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HEALTHCARE MARKET ACCESS POLAND

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 Country landscape

Poland, officially known as the Republic of Poland is situated in Central Europe, and bordered by Germany to the west, the Czech Republic and Slovakia to the south; Ukraine and Belarus to the east, and the Baltic Sea, Kaliningrad and Lithuania to the north. The total area of Poland is 312,679 square Kilometers, making it the 71st largest country in the world and the 9th largest in Europe.

The elections of 1989 and 1990, won by “Solidarity”, a political entity formed by liberal pro-democratic Polish laborers and trade unions, brought the communist dominated era to a close in Poland. With the democratization of the nation, the government started a series of reform processes (historically known as the “shock therapy” or “Balcerowicz Plan”), which included the release of price and currency controls, removal of state subsidies, and trade liberalization, thus transforming the economy into one of the most robust in Central Europe. This paved the way for Poland joining the North Atlantic Treaty Organization (NATO) in 1999 and the European Union (EU) in 2004 [1].

1.1 Economic environment

Poland has pursued a policy of economic liberalization since 1990 which succeeded to such an extent that the Polish economy was the only one in the EU to avoid a recession through the 2008-09 economic down turn. However, while the Polish economy has performed well over the past five years, the ongoing economic difficulties in the Euro zone, has meant growth slowed in 2012 and 2013.

The GDP of Poland is dominated mainly by three sectors: the service industry (62.7%), industry (33.3%), and agriculture (4%). The national Gross Domestic Product (GDP) (PPP) as per 2013 estimates stands at 814 billion USD, with a Real Growth Rate of 1.3%, while the GDP (PPP) per capita income is 21,100 USD. However, this GDP per capita remains significantly below the EU average of 34,500 USD [2]. As per the Gini index, the distribution of family income stands at 34.1 (2009 estimates) which indicates the existence of income disparity. The unemployment rate is quite high 10.3% as per 2013 estimates [1].

1.2 Demographics

The 2014 estimated population of Poland is about 38.35 million, with a negative growth rate of -0.112% [1]. As per 2011 estimates, 60.9% of the population lived in urban localities, in the country’s major cities, with a negative annual rate of urbanization of -0.04%. The major urban centers are Warsaw (the capital) and Krakow with a population of 1.7 million and 0.75 million, respectively [1].

Table 1: Demographic breakdown of Poland based on 2014 estimates

Age group (years)	Percentage of population (%)	Male	Female
0–14	14.6%	2,876,264	2,716,569
15–24	11.9%	2,333,627	2,235,228
25–54	43.8%	8,459,153	8,355,491
55–64	14.7%	2,658,106	2,973,933
65 and above	14.5%	2,224,569	3,513,339

Source: The World Factbook-Poland. 2014

With the median age group of 39.5 years a majority (43.8%) of Polish population belong to the economically productive age group of 25-54 years. This exemplifies the economic potential of Poland in terms of business opportunities in various sectors.

The median age of the population is 39.5 years with the majority of the population (43.8%) belonging to the economically productive age group of 25–54 years (Table 1) [1]. This has no doubt contributed to the economic robustness which Poland has been experiencing despite the problems in other parts of Euro zone. Furthermore, the changing trends of demographics in Poland indicates that the proportion of population which would be economically productive would continue to increase for next 15 years, which in turn would probably translate into better economic prospects for society and increased business opportunities. However, if the negative population growth is not addressed, over the coming decades the majority of the population who are currently productive economically might become economic dependents. Furthermore, the increasing percentage of population over the age of 55 years, could herald the increase of diseases and conditions which mainly afflict late age, highlighting the need for setting up infrastructure to cater to the healthcare needs of elderly.

Education in Poland is compulsory and it starts at the age of five to six. The system of education in Poland allows for 22 years of continuous, uninterrupted schooling and consumes 5.2% of its GDP. As per 2011 estimates, the literacy rate among 15 years and above who can read and write was 99.7% (male: 99.9%; female: 99.6%), the average school attendance was 16 years (male: 15 years; female: 16 years) and the unemployment rate among youth of ages 15 to 24 years was 26.5% (male: 24.1%; female: 30%) (Table 2) [1].

Table 2: Educational parameters

Parameter	Rate	Male	Female
Literacy rate (15 years and above)	99.7%	99.9%	99.6%
School attendance (years)	16 years	15 years	16 years
Unemployment rate (15 to 24 years)	26.5%	24.1%	30%

Source: The World Factbook-Poland. 2014

1.3 Political structure and environment

The Republic of Poland is a democratic state. The political system of Poland is defined by the Constitution, which was passed on 2nd April, 1997 [3], which ensures that there is freedom of the press and of other means of social communication, as well as freedom of belief, religion and philosophy, and it protects marriage. The system of government of the Republic of Poland is based on the principle that there is separation and balance between legislative, executive and judicial powers. Poland follows a multi-party political system where the Prime Minister is the head of government, and the President is the head of state and the supreme commander of the Armed Forces. Legislative power is vested in the two chambers of parliament: Sejm and Senate. The judicial power is vested in courts and tribunals. A social market economy, based on freedom of economic activity, private ownership and solidarity, dialogue and cooperation between social partners, is the basis of the economic system of the Republic of Poland [3].

2 Healthcare infrastructure

2.1 Healthcare system

The Ministry of Health (MoH) is the health policymaker and regulator in Poland. It has the administrative control over research institutes such as, Medical Centre of Postgraduate Education (Centrum Medyczne Kształcenia Podyplomowego (CMKP)), the Institute of Mother and Child and Institute of Cardiology and controls semi-autonomous medical academies, university hospitals and research institutes. MoH also supervises the authorities that are related to pharmaceutical product regulations, which include [4]:

- Chief Pharmaceutical Inspectorate (Główny Inspektorat Farmaceutyczny)
- Office for Registration of Medicinal Products, Medical Devices and Biocides (Urząd Rejestracji Produktów Leczniczych, Wyrobów
- Medycznych i Produktów Biobójczych (URPL,WMiPB))
- Chief Sanitary Inspectorate (Główny Inspektorat Sanitarny)

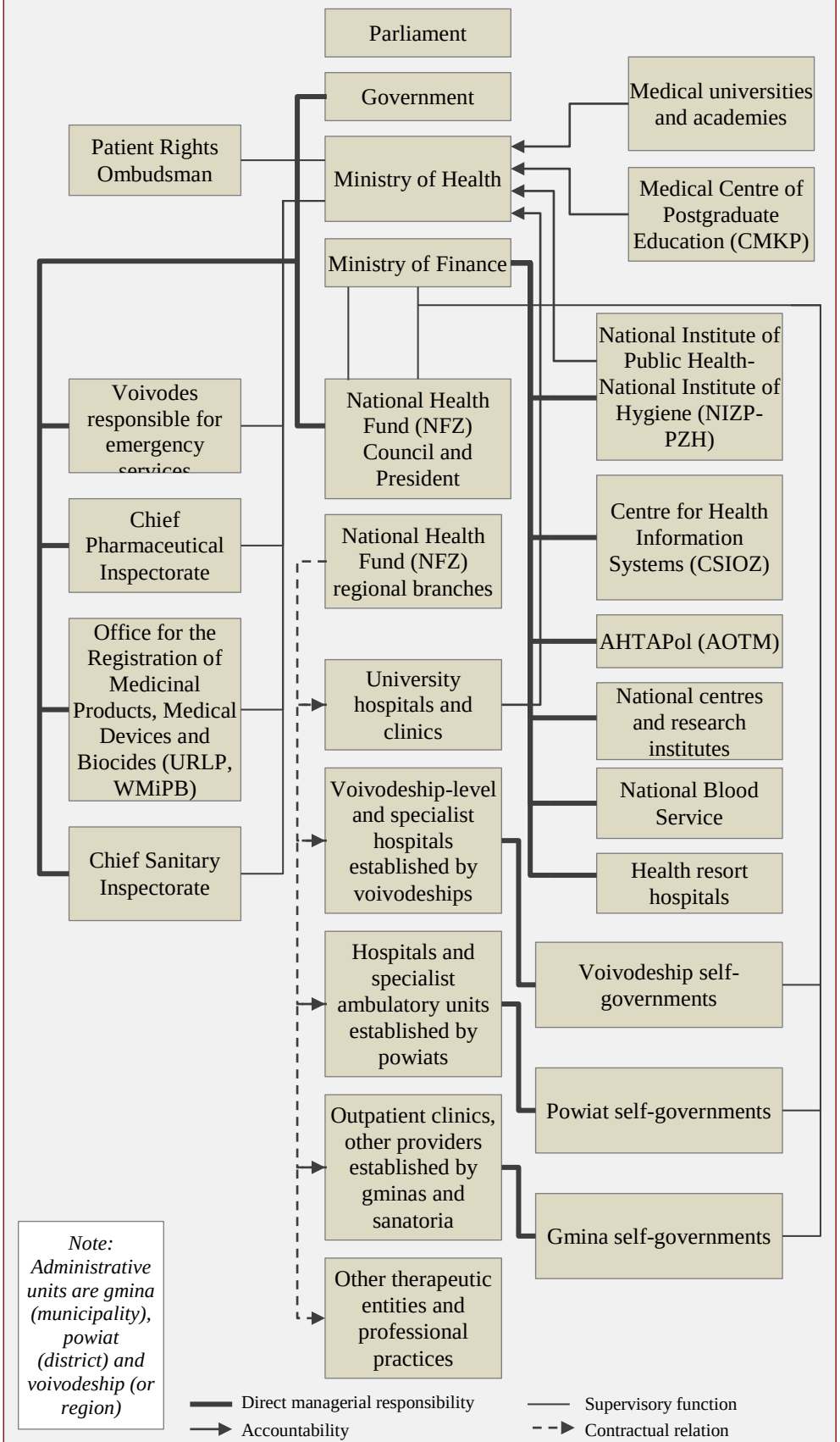
Apart from the central authority, there are regional authorities that are responsible for the health care in their respective regions. The administrative levels include gmina, powiat, voivodeship. The regional authorities are responsible for health tasks defined in the legislation, assessment of the adequacy of service provision and health care infrastructure, and for health promotion and prevention. In addition, voivodeship self-governments are responsible for health care strategy and planning based on the health needs of their populations and the voivodes are responsible for medical emergency services in their region [4].

The authorities responsible for healthcare system management in Poland include MoH, NFZ and territorial self-governments.

The health care services are provided by public health units, non-public health care units, individual physicians and group medical practices. Public units are owned by gmina, powiat, voivodeship or central level (Ministries), state university active in the field of medicine or by the Medical Centre of Postgraduate Education. Non-public healthcare units include former non-public ZOZs (niepubliczny zakład opieki zdrowotnej/healthcare units) and private practices [4]. Figure 1 provides an overview of the Polish healthcare system.

A primary care physician is usually the first point of care for a patient. He refers the patient to specialists, when required. However, the patient has the right to choose healthcare provider at each level of care. With the exception of certain specialists, such as gynaecologist, a referral is required to access specialist medical care [4].

Figure 1: Overview of the Polish healthcare system



Source: Poland health system review. Health Syst Transit, 2011

2.2 Health status

With increasing economic productivity and standard of living, the life expectancy at birth in the Poland is increasing: as per 2014 estimates it stands at an average of 76.65 years (male: 72.74 years, female: 80.8 years). Access to safe drinking water and improved sanitation facilities have been nearly completely attained throughout the nation (Table 3) [1].

Table 3: Access to safe drinking water and sanitation

Parameter	Urban	Rural	Total
Drinking water (Improved) (2012 estimates)	100%	Information not available	
Drinking water (Unimproved) (2012 estimates)	0%	Information not available	
Sanitation (Improved) (2008 estimates)	95.7%	79.7%	89.5%
Sanitation (Unimproved) (2008 estimates)	4.3%	20.3%	10.5%

Source: The World Factbook-Poland. 2014

Improved drinking water: piped water into dwelling, yard, or plot; public tap or standpipe; tubewell or borehole; protected dug well; protected spring; or rainwater collection.

Improved sanitation: use of any of the following facilities: flush or pour-flush to a piped sewer system, septic tank or pit latrine; ventilated improved pit (VIP) latrine; pit latrine with slab; or a composting toilet.

Unimproved drinking water: unprotected dug well; unprotected spring; cart with small tank or drum; tanker truck; surface water, which includes rivers, dams, lakes, ponds, streams, canals or irrigation channels; or bottled water.

Unimproved sanitation: use of any of the following facilities: flush or pour-flush not piped to a sewer system, septic tank or pit latrine; pit latrine without a slab or open pit; bucket; hanging toilet or hanging latrine; shared facilities of any type; no facilities; or bush or field.

2009 estimates indicate that the adult prevalence of HIV/AIDS in Poland is very low ~ 0.1% (total prevalence=27,000), indicating the successful of implementation of AIDS prevention programs. The total healthcare expenditure, as per 2011 estimates, of the country stands at 6.7% of GDP. The physician density of the country is 2.07/1,000 population (2010 data); this is slightly less than the WHO prescribed minimum density of 2.3/1,000 population. The hospital bed density is

6.6 beds/1,000 population (2010 data), which is relatively sufficient number of beds to cater to the healthcare needs of the country. Some of the healthcare indicators of Poland are mentioned in Table 4 [1].

Table 4: Healthcare indicators of Poland

Parameter	Data
Mean age of mothers at 1st birth (2011 data)	26.9
Total fertility rate (2014 est)	1.33 children/woman
Life expectancy at birth (2014 estimates)	76.65 years
Maternal mortality rate (2010 data)	5 deaths/100,000 live births
Infant mortality rate (2014 est)	6.19 death/1,000 live births
Total Healthcare expenditure (2011 est)	6.7% of GDP
Physician density (2010 data)	2.3/1,000 population
Hospital bed density (2010 data)	6.6 beds/1,000 population
The main causes of mortality	circulatory system disorders, cancers, accidents and poisoning, digestive system disorders, respiratory system disorders, diabetes, and nervous system disorders
Vaccination coverage (in %)	
Adult obesity prevalence (2008 data)	25.3%
Underweight children under age of 5 (2007 data)	

Source: The World Factbook-Poland. 2014

2.3 Health insurance

The concept of health insurance was introduced in Poland for the first time through a law in 1920; this insurance system covered only wage earning employees which constituted about 7% of the population. It was based on the Bismarck model of sickness funds. After the Second World War, public activities in the sphere of health focused on fighting infectious epidemics. Since 1989 however, health system reforms have followed the very quick transition from centrally planned to market economy [4].

The state healthcare system is funded in two ways - through government budgets to healthcare and through compulsory individual contributions to the state healthcare insurance scheme [5] or the National Health Fund (NHF). Employers compulsorily need to register their employees with the health insurance fund. Employees pay around 8.5% percent of gross salary as premium to the NHF which is deducted directly from the person's salary. Family members who are dependent on the employee are also covered. For self-employed people the contribution is determined by the income level. Even the low-income earner has to contribute towards health insurance, however, the amount of each person's contribution does vary according to income [5].

The major task of the NHF is to finance health services provided to the entitled population (from the collected insurance fees). It negotiates and signs contracts for service provision with health care providers (setting their value, volume and structure), monitors the fulfilment of contractual terms and is in charge of contract accounting. The NHF is also responsible for covering the costs of health care services provided in other EU Member States to Polish citizens. The NHF is prohibited from engaging in profit-making activities and cannot (directly or indirectly) operate, own or co-own health care institutions. The NHF has limited regulatory powers because these are generally held by the Ministry of Health [4].

The patients can register with the doctor of their choice and can also choose the medical center of their choice for healthcare. The general practitioners (GP) prescribe the drugs, treat acute and chronic illnesses, and provide preventive care and health education. The health centers provide outpatient care and specialist services. Generally all the basic health centers offer general practice, maternity care, child healthcare, dental care, emergency medical care as well as laboratory, radiology, and other diagnostic services [4].

The chemists sell medicines in Poland based only on the prescriptions of doctors and consultants. Prescription medicine is only available from a qualified and registered chemist or from a hospital pharmacy and it is subsidized through the NHF [4].

Till the end of 2009, approximately 97.6% of the Polish population had health insurance cover through NHF. Of the 37.2 million insured individuals, almost 28.7 million (about 77%) were insured on a mandatory basis and 8.5 million (about 23%) were covered as dependents. Children (must be under 18) and the students

Almost everyone is insured through (98% of the population) mandatory social insurance in Poland.

below 26 are covered as dependents. Parents, grandparents and other dependent relatives must live in the same household as the person through whom they obtain their coverage. Individuals who do not meet the criteria for mandatory insurance may apply, and are granted voluntary insurance through the NHF. This group includes employees on unpaid leave, contract employees, volunteers and foreigners who do not have health insurance. Family members of these individuals are also eligible for coverage. The primary benefits/coverage of health insurance includes [4]:

- primary health care (internal medicine, emergency medicine, family medicine)
- ambulatory specialist care
- hospital treatment
- psychiatric care and addiction treatment
- therapeutic rehabilitation
- nursing and long-term care services
- dental treatment
- health resort treatment
- provision of orthopedic and auxiliary medical devices
- medical rescue services
- palliative and hospice care
- highly specialized services (e.g. transplant surgery)
- health programs
- pharmaceuticals

Cost-sharing in insurance backed healthcare is very limited in Poland. Except for some medicines, medical products and devices, health resort treatments and certain dental procedures, the majority of the cost of healthcare is fully covered. The proportion of total health expenditure paid out-of-pocket has been decreasing: from 28.1% in 2004 to 22.4% in 2008. Medicinal products, medical and rehabilitation services account for the major portion of out-of-pocket expenses [4].

Out-of-pocket expenditure has declines since 2004, indicating that the government is keen to cover most of the healthcare expense.

However, patients suffering from long-term conditions and receiving rehabilitation placements will have bear more medical expenses. Their medical fees are generally higher: for adults, it might be 250% of the minimum old-age pension or 70% of the resident's monthly income (whichever is lower); and in the case of children (aged 18 or younger), or full-time students under 26, it could be 200% of the lowest pension or 70% of the average monthly income of one person in the family. Furthermore, the patients will have to pay for their non-emergency medical travel [4].

Legally, there is no necessity for a patient to pay the treating physician. However, informal payments are generally being done and they are commonly in the form of

gratitude payments and/or donations to financially support underfunded or indebted hospitals. Direct bribes to physicians to reduce the waiting times and for personal care are a known problem [4].

3 Overview of the pharmaceutical market

3.1 Market overview

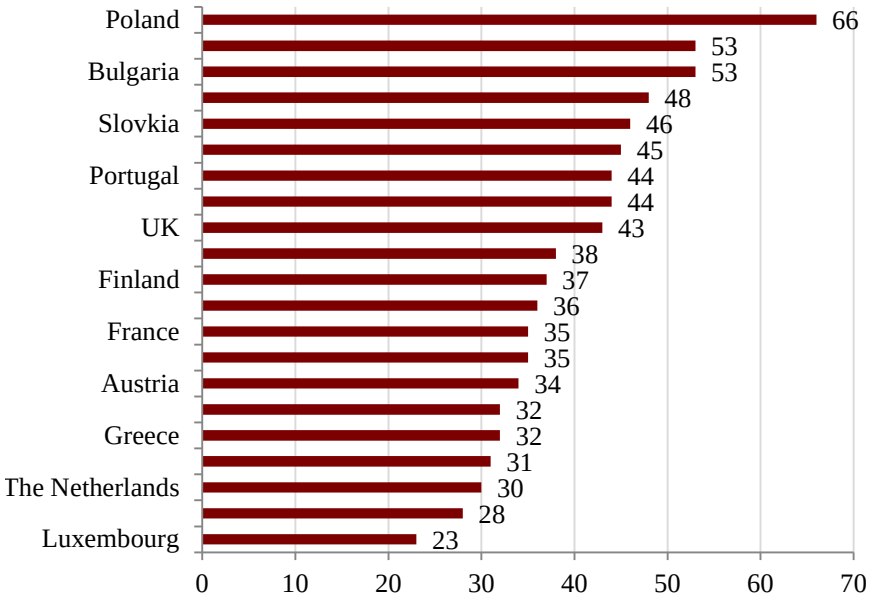
Poland accounts for nearly 4% of the estimated pharmaceutical market share of Europe. By the end of 2010, the value of the pharmaceutical market in Poland was estimated to be at Polish Zloty (PLN) 20.1 billion (USD 5.8 billion). In 2012 however, the pharmaceutical market in Poland recorded a negative growth for the first time in many years and fell 6% year on year. These developments were mostly driven by the entry of the Reimbursement Act, which was the main reason behind the hefty fall of 23% in the value of sales generated by the reimbursed pharmaceuticals segment in 2012. Before the Reimbursement Act came into force, in last quarter of 2011, there was panic buying and significant sales growth. Now that expectations have stabilized, the pharmaceutical market is expected to rebound and grow.

The pharmaceutical market is generic dominated and share of generics in Poland is highest among European countries.

In 2014-2015, further stability of the pharmaceutical sales is expected to be achieved in Poland with an estimated growth rate of 4.5-5.5%. During this period, Compound Annual Growth Rate (CAGR) is expected to amount to 4.7% and the market value is expected to reach USD 8.7 billion in 2015. The pharmaceutical market in Poland is estimated to grow to USD 18 billion by the end of 2016 [6, 7].

The market is dominated by generics (66% of national sales in 2012) and the share of generics drugs is the highest in Europe [8] (Figure 2).

Figure 2: Sales share of generic drugs by value in 2010, in pharmacies in some EU countries



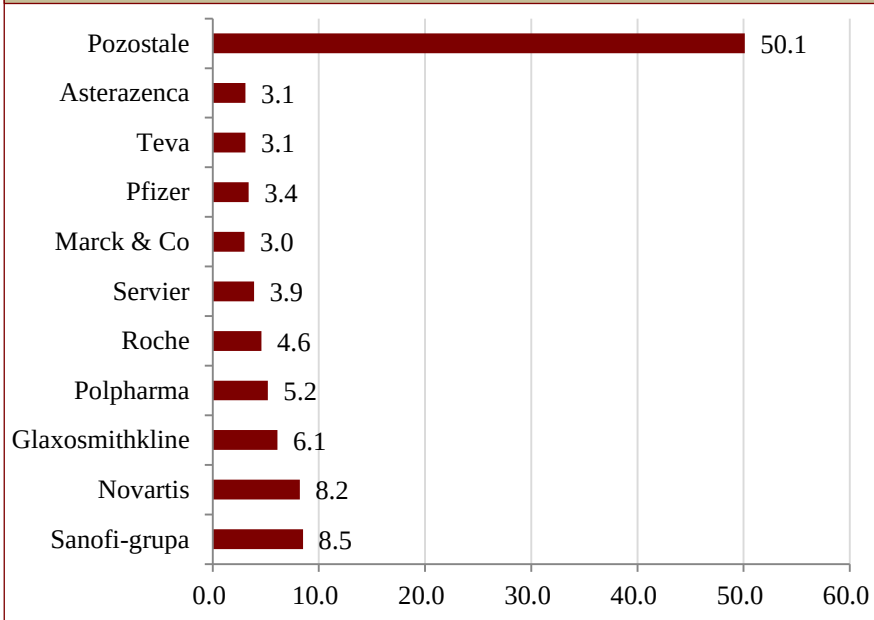
Source: Polish pharmaceutical industry; Available from: http://msp.gov.pl/en /polish-economy/economic-news/5468,Polish- pharmaceutical-industry.html

3.2 Major players

Domestic drug production caters to 60% of the national medical drug consumption in terms of volume [8]. Major indigenous pharmaceutical manufacturers include Polpharma, USP, Adamed and LEK-AM [8]. The large pharmaceutical manufacturers in Poland and their market share by value is shown in Figure 3 [8].

Majority of the pharmaceutical products consumed are manufactured by domestic companies indicating that they may be the biggest competitor .

Figure 3: Major pharmaceutical enterprises present in Poland (market share by value)



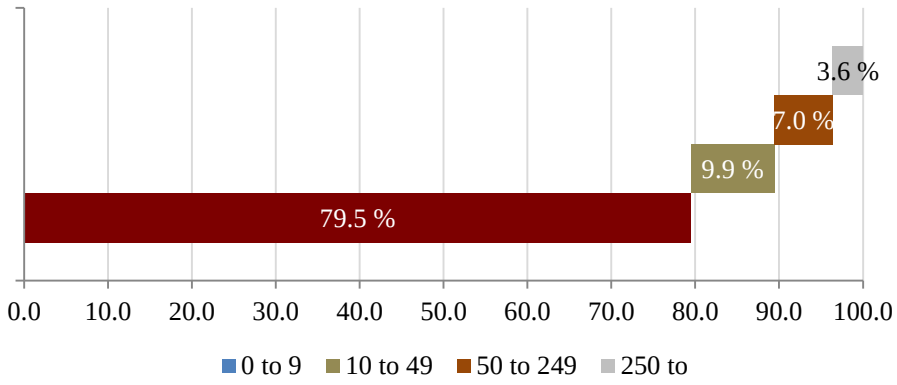
Source: Polish pharmaceutical industry; Available from: http://msp.gov.pl/en /polish-economy/economic-news/5468,Polish- pharmaceutical-industry.html

There were 687 entities working for pharmaceutical products (including medicines) and biotechnological research in Poland by Q3 2011. The former includes 532 entities, of which 182 dealt with manufacturing of basic pharmaceutical substances, and 350 with manufacturing of medicines and other pharmaceutical products. The remaining 155 (out of 687) are working in the field of biotechnological research [9].

In terms of employees, micro-enterprises which employ ~ 9 people dominate in the pharmaceutical and biotechnological sector (Figure 4). 10% of the entities are small-sized enterprises employing from 10 to 49 people. 7% are middle size entities employing 50-250 people and just 3.6% entities are large size entities employing over 250 people [9].

Majority of the products that are consumed in Poland are cardiovascular drugs (23.7%). This is followed by digestive system (14.6), nervous system (6.2%), respiratory system (6.2%) and oncology (3.7%) [9].

Figure 4: Companies operating in the pharmaceutical and biotechnological sector in Poland by employment size (%)



Source: Economic Information Department Polish Information and Foreign Investment Agency

4 Market access

4.1 Regulatory landscape

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is a government administrative authority responsible for [10]:

- Marketing authorization of medicinal products, excluding medicinal products which do not need marketing authorization
- Marketing authorization of biocidal products
- Marketing and use of medical devices – within the meaning and on the basis of the Act on Medical Devices
- Clinical trials, including veterinary clinical trials

Main Pharmaceutical Inspectorate is another authority, which earlier was a part of Ministry of Health. It supervises the condition of manufacturing and import of medicinal products for human and veterinary use, quality and trade in medicinal products for human use and supervises the trade in medical devices for human use [11].

Apart from this, there is a Health Technology Assessment Agency (AOTM), which was established as an advisory body to the Ministry of Health. The opinions of ATOM are important for MoH decisions but not binding: reimbursement may be granted by MoH with or without a negative opinion of AOTM or reimbursement may not granted by MoH after a positive opinion from AOTM [12].

4.1.1 Market authorization for pharmaceutical products

The decision-making process for registration of medicines in Poland begins with submission for approval by the national registration procedure. The processing an application for a drug registration includes the following steps [13]:

- Submission of the application for authorisation: For all EU registration processes, the binding format of documentation is CTD (Common Technical Document). The preferred format for submission is the electronic Common Technical Dossier (eCTD)
- Validation: The submitted forms are check for completeness. If any omissions are noted, then the application is returned as invalid and the applicant is given sometime to correct them. If the application is considered valid, it is further sent for assessment
- Assessment of the documentation (including review of SPC, labelling, leaflet etc.): The quality, efficacy and safety of the drugs is evaluated and

assessment of the active ingredient and medicinal product is performed. Apart from this, the nonclinical overview includes an assessment of the pharmacologic, pharmacokinetic, and toxicologic evaluation of the pharmaceutical. Clinical assessment includes analysis of all the relevant studies carried out with the product

- Granting of authorisation by President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

4.2 Pricing

The manufacturer can either seek reimbursement for a drug or market it freely, without any reimbursement. In the later scenario, prices are determined by the manufacturer and is called “free pricing”. However, in case the manufacturer requires reimbursement, the drug price is finalized after negotiations with Drug Management Team of the Ministry of Health. This team comprises of representatives from the Ministry of Health, the Ministry of Finance, the Ministry of Economy and the National Health Fund. The following criteria are taken into account while setting a drug price [12]:

- Production cost (provided by the manufacturer)
- Cost of daily treatment
- Cost of standardized therapy
- Risk-benefit ratio compared to alternative pharmaceuticals for that indication
- Therapy costs per day in comparison to products with the same efficacy
- Evaluation of the economic impact on the national health system
- Estimated sales of the new pharmaceutical product
- Prices in countries with similar GDP

Drug manufacturing cost, therapy cost, economic impact and price in similar countries are main factors determining price of a reimbursed drug in Poland

4.3 Reimbursement landscape

The registration for a medical product can be either obtained from the European Medicines Agency (EMEA) or from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of Polish Government [12]. In order to obtain approval for reimbursement the pharmaceutical company has to submit a reimbursement form to the Ministry of Health (MoH), Government of Poland. The decision on reimbursement is generally taken within 90 days; if the application is submitted along with the pricing application then it might take up to 180 days. The assessment for reimbursement is generally based on:

- necessity to provide health care for the society
- making medicines accessible
- safety
- importance of a drug in a treatment of conditions associated with high epidemiological threat
- influence of a drug on direct medical costs
- affordability for the public payer obliged to finance healthcare services

Generally there are 4 levels of reimbursement: 0% (non-reimbursed), 50%, 70% and 100% reimbursement [12]. The prices for non-reimbursed drugs can be set by the manufacturer. However, if a manufacturer seeks reimbursement for a product, then the price for the product will be set through a negotiation with Drug Management Team of the Ministry of Health (as mentioned in the Pricing section).

5 Appendix

5.1 Glossary

EU	-	European Union
GDP	-	Gross Domestic Product
CAGR	-	Compound Annual Growth Rate
EMEA	-	European Medicines Agency
GP	-	General Practitioners
AOTM	-	Health Technology Assessment Agency (in Polish)
MoH	-	Ministry of Health
NHF	-	National Health Fund (in Polish)
PLN	-	Polish Zloty (in Polish)
NATO	-	North Atlantic Treaty Organization
PPP	-	Purchasing Power Parity
USD	-	United States Dollar

5.2 Bibliography

1. Cetral Intelligence Agency, U. *The World Factbook-Poland*. 2014 [cited 2014 17th December]; Available from: https://www.cia.gov/library/publications/the-world-factbook/geos/pl.html.
2. Central Intelligence Agency, U. *The World Factbook-Eurpean Union*. 2014 [cited 2014 17th December]; Available from: https://www.cia.gov/library/publications/the-world-factbook/geos/ee.html.
3. PRESIDENT.PL. *Polish Political System*. 2014 [cited 2014 17th December]; Available from: http://www.president.pl/en/about-poland/polish-political-system/.
4. Sagan, A., et al., *Poland health system review*. Health Syst Transit, 2011. **13**(8): p. 1-193.
5. cities, P.b.E. *Healthcare in Poland*. 2014 [cited 2014 18th December]; Available from: http://www.europe-cities.com/en/633/poland/health/.
6. PMR. *Pharmaceutical and healthcare market in Poland 2013 Development forecasts for 2013-2015*. 2014 [cited 2014 23rd December]; Available from: http://ceepharma.com/analysis/9/pharma-market-in-poland-set-to-rebound-in-2013.
7. Economic Information Department, P.I.a.F.I.A., Warsaw, *Pharmaceutical and Biotechnological Sector in Poland*. 2011.
8. *Polish pharmaceutical industry*. 2014 [cited 2014, December 29; Available from: http://msp.gov.pl/en/polish-economy/economic-news/5468,Polish-pharmaceutical-industry.html.
9. *Pharmaceutical and Biotechnological Sector in Poland*. 2011, Economic Information Department Polish Information and Foreign Investment Agency.
10. *The Office*. [cited 2014, December 30; Available from: http://en.urpl.gov.pl/en-information-about-the-office.
11. *Tasks of the State Pharmaceutical Inspection*. 2014, December 30]; Available from: https://www.gif.gov.pl/en/activities-and-competen/tasks-of-the-state-phar/392,Tasks-of-The-State-Pharmaceutical-Inspection.html.
12. Research, I.S.f.P.a.O. *POLAND - REIMBURSEMENT PROCESS*. [cited 2014 23rd December]; Available from: http://www.ispor.org/HTARoadMaps/Poland.asp.
13. *Registration of medicinal products in Poland via national procedure*. 2014, December 30]; Available from: http://beijing.mfa.gov.pl/resource/d0a02998-0887-4017-ac6d-521b8ba9b54f:JCR;jsessionid=1C8513242F4AF3E67D2827F7B1566489.cmsap1p.

5.3 Methodology

5.3.1 Secondary research

In-depth and extensive secondary research was conducted to capture quantitative and qualitative information by a team of experienced consultants with advanced analytical skills and expertise in the pharmaceutical industry. The data was collected from multiple credible and authentic sources within public domain, including but not limited to:

- Websites of Ministry of Health and its affiliates as well as various regulatory and government bodies.
- Company websites, annual reports, investor presentations and press releases of various pharmaceutical companies and hospitals.
- Reports of various healthcare and pharmaceutical trade associations.
- Reports published by various internationally recognized bodies such as World Health Organization (WHO), United Nations (UN), and others.
- Reports and articles published by globally accredited institutions such as the World Bank, International Monetary Fund (IMF), Asian Development Bank (ADB), the Organization for Economic Cooperation and Development (OECD), Central Banks of respective countries and many more.
- News, press releases and bulletins of domestic as well as foreign newspapers and magazines.
- Publications in various scientific, healthcare and other related journals.

5.3.2 Data validation

Both the primary and secondary data was validated by a panel of experts including industry experts, KOLs, thought leaders and members of phamax Dendron Network.

5.4 Disclaimer

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