solutions regarding the distribution of medicinal products in Poland and Japan. The presented institutions take into account the

standards for *pharmacovigilance*[1], which is a priority for international pharmaceutical regulations. Safety is improved through rules on registration of medicinal products, reporting of adverse reactions and regulation of the distribution of medicinal products. To this end, mechanisms for the control and supervision of medicinal products and dietary supplements[2] are introduced in the European Union, and the sales system is subject to the international rules of Good Distribution Practice. The classification of medicinal products will also be discussed.

Sources of law[3]

The history of the Japanese pharmaceutical industry dates back to the *Yamato* period (from the mid-fourth century to the seventh century AD). At that time, medicines were available only to people born into the imperial family[4]. The first regulations on medicines were introduced in the nineteenth century. At that time, rules for marketing and handling of pharmaceutical products were drawn up[5].

[1] *Pharmacovigilance* is a process of monitoring the safety of medicines and taking measures to reduce the risks and increase the benefits of taking medicines. See more: European Commission, *Pharmacovigilance*, https://ec.europa.eu/health/medicinal-products/pharmacovigilance_en (access: 30.03.2019). About history and tasks of *pharmacovigilance*, see. More: G. Fornasier, S. Francescon, R. Leone, P. Baldo, *An historical overview over Pharmacovigilance*, source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6132952/ (access: 30.03.2019).

[2] A medicinal product as a basic concept in the work will be used interchangeably with the term drug. Pursuant to Pharmaceutical Law, a medicinal product in accordance with Article 2(32) of the Act of 6 September 2001 Pharmaceutical Law (hereinafter referred to as the Ph. Law), Journal of Laws 2017.2211 IU, is a substance or mixture of substances presented as having prevention or treatment properties in case of diseases occurring in humans or animals or administered for diagnosis or restoring, improving or modifying the physiological functions of the body through pharmacological, immunological or metabolic action.

[3] At European Union level, the key regulation of medicinal products is Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the community code relating to medicinal products for human use (Journal of Laws 311 of 28.11.2001, p. 67), guidelines of 5 November 2013 on good product distribution practice concerning medicinal products for human use, 2013/C 343/01. The most important national legal acts are: the Ph. Law, Regulation of the Minister of Health of 13 March 2015 on the requirements of Good Distribution Practice.

[4] H. Wanabe, *Japoński rynek farmaceutyczny oraz firmy farmaceutyczne*, p. 3, Portal Promocji Eksportu, https://japan.trade.gov.pl/pl/f/download/fobject_id:195948 (access: 25.02.2018). According to another source, the *Yamato* period is dated to third-eighth centuries AD, see: U. Muszalska, *Początki państwowości Japonii* [in:] ed. M. Sadowski, A. Spychalska, K. Sadowa, *Ze studiów nad prawem, administracją i ekonomią*, Wrocław 2014, p. 53.

[5] Institute for International Cooperation Japan International Cooperation Agency, *Japan's Experiences in Public Health and Medical Systems. Towards Improving Public Health and Medical Systems in Developing Countries*, source: *https://www.jica.go.jp/jica-ri/IFIC_and_JBICI-Studies/english/publications/reports/study/topical/health/pdf/health_03.pdf*, p. 29 (access: 30.03.2019).

Changes in the regulations result from the revolution of the pharmaceutical industry and the adaptation of Japanese legislation to the realities of the current market[6]. The regulations on health care and pharmaceutical law are laid down in the Constitution of Japan. Article 25 indicates the basic duties of the state to maintain the health of its citizens and safeguard public health: *All citizens have the right to maintain a certain minimum level of healthy and cultural life. In all areas of life, the state makes efforts to introduce and expand social care and social security and public health*[7]. This provision establishes a legal norm analogous to that contained in Article 68 of the Constitution of the Republic of Poland[8]. In addition, Polish pharmaceutical law is affected by the norms of the European Union law, among others: the Treaty on the Functioning of the European Union[9], Directive 2001/83[10] and Regulation 726/2004[11].

The current binding act regulating pharmaceutical law is the *Pharmaceutical and Medical Device Act* (hereinafter: PMDL), which is a revision of the 1943 Act. The changes made in the field of *pharmacovigilance* are the result of the WHO's reaction to the occurrence of tragic adverse effects of thalidomide[12]. PMDL, like the Ph. Law. in Poland, has an impact on public health by guaranteeing the quality, effectiveness and safety of medicines, cosmetics and medical products. It is also intended to prevent and reduce the risks associated with the occurrence of side effects of the above-mentioned products[13].

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[6] K. Masuyama, S. Isobe, *Social change and Pharmaceutical Affairs Law*, Yakushigaku Zasshi. 2010;45(1):78–81. Japanese. PMID: 21032892 (access: 26.02.2018).

[7] T. Suzuki, *Konstytucja Japonii*, Warszawa 2014, art. 25.

[8] The Constitution of the Republic of Poland of 2 April 1997, Journal of Laws 1997.78.483. Article 68 of the Constitution guarantees everyone, regardless of having Polish citizenship, the right to health protection. See: M. Gawrońska, *Prawo do ochrony zdrowia na gruncie Konstytucji Rzeczypospolitej Polskiej*, Przegląd Prawa Publicznego, 2/2014, pp. 7–17.

[9] Journal of Laws 2004.90.864/2. The Treaty imposes standards for the protection of human health (Article 168) respecting the responsibilities of the Member States to define their health policies as well as the organisation and delivery of health services and healthcare (Article 168(7)).

[10] Directive of the European Parliament and of the Council of 6.11.2001 on the community code relating to medicinal products for human use, EU Journal of Laws 1.2001.311.67. However, Member States have exclusive competence to determine health policy as well as the organisation and delivery of health services and medical care, are responsible for management of health services and medical care and the resources allocated to them. See. M. Malczewska, *Komentarz do art. 168 Traktatu o funkcjonowaniu Unii Europejskiej* [in:] ed. K. Kowalik-Bańczyk, M. Szwarc-Kuczer, A. Wróbel, *Traktat o funkcjonowaniu Unii Europejskiej. Komentarz.* Volume II (*Articles 90–222*), Warszawa 2012.

[11] Regulation of the European Parliament and the Council of 32.03.2004 establishing the European Medicines Agency, UE Journal of Laws 1.2004.136.1.

[12] About the side effects of thalidomide and the actions taken by the international community on *pharmacovigilance*, see.: G. Fornasier, S. Francescon, R. Leone, P. Baldo, *A Historical Overview...*

[13] M. Borkowski, *Bezpieczeństwo zdrowotne – wybrane prawa pacjenta w aptece*, Annales Universitatis Paedagogicae Cracoviensis, 3/2019, pp. 125 and 126.

The 2002 amendments to the PMDL increased the safety guarantees after the medicine was placed on the market. Modifications have also taken place in the system of licensing (approval) of medicinal products, affecting manufacturing companies that were responsible for putting safety measures in place within them, in compliance with international trends. These measures came into force on 30 July 2003, while the provisions modifying the manufacturing process, the placing of the product on the market and the rules on medical products came into force on 1 April 2005[14].

Classification of medicinal products

A medicinal product in Japanese law is defined as: 1. a drug listed in the pharmacopoeia[15]; 2. substances which are intended to be used for diagnosis, treatment or prevention of diseases in humans or animals and which are not equipment or instruments, including medical materials and sanitary materials; 3. substances having an effect on the vital functions of the human body or animals and which are not medical equipment[16].

The classification of medicinal products in Japan is different from the model adopted in Europe[17]. The Japanese law distinguishes pharmacy drugs – this concept includes prescription drugs and medicinal products that require consultation with a pharmacist. Their clinical efficacy is not the same as that of prescription drugs and they can be selected and used by the consumer/patient based on the information provided by the pharmacist. This category of products is sold exclusively in the *face-to-face* system (direct sales, in a public pharmacy).

[14] Japanese Association of Pharmaceutical Manufacturers, *Pharmaceutical Laws and Regulations*, p. 12 et seq. http://www.jpma.or.jp/english/parj/pdf/2017_ch02.pdf [access: 27.02.2018].

[15] Pharmacopoeia is a type of pharmacy code – official list of medications authorised in the country or territory concerned, and a list with the same reservations of raw materials used for manual preparation of some of these drugs in a pharmacy.

[16] The classification of a product as a medicinal product is of great importance because of the different rules concerning placing on the market, sale and supervision of safety. Guidelines and studies have been prepared in the European Union, and they are intended to help manufacturers in the process of launching products. The Regulation of the European Parliament and Council (EC) No 1223/2009 of 30 November 2009 on cosmetic products (UE Journal of Laws 2009.342.59) and the judgement of the European Court of Justice of 30 November 1983 in Case C-227/82, Lendet Van Bennekom, ECR 1983 and the judgment of the Court of Justice of 20 March 1986 in Case 35/85 Gerard Tissier, Zb. Orz. 1986, p. 1207, in which it is stated that substances which, although not themselves presented as having medicinal properties or preventing disease, are nevertheless intended (alone or in combination with other substances) to be administered to humans should also be classified as a medicinal product.

[17] The Ph. Law. introduces a division according to the category of availability. We distinguish medicinal products: issued without a doctor's prescription, issued with a doctor's prescription, issued with a doctor's prescription for restricted use, issued with a doctor's prescription, containing narcotic drugs or psychotropic substances, specified in separate regulations, used only in inpatient treatment.

OTC drugs are divided into three groups: high-risk drugs, moderate-risk drugs, and low-risk drugs. Low-risk drugs can be sold online. Also OTC drugs that have received this category after switching from prescription drugs can be sold online three years after a change in their status and after a risk assessment[18]. In Japan, it has been also decided to introduce a division of medicinal products sold without a prescription and distinguish between: high-risk OTC drugs, relatively high-risk OTC drugs, and relatively low-risk OTC drugs[19]. Such a procedure is intended to clarify the rules for the distribution of these categories of drugs. The principles of distribution and *pharmacovigilance* put Japan at the forefront of countries in which the reporting of side effects (39%) is carried out by pharmacists in public pharmacies[20]. This may indicate a high level of patient confidence in pharmacists, which predisposes this professional group to increase its role in the pharmacovigilance system and the development of pharmaceutical care[21]. PMDL distinguishes another group, the so-called *quasi-drugs* – for which legal requirements are less restrictive, but the products require approval before they can be placed on the market[22].

A separate issue is *the pricing* of medicinal products in a health protection system and access to generic medicines[23], which can contribute to reducing the

[18] Information in English on Japanese Regulatory Affairs, *Pharmaceutical Administration and Regulations in Japan*, source: http://www.nihs.go.jp/mhlw/yakuji/yakuji-e_20110502-02.pdf, pp. 21-22 (access: 21.03.2018).

[19] In the Ph. Law, only as regards veterinary medicinal products, there is an indication for the determination of the frequency of adverse reactions in the summary of product characteristics (Article 11(2)(4f)). The characteristics of a medicinal product for human use do not require inclusion of analogous data. The requirement to include information about possible side effects was introduced in § 6, point 5z of the Regulation of the Minister of Health of 20 February 2009 on the requirements for the labelling of the packaging of a medicinal product and the content of the leaflet.

[20] K. van Grootheest, S. Olsson, M. Couper, L. de Jong-van den Berg, *Pharmacists' role in reporting adverse drug reactions in an international perspective*, Pharmacoepidemiology and Drug Safety 7/2004, pp. 457–464.

[21] *Pharmaceutical care consists in continuously improving the way drugs are used. Maximizing the benefits of pharmacotherapy and avoiding the side effects of treatment requires cooperation between the patient, doctor, pharmacists and other medical professions.* See. The Supreme Chamber of Pharmacy, *Raport. Opieka farmaceutyczna. Kompleksowa analiza procesu wdrożenia*, source: https://www.nia.org.pl/wp-content/uploads/2021/04/raport_opieka_farmaceutyczna.pdf [access: 6.04.2021].

[22] By law, a product can be subordinated only into one category. About the so-called *borderline* products, see: Risk and Policy Analysts Limited, *Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products*, source: https://rpaltd.co.uk/uploads/report_files/j457-final-report-cosmetics.pdf [access: 30.03.2021], p. 4. M. Siwiec, *Różnice pomiędzy produktem leczniczym a suplementem diety, wyrobem medycznym oraz środkiem spożywczym specjalnego przeznaczenia*, source: https://www.prawo.pl/zdrowie/roznice-pomiedzy-produktem-leczniczym-a-suplementem-diety-wyrobem-medycznym-oraz-srodkiem-spozywczym-specjalnego,262107.html (access: 23.06.2021).

[23] See: A. Zawada, A. Korecka-Polak, B. Kobuszewski, *Ceny leków – teoria i praktyka*, Zdrowie Publiczne i Zarządzanie, 4/2019, pp. 194–202.

cost of pharmacotherapy[24]. Most of the medicinal products sold in Japan are innovative medicines. Sales of generic medicines in 2005 accounted for just over 30%[25] of sales of medicinal products. Since then, there has been an increased focus on developing the Japanese pharmaceutical market and increasing domestic production by supporting generic drug manufacturers[26]. In 2020, the generic drugs market almost reached the assumed level of 80% share[27].

The development of generic drugs makes the domestic market of medicinal products independent of political turmoil and prices on international markets[28] and is an element of the pricing policy[29].

Sales and production of medicinal products in Japan

Starting a business requires a permit from the prefectural authorities[30]. Depending on the type of medicinal products produced/sold, different authorisations

[24] On the importance of generic drugs, their impact on reducing expenditure on health care, without compromising the quality of medical care provided, see: Opracowanie Polskiego Związku Pracodawców Przemysłu Farmaceutycznego, *Znaczenie rodzimej produkcji leków dla polskiej gospodarki*, Piguła, July 2015, www.pharmalogica.pl/pigulka-52-lipiec-2015,i3899?download=3587 (access: 26.02.2018).

[25] The share of sales of generic drugs in Poland in 2010 was 66%, Data from: Polish Information and Foreign Investment Agency, *Sektor farmaceutyczny i biotechnologiczny w Polsce*, p. 3, http://www.paih.gov.pl/files/?id_plik=19607 (access: 28.02.2018). For example, in the Czech Republic, in 2010, the generic medicine market reached 13.8%, M. Lorinczy, *Impact of the crisis on the pharmaceutical market in the Czech Republic and Hungary*, p. 23, http://www.wsb.edu.pl/container/FORUM%20SCIENTIAE/numer%202/forum-2-2013-art2.pdf (access: 28.02.2018).

[26] H. Watanabe, *Japoński rynek farmaceutyczny oraz firmy farmaceutyczne*, p. 11 et seq., source: https://japan.trade.gov.pl/pl/f/download/fobject_id:195948 (access: 27.02.2018). According to forecasts, 8 out of 10 medicinal products sold in Japan are to be generics, see T. Togashi, *Japan: Generic Leading Expansion*, source: https://ispe.org/pharmaceutical-engineering/march-april-2019/japan-generics-leading-expansion (access: 23.06.2019).

[27] A comparison of the market share of generic medicines since 2005 in Japan, see: *Volume share of generics in prescription drug market Japan 2005–2020*, source: https://www.statista.com/statistics/799622/japan-generics-market-volume-share/ (access: 20.06.2021). About the Japanese generic market, see: Japan Health Policy NOW, *Generic Drugs*, source: https://japanhpn.org/en/section-6-2/ (access: 30.03.2018); P. Reed Maurer, *Generics in Japan*, source: https://www.thepharmaletter.com/article/generics-in-japan (access: 23.06.2019).

[28] J. Woroń, *Leki oryginalne i generyczne, czyli dlaczego potrzebna jest indywidualizacja farmakoterapii*, Forum Zaburzeń Metabolicznych 1(4) 2010, p. 242.

[29] On the effectiveness of generic drugs, their role in pricing policy, see: A. Świerczyna, *Zasady obrotu lekami generycznymi w Unii Europejskiej – ograniczenia i bariery* [in:] ed. D. Kornobis-Romanowska, *Aktualne problemy prawa Unii Europejskiej i prawa międzynarodowego – aspekty teoretyczne i praktyczne*, Wrocław 2017, p. 207.

[30] On the Japanese administrative system, see: B. Woźniczko, *Japońskie władze samorządowe*, source: https://japan.trade.gov.pl/pl/japonia/adresy/223336, japonskie-wladze-samorzadowe.html (access: 30.03.2019).

are required for: manufacture/production of medicines of the first type (according to the classification of medicinal products given in the previous subsection), manufacture/production of medicines of the second type, etc.

The distribution of prescription drugs is reserved for pharmacies, and their distance sale (via the Internet) is prohibited. Only OTC drugs can be sold in this distribution channel, only if they are the subject of sale in stores[31]. Retail authorisations for medicinal products are divided into (Art. 25 of the PMDL): distribution in shops where it is possible to sell medicines without a prescription and to obtain information on pharmacotherapy; *door-to-door* distribution[32]; wholesale licence[33].

Wholesale requires a licence issued by the governor of the prefecture relevant to the seat of the enterprise (Art. 25(1) and Art. 31 of the PMDL). Wholesale is defined as the sale or supply of medicines to the owner of a pharmacy, a marketing authorisation holder, a manufacturer, or a shop (in the case of OTC medicinal products). Deliveries are permitted when the marketing authorisation for a medicinal product traded in Japan is held. An entrepreneur running a wholesaler or pharmacy is obliged to employ a pharmacist at the registered office in which the business activity is carried out (Art. 35(1) and (2) of the PMDL).[34] The license is issued for 6 years[35].

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[31] The solutions are close to those used in the Ph. Law. Retail trade in medicinal products in Poland is reserved for public pharmacies (Art. 68 of the Ph. Law) and pharmacy outlets (Art. 70(1) of the Ph. Law.). Rationing of the sales market is designed to counteract adverse phenomena that may occur during the marketing process, it also strengthens the institution of control and supervision of goods of particular value for the life and health of patients. For more on rationing and the justification for its application, see: R.J. Kruszyński, *Obrót detaliczny lekami. Zagadnienia prawne*, Warszawa 2014, pp. 90–147. Introduction of the *pharmacy for the pharmacist* is justified by "the protection of public health and, more specifically, the objective of ensuring a reliable and adequate quality supply of medicinal products to the public". *Uzasadnienie do projektu zmian ustawy Prawo farmaceutyczne*, source: http://webcache.googleusercontent.com/search?q=cache:6uvnrds1l8j:orka.sejm.gov.pl/druki8ka.nsf/0/defd45ce43627fb9c1258087005dd49d/%2524file/1126-justification.docx+&cd=1&hl=en&ct=clnk&gl=en&client=safari (access: 30.03.2019).

[32] Article 25 of the PMDL Act indicates the possibility of selling medicines in shops. Salesmen should be people with the knowledge and experience necessary to conduct retail business of medicinal products (Art. 28 of the PMDL). This type of distribution refers to the sale of non-prescription medicines with a relatively long expiration date and refers to the *door-to-door* sales system.

[33] About sales system, see: S. Tago, A. Ueda, R. Kudo, L. Guedson I. Godo, *Distribution and marketing of drugs in Japan: overview*, source: https://uk.practicallaw.thomsonreuters.com/5-618-3562?transitionType=Default&contextData=(sc. Default)&firstPage=true (access: 30.03.2019).

[34] S. Tago, A. Ueda, L. Guedson, R. Kudo, *Distribution and marketing of drugs in Japan: overview*, https://content.next.westlaw.com/Document/I611772994da011e598dc8b09b4f043e0/View/FullText.html?contextData=(sc. Default)&transitionType=Default&firstPage=true&bhcp=1 (access: 28.02.2018).

[35] I have not found any provisions on the requirement to employ pharmacists during a shift in a pharmacy, which should certainly be additionally checked. It would also be worth checking the obligation to provide access to a pharmacy for the local population (mandatory duty hours are approved in Poland by the District Council, after consulting the vogts (mayors, city presidents) of municipalities from the district and the pharmacy self-government – Article 94 (2) of the Ph. Law).

Such liberal legal solutions seem particularly interesting in the context of the Ph. Law amendment limiting the operation of public pharmacies only to entities that are pharmacists or companies in which the majority shareholders are pharmacists[36].

In the case of the manufacture of medicinal products, obtaining a permit to conduct a business activity is also conditional on expressing the opinion of the Office for Medicinal Products on this issue and compliance with Good Quality and Manufacturing Practice. The license/permit is valid for 5 years. The issue of the quality and safety of medicines, as well as the control of these indicators, lie with: Chief Specialist for Compliance with the Medicines Market, Quality Assurance Manager, and Safety Management Manager responsible for quality control. Control powers are also stipulated in Article 14 of the Act. Pursuant to its regulation, the Ministry of Health, Labor and Social Welfare and the Agency for Pharmaceuticals and Medical Devices have the authority to compliance of the manufacturer's actions with the recommendations for production safety. In practice, the Pharmaceutical and Medical Devices Agency examines applications for marketing authorisation. Prefectural Governors are responsible for issuing permits for the sale/manufacture of OTC drugs. All legal restrictions on trade in medicinal products are listed in the PMDL[37].

Entities controlling the market for medicinal products[38]

The retail market of medicinal products in Poland is regulated by the Ph. Law. The Voivodeship Pharmaceutical Inspector is an entity authorised to issue a permit to operate a public pharmacy, and the rules for issuing a permit are set out in Article 99 et seq. The Ph. Law, as an authorizing body, is entitled to inspect or control the

[36] More about the amendment of the so-called pharmacy for the pharmacist, see the website of the Supreme Chamber of Pharmacy: http://www.nia.org.pl/2017/06/26/nowelizacja-ustawy-prawo-farmaceutyczne-tzw-apteka-dla-aptekarza/ (access: 27.02.2018).

[37] T. Sueyoshi, T. Kanda, Y. Nishikawa, *Life sciences: product regulation and liability in Japan*, https://www.lexology.com/library/detail.aspx?g=7bf94885-2826-41ab-9350-bb7b8564b133 (access: 28.02.2018).

[38] This competence is exercised in the first stage of the approval of medicinal products for placing on the market by the Minister of Health, Labour and Social Welfare or the Governor of the Prefecture, who is obliged to send data and documents to check their compliance as to the quality of the product, efficacy and security. The condition for the authorisation of a medicinal product is its compliance with Good Manufacturing Practice defining legal standards that regulate the hygiene of production and are designed to prevent the production of products that do not meet the quality requirements. This system is designed to ensure consumer safety by guaranteeing the origin of products from authorised producers whose activities are regularly inspected by the relevant inspection bodies. See more: Official website of the European Commission, *Wprowadzenie do Dobrej Praktyki Wytwarzania*, source: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2011_intro_en.pdf (access: 28.02.2018).

economic activity for which a permit has been issued (Art. 37at, (1) of the Ph. Law). In Japan, it is the prefecture's governor[39] who has control powers in the following areas: checking the status of an entrepreneur on the basis of the reports prepared by the relevant Ministry of Health, ordering an on-site inspection, recommending improvement in the event that the procedures used by the entrepreneur do not ensure adequate quality of production or internal supervision of medicines after placing them on the market does not comply with normative regulations[40]. In the event of a violation of the PMDL and related laws and regulations, the prefecture governor may revoke the license of the wholesale entrepreneur[41].

Prefectural governors are also responsible for appointing pharmaceutical inspectors whose task is to control the production, import, to label and advertise medicinal products. The inspection system also deals with detection of falsified drugs or low-quality drugs. Inspectors carry out an inspection, which also takes the form of supervision which shall take the following measures: withdrawal of the licence or the suspension of the economic activity of the entity distributing or producing medicinal products; withdrawal or amendment of an authorisation for a medicinal product; temporary suspension of the sale and disposal of medicines that do not comply with quality standards; order to withdraw products from the market; order to improve the condition of the infrastructure in which the economic activity covered by the authorisation is carried out[42].

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[39] This division corresponds to the Polish voivodships. Prefectures are administrative units larger than counties. See: Wikipedia, *Podział administracyjny Japonii,* source: https://pl.wikipedia.org/wiki/Podział_administracyjny_Japonii (access: 23.06.2021).

[40] This competence is based on the *Gyoseihido* institution, understood as "the idea of advice or instruction coming from top to bottom, i.e. within hierarchical dependencies", L. Leszczyński, *Japonia. Kontynuacje i negacje*, Lublin 1994, p. 39. It is an institution occurring in unequal relations, such as the one described, in which one of the entities has the so-called *empire*, e.g. administrative authority. See: U. Wach-Górny, W. Górny, *Instytucja gyoseihido jako japońska inspiracja dla rozwoju koncepcji alternatywnych form rozwiązywania sporów w prawie administracyjnym*, https://ruj.uj.edu.pl/xmlui/bitstream/handle/item/45165/wach-gorny_gorny_instytucja_gyoseishido_jako_japonska_inspiracja_dla_rozwoju_2017.pdf?sequence=1&isAllowed=y (access: 28.02.2018). The performance of control activities therefore rests on the shoulders of the executive authorities. The performance of control activities therefore rests on the shoulders of the executive authorities. More on the Japanese administrative system, see: B. Woźniczko, *Japońskie władze samorządowe*, source: https://japan.trade.gov.pl/pl/japonia/adresy/223336,japonskie-wladze-samorzadowe.html (access: 30.03.2019).

[41] Article 75(1) of the PMDL. The same is true in the Ph. Law, which, for example, indicates in Article 37ap that it is the authorising authority that withdraws the authorisation in the cases referred to by law.

[42] Japan Pharmaceutical Manufacturers Association, *Pharmaceutical Administration and Regulations in Japan*, source: https://www.jpma.or.jp/english/about/parj/eki4g600000078c0-att/2020.pdf (access: 30.03.2021), p. 48.

Summary

Setting legal standards for the safety of using medicinal products requires a search for optimal legal solutions that will focus on the use of available technical infrastructure, defining tasks for medical professionals or defining the categories of products available on the market.

The rules for the distribution of medicinal products in Japan, in selected fragments, use legal solutions unheard of in the Ph. Law, The implementation of some of them could translate into pharmacovigilance standards in Poland[43]. This applies in particular to the institutions related to the distribution system and classification of medicinal products.

The Japanese system of grouping medicinal products according to the level of risk posed by their use, i.e. drugs are divided into three categories, depending on the severity of side effects, should be praised. The sale of medicines of the first category (with the most severe adverse reactions) requires the application of a safety management system to them. Polish solutions require that the characteristics of the medicinal product include the frequency of occurrence of adverse reactions.[44]

The need to consult a pharmacist when using certain OTC medicinal products should also be positively assessed, which may translate into a reduction in the abuse of medicinal products.

Adding *quasi-drugs* to product types could help solve interpretation problems with the so-called *borderline products*. The Japanese solution imposes high registration standards for this category of products, ensuring a high level of consumer/patient's rights to access a safe product.

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[43] The example for a possible increase in standards for pharmaceutical care would be the implementation of of consultation rooms, functioning in the United Kingdom, in which the patient can discuss the details of pharmacotherapy with an experienced pharmacist. See: P. Łasocha, P. Merks, A. Olszewska, *Farmacja szpitalna i kliniczna w Wielkiej Brytanii*, Farmacja Kliniczna 9/2013, pp. 527–530; See: P. Merks, A. Olszewska, Ch. Dehili, M. Allan, T. Kilpeläinen, M. Grabowska, M. Kozłowska-Wojciechowska, *Pokoje konsultacji jako jeden z mechanizmów wdrażania zaawansowanych usług farmaceutycznych w Polsce*, source: https://www.researchgate.net/profile/Piotr_Merks/publication/307397962_Merks_P_Olszewska_A_Dehili_Ch_Allan_M_Kilpelainen_T_Grabowska_M_Kozlowska-aWojciechowska_M_Consultation_room_as_one_of_the_important_aspects_of_implementation_of_advanced_pharmaceutical_services_in_Pol/links/57c53eac08aecd4514165830.pdf?origin=publication_detail (access: 30.03.2019).

[44] On the risk assessment of medicinal products, see. K. Orzeł, O. Żebrowska, K. Wołowiec, *Ocena bezpieczeństwa leku w kontekście oceny technologii medycznych*, source: https://power.aotm.gov.pl/static/Materialy/7.%20Ocena%20bezpieczeństwa%20leku%20w%20kontekście%20oceny%20technologii%20medycznych.pdf (access: 23.06.2021). Posting information about adverse effects in medicinal product characteristics is mandatory (Art. 11 of the Ph. Law.). In the leaflet, there should also be described, among others, the effects of overdose. See: K. Kumala, J. Piecha, R. Stankiewicz, *Charakterystyka Produktu Leczniczego* [in:] ed. R. Stankiewicz, *Instytucje rynku farmaceutycznego*, Warszawa 2016, LEX.pl.

The Japanese healthcare system is trying to take advantage of the potential of the pharmaceutical industry, which is able to produce safe and cheap generic drugs, just after the end of patent protection for innovative drugs. This is achieved, among others, by the Japanese government's use of financial incentives for hospitals, doctors and pharmacies to increase market share in generic medicines[45]. The system of distribution of medicinal products, by reason of the work ethos of pharmacists, the level of technical development, makes it possible to adopt liberal provisions concerning the operation of pharmacies[46].

List of abbreviations

PMDL – Pharmaceutical and Medical Device Act
Ph. Law. – Pharmaceutical Law

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[45] M. Ueyama, K. Idehara, Y. Onishi, M. Toumi, *Recent Japanese Generic Drug Policy and Future Directions*, source: https://www.valuehealthregionalissues.com/article/S2212-1099(20)30496-9/fulltext#relatedArticles (access: 23.06.2021).

[46] In Poland, the introduction of changes in the pharmaceutical care system is made by limiting the possibility of starting and performing pharmacy activities for people with a master's degree in pharmacy. See: The Supreme Chamber of Pharmacy, *4 lata „apteki dla aptekarza" – najważniejsze fakty dotyczące regulacji*, source: https://www.nia.org.pl/2021/08/18/4-lata-apteki-dla-aptekarza-najwazniejsze-fakty-concerning-regulation/ (access: 10.09.2021).

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Graph

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