Chapter 15
Pharmaceutical Policy in Poland

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Abstract The Polish healthcare system has undergone a number of changes in recent years related to the reimbursement of pharmaceuticals. The public healthcare system is primarily supported through government-funded public health insurance. The reimbursement system in Poland is one of the most restrictive systems in Europe. In addition, as a member of the European Union (EU), Polish legislation must frequently adapt to the changing requirements within this environment. The pharmaceutical market in Poland has been steadily growing over the last two decades. Pharmaceutical companies are important players in the national economy and are valuable employers that contribute significantly to the economy. As a nation, Poland is also known throughout the pharmaceutical industry as a country with sound outsourcing potential, there being interest from numerous multinational pharmaceutical companies. One of the most important characteristics of the pharmaceutical market in Poland is the high market share enjoyed by generic medicines, as well as the growing popularity in use of over the counter (OTC) medicines. Over recent years, there has been an increase in the number of pharmacies and a corresponding increase in the average patient's expenditure on medicines and dietary supplements. In line with this positive growth, Poland has had to struggle with a number of obstacles associated with pharmaceutical use, including the illegal export of cheap drugs from Poland and an undersupply of physicians that can prescribe these agents. There are also several major health reforms on the horizon that are likely to significantly change the landscape of the pharmaceutical sector in Poland.

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Abbreviations

AHTAPol	The Agency for Health Technology Assessment in Poland
CVS	Cardiovascular
EMA	European Medicines Agency
EU	European Union
GDP	Gross Domestic Product
GIF	Main Pharmaceutical Inspectorate (*Główny Inspektorat Farmaceutyczny*)
GP	Gross Profit
INN	International Nonproprietary Names
MA	Marketing Authorization
MAH	Marketing Authorization Holder
MoH	Ministry of Health
MS	Member State
NFZ	National Health Fund (*Narodowy Fundusz Zdrowia*)
OECD	Organisation for Economic Co-operation and Development
OTC	Over the Counter
PF	Pharmaceutical Law (*Prawo Farmaceutyczne*)
PPA	Polish Public Procurement Act
R&D	Research and Development
RA	Reimbursement Act
URPLWMiPB	Office for Registration of Medicinal Products Medical Devices and Biocidal Products (*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych I Produktów Biobójczych*)
WHO	World Health Organization
WIF	Voivodeship Pharmaceutical Inspectorates (*Wojewódzkie Inspektoraty Farmaceutyczne*)

15.1 Health System of the Country

15.1.1 Health System in Poland

The healthcare system in Poland went through a degree of transformation in 2003 with the introduction of public insurance and the National Health Fund (*Narodowy Fundusz Zdrowia*, NFZ). The NFZ is currently the executor of the public health insurance scheme and its main principles are social solidarity (the amount of health insurance premium contributed does not affect quantity, quality, and types of services received), equal treatment of citizens, as well as the free choice of healthcare service providers [1, 2]. The Ministry of Health (MoH) and NFZ are committed to fund the provision of healthcare services through government funding [3]. In brief,

public expenditure on healthcare (pharmaceuticals and medical services) in Poland is covered to some degree by the NFZ, with a significant contribution through patient copayments, with a lesser contribution coming from the country's health funding envelope [1, 4].

In 2011, healthcare-related spending in Poland amounted to PLN 105 billion, which was 6.9% of the Polish Gross Domestic Product (GDP). A large portion of the expenditure in 2011 was consumed by the provision of health services (approximately 93% of the total amount). Investment and development expenses amounted to 7% of the total expenditure. A major part (55%) of the total expenditure was related to patient treatment and rehabilitation [4].

Those who are employed, the self-employed, children, students, pensioners, and registered unemployed persons are all covered by the public health insurance scheme [5]. Patients must confirm their right to medical care through registering with a healthcare entity either via an online electronic system, known in Poland as eWUS, or by presenting a hard copy of the document that proves the right to publicly funded healthcare services [6]. Patients' rights are regulated by the Act of 6 November 2008 on Patient Rights and the Patient Rights Ombudsman, which lists among others, the right to free healthcare benefits and the right to dignity, privacy, and confidentiality about health [7, 8].

15.1.2 National Health Status

The outcomes for the basic health indicators in Poland are mostly on the lower side as compared to other OECD (Organization for Economic Co-operation and Development) countries [9]. According to OECD data, mean life expectancy in Poland is 77 years, which is 3 years less than the average in OECD countries [4]. Nonetheless, the average life expectancy in Poland has increased by 7 years from 70.7 years in the early 1990s (70.7 years) [10].

Another health indicator reported by the World Health Organization (WHO), is the age-standardized mortality rate (per 100,000 population). In 2012 in Poland, the rate amounted to 565.9 for both genders combined. Diseases of affluence are a significant cause of death in Poland. Morbidity rate due to cardiovascular (CVS) diseases was 253.4 (almost a half of these deaths are the consequence of ischemic heart disease) and for diabetes mellitus it was 9.4 [11]. The estimated mortality rate for malignant neoplasm combined for male and female was 149.7, which closely follows CVS diseases. Infectious and parasitic diseases had a lower rate of 3.2, and for tuberculosis, even lower at 1.2 [11].

With regard to access to healthcare in Poland, in 2011 the statistics show that 14.2% of Polish citizens reported they had unmet medical care needs. There may be several reasons for this situation; the main one being financial constraint and another being waiting times for visits due to the low number of healthcare professionals available per patient [10].

15.2 Pharmaceutical Situation in Poland

15.2.1 Overview

The value of the pharmaceutical market in 2015 reached PLN 30 billion (which is equal to around USD 7.8 billion) [12] and this number has been growing consistently over the last two decades [13]. In October 2015, the value of sales of the pharmaceutical market was nearly PLN 2698 million representing over 5% (+ 5.7%) growth compared to October 2014. Sales of reimbursed drugs in October 2015 amounted to PLN 1000 million (+ 5.4% compared to October 2014). Mean turnover of a regular community pharmacy in October 2015 amounted to PLN 185.5 thousand (gross retail prices), and was 3.1% higher than in October 2014. The average retail price of a drug sold in a pharmacy was PLN 17.07[1] [14].

Poland is in the Tier 3 group of "pharmerging" countries; those are the countries where the use of and expenditure on pharmaceuticals is growing rapidly and where GDP is less than $25,000 per individual [15, 16]. Countries from the Tier 3 category are expected to spend $96 on drugs per capita in 2016 [15]. In Poland, products distributed in the pharmaceutical market belong to one of three main segments: reimbursed medicines, nonreimbursed prescription drugs, and over the counter (OTC) medicines [17].

The number of community pharmacies in Poland has been steadily growing in past years. In 1997 the total number of pharmacies 8000 approximately, whereas in 2011 the number had grown to 13,500 [18]. In 2013, around 50 new pharmacy chains opened into the Polish pharmaceutical market. In 2014, more than 29% of pharmacies were members of pharmacy chains and nearly half (44%) of sales of community pharmacies were generated by chain pharmacies [19]. The consequence of this situation is an increase in the level of competition between pharmacies and a lower number of patients per pharmacy. In 2002, there were 4000 patients per pharmacy; in 2011, this number had decreased to 3600. This has pressured pharmacy owners to join large pharmacy chains, group purchasing organizations or franchises [18].

15.2.2 The Pharmaceutical Industry in Poland

According to a report by the Independent Center for Economic Studies (*Niezalezny Osrodek Badan Ekonomicznych*, NOBE) in 2010, the development of the pharmaceutical industry in Poland was occurring at a much higher rate than observed by overall Polish economy. Despite this, Poland's share of the overall European pharmaceutical market was still relatively low [20].

The Polish market contains more than 300 companies that market drugs, dietary supplements, and medical devices [13]. Pharmaceutical companies play a signifi-

[1] For a drug from the reimbursement list the average retail price was PLN 27.73.

cant role in the national economy. In 2010, the pharmaceutical industry's contribution to the total industrial output of Poland amounted to 1.5%. The other key advantage that large pharmaceutical corporations bring to the Polish economic environment is the creation of relatively stable employment conditions. In 2010, three leading pharmaceutical companies (GlaxoSmithKline®, Novartis®, Sanofi-Aventis®) with affiliate offices in Poland hired more than 4000 people [20]. Additionally, some pharmaceutical companies (e.g., Polpharma®, Johnson & Johnson®) demonstrated and emphasized Corporate Social Responsibility (CSR) activities and have a general positive impact on Polish society [21].

A decrease in financial performance was seen in the Polish pharmaceutical market for the 2011–2012 period. Gross profit across the entire market in 2010 amounted to PLN 1.81 billion, whereas in 2012 it fell to PLN 0.99 million. However, rebound in the industry was observed in 2013. In 2010, the gross margin in the pharma sector was 11.35%, which in 2012 decreased to 7.17%, but in the third quarter of 2013 increased again to 11.82% [22]. The reasons for that decline could be the "patent cliff" in 2012[2] as well as the implementation of Reimbursement Act (RA) [23, 24].

A specific feature of the Polish pharmaceutical market is the high share of generic medicine sales, which amounted to 66% of the market in 2012, being one of the highest rates in Europe. The reason for this high market share in Poland is the fact that generic prices are much lower when as compared to originators and there is active promotion of generics in the market [22]. It has been observed that Poland is among those countries where companies outsource research and development (R&D), for example, clinical trials. This is due to the lower costs of clinical trials implementation and maintenance, when compared to the United States or Western Europe [25]. Poland has also been recognized as an attractive place to establish pharmaceutical manufacturing sites [26].

The pharmaceutical sector in Poland is a national industry leader in terms of expenditure on research and development (R&D) and technological innovations. In 2013, expenditure on these activities amounted to 60% of the total expenditure, while the average in all types of industries is around 23%. The pharmaceutical sector launches the greatest number of innovative products in Poland every year, relative to other industries. This is supported by the fact that during the period from 2012 to 2014, 42.5% of companies in the pharmaceutical industry launched new products, and as a consequence this sector has moved ahead of the refined petroleum products industries, which were previously the leading industry sector [27].

15.2.3 Pharmaceutical Trade in Poland

There are significant supply side issues with pharmaceutical availability in Poland with one report suggesting local production was only able to meet one third of the societal demand for medicines [20]. Drugs that do not have a Marketing Authorization

[2] It was the culmination of the expiry of many drug patents.

(MA) in Poland can be imported via direct import, which is regulated by the MoH [28]. Drugs imported in this way do not need an additional authorization to be sold, as long as they meet the following conditions: they must be necessary to save the life or improve the health of a patient and they cannot be registered in Poland as an equivalent drug with the same active ingredient [29]. An example of not meeting these requirements was the attempt to launch Kalydeco®—an orphan drug, in the Polish market. It did not meet the direct import rules, due to the fact that it was registered through the EU centralized procedure and in this way it was registered in the Poland [28].

Poland had the third largest increase in the level of export of medicines for the first decade of the twenty first century in Europe (+ 30%). However, this increase could be due to the small share of the international drug market that Poland had in the beginning of the century [25]. It has been reported that drugs from Poland, which have much lower prices than those sold in the Western European markets, are illegally exported to Western European countries. The easiest and most popular way of illegal export is designated as "resale", which involves the selling of a drug from a pharmacy back into a pharmaceutical warehouse. This can be undertaken by sending back to a warehouse those medicines for which allegedly there is no demand and making a relevant correction of the invoice. The illegal export creates a "double chain of distribution" and allows medicines to be purchased for higher prices in Western Europe [30, 31].

There is a new Act regulating drug exports which came into force in Poland on 12 July 2015. The amendment of the law means that wholesalers are obliged to report to the Main Pharmaceutical Inspectorate (*Główny Inspektorat Farmaceutyczny*, GIF) an intention to export medications from the country. The obligation covers products for which there is an identified risk of unavailability in Poland [32].

15.3 Polish Regulatory Environment

15.3.1 Medicines Regulatory Authority

In Poland, as in other EU Member States, after completion of phase III clinical trials, it is possible to apply for registration and Marketing Authorization for a medicinal product. The authority that deals with registration of pharmaceutical products is the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych I Produktów Biobójczych*, URPLWMiPB). The process of drug registration is aligned with the European Commission Directive 2001/83/EC (the directive on the Community code relating to medicinal products for human use). The registration can be carried out in accordance with one of four procedures: purely national, centralized, mutual recognition or decentralized. The registration procedure should be completed within 210 days (it can be extended, when it is necessary to complete gaps in documentation or clarify explanations with the applicant). Each of the

different registration pathways has benefits and drawbacks, and the choice between them depends primarily on the characteristics of a product. However, there are restrictions and some kinds of medicinal products such as orphan drugs which must be registered via centralized procedures [33–36].

The process of registration of medicines in the Polish Republic requires the applicant to go through several stages, during which collected documentation is analyzed both from a scientific and technical point of view. The registration dossier is also assessed as to whether it meets administrative requirements. The dossier that is submitted to the regulatory authority must be in the form of a Common Technical Document, which consists of five specific modules. The result of the procedure might be either granting or denial of a Marketing Authorization. The Marketing Authorization for the medicinal product is issued for a period of 5 years with the possibility of shortening or extension. As a result, a new entry in the register of medicinal products authorized in Poland is created [33].

The process of drug registration is considered to be expensive, complicated and time-consuming. Nonetheless, it is much easier in the case of the registration procedure for generic medicines. The potential Marketing Authorization Holder (MAH) for a generic product is not obliged to show the results of clinical and preclinical trials. Other documentation requirements are the same as in the case of innovative products, including summary of product characteristics, information about the experts, and the manufacturing process details. In addition, it is necessary to prove the bioequivalence of a generic and an original product with the appropriate studies [36].

15.3.2 Quality Control of Medicines

For every pharmaceutical product that is granted Marketing Authorization in Poland, the sponsoring company is obligated to abide by Good Manufacturing Practices (GMP) that helps to ensure the high quality and safety of drugs. The document that describes methods of drug and raw materials testing and packaging is the Polish Pharmacopeia, which is aligned to the European Pharmacopeia [37].

The majority of raw materials used in Poland are imported from abroad, largely China or India, which may be of varying quality. However, the efforts of large pharmaceutical companies to maintain a high level of quality through their careful monitoring and planning of the production processes and detail risk management is often impacted by this [38]. The authorities designated by Polish Pharmaceutical Law (*Prawo Farmaceutyczne*, PF) to supervise the quality of drugs are the GIF and 16 Voivodeship Pharmaceutical Inspectorates (*Wojewódzkie Inspektoraty Farmaceutyczne*, WIF) [37, 39]. WIF and the GIF are able to suspend marketing of a certain batch or series of a medicinal product. If issues arise, the sale of the identified series or batch of a particular drug product is stopped by WIF or GIF at the level of wholesalers and pharmacies, until the laboratory testing results confirm or exclude a quality issue. If an issue relating to the quality of a product is confirmed

and is deemed serious enough, then GIF might decide to action the drug's withdrawal [39].

At the European level, the quality of medicines is controlled by the Official Medicines Control Laboratory Networks, which is in-turn controlled by the European Directorate for the Quality of Medicines. The Polish entity that belongs to this network is the National Medicines Institute (National Control Laboratory of Medicinal Products, Medical Devices, and Biocides). This performs laboratory tests on drug samples to confirm compliance with their specifications [40].

15.3.3 Pharmacovigilance

Pharmacovigilance-related activities in Poland are regulated by two legislative Acts that were implemented by the European Medicines Agency (EMA): Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010. The new EU legislation contributed to enact a relevant Polish law on 13 September 2013. It was expected that this law would reduce any potential medicines-induced harm [41, 42].

According to Pharmaceutical Law any patient can report an adverse event to a medicine. Adverse events may be reported to a healthcare professional, to the President of the Regulatory Authority or to the MAH of a suspected drug [43]. In the case of a justified signal that a product may indeed cause serious side effects, Pharmaceutical Law gives mandate to the Main Pharmaceutical Inspectorate to decide upon temporary suspension of the product's marketing, or its full withdrawal [37, 43]. One of the innovations in adverse event reporting in Poland is the option of transmitting information to the Regulatory Authority via a special mobile application [44].

15.3.4 Counterfeit Medicines

As far as the authors are aware, at the time of writing, the global problem of the availability of counterfeit drugs does not seem to be a concern for Polish community pharmacies. National research laboratories conduct tests on samples of medicines taken from pharmacies and pharmaceutical warehouses and to date there has been no evidence to suggest the availability of counterfeit medicines in the Polish market [45].

The most common sources of counterfeit medicinal products as well as drugs not having a Marketing Authorization in Poland are via illegal online stores. These products can also be found in commercial establishments including sex shops, stores with nutritional supplements for athletes, service providers (e.g., fitness clubs, massage parlors), bazaars, and marketplaces. The punishment for selling counterfeit drugs in Poland is up to 8 years of imprisonment [46].

15.4 Medicines Supply System

15.4.1 Procurement

Currently, drugs in the EU that are subject to public contracts are regulated by national legislation on public procurement. Nevertheless, they must comply with the European directives on procurement procedures: Directive 2004/17/EC and Directive 2004/18/EC [47, 48].

Entities that procure medicines for the healthcare sector in Poland are the Ministry of Health (major awarding entity), public healthcare entities, and nonpublic healthcare entities. Their activities regarding public procurement must comply with the regulations mentioned previously. The procurement process is supervised each step of the way by the GIF and Regulatory Authority. All "contracting authorities" (Ministry of Health and public entities as well as nonpublic entities under some conditions) must apply to the Polish Public Procurement Act (PPA) if a contract's worth is greater than EUR 14000. When a hospital selects a supplier, there are specific criteria for the award, from which at least 50% of the weighted average of the award criteria is the price of a supplied product. Hospital pharmacies in Poland are trying to coordinate this process through the implementation of drug management programs, which involve the opinion of clinicians. Nonpublic entities, when not forced by the PPA, tend to purchase medicines through tender processes [47].

15.4.2 Distribution

The market distribution of pharmaceuticals has undergone many changes in Poland over recent years, including privatization of warehouses, development of pharmacy chains and the growth of nonpharmacy drug trading. The distribution of medicines is strictly regulated by Pharmaceutical Law [49–53]. The wholesaling of medicinal products must be performed only by pharmaceutical wholesalers and/or bonded or consignment warehouses. The introduction of a medicinal product to the wholesale trade market requires prior notification to the Marketing Authorization Holder and to the President of the Regulatory Authority [49, 50].

In order to operate a pharmaceutical warehouse, an applicant is required to obtain a permit from the Main Pharmaceutical Inspectorate. An additional permit is required for the wholesale trade of narcotics, psychotropic substances, and precursors of the I-R group (this group consists of any substances that can be transformed into a narcotic drug or psychotropic substance, e.g., pseudoephedrine, lysergic acid). Wholesalers are required to work in accordance with the Good Distribution Practices guidelines, which describe the specific requirements for pharmaceutical premises, storage of drugs, receipt of consignments, loading and transport [24, 49, 51].

The total value of drugs in the pharmaceutical wholesale warehouses in Poland is around PLN 1.6 billion (including the value of reimbursed drugs that amounts to

PLN 500 million). However, due to the effect of PF changes the revenue of Polish warehouses has been decreasing since the RA was introduced in 2012. At present, the Polish wholesale pharmaceutical market is preparing to introduce new demands pertaining to the EU Directive 2011/62/EU on preventing the launch of counterfeit medicinal products into the legal supply chain [24].

More and more companies in Poland are interested in a novel way of drug supply denoted "Direct to Pharmacy" distribution. This method of delivery leads to the omission of wholesaler activity and products are purchased by pharmacies without intermediaries being involved. The first "big pharma" company that introduced this system in Poland was Astra Zeneca and despite the fact that it faced criticism from Polish pharmacists, the popularity of this form of distribution has been on the increase. There are a number of companies that specialize in providing the pharmaceutical industry with comprehensive support associated with this "Direct to Pharmacy" distribution mechanism [52]. Direct contact between a pharmaceutical company and a pharmacy is aimed to improve the process of production planning and supply chain management, which should lead to better access to key medicines in the market [53].

15.5 Medicines Financing

15.5.1 Medicine Expenditure in General

In the scale of the entire national economy of Poland expenditure on pharmaceuticals constitutes approximately 30% of the total healthcare spend [54]. Drug prices in Poland are much lower when compared to other European markets [49]. According to Pharma Experts, expenditure on drugs in 2015 grew by 5.1% compared with 2014 [13].

According to IMS data, Poland spent PLN 27.3 billion on drugs in 2014 (including PLN 11.4 billion on OTC drugs), which is PLN 3.3 billion more when compared to the previous year [55, 56]. The Central Statistical Office of Poland informs that the average per-capita expenditure on drugs for Polish citizens in 2015 was PLN 58 per month, which is approximately 10% more than in 2014. These costs increase under the scenario of patients suffering from chronic diseases and may even reach PLN 700 monthly in this case [57]. For around 40% of people in Poland, medicines are unaffordable to some extent, medicinal products are a burdensome expense, where affordability is low [58].

15.5.2 Pharmacoeconomics in Poland

Pharmacoeconomic analyses are used by the National Health Fund in cooperation with The Agency for Health Technology Assessment in Poland (AHTAPol). This is in order to determine the prices of individual medicines, amount of reimbursement, validity of registrations and cost-effectiveness of preventive actions [59].

AHTAPol issues recommendations inter alia on the merits of drug reimbursement. It also performs economic evaluations that include the cost-effectiveness of therapies and the impact they may have on the national pharmaceutical budget. Establishment of AHTA Pol has contributed to the popularization of pharmacoeconomics and its application within the Polish market. According to the guidelines of AHTA Pol, each Marketing Authorization Holder that applies for reimbursement of drugs must provide a cost-effectiveness analysis and a budget impact analysis [60].

15.5.3 Medicines Pricing and Access

The Reimbursement Act (RA) was implemented on 1 January 2012 and caused far-reaching changes in the reimbursement system in Poland. The Reimbursement Act introduced fixed reference prices of reimbursed drugs and the limitation of pharmaceutical product price adjustments (such as discounts). It also changed the access of drugs for patients, since review of the reimbursement list occurs every 2 months. However, the impact of frequent changes to the list has been disputed. The Reimbursement Act was intended to completely readjust Polish legislation to meet the requirements of Directive 89/105/EWG on transparency of pricing regulations for medicinal products and their inclusion in the scope of the public health insurance system [61]. Control of drug prices has a significant impact on the pharmaceutical market, which can be carried through individual negotiations with drug manufacturers. The reference price is determined on the basis of an application for the establishment of such a price, which is required to be submitted to the MoH, together with an application for the drug's reimbursement, which are then simultaneously evaluated. Review of an application for reimbursement and establishment of a reference price is required to be undertaken in 180 days or less. However, a deadline for the submission of applications is outlined on a quarterly basis and the average number of applications to the Ministry of Health is approximately 150–200 per quarter. The processing of this number of applications can result in delays. The price of drugs that are not reimbursed fall under the decision of companies that have the right to commercialize them (Marketing Authorization Holders) [62–64].

Drugs, foodstuffs, or medical devices can be reimbursed by NFZ if they are prescribed on a properly issued prescription, purchased in a pharmacy and if they are on the reimbursement list. In Poland, there is a relatively complex pricing schedule and the following levels of payment apply to reimbursed drugs: those that are free (up to the limit), lump sum, 50% (for a fee of 50% up to a limit of financing, which is the amount of reimbursement for a drug), and 30% (for a fee of 30% up to a limit of financing). If a retail price of a reimbursed drug exceeds a limit of publicly funded reimbursement, then a patient has to pay the difference between the actual price and the ceiling limit for reimbursement. There are also additional special reimbursement privileges for groups such as veterans, military invalids, or honorary donor transplants [65, 66].

Currently, the list of reimbursed drugs is kept well up to date with it being issued by the Ministry of Health every 2 months [67]. According to the Official Journal of

the Ministry of Health from 29 June 2016, there are 3875 different reimbursed drugs available in pharmacies on prescription. This includes the entire range of approved indications or in the indication for a specific clinical state, 67 foods for particular nutritional uses, 302 medications available within a drug program, and 545 medical devices [68]. When compared to the other EU countries, the level of reimbursement in Poland is much lower and the pharmaceuticals on reimbursement lists are indicated for a much narrower range of diseases [27].

15.5.4 The Generic Medicines Market in Poland

According to IMS data, the Polish pharmaceutical market has one of the largest shares of generics in Europe [69] and the generic market is considered to be mature [70] and is also of high-volume and of low-value products [71]. A generic drug may only be marketed in Poland provided once all patents and supplementary protection certificates covering the original drug have expired [72, 73].

Polish law guarantees the patient the opportunity to replace an original drug with a generic equivalent and pharmacists are required to present to their patients an original drug's substitutability to a cheaper generic. In Poland, most of the generic drugs on the market are branded generics, which means they have their own trade names [74]. The generic products in the market can be up to 90% cheaper than originator branded medicines [71]. According to the RA, in order for a generic drug to be placed on the reimbursement list, its price must be at least 25% lower than the price of the originator branded drug [75].

Biosimilars are not very common in Poland and pharmacists' knowledge about them is considered to be limited [76]. The most important advantage for a Polish patient in the case of biosimilar medicines is that they have much lower prices than original biological agents. It was estimated that biosimilars in 2009 generated savings of EUR 1.4 trillion within the EU. This perhaps shows that there will be room for growth in the Polish biosimilars marketplace [68].

15.6 Medicines Use

15.6.1 Issues Impacting on Rational Medicines Use in Poland

In Poland, a very large share of the market belongs to OTC drugs, which is linked to the fact that Polish patients have a strong tendency to self-medicate [77]. The most popular OTC drugs are those indicated for treating pain and the common cold, as well as vitamins [78]. Patients can ask for help from a pharmacist when choosing a product; however, OTC medicines are available in numerous places other than pharmacies, such as supermarkets and petrol stations. When patients are selecting medicines, they often make their decisions based on information presented in advertising, not by

recommendations from pharmacists or doctors [77, 78]. This happens despite the general opinion that medicines advertisements are not trustworthy and unreliable [79].

Constantly increasing access to OTC medicines escalates the risks arising from improper use and possible interactions. Patients also often do not read drug labels [77]. Despite the constantly rising prices of medicines (in 1997 the average price of a drug in a pharmacy was PLN 3.80, in 2011 it was PLN 16.20 [18]), the trend of the growth in medicines consumption initiated in the early 90s, remains today [80]. On the other hand, unfortunately, there are people in Poland who cannot afford to purchase all the medicines which are prescribed to them and the main reason for this is the cost of drugs which is too high compared to their earnings [81]. According to the data from Pentor Research International Agency, one in four chronically ill patients reported purchasing only part of their prescribed drug regimen [82].

15.6.2 Medicines Use in Community Pharmacies

It was reported in January 2015 that people in Poland still buy most of their drugs in pharmacies and nonpharmacy sales represent only 1.5% of the market. There has also been a steady increase in the range of products offered in pharmacies, since many new products are launched into the market every year [83].

In the last few years, it has been observed that there is a trend to purchase medicines online. Such sales are regulated by pharmaceutical laws along with the decree issued on 26 March 2015 by the MoH. These requirements ensure that the legal sale of prescription drugs can be undertaken through pharmacies and that the shipment of drugs does not harm the safety and quality of the products. All websites that have a legal permission to sell drugs have a common green logo with a link below, which signifies that the pharmacy is on the National Register of Permits to Operate the Pharmacies, Pharmaceutical Dispensaries and the Registry of Granted Approval for the Hospital and Workplace Pharmacies [84].

Since 1 July 2015, new regulations have been implemented that aim to reduce drug abuse. Medicines used for cold and cough that contain pseudoephedrine (which may be used in the synthesis of methamphetamine), dextromethorphan, or codeine, that could be purchased in any amount, are now limited to one pack per adult. Breaking this law could result in fines for a pharmacist amounting to PLN 500,000. Additionally, these drugs cannot be sold on the Internet [85].

15.6.3 Medicines Use in the Hospital Sector

Pharmaceutical expenditure in the hospital sector in 2013 amounted to PLN 3,091,235,244 (net wholesale prices), which equates to 67,948,318 units and 16% of the pharmaceutical market in Poland [86]. Hospitals have the option of creating purchasing groups, which are associations of hospitals carrying out joint purchases

and thus lowering their costs through volume and preferred supplier arrangements [87]. The downside of this approach is that it shifts the procurement focus to very standardized product orders and consequently there has been a significant reduction in the range of products available in Polish hospitals [86].

15.6.4 Standard Treatment Guidelines and Prescribing Behavior

Standard treatment guidelines in Poland are developed by medical associations, which consist of experts in relevant fields of medicine. Their decisions are made in compliance with current medical knowledge and the principles of evidence-based medicine [88].

It was observed during the project Happy Audit 2 (which was intended to describe the therapeutic decisions of family doctors with an emphasis on antibiotics) that the most commonly used antibiotic in Poland is amoxicillin, and the most common prescribed antibiotics groups are cephalosporins and macrolides [89].

It was estimated that in 2013 around 40% of Polish primary care physicians doubted that in terms of effectiveness generic medicines and original drugs are equal. Promotion of the Polish pharmaceutical industry, which is based on generic medicines, could therefore positively influence both the Polish domestic industry and doctors' prescribing behaviors associated with the generic drugs [90]. The use of cheaper equivalent drugs has been shown to enhance patient compliance [74]. Doctors are able to prescribe generic drugs either by writing the name of an originator (a pharmacist can still propose to a patient the generic equivalent if it is not clearly stated on the prescription that the doctor does not wish the drug to be substituted), the trade name of a generic or its INN (International Nonproprietary Name) [79]. Special precautions in the generic switching process are only required for drugs with a narrow therapeutic index (TI) or for modified release preparations [91].

Since 1 January 2016 in addition to doctors, registered nurses and midwives have been able to prescribe drugs in Poland as well. This legislation should reduce waiting time in clinics. The list of drugs that can be prescribed by a nurse consists of about 30 medicines [92]. Pharmacists are also able to issue pharmaceutical prescriptions in the case of emergency and danger to patients' lives. In such situations, the patient may purchase the smallest available package of a drug for 100% of the price regardless of whether the drug has reimbursement status [93].

15.6.5 Medicines Promotional Practices

The pharmaceutical industry is the second largest advertiser in Poland [55] with greater spend on advertising than banks or mobile network companies. In 2014, spending on advertising by Polish pharmaceutical companies amounted to PLN 871

million, which was 9% higher than in 2013. One of the leaders in this sector is Aflofarm® that mainly produces food supplements. Its expenditures on advertisements amounted to PLN 200 million in 2014 [56].

It is prohibited in Poland, pursuant to Pharmaceutical Law (PF), to advertise prescription only drugs. However, pharmaceutical company representatives provide doctors with gadgets that are labeled with their companies' logos. According to PF, the value of gifts that are handed to doctors cannot exceed PLN 100 (which is equal to around USD 26) [94, 95]. In order to reach the audience, pharmaceutical companies sponsor various conferences and promote these events through media [95].

An example of the effect of promotion on sales of drugs is the case of the OTC drug Metafen®. It is a medicine that contains two active ingredients: ibuprofen and paracetamol. The design of the drug's package was completely changed upon acquisition by Polpharma® and an intensive marketing campaign based mainly on television advertising was prepared. Until the launch of a promotional campaign, sales had been relatively low, but following intensive promotion sales growth of nearly 900% was achieved [96].

15.6.6 Role of the Pharmacist

In accordance with Article 90 of Pharmaceutical Law all activities in a pharmacy must be performed only by pharmacists (holders of Masters of Pharmacy degrees, trained for 5.5 years in medical universities) and pharmacy technicians within their professional capacity [49]. The professional role of the pharmacist[3] is to protect the health of the public, which includes provision of pharmaceutical care, collaboration with patients and doctors and taking care of pharmacotherapy in order to optimize treatment and to improve patients' quality of life [49, 97]. Pharmaceutical technicians perform similar tasks as qualified pharmacists; however, they are not allowed to sell very potent drugs or medications containing active ingredients considered to be poisons, or opioids [98].

Pursuant to Pharmaceutical Law, each pharmacy in Poland must have a manager who is responsible for the pharmacy. A pharmacist may transition to a pharmacy management role when they have 5 years of experience or 3 years of experience if they are specialized in retail pharmacy by training. Pharmacy managers in Poland must ensure the quality of medicinal products, as well as proper organization of work in a pharmacy, records of prescription medicine transactions, and reporting of adverse drug reactions [49].

There are also hospital pharmacists that according to Pharmaceutical Law are allowed to perform various tasks within a hospital pharmacy or a hospital ward, for example, rationalization of pharmacotherapy, monitoring of adverse reactions, and supporting of clinical trials are among some of these tasks [86, 99, 100]. The hospital pharmacist in Poland is usually a member of the pharmacy and therapeutic

[3] Regulated by the Act of 19 April 1991 On Pharmaceutical Chambers.

committee and contributes to selection and updating of hospital formularies [86, 101]. Nevertheless, pharmacists in Poland rarely take part in making decisions about treatment of individual patients or recommend alternative pharmacotherapeutic options. Additionally, in contrary to Western European countries, only a few Polish hospitals hire clinical pharmacists [99].

15.6.7 Pharmaceutical Care Interventions

During their studies, pharmacists in Poland are trained to provide pharmaceutical care [102]. Nevertheless, pharmaceutical care within the definition of the Western European countries (constructive intervention in the course of treatment) does not exist in Poland. Several organizations, such as the Polish Pharmaceutical Chamber, are working on development of pharmaceutical care programs [103, 104]. There is evidence that some pharmacies are organizing campaigns to promote health, diabetes care, or smoking cessation in Poland [103]. A pharmacist is often the first person that people make contact with about their health issues, due to the fact that contact with a doctor is difficult, more expensive, and time consuming. It is also stipulated that pharmacists in Poland make sure that a patient's self-diagnosis and the choice of a product when dispensing an OTC drug is correct [105].

Factors that hinder the implementation of pharmaceutical care in Poland are as follows [106, 107]:

- Due to the high level of competition in the pharmaceutical market, a pharmacist must be focused on activities directed to increase the pharmacy's profitability (e.g., looking for discounts and low-cost warehouses).
- Pharmacists are often reluctant to take responsibility for a patient's pharmacotherapy regime.
- Patients are often not aware that pharmacists can have the oversight of their drug therapy.

15.7 The Way Forward

The Polish government is required to align with numerous stipulations of EU law as well as society's demands to meet their health needs. This will require some adjustment and the EU requirements often exceed what can be done within the available healthcare budget in Poland. With Poland's ageing population and escalating levels of chronic disease (as with the rest of the world) demand continues to increase. In 2020, Member States of the EU are expected to spend 16% of their GDP on the healthcare sector [108].

Polish law regarding pharmaceutical industry market development and drug reimbursement is complex and could benefit from simplification. The obstacles that

investors face due to unfriendly regulations (e.g., regarding reimbursement of drugs) may inhibit interest in investment and development of the Polish pharmaceutical market [20]. According to experts from the Polish Association of Pharmaceutical Companies INFARMA, legislation in Poland should be more predictable, should better achieve the objectives of Pharmaceutical Law and should reduce negative impacts on healthcare entities and pharmaceutical companies. It would also be desirable if the Ministry of Health were to engage more with patients, healthcare specialists, and representatives of the pharmaceutical industry [109].

The pharmaceutical and general healthcare sector requires support to educate more healthcare professionals to have the required training to bolster the Polish health system [10, 20]. Polish people perceive their health system to be getting worse each year, which may be a consequence of Polish peoples growing expenditures on health services and drugs, as well as insufficient numbers of doctors available to service their medical needs (there are about 2.2 physicians for 1000 citizens) [58, 110].

According to the announcement in November 2015, there will be a number of reforms pertaining to the Polish healthcare system and medicines expenditures. This is due to the change in the governmental party in October 2015 (the party that had a majority in parliament for the last few years, Civic Platform, was replaced in the last election by the national-conservative Law and Justice party). Law and Justice considers returning to a healthcare system based on public budget funding, instead of the current national public healthcare insurance system The party also claims that drugs would be available for free to underprivileged people over the age of 75 years, which would cause substantial expense to the tax-payers in the population [111]. The initiative was launched in June 2016; however, not all the drugs are free as it was promised; the list of free drugs contains 84 active substances and the cost of the project is estimated to reach PLN 125 million [112].

15.8 Summary

The healthcare system in Poland is based on the public health insurance scheme, which is coordinated by the National Health Fund, in cooperation with the Ministry of Health. Most of the policies controlling the pharmaceutical market in Poland are pursuant to the Pharmaceutical Act; established in 2001 in Poland. Another source of medicines controlling legislation is European Union law, since Poland joined the EU in 2004. Moreover, reimbursement of medicinal products regulations is featured in the controversial Reimbursement Act, which was implemented in 2012.

Since the beginning of the Polish political transformation in the late 80s, the pharmaceutical market has developed rapidly and its value in market terms has doubled. In the last two decades, the wealth in Polish society has increased and the government has implemented a number of constructive reforms. There has been significant progress in privatization of the healthcare sector and an improvement in the quality of health service provision as well as increased access to drugs. Poland

is recognized as a low-cost country, which makes it an attractive place for outsourcing of expensive stages of clinical research into drug treatment, for example, conducting of clinical trials. Nonetheless, there are numerous difficulties for potential investors, such as low prices of reimbursed medicines and restrictive regulations on drug reimbursement.

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