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Distribution of Medicinal Products in Poland - Light of Legislative Regulations

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Abstract

The main aim of creating legislation relating to the pharmaceutical industry is ensuring protection of life and health for the society, which uses the services of pharmaceutical companies. The basic legislative act regulating distribution operations on the pharmaceutical market is the Pharmaceutical Law Act (Journal of Laws 2001 No. 126 item 1381). The distribution of medications is also regulated by Good Distribution Practice (GDP).

This paper presents and analyses legal regulations from the aspect of specific entities taking part in the distribution process on the pharmaceutical market. The following distribution chain links were analysed and characterised: producers of medicinal products, marketing authorisation holders, importers of medicinal products, pharmaceutical market intermediaries: wholesalers, pharmacies, physicians, non-pharmacy retail outlets. Hypothesis of the following manuscript is that the distribution of medicinal products must be regulated by legislative acts, because it has an influence on the health and life of the population.

Keywords: Distribution; Good distribution practice; Trading medicinal products; Pharmaceutical law act

Introduction

The main aim of creating legislation related to the pharmaceutical industry is ensuring protection of life and health for the society, which uses the services of pharmaceutical companies. As medicinal products are endangered with loss of quality when being transported through links of the distribution channels from manufacturers to patients, it is necessary to introduce legal regulations of their circulation. Legislative regulations ensure appropriate quality of medicinal products, and protect the interests of the state, citizens, and the entrepreneurs themselves.

The first part of this paper presents basic information on legal regulations of trading medicinal products and medical devices in Poland. The second part is dedicated to presenting and analysing legislative regulations of distribution on the pharmaceutical market from the aspect of specific entities participating in this process. These entities include manufacturers, marketing authorisation holders, importers, wholesalers, pharmacies, physicians, non-pharmacy retail outlets.

Medicinal product - legal definition and classification

A medicinal product is "any substance or combination of substances presented as able to prevent or treat disease in human beings or animals, or administered with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions of an organism through pharmacological, immunological or metabolic action" [1].

The Pharmaceutical Law act of 6 September 2001 (Journal of Laws 2001 No. 126 item 1381) distinguishes between medications prescribed by the physician (Rp), dispensed without prescription (over-the-counter, OTC), and medications available only for hospital use. The same act divides medicinal products in an even more detailed manner, into twelve groups, i.e.: officinal formulas, proprietary medicinal products, magistral formulas, homeopathic medicinal products, immunological medicinal products, blood-derived products, herbal medicinal products, veterinary medicinal products, radiopharmaceutical products, basic medications, prescribed medications and supplementary medications. There is also a distinction between original (innovative) and generic medications. Another indicator for classifying medicinal products is their membership in a determined Anatomical Therapeutic Chemical group (ATC). It consists in assigning each product a seven-character code. The first letter of this code is the type of the medication's anatomical group, subsequent characters define its therapeutic, pharmacological, and chemical sub-groups.

The scope of legislative regulations of medicinal products' distribution

The basic legislative act regulating operations on the pharmaceutical market is the Pharmaceutical Law (Journal of Laws 2001 No. 126 item 1381). The distribution of medications is also regulated by Good Distribution Practice (GDP). Certain legal regulations, or regulations which are not enacted, may be found in other documents. Those include: ordinances of the Minister of Health[1]; the Code of Ethical Pharmaceutical Marketing; market agreements concluded between entities operating in the pharmaceutical sector.

The Pharmaceutical Law lays down the rules and procedures for authorising medicinal products for marketing; conditions of conducting clinical trials; requirements as regards advertising of medicinal products; terms of trade in medicinal products; requirements for pharmacies, wholesalers and non-pharmacy sales points; duties and authority of the Pharmaceutical Inspection.

The GDP rules were drawn up by the European Union Commission to ensure high quality of medicinal products from the moment they are produced, to the moment they are delivered to the end user (patient). In Poland, these rules are regulated by the Ordinance of the Minister of Health of 26 July 2002 on procedures of Good Distribution Practice (Journal of Laws No. 144, item 1216).

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The determined rules of the Ordinance of the Minister of Health of 26 July 2002 on procedures of Good Distribution Practice:

- maintaining appropriate technical and sanitary condition of the premises,
- correct manner of running a pharmaceutical wholesale store,
- rules of storing, procedures of accepting and dispensing medicinal products,
- conditions of transport and handling,
- procedures of handling products not meeting quality standards and being returned under complaint procedure,
- method of appointing qualified person responsible for operating the wholesale store.

Links of the distribution process in light of legislative regulations

Distribution of medicinal products requires obtaining a permit, and the products, which the permit relates to, must be authorized for marketing. The body entitled to grant such permits in Poland is the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. The products which obtained a permit from the Council of the European Union or from the European Commission are also authorized for marketing on the territory of Poland.

Magistral formulas, officinal formulas, radiopharmaceutical products prepared at the time of use, whole blood and whole plasma, pharmaceutical raw materials not intended for the preparation of magistrals or officinal formulas, and advanced therapy medicinal products prepared on the territory of Poland are authorized for marketing without the necessity for obtaining a marketing authorization.

It is also not required to obtain a marketing authorization for medicinal products which are: used only for scientific research conducted by entities conducting medical activities; used by manufacturers; used for clinical trials or veterinary clinical trials entered in the Central Register of Clinical Trials; half-finished products manufactured for the purpose of being used for further manufacturing process.

The medicines may only be traded before their specified expiration date. Immunological products intended for humans (vaccines containing living microorganisms, vaccines for infants and other risk groups, vaccines used in public health immunisation programmes, new immunological medicinal products, immunological medicinal products manufactured using new kinds of technology during a period specified in the marketing authorisation), blood-derived products, and raw materials used for preparing magistral or officinal formulas may only be traded after an initial batch control.

The subsequent part of this paper presents and analyses legal regulations from the aspect of specified entities taking part in the distribution process on the pharmaceutical market. The following distribution chain links were analysed and characterised: producers of medicinal products, marketing authorisation holders, importers of medicinal products, pharmaceutical market intermediaries: wholesalers, pharmacies, physicians, non-pharmacy retail outlets.

Manufacturers of medicinal products: A manufacturer is an entrepreneur who was granted a manufacturing authorisation for medicinal products or active substances constituting ingredients for drug production. Authorisation is not required when the production consists in preparing a tested medicinal product before use, or changing the packaging, when this is performed in entities rendering health services [1].

The main tasks of medicines manufacturers is to assure the highest quality of manufactured products, i.e. observing the guidelines of Good Manufacturing Practice, and if they manufacture products from human blood, additionally the rules of pharmacopoeia. They must establish cooperation with a qualified person, who will be responsible for controlling batches of medicinal products before their market placement. Manufacturers should inform the Main Pharmaceutical Inspector about important changes taking place in their companies, cooperate with the inspectors, and store archival samples of medicinal products.

Manufacturers should possess appropriate premises and technical and control equipment, which is indispensable for the manufacturing processes they are authorized to conduct. Providing access to production rooms for pharmaceutical inspectors is also among the obligations of manufacturers. Such inspection may be ordered by the Main Pharmaceutical Inspector in the event of reasonable suspicion of transgressions posing threat to the quality, safety, application, or efficiency of the manufactured medicinal products. Irrespective of the time the inspection is conducted, the pharmaceutical inspector responsible for manufacturing verifies whether the manufacturers fulfil the duties under the act at least once in 3 years.

Manufacturers sell medicines or active substances intended for further processing to other manufacturers or to pharmaceutical wholesale stores. Medicinal products used at granting healthcare services performed under agreements with the National Health Fund may also be sold to hospitals and similar institutions. Obtaining a

[1]Ordinance of the Minister of Health of 2 February 2009 on the qualifications of persons dispensing medicinal products in out-of-pharmacy stores, and the requirements for the premises and the equipment of such stores and pharmacy outlets (Journal of Laws No. 21 item 118); Ordinance of the Minister of Health of 2 February 2009 on the criteria for classifying medicinal products which may be authorised for marketing in out-of-pharmacy stores and pharmacy outlets (Journal of Laws No. 24 item 151); Ordinance of the Minister of Health of 28 October 2008 on initial batch inspection (Journal of Laws No. 197 item 1224); Ordinance of the Minister of Health of 1 October 2008 on the requirements of Good Manufacturing Practice (Journal of Laws No. 184 item 1143, as amended); Ordinance of the Minister of Health of 15 September 2008 on the amount charged for granting a license for operating a pharmaceutical wholesale store (Journal of Laws No. 157 item 1317); Ordinance of the Minister of Health of 14 March 2008 on the conditions of mail order sale of OTC medicinal products (Journal of Laws No. 60 item 374); Ordinance of the Minister of Health of 12 March 2008 on the detailed rules and procedure of withdrawing and suspending the sale of medicinal products and medical equipment (Journal of Laws No. 57 item 347); Ordinance of the Minister of Health of 2 February 2006 on the requirements for the qualified person responsible for quality and inspection of batches of medicinal products before their market placement (Journal of Laws No. 23 item 178, as amended); Ordinance of the Minister of Health of 16 December 2002 on the list of medicinal products which may be immediately delivered in connection with the provided health service, and the list of medicinal products included in life-saving anti-shock first aid kits (Journal of Laws No. 236 item 2000); Ordinance of the Minister of Health of 12 December 2002 on the entities authorised to purchase medicinal products in pharmaceutical wholesale stores (Journal of Laws No. 216 item 1831); Ordinance of the Minister of Health of 18 October 2002 on dispensing medicinal products and medical equipment in pharmacies (Journal of Laws No. 183 item 1531); Ordinance of the Minister of Health of 18 October 2002 on the basic requirements for operating a pharmacy (Journal of Laws No. 187 item 1565); Ordinance of the Minister of Health of 30 September 2002 on detailed requirements for pharmacy premises (Journal of Laws No. 171 item 1395); Ordinance of the Minister of Health of 26 September 2002 on the information required for technical description of the premises where a generally accessible pharmacy is to be established (Journal of Laws No. 161 item 1337); Ordinance of the Minister of Health of 26 September 2002 on the list of rooms included as basic and supplementary area of a pharmacy (Journal of Laws No. 161 item 1338).

manufacturing authorisation does not discharge the manufacturer from penal or civil liability arising from the use of the medicinal product.

Manufacturers of medicines take the most difficult decisions concerning distribution. Diversity of entities on the market causes the selection of intermediaries in distribution channels to be a complicated issue. The knowledge about changes in the behaviour of patients, which the manufacturing possesses, became a value offered to wholesalers and pharmacies. This considerably increases the scope of services offered by the manufacturers, but simultaneously forces them to expand beyond producing medications [2].

Marketing authorisation holder: Under the Pharmaceutical Law act, a marketing authorisation holder is "an entrepreneur as construed by the Act of 2 July 2004 on Freedom of Business Activity (Journal of Laws of 2007 No. 155 item 1095 and No. 180 item 1280), or an entity conducting business activity in a European Union Member State or a European Free Trade Association (EFTA) Member State" [1].

Pursuant to the law, the marketing authorisation holder submits an application to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products for marketing authorisation of medicinal products. Among other things, this application includes results of pharmaceutical, nonclinical, and clinical trials, description of adverse reactions monitoring, characteristics of the medicinal product, and a copy of the manufacturing authorisation.

Having obtained the authorisation, the Marketing Authorisation Holder is obliged to maintain a register of reported adverse effects, cooperate with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, indicate the person responsible for supervision over the safety of use, meet the demand for its products, and fulfil the requirements regarding appropriate packaging of the medication.

The marketing authorisation holder may address the product only to pharmaceutical wholesale stores, hospital pharmacies, research and development entities, scientific departments of the Polish Academy of Sciences, public universities for the purpose of scientific research, or export the medicines as well as commission their export.

Importers of medicinal products

- **Business activity in the area of importing medicinal products:** Business activity in the area of importing medicinal products consists in bringing in finished products from outside the territory of the country and storing them, controlling the quality of released batches, and distributing them. Such trade in medicines also must be preceded by obtaining an authorisation. There are two types of import: import in exceptional circumstances, and parallel import.
- **Import:** Import in exceptional circumstances consists in bringing in medications from abroad which are not registered in Poland and have no local generic counterparts. It is only possible when they are indispensable for saving life or health of patients and they are authorized for marketing in the country they are imported from. Import in exceptional circumstances is conducted at the request of a hospital or a physician responsible for the treatment. In the second case, the necessity to import the medicine must be confirmed by a national consultant in the particular branch of medicine. The import takes place through the intermediary of a pharmacy after obtaining an authorisation from the Minister of Health.
- **Parallel import:** Parallel import consists in bringing in a medicinal product from the countries of the European Economic Area, which fulfils at least "the same indications up to the 3rd level of the ATC/ATCvet code (code of the Anatomical Therapeutic Chemical Classification), the same strength, the same route of administration and the same form as the medicinal product authorised for marketing in the territory of the Republic of Poland or has at least a similar form which does not result in any therapeutic differences as compared to the medicinal product authorised for marketing in the territory of the Republic of Poland" [1]. Applications for licenses for activity connected with parallel import should be placed with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Import licenses are granted for the period of 5 years. Companies engaging in parallel import buy cheaper medicines in certain countries and sell them in the countries where the price is higher. A special feature of the companies dealing in parallel import is their authorisation to open external packaging and conduct visual control of the medicines [3].

Pharmaceutical market intermediaries in light of legislative regulations: The main distributors of medicinal products and medical equipment include the following: pharmaceutical wholesale stores, pharmacies, physicians, non-pharmacy retail outlets.

Pharmaceutical wholesale stores: Pharmaceutical wholesale stores are the main intermediaries between the marketing authorisation holders and the pharmacies.

Pursuant to the Pharmaceutical Law, wholesale trade is the activity consisting in acquiring, storing, exporting, importing medicinal products authorised for marketing concluded with pharmacies, importers, manufacturers or other wholesale stores, excluding direct sales of medicinal products to individuals.

Wholesale trading in medicines may be conducted only by pharmaceutical wholesale stores, customs bonded and consignment warehouses, which obtained a permit for such type of activity from the Main Pharmaceutical Inspector. The sale of narcotic agents, psychotropic substances and raw ingredients for their production (so-called I-R group drug precursors) is also subject to additional permits. It must be pointed out, that the products being a part of humanitarian aid are not a subject of retail sale.

Wholesale stores may be specialized in offering different types of products, e.g. only in distribution of medicines from a certain manufacturer, only OTC medicines or technical equipment for hospitals. They may offer full assortment of products, and other agents sustaining or improving health, e.g.: dietary supplements, baby care products, special food, etc.

An entity planning to open a pharmaceutical wholesale store first needs to possess premises fulfilling the necessary requirements and hire a pharmacist who has at least two years of experience in working in a wholesale store/pharmacy for the position of the manager (in the case of wholesale stores selling medical gases, a person possessing a maturity certificate who has undergone an occupational health and safety training may be the manager).

The duties of the wholesale store owner include maintaining continuous supply and purchasing medicinal products from entities authorised to manufacture them or to conduct wholesale trade. According to the Ordinance of the Minister of Health on entities authorised to purchase medicinal products in pharmaceutical wholesale

stores, the sales may be addressed to: pharmaceutical wholesale stores, retail pharmacies, pharmacy outlets, entities providing medical services, herbal medicine stores, specialized stores with medical supplies, chemist's and herb stores, and generally accessible stores [4]. Owner of wholesale stores must provide quarterly sales reports to the President of the Office for Registration of Medicinal Products, Medical Equipment and Biocidal Products, and store this data for 5 years.

It is the duty of a wholesale store manager to cooperate with the Pharmaceutical Inspection during the control, inform about cases when medicinal products do not meet quality requirements, and organize trainings for other employees. The wholesale store manager may not work in a pharmacy or another wholesale store on the same position.

An entrepreneur owning a pharmaceutical wholesale store and the person occupying a managerial post are obliged to observe the rules of Good Distribution Practice. All procedures conducted within this activity should be documented and stored for the required time [5]. Temperature and humidity log for the given calendar year must be stored for 12 months from the first day of the year subsequent to the year the entry applies to. The register of returned products should be stored for 3 years.

In line with GDP, pharmaceutical wholesale stores should consist of a delivery room and a shipping room with separate entrances, as well as storage, office and social rooms. The premises and the surrounding area must be kept clean and insulated from external conditions, and the internal areas should be easy to clean and should prevent dust from settling. Additional devices include temperature regulating and ventilation equipment supervised by auxiliary control and measurement equipment. Only authorised persons should have access to the wholesale store rooms, i.e.: employees, persons conducting an inspection. Medicinal products should be stored in original packaging; and those which exude a strong scent, are flammable or corrosive must be stored in separate closets or rooms. Receiving and dispensing of pharmaceuticals takes place in a transitory room separated from the storage space, protected against atmospheric factors. Before shipping medications it is also necessary to verify whether their packaging is not damaged, the batch complies to the order, and the transport ensures appropriate conditions - cold chain.

The pharmaceutical market includes features like pre-wholesale and half-wholesale [6]. Pre-wholesale is trading of medicinal products between manufacturers, large/central wholesale stores, and lesser/regional wholesale stores. Half-wholesale is conducted by means of van-selling. The representative engaged in van-selling is to reach the customer with a specified product range.

Pharmaceutical wholesale stores offering a wide range of products fulfil orders on just-in-time basis. They cooperate with pharmacies and possess broad knowledge on the local market and its needs. Challenges connected with the area of wholesale stores activity include skilful inventory management leading to decreasing warehousing costs. Wholesale companies, in order to achieve success on the pharmaceutical market, must also promote their services and often ensure free transport of medicinal products to the recipients, which negatively influence the costs of such activity.

Pharmacies: A pharmacy is a public health protection unit, which particularly provides pharmaceutical services.

It needs to obtain appropriate permits to conduct its business activity. Pharmacies, according to the Pharmaceutical Law act are classified as: generally accessible, hospital and onsite pharmacies. These types of pharmacies are differentiated by location and founding bodies, but also by the services they render. A generally accessible pharmacy sells medicinal products and medical equipment, but it is also responsible for maintaining appropriate assortment of products, providing information on medications and preparing magistral formulas within 48 hours (4 hours for narcotic agents) and officinal formulas. A magistral formula is a "medicinal product prepared in a pharmacy on the basis of a physician's prescription" [1], and an official formula is a "medicinal product prepared in a pharmacy in accordance with the prescription in the pharmacopeia, intended to be dispensed at that pharmacy" [1]. Pharmacies are not obliged to sell narcotic (I-N) and psychotropic (II-P) agents. They may sell them subject to obtaining additional license. Medications are dispensed on the basis of prescriptions (Rp medications), without prescription (OTC medications), as supplies for authorised entities and persons, and in life threatening cases, prescribed medications are dispensed without prescription (the smallest packaging of medication excluding narcotic and psychotropic agents and I-R group drug precursors). This task is regulated by the Ordinance of the Minister of Health of 18 October 2002 on dispensing medicinal products and medical equipment from pharmacies [7]. A medicinal product currently not offered by the pharmacy is brought in at the customer's request in an agreed time. Only products of faulty quality and dispensed contrary to physician's recommendation may be returned. An employee of the pharmacy may refuse to dispense a medicine if it would pose a threat to life or health of the patient. Hospital pharmacies are created in hospitals or in stationary/twenty-four-hour healthcare entities. Hospital pharmacies, apart from basic pharmaceutical services, offer additional ones, including: preparation of drugs for parenteral nutrition, preparation of drugs in daily doses, participation in clinical trials conducted in a hospital. Onsite pharmacies provide medications to healthcare entities created by the Minister of National Defence and the Minister of Justice, doctor's offices in those entities, special treatment units, as well as other healthcare entities providing onsite and constant healthcare services [1].

A manager of a generally accessible, hospital, or onsite pharmacy may be a pharmacist who is not older than 65 years. Subject to permission of the Regional Pharmaceutical Inspector this limit may be raised to 70 years. The manager should be present in the pharmacy in its opening hours, and when he is not present he must assign a substitute in writing. The tasks of the pharmacy manager connected with distribution include: coordinating deliveries, purchasing medicinal products and medical equipment from authorised entities, representing the interests of the pharmacy before the National Health Fund, cnveying necessary data to the President of the Office for Registration of Medicinal Products, Medical Equipment and Biocidal Products, informing the Pharmaceutical Inspection about products not meeting quality requirements, conveying information to the Pharmaceutical Chambers, withdrawing products or suspending their sale, maintaining employee records and assigning tasks to employees.

Only pharmacists and pharmacy technicians may be employed for dispensing medications in pharmacies. Pharmacists are obligated by the legislators to constantly acquire new abilities [1].

Organisation of pharmacy premises is subject to relevant regulations, mainly the Pharmaceutical Law act and ordinances of the Minister of Health [8,9]. Premises of a generally accessible pharmacy may exist as a separate building or be separated in another facility. Adjusting the floor of pharmacies to the needs of disabled people is an important issue. Hospital pharmacy premises must be appropriate for the type of activity conducted there.

Generally accessible pharmacies have the duty to provide medications and medical equipment at every time of day and night. Opening hours of pharmacies, in particular night and holiday duties are subject to decisions of District Councils, and collecting additional charges for sales in this period is regulated by the ordinance of the Minister of Health of 2002 on the maximum amount of additional charges collected by pharmacies for dispensing medicinal products during night time and determining the group of medicinal products for which no additional charges are collected in such case [10].

Generally accessible pharmacies are targets of large influencer marketing actions. The reason is close contact of such stores with the customer, who often knows the person dispensing the medications, trusts this person, and expects advice on treatment.

An important term connected with marketing management of a pharmaceutical store is pharmacy merchandising. It is a set of marketing activities related to product management, price changes, distribution, promotion of the pharmacy and HR management. Marketing activities in a pharmacy are based on selecting the optimal location for the pharmacy, designing appropriate interior, choosing the manner in which products are displayed on the shelves, talking to customers, and providing proper outfits of the employees.

Apart from pharmacies, retail trade in medicinal products may be conducted by pharmacy outlets. Under article 70 item 3 of the Pharmaceutical Law, they may be situated only in rural areas, if there is no generally accessible pharmacy nearby. As in the case of pharmacies, a permit is required to start business activity. A pharmacist with at least one year experience in this profession or a pharmacy technician with three years' experience in a pharmacy outlet may be a manager in a pharmacy outlet [1]. The regulations concerning pharmacies apply per analogy to storing and keeping the documentation of the purchased and sold medicinal products, conducting inspections and conveying information to appropriate authorities.

Mail order sales of medicinal products dispensed without a physician's prescription is an additional activity which may be undertaken by generally accessible pharmacies and pharmacy outlets. It is allowed under the Pharmaceutical Law, and regulated in detail by the Ordinance of the Minister of Health of 14 March 2008 on the conditions of mail order sale of OTC medicinal products [11]. It is a fairly new practice which develops along with the development of computerization and services rendered via the Internet. The customer communicates the will to buy pharmaceuticals by placing an order via telephone, fax, e-mail, form on the e-pharmacy's website, or personally by visiting the pharmacy's premises.

A pharmacist or a pharmacy technician with at least two years of experience working in a pharmacy must be appointed for supervision of mail order sale. Additionally, an entity conducting such activity should ensure telephone contact with its office in the opening hours and place a link to its permit for conducting online sales of medications on its webpage. The law bans mail order sales of prescription medications. It is possible to order them via the Internet, but they have to be collected at the pharmacy. This ban was introduced due to concern for the safety of patients who might use medication to the detriment of their health or life [1].

Physicians, dentists, and feldshers: Physicians and dentists have a great influence on buying particular medications by the patients. That is why marketing authorisation holders and pharmaceutical wholesale stores emphasise promotion of medicinal products in the physicians' community.

A prescription is the carrier of a physician's, dentist's or feldsher's order to dispense a medication to the patient by the pharmacy. Details regarding the appearance of prescriptions and their filling are regulated by the ordinance of the Minister of Health of 23 December 2011 on physicians' prescriptions [12]. It should be pointed out, that in order to prescribe a reimbursed drug, the patient must be eligible for such benefits. Prescriptions may be issued by physicians, dentists, feldshers or senior feldshers, who: are so-called health insurance physicians, concluded a contract with the National Health Fund empowering them to issue prescriptions, or who are not performing their professions, but have a contract with the fund, and issue prescriptions intended for themselves and their next of kin.

Thanks to direct contact with the end users, i.e. patients, the physicians are an excellent source of market information. They may describe the needs of their patients, difficulties in using medicinal products, or inform about adverse reactions. The duty to report occurrences of adverse reactions to marketing authorisation holders and to the President of the Office for Registration of Medicinal Products, Medical Equipment and Biocidal Products is imposed on physicians by the Act of 5 December 1996 on professions of physician and dentist [13]. When physicians issue a prescription for a given medication, they significantly contribute to raising its sales. They often advice patients on OTC medications or dietary supplements. A physician's opinion enjoys great trust in the society. [14].

Non-pharmacy retail outlets: The out-of-pharmacy distribution channel is used in intensive distribution strategy which consists in offering products in as many sales outlets as possible.

Out-of-pharmacy trade in medications is regulated by the Pharmaceutical Law and regulations formulated on its basis, like the Ordinance of the Minister of Health of 2 February 2009 on the criteria for classifying medicinal products which may be authorised for marketing in out-of-pharmacy stores and pharmacy outlets [15], and the Ordinance of the Minister of Health of 27 March 2003 on authorisation of medicinal product for marketing in out-of-pharmacy stores and pharmacy outlets [16]. The latter ordinance determines the qualification criteria and the list of medicinal products, excluding veterinary medicinal products, authorised for marketing in non-pharmacy stores and pharmacy outlets.

Product qualification criteria include the type of store, where it is sold, as well as the name of the active substance, route of administration, maximum single dose, largest package size, and possible remarks. The list of medicinal products authorised for sale in out-of-pharmacy and pharmacy outlets is updated every 12 months.

A non-pharmacy retail outlet may offer over-the-counter medicines, vitamin and mineral supplements, as well as dietary supplements. The following stores are the main non-pharmacy retail outlets in Poland: booths, petrol stations, groceries, herbal medicine stores, special stores with medical supplies, as well as hypermarkets and supermarkets. Pursuant to the Pharmaceutical Law act, a herbal medicine store may only be operated by a pharmacist, a pharmacy technician, a person who completed a second-degree course in herbal commodity science or by entrepreneurs who employ the above-listed persons.

The standards for appearance of non-pharmacy stores selling medicinal products and the qualifications of the persons dispensing those products are regulated by the Ordinance of the Minister of Health of 2009 on the qualifications of persons dispensing medicinal products in out-of-pharmacy stores, and the requirements for the premises and the equipment of such stores and pharmacy outlets (Journal of Laws No. 21 item 118) [17].

The owners of general stores eagerly expand their offer to include medicinal products, because they occupy little space on the shelves, they are characterised by large sales margins and the customers often ask about them. This practice is also profitable for marketing authorisation holders, as the number of distributors reaching the end users increases significantly.

Supervision of the main pharmaceutical Inspector over the distribution of medicinal products

Distribution of medicinal products is supervised by the Main Pharmaceutical Inspector. This oversight is aimed at ensuring safe use of medicines. Trading and manufacturing of medicinal products and medical equipment in units supervised by the Minister of National Defence are inspected by designated subordinated units. The Minister of Health coordinates the tasks performed by these units. The Minister of National Defence and the Minister of Health determine the forms of cooperation between military authorities with Pharmaceutical Inspection by ordinances.

The Main Pharmaceutical Inspector, suspecting or finding the quality of medications to be inadequate or improper distribution or distribution of product not authorised for marketing on the territory of Poland, suspends, withdraws or bans the sale of medications. Illicit practices of entrepreneurs may lead to amending, cancelling or refusing to grant a license for operating a pharmacy or a pharmaceutical wholesale store, or for manufacturing medicinal products. One of the tasks of the Pharmaceutical Inspection is to issue opinions on the premises where a pharmacy or a pharmaceutical wholesale store is to be established. The Inspection maintains a register of all generally accessible pharmacies, hospital pharmacies, pharmacy outlets, pharmaceutical wholesale stores and manufacturers.

Conclusion

Access to medications has a positive influence on the health condition and life expectancy of the population, thus contributing to creating a society where individuals fulfil their roles efficiently. Healthy population is also conductive for financial stability of the state, which provides its citizens a feeling of safety and social solidarity.

No medicinal product could reach the patients without the entities participating in the distribution process, like manufacturers, pharmaceutical wholesale stores, pharmacies, physicians, and even non-pharmacy retail outlets. The number of intermediaries and the cooperation between them influences the availability of the merchandise and its final price, and so the customer's satisfaction.

Legal regulations pertaining distribution of medicinal products and medical equipment are extremely necessary, and their level of detail and severity is to ensure safety for patients and honest competition on the pharmaceutical market.

Meeting all demands connected with trading medicinal products and medical equipment is a considerable challenge, which has to be faced by pharmaceutical market entities.

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