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## КВАЛІФІКАЦІЙНА МАГІСТЕРСЬКА РОБОТА

на тему «Економічний аналіз міжнародного та національного ринку  
фармацевтичної продукції»

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## РЕФЕРАТ

кваліфікаційної магістерської роботи на тему  
«Економічний аналіз міжнародного та національного ринку фармацевтичної  
продукції»

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Актуальність теми, обраної для дослідження, визначається тим, що в умовах глобалізації світової економіки та збільшення потенційних можливостей підприємства щодо реалізації бізнес-інтересів на національному та міжнародному ринку фармацевтичної продукції завдання формування і вдосконалення організаційно-економічного механізму підвищення конкурентоспроможності підприємств стає одним із головних чинників виживання та розвитку.

Мета кваліфікаційної магістерської роботи полягає у проведенні галузевого аналізу світового та українського ринку фармацевтичної продукції, вивченні головних факторів успіху, переваг і недоліків. Він також визначає можливості та загрози, які існують у галузі, державне регулювання та інші фактори, що впливають на діяльність компаній та їхні зароблені прибутки.

Об'єктом дослідження є міжнародний та національний ринок фармацевтичної продукції.

Предметом дослідження є огляд фармацевтичної галузі у світі та в Україні, її ризиків та переваг, головних факторів впливу.

Для досягнення поставленої мети та завдань були використані загальнонаукові методи дослідження: систематизації та узагальнення (при проведенні загального аналізу фармацевтичної галузі), системного аналізу (під час дослідження ланцюга постачання у фармацевтичній галузі).

Інформаційною базою кваліфікаційної магістерської роботи є наукові статті зарубіжних та вітчизняних авторів, дослідницькі проекти, річні звіти фармацевтичних компаній, офіційні веб сайти фармацевтичних компаній,

фармацевтичні словники, законодавчі документи та ін.

Основний науковий результат роботи полягає у такому:

- 1) визначенні найбільш вагомих гравців на міжнародному та національному фармацевтичному ринках;
- 2) дослідженні сучасного стану галузі;
- 3) визначенні сил, які впливають на сучасний глобальний ринок фармацевтичної продукції;

Одержані результати можуть бути використані міжнародною фармацевтичною компанією під час формування стратегічних планів щодо удосконалення конкурентних переваг на національному зовнішніх ринках, а також при визначенні стратегії міжнародної конкурентоспроможності підприємства.

Ключові слова: market of pharmaceutical products, economic analysis, the five forces, SWOT analysis, competition, supply chain, generic drugs, patented drugs, OTC drugs, market volume, trade of pharmaceuticals.

Зміст кваліфікаційної роботи викладено на 62 сторінках, зокрема список використаних джерел із 46 найменувань, розміщений на 4 сторінках. Робота містить 2 таблиці, а також додатки, що містять 13 рисунків, розміщені на 7 сторінках.

Рік виконання кваліфікаційної роботи — 2018 рік.

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«\_\_» \_\_\_\_\_ 20\_\_ р.

ЗАВДАННЯ НА КВАЛІФІКАЦІЙНУ МАГІСТЕРСЬКУ РОБОТУ  
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4. Об'єкт дослідження \_\_\_\_\_

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6. Кваліфікаційна робота виконується на матеріалах \_\_\_\_\_

7. Орієнтовний план кваліфікаційної магістерської роботи, терміни подання розділів керівникові та зміст завдань для виконання поставленої мети

Розділ 1 \_\_\_\_\_  
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\_\_\_\_\_ (зміст конкретних завдань до розділу, які має виконати студент)

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Розділ	Прізвище, ініціали та посада консультанта	Підпис, дата	
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## ABBREVIATIONS

ADR — adverse drug reaction

API — active pharmaceutical ingredient

ERP — energy related products

IT — information technology

OTC — over the counter drugs

QC — quality control

R&D — research and development

US — United States

WHO — World Health Organization

WTO — World Trade Organization

## INTRODUCTION

The relevance of the topic chosen for the study is determined by the fact that in the globalization of the world economy and increasing the potential of the enterprise in terms of business interests in the national and international pharmaceutical market, the task of forming and improving the organizational and economic mechanism for increasing the competitiveness of enterprises is becoming one of the main factors survival and development.

The aim of the qualification master's thesis is to carry out analysis of the global and Ukrainian pharmaceutical market, studying the main factors of success, advantages and disadvantages. It also identifies the opportunities and threats that exist in the industry, government regulation, and other factors affecting the activities of companies and their earnings.

The tasks set during the preparation of this are as follows:

- 1) conduct the general analysis of the pharmaceutical industry;
- 2) define the product segments, as well as demand and supply chain;
- 3) describe the instruments for market analysis;
- 4) analyse the global and Ukrainian market of pharmaceutical products using the described instruments;
- 5) identify the global trends in pharmaceutical industry;
- 6) give general characteristics of the Ukrainian pharmaceutical market;
- 7) explore competition on the Ukrainian pharmaceutical market.

The object of the study is the international and national pharmaceutical market.

The subject of the study is an overview of the pharmaceutical industry in the world and Ukraine, its risks and benefits, the main factors of influence.

In order to achieve the aim and objectives of the study, the following general scientific methods of research were used: systematization and generalization (in the general analysis of the pharmaceutical industry), system analysis (during the research of the supply chain in the pharmaceutical industry).



The information base of the qualification master's work is the scientific articles of foreign and domestic authors, research projects, annual reports of pharmaceutical companies, official websites of pharmaceutical companies, pharmaceutical dictionaries, legislative documents, etc.

The main scientific result of the work is as follows:

- 1) identify the most important players in the international and national pharmaceutical markets;
- 2) research of the current state of the industry;
- 3) determine the forces that affect the modern global market for pharmaceutical products.

## GENERAL CHARACTERISTICS OF INTERNATIONAL MARKET OF PHARMACEUTICAL PRODUCTS

### 1.1. General analysis of pharmaceutical industry

Before giving general characteristics to the pharmaceutical market, let us have a very common look at the pharmaceutical industry itself.

According to Encyclopaedia Britannica, pharmaceutical industry is “discovery, development, and manufacture of drugs and medications (pharmaceuticals) by public and private organizations” [30]. However, some special features characterize it making it very different from what is commonly considered as an industry. There are some contradictions about this industry. For instance, notwithstanding the acknowledged fact that for more than a century the pharmaceutical industry has made a significant contribution to human welfare and decreased the amount of illnesses and pain, it is nevertheless regularly considered as one of the least trusted industries by the public in opinion surveys, often being unfavourably compared to the nuclear industry. For sure, this business is associated with high risks, yet it is regarded by the general public to be extremely profitable. The major pharma corporations rightly advertise themselves as research-based organisations, but most people believe that they spend more on marketing than on research [10]. However, in spite of the profitable nature of the pharmaceutical industry, it is nevertheless an instrumental part of healthcare [4].

The pharmaceutical industry belongs to the most industrialized ones, it consists of several thousand companies. Notwithstanding the huge number of market participants, yet, a small number of big players control the industry. Due to the fact that the biggest pharmaceutical companies are highly exposed to public, there is a perception that the supply side of this market is an oligopoly [18, 39]. This opinion is backed by a more accurate and precise study of the pharmaceutical market, considering its particular structure. The pharmaceutical market of the world comprises several thousand products for a limited number of indications. Covering all the fields would be ineffective for a pharmaceutical company. Taking into account budgetary limitations to conduct R&D,

pharmaceutical producers focus on specific therapeutic areas, thus decreasing the number of potential competitors. This leads to a relatively low competition inside the therapeutic areas, with the market being actually much more dynamic [36]. The low competition level is supported by the evidence that because of high R&D costs, it is difficult to enter the pharmaceutical market. Another barrier for new competitors is granting of patents<sup>1</sup> [15]. Despite the fact that the supply side of the pharmaceutical market seems to be less competitive compared to other industries, it would be a mistake to regard it as having no competition. Perspective therapeutic areas will draw competition, which means development of pharmaceutical products having equivalent therapeutic effect and direct competition with the existing products [40]. There exist so-called me-too drugs<sup>2</sup> designed for similar purpose but having some small advantages. They are not innovative products, yet they stimulate competition in the pharmaceutical market. Another factor of the competition growth is generic<sup>3</sup> drugs. Research-based companies develop new pharmaceutical products or at least license them. As soon as the patent protecting these products expires, the manufacturers of generic drugs are permitted to produce the generic version of the former protected pharmaceutical product without costly R&D [36]. This means lower costs of production for the manufacturer and therefore lower costs for the products at the market. When generic medicines appear in a particular therapeutic area, competition rises automatically [40].

The pharmaceutical industry is among the most rapidly developing industries in the world. This development and growth is due to the fact that such factors as ageing of the populations, rising incomes, innovative products and growing consumer expectations concerning health and long life all contribute to accelerating demand. Besides, the industry apparently has a global focus. The top global pharmaceutical companies come from the US, Europe and Japan, but search for the medicinal discoveries wherever they are made, regularly create international partnerships, initiate clinical studies in a range of developed countries and place the new manufacturing

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<sup>1</sup> A license conferred by the authorities, which gives a temporary monopoly for the use of an invention [44].

<sup>2</sup> Drugs suggesting alternative treatment with wider therapeutic options and lesser adverse effects in particular populations of patients [11].

<sup>3</sup> For definition, see section 1.2 Demand, supply chain and product segments in the pharmaceutical market.

facilities taking into account market and commercial demands [6].

The industry remains quite profitable, but the sales of most brand name manufacturers have been affected by the growth of generic drug manufacturing. These drugs are often sold to consumers for much less than brand name drugs and most health insurances prefer them for this reason [4].

From 2012 to 2017, the pharmaceutical industry accumulated USD 174.1 bn revenue with USD 39.2 bn in profits with an annual growth rate 3.6%. The loss of patent exclusivity has made possible the competition with the manufacturers of generic drug products. Because of the patents' expiration and competition, many companies started to focus on development of biological drugs and outsourcing research and development and contract research organizations to decrease operational costs and enhance competitive positioning [4].

At present time, the pharmaceutical industry is in the mature stage of its life cycle. The value added is growing; however, it is expected that the increase of revenue will be brought by particular therapeutic classes, besides trimming the workforce and the consolidation of operations [4].

State compensation and health insurance coverage can be regarded as the driving forces of the industry. Since the cost of the brand-name pharmaceutical products is higher than for generics, an average consumer is not able to pay for them out of pocket. So, the average consumer will rely on the prescription<sup>4</sup> drug coverage (e.g. the program "Affordable Medicine"). The insurance providers will be able to negotiate process and probably influence the sales of the brand-name pharmaceutical products [4].

*Legislation and regulation.* Nowadays, all over the world, both in the developed and developing countries, drug-safety and quality-related issues still exist. There were cases, which resulted in tragedy, often children were affected. This happened because of the use of medicines containing substances having toxic effect or containing impurities, or medicines that were not properly studied, having unknown severe adverse reactions, substandard preparations, or falsified and counterfeit pharmaceutical

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<sup>4</sup> For definition, see section 1.2 Demand, supply chain and product segments in the pharmaceutical market.

products. That is why effective regulation is required to guarantee safety, efficacy and quality of the pharmaceutical products, as well as the correctness and appropriateness of information about the preparation, which is available to the public [14].

The existing structures of pharmaceutical regulation include laws, regulatory agencies, evaluation boards, QC laboratories, and information centres. All of them were formed and developed gradually, representing a response to the problems and needs of the society. Therefore, drug laws must be constantly updated to correspond to the changes and emerging challenges of the society [14].

Regulation of drugs comprises a number of functions, the most important ones are inspection of manufacturing facilities and distribution channels, licensing, QC, product evaluation and registration, ADR monitoring, control of advertising and of clinical studies. Each one is aimed at a particular aspect of pharmaceutical activity. They all have to act in harmony altogether to provide sufficient protection for the consumers (patients) [14].

There are countries where all functions regarding the drug regulation are performed by one agency. It has full authority to control these functions and is fully responsible for their effectiveness. On the other hand, there are countries where the drug regulatory functions are performed by two and more agencies; they may act at the same or at different levels of government [14].

In recent years, globalization of pharmaceutical issues is observed, it also influences the national legislation of the countries. This globalization can be seen in changes in the international trade, patent protection and pricing, which lead to a number of initiatives, examples of which are given below [32].

Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the WTO is aimed at reduction of gaps in protection of the intellectual property rights in different countries and bringing them under common international rules [32].

International Conference on Drug Regulatory Authorities (ICDRA) organized by WHO gathers officials from the authorities of drug regulation from all WHO member countries at a forum to improve cooperation and collaboration. Held since

1980, ICIDRA helps the regulatory authorities to harmonize the regulation and improve the safety, efficacy and quality of the medicinal products [32].

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project where drug regulatory authorities and experts from Japan, US and Europe discuss specific and technical peculiarities of registration of pharmaceutical products [32].

Pharmacopoeias are the documents containing technical information procedures for production and testing, standards for API and pharmaceutical products. Germany and Thailand have special pharmacopoeias for herbal products. A pharmacopoeia usually forms part of a country's pharmaceutical laws, so its procedures and standards are legally enforceable [32].

However, no matter how strictly the pharmaceutical market is regulated, obliging a pharmaceutical product to have sufficient safety, efficacy and quality before entering the market, the safety profile of the product is still not complete at market entry [37]. Therefore, a pharmacovigilance system aimed at monitoring the product's safety (and sometimes efficacy) during its life cycle [41].

Not only the production, distribution and demand for pharmaceutical products is regulated, their marketing is regulated as well [40]. It is allowed to advertise OTC drugs in most industrialized countries, while direct consumer advertising of prescribed drugs is permitted in New Zealand and US [21].

## 1.2. Demand, supply chain and product segments in the pharmaceutical market

*Demand.* From the point of view of demand at the pharmaceutical market, there are two groups of products: OTC<sup>5</sup> drugs and prescription drugs [6]. A more or less definite structure can be recognized at least for the prescription drugs. According to

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<sup>5</sup> For definition, see section 1.2 Demand, supply chain and product segments in the pharmaceutical market.

Govin Permanand, it is not the consumer who chooses to be sick and creates the demand. It is a prescribing doctor who creates the demand (proxy demand), there may also be a third party (medical insurance company or state via some compensation program) which pays [40]. This is where the market imperfection is observed because of the asymmetric information distribution among the manufacturers and consumers. The patients do not have enough information and training to decide on the pharmaceutical product they need for certain treatment. Besides, if the cost of a pharmaceutical product is compensated by a third party, the patients may be not aware of the cost. But normally a patient would expect to receive the best treatment. It could seem that price-inelastic demand is contributory to business interests since it helps to compensate the R&D expenses and make profit through increasing the prices. Demand in the pharmaceutical market does not depend on prices as much as in other industries [9]. Moreover, the pricing strategies of pharmaceutical companies are restricted in most developed countries [40].

*Supply chain.* As it was already mentioned above, the global pharmaceutical market is characterized by high R&D spending. Other traits are lengthy and risky clinical trials process, extensive regulation to protect patients, several new product launches every year, sophisticated marketing activities and frequent litigation.

The pharmaceutical supply chain is one of the most complex supply chains in the world, which was historically resistant to transformation. A simplified description of the typical value chain of a pharmaceutical company is illustrated in the Figure 1.

According to estimations, the supply chain trends for 2017 were as follows:

*Entering the emerging markets for growth.* Striving for new opportunities and chances for development and growth, pharmaceutical corporations proceeded to rump-up their efforts in the emerging markets, particularly in the BRIC +T regions (Brazil, Russia, India, China, and Turkey). Countries that used to be small volume export markets are currently turning to be regions of significant growth and investment. Complete integration of these regions into the international supply chain management is of supreme importance for supporting this growth [1].

*Shifting to the global inventory management.* While the growth and propagation of the markets is serviced, the companies are stimulating the global inventory management systems to guarantee that every region is covered with service with least possible additional charges. End-to-end visibility is a common issue at the majority of the pharmaceutical supply chain conferences, and the companies spend large amounts each year to consolidate their ERP footprint and for harmonising what is still left. To utilise this opportunity, regarding the amount of data, transformation becomes an imperative [1].

*Unlocking the Artificial intelligence, Big Data, and Cloud technologies.* Aiming to implement the significantly developed practices, the companies begin to use a lot of freshly developed solutions to “turn on” their supply chains. These new practices make them business-aware and ready to forecast the consequences and direct their steps autonomously. Uber, Amazon Prime Now, and other models of services in different industries using such new technologies as cloud, Big Data, and machine learning. Significant returns on investment in supply chain automation tools are expected, which means that the pharmaceutical companies are also going to use these tools. This evolution of advancements continues and the supply chain is becoming autonomous [1].

The major pharmaceutical *product segments* are:

*Originator chemical drugs* (originator brand, innovator, brand name drugs) are developed as a result of expensive R&D and clinical trials *in vitro*<sup>6</sup> and *in vivo*<sup>7</sup> (animals and humans) prior to being approved. The originator drug is first authorised for marketing worldwide and relies on patents and other forms of intellectual property rights to justify the investment required bringing a product to market. The originator drug always has a brand name, which may vary in different countries [31, 44].

*Generics* are produced without a license of the originator producer after the patent expiry. They are almost identical copies of innovator chemically-synthesized preparations, they have the same active substance in their formulation, they are equal

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<sup>6</sup> An experiment conducted in an artificial environment under control [43].

<sup>7</sup> An experiment conducted in a living subject [43].



in strength, dosage form, and administration route. It is obligatory that the generic medicinal products is bioequivalent<sup>8</sup> to the originator medicinal product and that all other regulatory requirements are fulfilled. No clinical trials are required for the generic drug to receive marketing authorization, except for the bioequivalence trials. Generics that are marketed under the non-proprietary (chemical name of the active substance) name are called “commodity generics”. The commodity generics are often produced by several pharmaceutical companies and compete mainly on price. The so called “branded generics” are sold by a pharmaceutical company under its own label and normally their prices are higher than the prices of the non-brand generics [31].

*Prescription drugs* can be purchased by customers only under prescription.

*Over-the-counter drugs* (OTC) (may be originator and generic) are distinguished from the prescription drugs in that prescription is not required for the consumers to purchase them at a pharmacy store.

*Pharmaceutical Substances* include Active Pharmaceutical Ingredients (APIs) and Excipients. The dosage form of a drug contains active pharmaceutical ingredient(s) and excipient(s). APIs are the substances that actually determine the effect of the drug. Excipients are the inactive substances. They define the dosage form of the drug and serve as a delivery vehicle, which transports the API to the site in the body where the drug is supposed to act [31].

*Biologicals*. Unlike the *chemically-synthesized* drugs with a well-defined structure that can be thoroughly verified, biological drugs are produced from living material, are much larger and have a more complex structure. The biologicals are the end-result of extensive R&D and clinical trials as well as the originator chemical medicinal products [31].

*Biosimilars* are versions of biological products that refer to the originator biological product when applying for marketing authorization to the regulatory bodies [31].

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<sup>8</sup> Having equivalent effect on the organism as another preparation, usually having the same chemical formulation [22].

### 1.3. Instruments for market analysis

The *Five Forces analysis* was first described by Michael Porter in 1979 in Harvard Business Review article. This was a revolutionary tool, which continues to be applied in business practice and academic thinking. Companies can benefit from it through evaluation of competition in the industry and understanding their positioning in the market [42]. The basic concept of the theory describes the five forces defining competitive strength and attractiveness of a market [33].

These forces include (see Figure 2):

1. Bargaining power of suppliers (estimates how easy the suppliers can raise the prices, taking into account: number of suppliers, product/service uniqueness, supplier size/strength, switching cost) [33];
2. Bargaining power of buyers (estimates how easy the buyers can lower the prices, taking into account: individual buyer importance, switching cost);
3. Rivalry among existing competitors (number and power of competitors) [33].
4. Threat of substitute products or services (substitute products raise the probability of switching reducing suppliers' power and market attractiveness) [33];
5. Threat of new entrants (new entrants decay profitability) [33].

However, it should be kept in mind that the industry structure is changing in dynamics. As time passes, the power of suppliers or buyers rises or falls. New entry to the market or new appearance of new substitution products can be more or less possible due to innovations in the industry, technology or management. The entry barriers as well as the competition strength can be subject to changes because of changes in regulation. Some innovative approaches to pricing or distribution can influence the competition etc. [42].

There is also a point of view that government may also be considered as a sixth force in this analysis since regulation, taxation and trade policies also have a noticeable effect at many industries [33].

*A SWOT analysis* identifies and assesses the strengths, weaknesses, opportunities and threats an organization faces. This is a tool for strategic planning and management. The internal factors of the organization are strengths and weaknesses while the external ones are opportunities and threats. It was first mentioned in the literature in 1960's, along with the start of using the notion of strategy in business management. The origin of the SWOT analysis is questionable; scientists attribute its appearance either to Harvard Business School or to Stanford University [38].

## 2. ECONOMIC ANALYSIS OF INTERNATIONAL MARKET OF PHARMACEUTICAL PRODUCTS

### 2.1. Global pharmaceutical market outlook

The global pharmaceutical spending was USD 1,100 bn in 2016, equating to 14.5% of healthcare spending and 1.4% of global GDP, reaching USD 1,147 bn in 2017. The global pharmaceutical market stratifies into patented drugs, generic drug and OTC medicine sub-sectors. While these three businesses have the common enterprise of commercializing medicines, they are quite distinct operations in terms of product development, supply chain management, promotional activities and regulatory requirements (see Figure 4) [7].

According to BMI research, the global pharmaceutical market was valued at USD 1,100 bn in 2016 and is forecasted to expand to USD 1,321 b, with a 4.4% compound annual growth rate (CAGR) at constant exchange rates (CER), through to 2021. The fastest growing region is expected to be Sub-Saharan Africa (7.1% CAGR), followed by Latin America (7.0% CAGR), the Middle East and North Africa (6.6% CAGR), Asia Pacific (6.1% CAGR), North America (3.7% CAGR) and Europe (3.2% CAGR). The global pharmaceutical market will post a five-year CAGR of 3.7% in US dollar terms and 2.6% in euro terms (see Figure 5) [8].

Currency fluctuations are generally underappreciated by multinational pharmaceutical companies and their investors. Such firms historically focused on few countries — mainly developed states — and domestic revenue accounted for a higher proportion of their overall sales. Due to the rise of emerging markets, drug manufacturers are increasingly entering non-traditional markets. These countries often have volatile currencies, which can dramatically affect the level of repatriated revenue from year-to-year and quarter-to-quarter [7].

According to the Doctor Reddy's Laboratories analytics, it is expected that between 2017 and 2021, the global pharmaceutical will to increase revenues by 4% to 7% and obtain almost USD 1.5 trillion. This means an increase of USD 370 bn

compared to the estimated spending level of 2016. A slightly lower growth rate in comparison with the growth rate observed in 2014 and 2015 is explained by the fact that an unprecedented global surge in new hepatitis and cancer drugs was marked in these two years. The US stay the largest pharmaceutical market in the world [13].

The overall revenue growth is expected to be propelled by innovative medicinal products in developed markets and by notably expanded volume in the Emerging (“pharmerging”) Markets. Confronted by the aging of population, developed countries will go on to offset the growing costs from new medicinal products with the administration on generic products, paying more attention to the pricing and access measures. Pharmerging markets will accelerate growth by seeking to improve the access of medicine across the population. These countries will include nine of the top 20 markets of the world; and due to its growing volumes, China will be the clear number two after the US [13].

The new medicinal products that, according to the estimates, will drive growth will mostly represent the ‘specialty’ products. In ten years, the share of specialty medicinal products has increased from 20% in 2006 to 30% in 2016 and will expectedly exceed 35% by 2021. These medicinal products address significant unmet medical needs in “cancer, autoimmune diseases, metabolic disorder, nervous system dysfunction and others. Specialty medicines will approach half the pharmaceutical spend in the US and the EU4 (France, Germany, Italy and Spain) plus Great Britain” [13].

For the majority of large Indian pharmaceutical companies manufacturing generic medicinal products, the US accounts for anywhere between 0% to 60% of consolidated revenues. According to the estimations, the US pharmaceutical market will increase “from USD 462 bn in 2016 to between USD 645 bn and USD 675 bn in 2021” [13]. During the following several years, the branded medicinal products approximately having a value of USD 65 bn will go off patent. Unquestionably, the off-patent opportunity value is decreasing; nevertheless, this does not indicate that the opportunity landscape is narrowing [13].

*Global competition.* The pharmaceutical sector is dominated by publicly-listed multinational companies from the US, Western Europe and Japan. Most companies focus purely on the commercialization of medicines, but some are involved in other businesses, usually medical devices. There are frequent mergers and acquisitions, and licensing of products and technologies by the large companies is common. Below we give a brief description of the 10 major market players according to Pharm Exec [28].

Table 1. Global competitors

Company	2016 Sales (USD in m)	2016 Spend R&D (USD in m)	Activity
Pfizer New York, USA	45,906	7,841.0	Pfizer develops and produces medicines and vaccines for a wide range of conditions in the areas of immunology and inflammation, oncology, cardiovascular and metabolic diseases, neuroscience and pain. The company has a diversified global health care portfolio which includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products [27].
Novartis Basel, Switzerland	41,554	7,916.0	Novartis provides healthcare solutions and offers a diversified portfolio of pharmaceutical products: innovative medicines, eye care products, “cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools” [25].
Roche Basel, Switzerland	39,552	8,717.1	The company “discovers, develops and provides innovative diagnostic and therapeutic products and services that deliver significant benefits to patients and healthcare professionals — from early detection and prevention of diseases to diagnosis, treatment, and treatment monitoring” [34].

Company	2016 Sales (USD in m)	2016 Spend R&D (USD in m)	Activity
Merck & Co Whitehouse Station, New Jersey	35,563	9,760.0	Merck is a global healthcare company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies, and consumer and animal health products. Product offering categories include heart and respiratory health, infectious diseases, sun care and women's health [23].
Sanofi Paris, France	34,174	5,722.0	Sanofi is a diversified global healthcare company engaged in the research, development, manufacture and marketing of healthcare products. Sanofi's business includes pharmaceuticals (prescription drugs, consumer healthcare and generics), vaccines and animal health [35].
Johnson & Johnson New Brunswick, New Jersey	31,671	6,967.0	<p>“The Pharmaceutical segment’s broad portfolio focuses on unmet medical needs across several therapeutic areas: cardiovascular &amp; metabolism, immunology, infectious diseases &amp; vaccines, neuroscience &amp; pain, and oncology”. These products are distributed directly to retailers, wholesalers and health care professionals for prescription use.</p> <p>The Medical Devices and Diagnostics business segment “produces a broad range of innovative products and solutions used primarily by health care professionals in the fields of orthopedics, neurological disease, vision care, diabetes care, infection prevention, diagnostics, cardiovascular disease, and aesthetics” [20].</p>
Gilead Sciences, Foster, USA	29,992	3,925.0	“A research-based biopharmaceutical company that discovers, develops and commercializes

Company	2016 Sales (USD in m)	2016 Spend R&D (USD in m)	Activity
			innovative medicines in areas of unmet medical need. Company's portfolio of marketed products includes a number of category firsts, including complete treatment regimens for HIV infection available in a once-daily single pill and the first oral antiretroviral pill available to reduce the risk of acquiring HIV infection in certain high-risk adults" [16].
GlaxoSmithKline Brentford, England	27,775	4,696.6	A science-led global healthcare company that researches and develops a broad range of innovative medicines and brands. The company has three primary areas of business in pharmaceuticals, vaccines and consumer healthcare [19].
AbbVie North Chicago, Illinois	25,229	4,152.0	AbbVie, Inc. is a "research-based biopharmaceutical company. It engages in the discovery, development, manufacture and sale of a broad line of proprietary pharmaceutical products". The company's products are used to treat rheumatoid arthritis, psoriasis, Crohn's disease, HIV, cystic fibrosis complications, low testosterone, thyroid disease, Parkinson's disease, ulcerative colitis, and complications associated with chronic kidney disease, among other indications [2].
Amgen Thousand oaks, California	21,892	3,755.0	Amgen is a research-based biotechnological company. The company is engaged in research and development of medicines, biosimilars and gene products, conducts clinical trials. Amgen's medicines treat serious illnesses and typically



Company	2016 Sales (USD in m)	2016 Spend R&D (USD in m)	Activity
			address diseases with a limited number of treatment options [3].

## 2.2. The five forces and SWOT analysis of the global pharmaceutical market

The bargaining power of suppliers is considered high as the R&D, manufacturing and sale is under control of the manufacturing companies who establish the prices hoping to compensate the R&D costs. However, the control of the prices is moderated by health insurance payers and the government [4].

The bargaining power of buyers in the pharmaceutical market is restricted by the character of pharmaceutical products in general [4]. For example, when the pharmaceutical giant Mylan increased the price for its drug EpiPen (a life-saving device for allergies) from about USD 103.50 in 2009 to more than USD 608.61 in 2016, the patients were outraged, but they had no choice but to pay this price as the product is considered life-saving [24].

In most countries, healthcare is provided by a mixture of public and private spending. Public spending may be funded through general taxation (such as in the UK), and/or payroll contributions to a specific health insurance fund. Private spending may include private-sector health insurance companies, and also out-of-pocket expenditure by patients. Private health insurance may be either voluntary or mandatory; the Netherlands uses the latter approach. The system may be 'free at the point of use', as in the United Kingdom, or involve full or partial reimbursement of costs by insurers [17].

It is quite common to find that healthcare insurance does not cover (or only partially covers) purchases of drugs from pharmacies. This has been an issue in

Ukraine, for example, where patients' out-of-pocket expenditure on drugs is a considerable proportion of private health spending [17].

The bargaining power of buyers is strengthened by the oligopsony status and price control policies of state and private sector institutions that are ultimately the major purchasers of drugs. Obtaining high quality materials, equipment, personnel, and third-party clinical testing services is vital to the business of pharmaceutical companies.

Rivalry among the existing competitors is quite strong due to the presence of large scale global competitors and smaller generics companies fighting for each drug approval in a lucrative market. In 2017, more than 40% of the total revenue of the industry belonged to four largest pharmaceutical companies (see Figure 3). This was caused by many different reasons, for instance because of the patent cliff<sup>9</sup> many manufacturers of originator drugs decided to merge their companies to increase the operational effectiveness (e.g., Pfizer-Wyeth, Merck-Schering-Plough, Roche-Genentech) [4].

Threat of substitute products in the pharmaceutical industry is relatively high, Non-drug therapies are substitutes for many pharmaceuticals. In addition, research-based drugs that are no longer protected by patents may be substituted by cheaper generic copies, with many 'blockbuster' drugs coming off patent in the next few years giving the market a so-called patent cliff to negotiate. As the patents expire, the manufacturers of generic medicinal products may copy the brand-name preparations without spending money on the costly R&D. Moreover, it is not obligatory that the composition of a generic product is identical to the one of originator drug. The active substance and its dosage must be identical, as to the excipients, a generic drug product may contain cheaper ones [4]. This makes the cheaper generics a real threat for the brand-name drugs. This risk is however mildly reduced as not all drugs have an effective generic replacement, meaning the original is able to be sold unhindered by competitors even after the patent ends. In some instances, it is even the original

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<sup>9</sup> A quick drop in earnings after the patent termination [26].

company that produces the generic in order to try to prevent generic makers from muscling into the market.

The threat of new entrants is strongly affected by legal and regulatory frameworks. New entrants must satisfy regulators that their products are safe and effective. Another barrier faced by the new entrants to the pharmaceutical market is the cost of R&D. In this industry, a higher percentage of revenue must be invested in R&D. Consequently, it is very unlikely that a small new business enters the market and operates successfully without a substantial capital. Besides, the process of discovering a new medicine may be very slow and costly [4].

A SWOT analysis of the pharmaceutical industry demonstrates what the industry is excelling in, what improvements are necessary, where growth is likely and what anticipatory actions are required to protect shareholder or company value. A simplified SWOT analysis of the global pharmaceutical industry is given below:

#### *Strengths*

- High levels of R&D spending facilitates innovation.
- The ability to charge premium prices during product patent terms.
- Low debt levels means that merger & acquisition activity is not limited by credit ratings.

#### *Weaknesses*

- Limited product lifecycles due to patent expirations.
- No direct-to-consumer advertising in most markets.
- A reputation for questionable business ethics on occasions.

#### *Opportunities*

- Rising burden of disease from expanding and ageing populations.
- Urbanization will widen healthcare access.
- Economic growth and rising incomes in emerging markets.

#### *Threats*

- The increasing influence of politics on the provision of medicines, specifically more pricing controls.

- Disruptive technologies such as cell therapy, immunotherapy and gene therapy.
- Involvement of information and communications technology companies in the healthcare sector.

### 2.3. Global trends in pharmaceutical industry

*Mergers and acquisitions (M&A)* remain one of the main growth strategies of the pharmaceutical sector. Taking into account the pricing pressure, consolidation becomes inevitable to extend the current product portfolios and refill pipelines exhausted by patent expiry; to expand or develop capabilities in priority fields; to penetrate the new markets; and to "acquire innovative technologies to leverage current assets or generate cost-saving synergies" [13]. Gradually, larger and larger deals come into action and the pharmaceutical companies spend more and more money to finance M&A [13].

*Collaborations to continue in the R&D space.* Since the R&D costs are growing, large pharmaceutical companies are increasingly interested in sharing their risks, pooling R&D resources and improving capabilities for better R&D productivity [13].

*Digital pharma.* High-profile collaborations between the IT giants and largest pharmaceutical companies have been observed not so long ago. For instance, "Google and its parent company Alphabet formed partnerships with GSK and Sanofi, while IBM has allied with Teva, Celgene and Quest Diagnostics" [13]. The purpose of such collaborations is to provide innovative and advanced technologies R&D, support creation of innovative personalized tools for diagnostics using big data and IT-driven pathways, create more intelligent pharmacovigilance etc. IT will go on to streamline the production costs and afford options that provide for affordable, personalized, designed intensive variations to include everything from a small-scale batch of a

medicinal product for a clinical study to mass production of medicines for chronic diseases. Eventually, these IT-pharma deals will become the norm very soon [13].

*A 3D future.* “The fabrication of complex specialty drugs through 3D printing of living tissues” is considered to be the next level of using technology for production of personalized medicinal products [13]. 3D printing can be described as a process of creating a three-dimensional object by mounting successive layers of raw materials. “Each new layer is attached to the previous one until the object is complete. The flexibility of 3D printing allows designers to make changes easily; and it enables manufacturers to create patient-specific devices matched to a person’s anatomy as well as those with very complex internal structures. These capabilities have created major interest in 3D printing of medical devices” [13]. Viewing this, the United States Food and Drug Administration has drafted guidance that provides the regulator’s primary considerations regarding the matter, particularly technical considerations concerning devices that apparently will be manufactured by 3D printing [13].

*Higher regulatory scrutiny on pricing.* The pricing pressure is going to become a common factor due to the growing financial pressure on governments to decrease their healthcare burden. The governors are more and more observant of price increases taken by companies, this concern has recently come into the focus of international attention in connection with huge EpiPen price hikes in the US. Many large companies were subpoenaed because of the price rises. “Reforms are being implemented, drafted or floated by various nations as to how pricing can be constrained to mitigate the stress on healthcare costs” [13]. The examples are given below:

- President Trump has suggested creation of a bidding procedure to control the increasing drug prices.
- The EU council has recommended a more vast international collaboration on pharmaceutical pricing, which involves “joint horizon scanning, proactive sharing of pricing information and joint price negotiations across ‘coalitions’ of member states” [13].
- China has declared than in 2016-2020, the control over the pharmaceutical pricing will be increased.

- In December 2016, the Japanese government has announced its plans to add annual price reviews in the off-years of the biennial price revision process.

As a result, some large pharmaceutical companies have promised to restrict the price hikes to single digits, quit unethical practices like incentivizing physicians to promote their drugs and increase the quality and safety assurance of their drugs. Such attitude is expected to become standard, as the big players take these commitments and their rivals will be forced to follow their example [13].

Global companies have been subpoenaed by lawmakers because of the price rises. Policies that constrain price hikes are either considered or actively executed by the governments of the US, the EU, China and Japan. This will only progress in future, as more aged people require “direct and indirect healthcare support from their governments” [13].

*Increased importance of Emerging Markets.* In recent years, this tendency has developed steadily and will continue to develop. “Pharmerging markets already account for a third of global pharmaceutical revenues” [13]. In the following ten years, this share will continue to grow [13].

*Patient centricity.* Nowadays, there is a huge amount of information about medicines available online, due to which patients are much better informed about the drugs they are being prescribed than ever before. This means that the pharmaceutical companies have to recognise the centrality of the patient experience and react to this new reality. For example, in 2015, Sanofi has created a new role of chief patient officer and introduced three-pillar strategy for patient centricity which is based on “input and understanding, solutions and outcomes, and culture and community”. Starting from 2016, patient-centric clinical trials are have become a very important issue for such organizations as the European Union Patients’ Academy for Therapeutic Innovation (EUPATI). Greater patient involvement in the process of R&D as well as planning of the clinical trials is promoted. It is reasonable to give patients an active role in trial design as this is supposed to help encourage patient recruitment, decrease the cost clinical trials and eventually facilitate the process of going to market [13].

*Rapid urbanization and an ageing population.* According to the estimations, about two-thirds of the world's population will be urban resident by 2050. The advantages of organized and efficient cities are clear, however, fast and unplanned urbanization unexceptionally results in “unmanageable population densities, poverty of a growing under-class and the lack of infrastructure” [13]. These are perfect conditions for contagious diseases and epidemics. Affordable anti-infective drugs and respective prophylactics will be increasingly demanded. The global population aged 60 years and above is forecasted to grow by 56% between 2015 and 2030 and reach an estimated 1.4 bn. And by 2050 this figure will reach 2.1 bn. The ageing population is associated with spending more money on healthcare. Higher healthcare spending is in its turn associated with “higher incidences of cancer, dementia, Parkinson's disease and heart-related disorders” [13]. For instance, the number of cancer cases, which is associated with ageing, is supposed to rise to 17 million by 2020 and 27 million by 2030. It is necessary that the healthcare systems get ready for growing incidence of chronic diseases due to progressively ageing populations, special attention should be paid to preventive care rather than to reactive. [13].

*Rising income levels and changing lifestyles.* In Emerging Markets, the middle class has been rapidly growing. The middle class families have greater disposable income and can afford better healthcare solutions, consequently. For example, in India, according to the national sample survey on consumer expenditure, per capita spends on the children's education and healthcare show the most rapid growth. Hence, the demand for affordable pharmaceutical solutions is rapidly growing. Besides, change in the lifestyles results in such problems as unhealthy eating habits, lack of exercise, lack of normal sleep, stress and strains that have not been observed in the past. The result of the above are “higher obesity rates, diabetes, poor digestion, cardiovascular problems, hallucinations, breathing difficulties, back and neck troubles and other ailments” [13]. Due to these chronic lifestyle diseases, a demand for vitamins and minerals, health supplements appeared, and the dependence on medications has become significantly greater [13].

*Immuno-oncology drugs.* The scientific progress brings new treatment options to an increasing number of patients, which means that the oncology landscape is changing rapidly. “Regulatory pathways, diagnostic and treatment infrastructure and financing mechanisms are required to gear up to this shift to meet the needs of populations” [13]. In the last five years, new treatment options have appeared and become available. It is expected that the wave of innovations will continue as numerous and various pharmaceutical companies are researching and developing new drugs [13]. For example:

- “Over 20 tumor types are being treated with one or more of 70 new cancer treatments that have been launched over the past five years” [13].
- “The impact of these new medicines on patient care is exemplified by the case of the two PD-1 immuno-oncology drugs, whose rapid uptake reflects their remarkable clinical profile and successive expansion of indications” [13].

The accessibility of such immuno-oncology drugs still needs to be increased, as only in six countries in the world “more than half of the recently launched drugs available for patients and even less are reimbursed under public insurance programs” [13]. The perspectives are positive as many innovative medicinal products are being developed and as there is “significant scope for widespread reach to the patient population” [13].

*Bump up for biosimilars.* Biosimilars are marketed not only in emerging countries; they are also inevitable in developed nations including the US. In other words, biosimilars are more than therapeutic innovations. In the US and Europe, they are necessities, as their cash-strapped health systems are programmed for money saving for the next five years. In the US, for instance, it is expected that the patents will expire for biological products worth USD 27 bn to USD 58 bn. In the next five years, it is expected that biosimilars will significantly influence the spending. Approximately 25 to 35 such molecules are being developed now, and a significant part of them can be expected to enter the US market by 2021 on condition of regulatory review and litigation. However, the harmonization of the regulatory standards is still slow. On the other hand, the national regulators accept data extrapolation, due to which a biosimilar



drug can be approved for many indications, along with this no additional clinical trials are required. Notwithstanding, stakeholder education and greater outreach are required [13].

Considered the above, the global pharmaceutical industry at present day is at an interesting stage having to cope with specific challenges and to take the future opportunities. The companies are constantly re-evaluating and improving their business models in order to cope with the dynamic business environment. They take such steps as product portfolio enhancement; they create innovative and more complex products, they increase their capacity and enter new regions, target cost leadership and establish lean structures. It is expected that innovative and flexible companies are able to address the concerns and find the pathways for growth and development. [13].

### 3. UKRAINIAN PHARMACEUTICAL MARKET: MARKET ANALYSIS FOR AN INTERNATIONAL COMPANY

#### 3.1. General characteristics of the Ukrainian pharmaceutical market

*Market volume.* Ukraine's pharmaceutical market was observed to grow by 15.2% y-o-y in local currency terms (12.4% in US dollar terms) in 2017 to UAH 67.6 bn (USD 2.57 b), from UAH 58.7 bn (USD 2.29 b) in 2016. By 2021, the market is forecast to reach UAH 106.7b (USD 3.59 b), with a five-year local currency compound annual growth rate (CAGR) of 12.7% (9.4% in US dollar terms). Over the extended 2018-2026 forecast period, BMI forecasts the drug market to grow at a CAGR of 11.0% in local currency terms and 8.8% in US dollar terms, reaching a value of UAH 167.0 bn (USD 5.30 b), with spending per capita growing from USD 51 in 2016 to USD 126 in 2026 [8].

While the market growth rates appear high, particularly in comparison to Western markets, this is principally due to high levels of inflation. Consumer price inflation (CPI) growth peaked at 48.5% y-o-y in 2015 due to the depreciation of the hryvnia brought on by the oil price drop. While inflation has fallen since the country's return to economic stability, inflation will plateau at 5.0% y-o-y by 2022. It is therefore valuable to measure the pharmaceutical market's growth in real terms. Over the extended forecast period, the market is forecasted to grow at an average of around 4.2% in real terms.

*Retail sales.* According to the data of Ezhenedelnik Apteka, a dramatic growth has been observed in the Ukrainian pharmaceutical market starting from 2010 (19.7 bn UAH of retail sales and 3.5 bn UAH of hospital procurement) till 2017 (61.2 bn UAH of retail sales and 3.5 bn UAH of hospital procurement). However, if we regard drug sales in terms of mln packages, there was a decrease in both retail and hospital procurement reaching the lowest point in 2016. Drug sales have a positive trend and slightly get the pre-crisis level. As to the drug sales structure in money terms, share of

retail sales increased by 4% in 2012 compared to 2007, and by 2% during the following 5 years. The share of hospital procurement decreased respectively (see Figure 6) [46].

Considering the results of three quarters of 2017, the annual growth of prescription drugs<sup>10</sup> retail sales is higher than of OTCs<sup>11</sup> in both in real and monetary terms, which contributes to the further shift of the consumption structure (see Figure 7) [45].

Thus in real terms prescription drugs sales amounted to 38.5% in 2017 (shift from 36.7% in 2016) in overall structure of retail sales. In monetary terms prescription drugs sales amounted to 59% in 2017 (shift from 58% in 2016).

The annual growth retail sales in domestic and imported drugs is almost identical in monetary terms, whereas the growth of imported drugs sales in real terms was higher, which in turn led to their strengthening of their market positions.

Thus in real terms imported drugs sales amounted to 24% in 2017 (shift from 22.9% in 2016) in overall structure of retail sales. In monetary terms, imported drugs sales amounted to 57.1% in 2017 as well as in 2016 (see Figure 8).

#### *Products segmentation. Prescription drugs*

The prescription market benefits from reforms to the pharmaceutical sector aimed at increasing access to medicines and improved use of funds. According to BMI, this will manifest in robust growth over the forecast period, driven by growth in demand for generic medicines.

Prescription drugs accounted for 63.4% of total drug sales in 2016, amounting to UAH 37.2 bn (USD 1.45 b). According to expectations, prescription drug sales will grow at a compound annual growth rate (CAGR) of 13.3% in local currency terms and 10.0% in US dollar terms to a value of UAH 69.4 bn (USD 2.33 b) by 2021. Over a 10-year forecast period, it is expected that the prescription market will grow with a local currency CAGR of 11.3% and a US dollar CAGR of 9.0% to a value of UAH 108.6 bn (USD 3.45 b) by 2026. By 2026, it is expected that the prescription segment will account for 65.0% of the total drug market in value terms.

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<sup>10</sup> A pharmaceutical drug that legally requires a medical prescription to be dispensed.

<sup>11</sup> Over the counter drug is sold directly to a consumer without a prescription from a healthcare professional.

The prescription medicine market will be driven the country's planned healthcare reforms, which aim to increase the accessibility and quality of healthcare services. In April 2017, the Ministry of Health implemented its “Affordable Medicine” program of rudimentary medicine reimbursement for the most in-demand medicines, treating the most socially significant diseases: cardiovascular, type II diabetes and asthma. While this reimbursement list covers only 17 active substances for the treatment of cardiovascular diseases, 3 for bronchial asthma and 3 for type II diabetes [47], it is expected that the list will expand given more substantial reforms to the healthcare financing model. This introduction of medicine reimbursement will enable far greater access to medicines given the overwhelming reliance on out-of-pocket payments for medicines at present (about 90%).

The prescription market is expected to be dominated by generic medicines, which is amplified by the weak hryvnia making imported innovative medicines more expensive and the aim to rationalize medicine spending to enable greater access to medicines. It is expected that the successful implementation of healthcare reforms will pose upside to market growth as accessibility and affordability to basic care increases.

#### *Patented drugs*

Patented medicines are expected to continue to hold a minimal share of Ukraine's total pharmaceutical market. While the market as a whole is forecast to experience robust growth over the forecast period, innovative drug sales will underperform due to a high preference for generic drugs. Moreover, innovative drug manufacturers continue facing significant regulatory challenges including weak intellectual property protection.

Ukraine's patented drug market reached a value of UAH 7.52 bn (USD 293 m) in 2016, accounting for 12.8% of the total drug market by value. By 2021, it is expected that the innovative drug market will grow to UAH 14.21 bn (USD 477 m), with a compound annual growth rate (CAGR) of 13.6% in local currency terms and 10.3% in US dollar terms. Until 2026, according to the forecast, patented sales will increase to a value of UAH 20.56 bn (USD 653 m), accounting for 12.3% of the total drug market and reflecting a local currency CAGR of 10.6% (8.3% in US dollar terms).

The share of patented medicines in the market remains lower in Ukraine than in virtually any other Central and Eastern Europe market, largely due to lower spending power. While medicine reimbursement has been introduced in April 2017, this will have minimal impact on the patented medicine market at least in the short term given the program only covers the cheapest generic medicines for cardiovascular disease, Type II diabetes and asthma. Proposed reforms to the healthcare system, if successfully implemented, will pose upside to the market forecast given an increase in medicine accessibility, however the preference for generic medicines will remain. Moreover, it is worth to note that the progress of healthcare reform has stalled.

*Generic drugs.* Generic medicine sales will be fastest subsector of Ukraine's pharmaceutical market due to the heavy preference for these lower-value drugs. The government's healthcare reforms, including the introduction of rudimentary medicine reimbursement, will ensure sustained robust growth within the subsector as access to medicines increases.

Ukraine's generic medicine market reached a value of UAH 29.7 bn (USD 1.06 b) in 2016, accounting for 50.6% of the total drug market by value. By 2021, it is expected that the generic drug market will be worth UAH 55.2 bn (USD 1.85 b), accounting for 51.7% of the total drug market and reflecting a compound annual growth rate (CAGR) of 13.2% in local currency terms and 9.9% in US dollar terms over the five-year forecast period. According to extended forecast to 2026, generic medicine sales will grow to UAH 88.0 bn (USD 2.79 b), with a 10-year CAGR of 11.5% in local currency terms (9.2% in US dollar terms). This will account for 52.7% of the total pharmaceutical market.

Given the rapid expansion of the state healthcare budget and forecasted growth of the private healthcare market, both on account of wage hikes, medicine expenditure are estimated to grow significantly in 2017. Long-term growth will be driven by the government's reforms to healthcare, such as the proposal to move to a state-run insurance-based healthcare system. Moreover, the introduction of basic medicine reimbursement (April 2017), covering generic medicines to treat cardiovascular diseases, Type II diabetes and asthma, will further boost the generic medicine market.

These reforms, which are aimed at increasing the availability and affordability of medicines, will ensure the heavy preference for cheaper generic medicines remains in order to maximize the efficiency of expenditure.

*OTC medicines.* Wage rises create a tailwind to household consumption, allowing high levels of growth within the OTC market. However, the introduction of rudimentary medicine reimbursement for socially significant diseases results into reduction of self-medication, causing the OTC segment to lose market share.

The formal over-the-counter drug (OTC) market accounted for 36.6% of the total pharmaceutical market at consumer prices in 2016, or UAH 21.5 bn (USD 836 m). By 2021, it is expected that the OTC drug market will be worth UAH 37.3 bn (USD 1.25 bn), accounting for 35.0% of the total drug market and representing a compound annual growth rate (CAGR) of 11.7% in local currency terms and of 8.5% in US dollar terms. Until 2026, it is expected that the sector will post a CAGR of 10.5% in local currency terms and 8.3% in US dollar terms, reaching a value of UAH 58.4 bn (USD 1.85 bn). By this point, its share of the total market will have decreased to 35.0 % of the total pharmaceutical market.

The OTC market experiences robust growth due to the strong outlook for household consumption, the key driver of economic growth. Long-term growth will be outpaced by prescription medicine growth as government reforms are introduced that will increase the accessibility to healthcare services and therefore lower self-medication, such as the 'Affordable Medicines' program of reimbursement for drugs treating cardiovascular diseases, Type II diabetes and asthma. Indeed, available data for this program has indicated a significant uptick in consumption of the reimbursed medicines. Although the growth of the market appears high, this will be driven by inflationary pressures, with growth in real terms forecast to remain in the mid-single digits to 2026.

The structure of pharmaceutical sales on Ukrainian market is represented in Figure 9.

*Trade of pharmaceuticals.* Domestic medicine production is limited on both quality and quantity in Ukraine. The market is therefore expected to remain highly

reliant on imported pharmaceuticals irrespective of the weakness of the hryvnia. Exports is expected to remain minimal, although they will increase in competitiveness with the weak currency.

*Export and import.* Pharmaceutical imports reached UAH 32.6 bn (USD 1.27 b) in 2016, posting a local currency y-o-y increase of 12.5%. Top import directions in Ukraine in 2017 were Germany, India, France, Italy, Hungary, United Kingdom, Austria, Slovenia, Spain and USA (see Figure 10). According to the forecast, pharmaceutical imports will grow over the next three years at a compound annual growth rate (CAGR) of 13.5% in local currency terms and by 10.2% in US dollar terms to UAH 61.5 bn (USD 2.07 b) by 2021.

Pharmaceutical exports were worth UAH 3.43 bn (USD 134 m) in 2016 and are forecast to increase by 6.8% in local currency terms to UAH 3.67 bn (USD 139 m) in 2017. In 2017, top export directions from Ukraine were Uzbekistan, Russia, Kazakhstan, Belarus, Moldova, Azerbaijan, Georgia, Vietnam, Kyrgyzstan, and Latvia (see Figure 11). According to the forecast, pharmaceutical exports will grow at a CAGR of 9.8% in local currency and 6.6% in US dollar terms over the next five years to UAH 5.48 bn (USD 184mn) by 2021. The negative trade balance will therefore grow from UAH 29.2 bn (USD 1.14 b) in 2016 to UAH 56.0 bn (USD 1.88 b) by 2021.

The weakness of the hryvnia has had a profound impact on both imports and exports in recent years. Export growth — in local currency terms — has been boosted by the currency's depreciation; however, this disguises the fundamentals of Ukrainian pharmaceutical manufacturing. There is little demand for Ukrainian-made medicines given the relatively underdeveloped domestic industry's paucity of GMP-certified facilities. Nevertheless, the hryvnia will boost export competitiveness.

Despite the currency making pharmaceutical imports more expensive, Ukraine will remain reliant on foreign-manufactured drugs for the majority of its demand. The outlook for imports will be boosted by the relaxation on medicine registration for medicines approved by the authorized agencies in the US, Switzerland, Japan, Australia, Canada and the EU. This change has shortened the registration requirements for such medicines and should allow for approval in just 10 days. The Ministry of

Health announced a ban of Russian-made medicines in April 2017 due to the conflict between the two countries. Russia will reportedly lose some USD 30 mln through this sanction. According to the Ministry of Health, this will not have an impact on Ukrainian patients as almost every medicine that will be banned (187 of 12,877 registered as of March 2017) has an analogue registered on the market. Imports are therefore likely to be minimally impacted.

### 3.2. Economic analysis of Ukrainian market of pharmaceutical products

*SWOT analysis.* A simplified SWOT analysis of the Ukrainian pharmaceutical industry would depict the following features:

#### *Strengths*

- Ageing population and epidemiological profile to sustain demand for innovative pharmaceuticals.
- Large absolute market and population size.
- Market relatively fragmented, offering low barriers to entry.

#### *Weaknesses*

- Ukraine's per capita drug spending is very low, even compared to other Central and Eastern Europe states.
- The pharmaceutical regulatory system is cumbersome, changes rapidly and drug tender procedures to supply state institutions lack transparency and efficiency.
- Domestic patent law remains far below international standards, particularly concerning enforcement by the police and courts.
- Reliance of the market on out-of-pocket spending limits market opportunity largely to generics and over-the-counter medicines.



### *Opportunities*

- Approved widespread health reforms pose significant upside to healthcare accessibility.
- The demand for low cost generic drugs should increase due to low spending capacity and pent-up demand for affordable treatments.
- Considerable unmet demand for modern treatments will remain for the near future, creating ongoing opportunities for multinationals to launch new products.
- World Trading Organization accession and new reform agenda has led to the removal of tariffs on pharmaceuticals, lessened regulatory load on multinationals and added opportunities for importers.

### *Threats*

- The overburdened and corrupt judiciary system and a lack of effective policing of the sector will continue to prevent the enforcement of patent laws on the ground.
- Continued uncertainty about the implementation of reforms.
- The lack of competitiveness of the local industry could lead to new forms of discrimination against imports and undermine progress on intellectual property.
- Geopolitical tension with Russia threatens civil stability.
- Foreign direct investment to remain subdued in relation to other comparable markets, because of protectionist measures and similar factors.

Ukraine's low per capita pharmaceutical expenditure limits the opportunities for innovative drug manufacturers. Economic and political risks are high, dissuading foreign investment, while the regulatory environment is also highly challenging.

*Industry rewards:* The large size of Ukraine's population bolsters the opportunities for drug manufacturers. Ukraine's pharmaceutical expenditure on a per capita basis is amongst the lowest in the Central and Eastern European (CEE) region, reflecting minimal demand for high-value medicines. Given this underdevelopment of

the market, with increased access to healthcare services for the population, Ukraine has the potential for substantial growth over the coming years.

*Country Rewards:* The degree of urbanization amongst country's population is low which results in weak access to high-quality healthcare services. Moreover, the population size is set to fall considerably over the coming years, leading to a negative impact on medicine demand. Posing upside potential to drug manufacturers' opportunity is the relatively high age of the population, which directly correlates to increased demand for chronic disease drugs.

*Industry Risks:* While the regulatory environment has undergone significant change in recent years and months, notably with the introduction of state regulation of drug prices and medicine reimbursement, regulatory oversight remains minimal. Corruption is rife, particularly within healthcare procurement, and intellectual property enforcement is weak.

*Country Risks:* The conflict in the Donbass region has intensified in recent months between Ukrainian forces and pro-Russian separatists, despite renewed calls to fully implement the Minsk II ceasefire agreement. Moreover, public approval of the government will remain low as the governing coalition continues to implement unpopular structural reforms. From an economic standpoint, the conflict will continue to weigh on exports, widening the current account deficit. The parliamentary approval of pension reforms will increase the likelihood for the next IMF bailout disbursement, which will boost economic activity and investor sentiment.

### 3.3. Competition on the Ukrainian pharmaceutical market

The Ukrainian pharmaceutical market is highly competitive, with market share dispersed among a large group of multinational and domestic companies. Local companies such as Farmak and Darnitsa still account for around two-thirds of market by volume due to their low-cost, familiar brands. Most Ukrainian firms are based in

the capital, Kyiv, as well as some large regional cities such as Lviv, Kharkiv, Odessa (see Figure 12). Local companies tend to produce generic medicines, branded generic drugs and vitamins. At the same time, around 600 foreign companies are currently present in the market, the majority of which are marketing generic and OTC medicines. Foreign drug manufacturers continue to dominate Ukraine's drug market in value terms.

There were 115 licensed manufacturers as of March 2018, in comparison to 770 pharmaceutical companies in existence in 2006, around a quarter of which were Ukrainian. The weakness of the domestic production sector led to the closure of 35 plants in 2011, according to statistics from the State Medicines Agency, which attributed the closures to harmonization with EU production requirements. Domestic production mainly comprises low-cost generic and branded generic drugs and vitamins. Production standards are low compared to the West, but they are slowly starting to improve.

Leading companies include Farmak, Darnytsa pharmaceutical factory, Kyiv Vitamin Factory, Corporation Arterium, Borshchahivskiy Chemical and Pharmaceutical Plant (see Figure 13). The production sector has been privatized almost completely, with most changes taking place in the mid to late 1990s. In many cases, ownership was transferred to employees through voucher privatization. Some companies remain under state control — in particular, those that supply drugs such as insulin and vaccines to the state healthcare system. Generally speaking, the government plays a minimal role outside of the research sector, where so-called NII scientific-research institutes remain important, despite harsh funding constraints.

The rise in import demand over the past five years has attracted leading firms from Eastern Europe as well as Indian companies such as Ranbaxy (now part of Daiichi-Sankyo).

The Ukrainian pharmaceutical market has presented limited benefits to research-based, multinational drug manufacturers; given that drug purchases are overwhelmingly driven by consumer demand, there has not been a large market for patented drugs, which are the sales and profit drivers of innovative companies.

Furthermore, expensive, innovative drugs are often sold to hospitals and other state institutions at procurement offerings. With the Ukrainian government experiencing severe budgetary shortfalls and shifting funding from healthcare and social spending towards defence, the market for innovative drugs is expected to shrink even further in the short term, with distressed consumers unable to purchase expensive medicines out-of-pocket.

Nevertheless, many large multinationals have deepened their presence in Ukraine beyond just establishing a sales office in the country. Roche has entered into a joint venture with Lumier Pharma, a domestic pharmaceutical manufacturer, enabling the Ukrainian company to manufacture *MabThera* (rituximab) and *Herceptin* (trastuzumab) in Ukraine. Farmak has a multi-year agreement with Eli Lilly for the production of recombinant insulin.

Table 2. Multinational activity on Ukrainian market

Company	Operations
Novartis	Multinational drugmaker Novartis is one of the leading global manufacturers of innovative medicines, eye-care products, generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. The company was created in 1996 through the merger of Ciba-Geigy and Sandoz [25].
Pfizer	Following a change of CEO in late 2010, Pfizer has re-focused on original R&D, which is a sound long-term change of strategic direction. The company faces numerous near-term challenges, notably the loss of patent protection for the mega-blockbuster Lipitor in developed states. Pfizer is also de-diversifying its business operation [27].
Roche	Roche has two core businesses: pharmaceuticals and diagnostics. Within its pharmaceuticals business, Roche focuses on five therapeutic areas: oncology, virology, inflammation, metabolic disorders and central nervous system. Roche's diagnostics product

Company	Operations
	line caters to patients and scientific and clinical researchers. Roche continues to demonstrate the success of its oncology franchise protection strategy, supporting our view that it should retain its leadership position in the field [34].
Sanofi	Sanofi offers vaccines, which gives it an advantage in emerging markets, such as Ukraine. In March 2009, Sanofi-Aventis completed its takeover of Czech Zentiva, which has an established position in the Ukrainian market. In June 2009, the French drugmaker launched a limited liability company subsidiary in Ukraine, increasing its market footprint and allowing it greater scope to market directly to healthcare professionals [35].
Merck & Co	Established as an independent company in 1917, US-based Merck & Co focuses on prescription drugs, consumer health medicines and animal care products. The firm conducts research in a range of therapeutic categories such as cardiovascular, infectious diseases, vaccines, cancer, neurology and women's health. Despite a lower R&D expenditure of USD 8 bn forecast for 2011, CEO of Merck & Co Kenneth Frazier stated that developing the company's pipeline would be essential to bring the firm forward [23].
Johnson & Johnson	Johnson & Johnson's products are manufactured in Europe and the US, and are sold to officially appointed distributors and hospitals [20].
GlaxoSmithKline	GlaxoSmithKline first entered Ukraine in 1994 by opening a representative office in Odessa (as Glaxo). In the following year, a Kyiv-based Wellcome office partnered Glaxo to become GlaxoWellcome. In 2001, following the global merger with SmithKlineBeecham (which was also independently present in

Company	Operations
	Ukraine), the local GlaxoSmithKline operations merged in the Kyiv office [19].
AstraZeneca	AstraZeneca is facing a steep drop in sales in coming years. Its priorities include geographic expansion; creating a product portfolio suited to emerging markets; and enhancing productivity via the divestment of non-core business operations and restructuring activities [5].
Takeda	Takeda redefined its corporate strategy in early May 2012, in conjunction with the release of its financial results for fiscal 2011. Under its 2012-14 Mid-Range Plan, entitled 'Transformation into a new Takeda', the company will consolidate its global position through integrating its recent acquisitions Nycomed and URL Pharma, which give it increased presence in Europe/ emerging markets and the US, respectively [39].
AbbVie	AbbVie generates revenues mainly through the sale of pharmaceutical products. These products are targeted at some of the most complex and serious diseases. The company has a strong portfolio of drugs such as Humira, Imbruvica, Viekira Pak, Creon, Synagis, Lupron, Synthroid, Kaletra, AndroGel, Sevoflurane, Duodopa and dyslipidemia products [2].

*Generic drug manufacturers.* Given that the Ukrainian pharmaceutical market is dominated in volume and value terms by generic drugs, the country has attracted numerous generic drug manufacturers from abroad as well as supporting expansion of the domestic industry. Local companies tend to produce generic medicines, branded generic drugs and vitamins. These firms still account for around two-thirds of market by volume due to their low-cost, familiar brands. Most Ukrainian firms are based in the capital, Kyiv, as well as some large regional cities such as Lviv, Kharkiv, Odessa. Around a quarter of pharmaceutical companies in Ukraine are domestic.

Large, multinational generic companies with a presence in Ukraine include Stada, Gedeon Richter, Egis, Teva, Krka and Novartis. Indian generic drug manufacturers are also present in the Ukrainian market. Ranbaxy gained additional exposure to the Ukrainian market through its acquisition of Romanian generic drugs maker Terapia in mid-2006. Indian firm Dr Reddy's has previously identified Ukraine, along with Kazakhstan, as one of its fastest growing markets in the Commonwealth of Independent States.

Despite Ukraine's large pharmaceutical market, many foreign generic drug manufacturers have held off establishing manufacturing facilities in the country, as seen in Russia. Given the fragmented nature of the Ukrainian pharmaceutical market, entry barriers for foreign generic drug manufacturers are low, and thus importing medicines has been the preferred method for delivering pharmaceuticals to consumers in Ukraine.

*Pharmaceutical distribution.* The private sector has taken the lead in modernizing the retail sector, with modern pharmacy chains and so-called “pharmacy supermarkets” emerging in larger cities alongside developing hypermarket and supermarket chains.

Smaller players continue to hold on in the regions, and the government is loath to put cheaper producers out of business given the political repercussions involved. Therefore, the wholesale market in Ukraine is still perhaps the most fragmented and opaque of the major Central and Eastern Europe pharmaceutical markets. Nonetheless, a number of market leaders have emerged, such as BaDM and VVS Ltd, possessing their own warehouse complexes and sales presence in all or most of the country's 27 administrative regions.

Most pharmaceuticals are distributed to state-run or private pharmacies and hospitals via wholesalers, although some are supplied directly from manufacturers. Among large distributors are Optima-Farm, Alba Ukraine, BaDM, VVS, Fra-M, Artur-K, Aptechny Holding, Falbi, Venta and Medfarkom.

It is anticipated that the sector will consolidate further, although Ukraine's business environment promotes an unusual degree of regionalism and the continued

existence of a fractured retail market, which will probably deter larger international distributors from establishing a major presence in Ukraine for the near future [8].

Considering the results of the three quarters of 2017, five biggest distributors account for 85.3% of the drugs wholesale supply in monetary terms. At the same time three biggest distributors, namely BaDm, Optima-Farm and Venta, account for 78.8% supplies [45].

*Retail sector.* By law, only pharmacies and kiosks can sell prescription drugs; outlets are only permitted to sell over-the-counter drugs (OTCs). Ukraine currently permits both manufacturers and wholesalers to operate retail pharmacies and many distributors have a retail presence.

In December 2011, the Ministry of Health's order No. 723 came into force. The order banned the distance selling of prescription drugs. Rural areas and areas without access to a pharmacy are an exception. In these areas, trained medical personnel can sell prescription drugs in hospitals and clinics.

Altogether, 6,419 businesses are engaged in the trading of pharmaceuticals. Private pharmacies prefer to obtain foreign drugs that can be sold with a high mark-up, earning the store better commission. Additionally, foreign drugs are more exposed to the consumer through advertising campaigns and consequently more popular with the general public.

On the other hand, around 20-30% of pharmacies are publicly owned (by municipal and state authorities). State-run pharmacies are largely stocked with well-known and inexpensive locally manufactured brands and those from Eastern Europe. Many doctors trained under the old system are familiar with those drugs and continue prescribing them. Additionally, in the face of rapidly rising medicine costs, many regions and municipalities have been looking to expand or launch so-called 'social pharmacies', which stock essential medicines and charge little or no mark-up [8].



## CONCLUSIONS

Based on the conducted analysis the following features of the pharmaceutical market may be regarded as significant:

The global pharmaceutical market benefits from growing volumes sales, but this upside is partially offset by pricing pressure. Innovative medicine costs are increasingly scrutinized by payers, and the low-end sector becomes commoditized.

Companies operating at the pharmaceuticals market mainly generate value at the drug development stage, primary manufacturing level and the detailing stage. These stages involve the work of highly skilled and educated individuals, require significant funding and are characterized by higher risk.

Innovative pharmaceutical companies will be making more concessions to governments, health systems and large payers in emerging markets. As in developed states, these stakeholders have limited budgets but also want to widen access to the latest treatments.

Growth of the market in the developed countries is slowing down, while pharmaceutical companies that have a strong presence in emerging markets have a better position in maintaining high revenue streams. Emerging markets, on the other hand are more risky in terms of industry specific concerns, frequently changing regulations and macroeconomic situation as a whole.

Overall sales on the Ukrainian market demonstrated moderate growth in 2017, which was partly caused by the hryvnia`s stabilization. The expected growth (1.9%) in USD is, however, lower than in other European countries. Economic and political risks are high, dissuading foreign investment, while the regulatory environment is also highly challenging.

Ukrainian pharmaceutical industry is subject to government regulation, in particular with regard to pricing, reimbursements, quality control, registration procedure and advertising of pharmaceuticals.

Considering sales structure on Ukrainian market, a shift was seen toward imported prescription drugs. However, overall, sales in the low-priced OTC drugs prevail.

The Ukrainian pharmaceutical market is highly competitive, with market share dispersed among a large group of multinational and domestic companies, where several manufacturers and distributors account for the biggest market share.

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# ANNEXES

## Annex A

### SUMMARY

Hrabovska O.V. Economic analysis of international and national market of pharmaceutical products — Masters-level Qualification Thesis. Sumy State University, Sumy, 2018.

The master's thesis focuses on the analysis of the global and Ukrainian market of pharmaceutical products. It examines the current situation on the market, its risks and benefits, the main driving forces and the main players on the market. The main aim of this study is to conduct the market analysis for an international company.

Keywords: market of pharmaceutical products, economic analysis, the five forces, SWOT analysis, competition, supply chain, generic drugs, patented drugs, OTC drugs, market volume, trade of pharmaceuticals.

### АНОТАЦІЯ

Грабовська О.В. Економічний аналіз міжнародного та національного ринку фармацевтичної продукції. — Кваліфікаційна магістерська робота. Сумський державний університет, Суми, 2018 р.

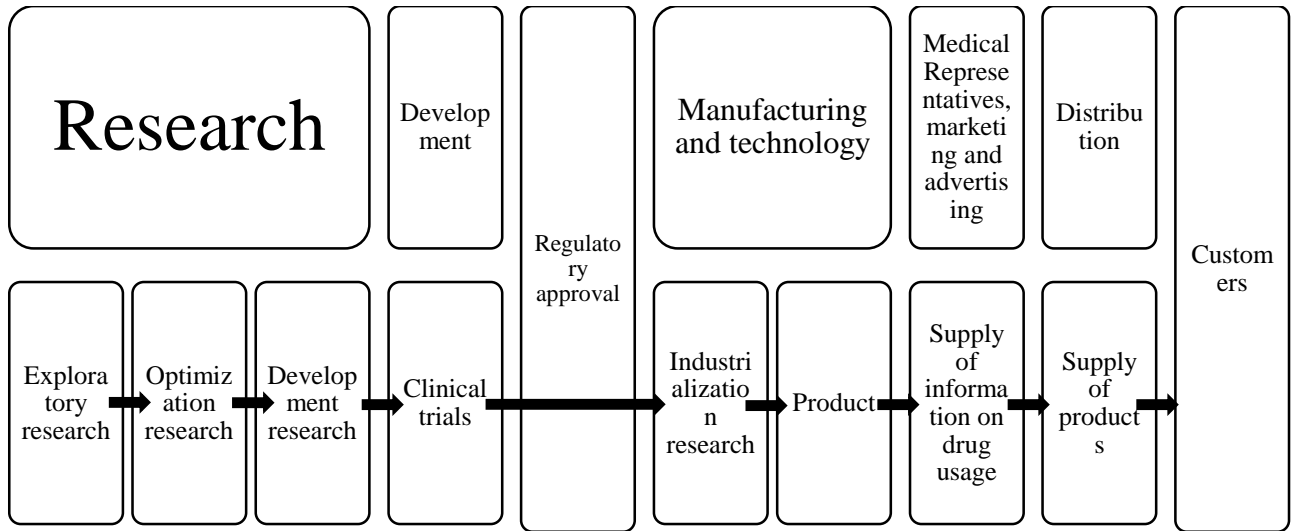
Магістерська робота присвячена аналізу глобального та українського ринку фармацевтичної продукції. Вона аналізує поточну ситуацію на ринку, ризики та переваги, основні рушійні сили та основних гравців на ринку. Головна мета цього дослідження — провести аналіз ринку для міжнародної компанії.

Ключові слова: ринок фармацевтичних продуктів, економічний аналіз, п'ять сил, аналіз SWOT, конкуренція, ланцюжок постачань, генеричні препарати, запатентовані препарати, позабіржові препарати, обсяг ринку, торгівля фармацевтичними препаратами.



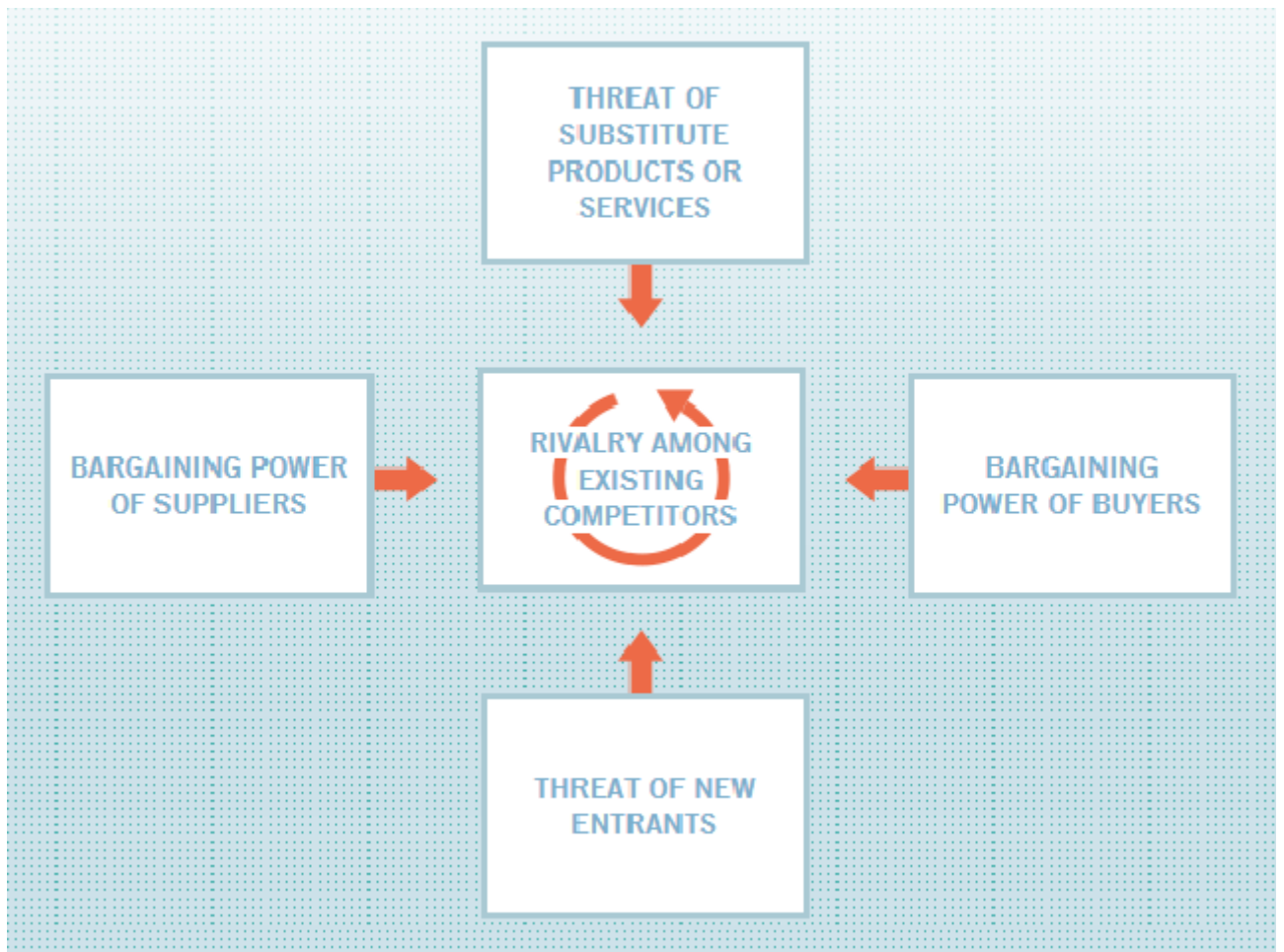
Annex B

Figure 1. Pharmaceutical value chain



Source: [8].

Figure 2. The Five Forces



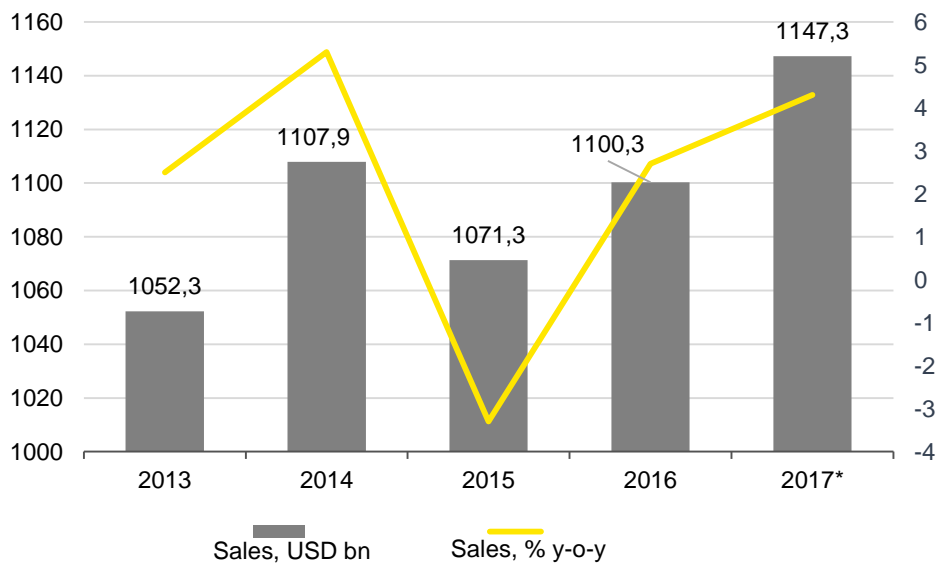
Source: [42].

Figure 3. Top 10 pharmaceutical companies in 2017



Source: [29].

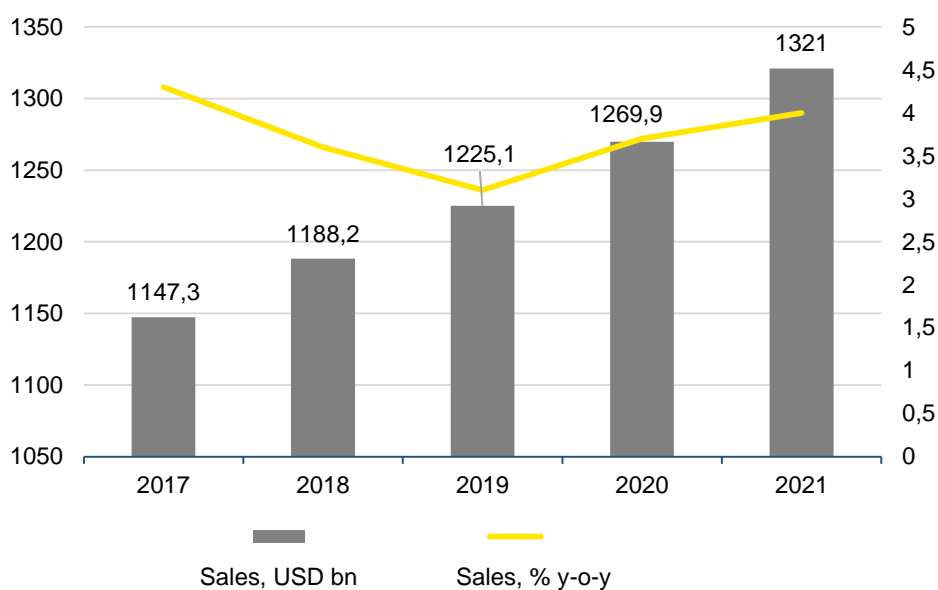
Figure 4. Pharmaceutical sales dynamics



\* — estimated value

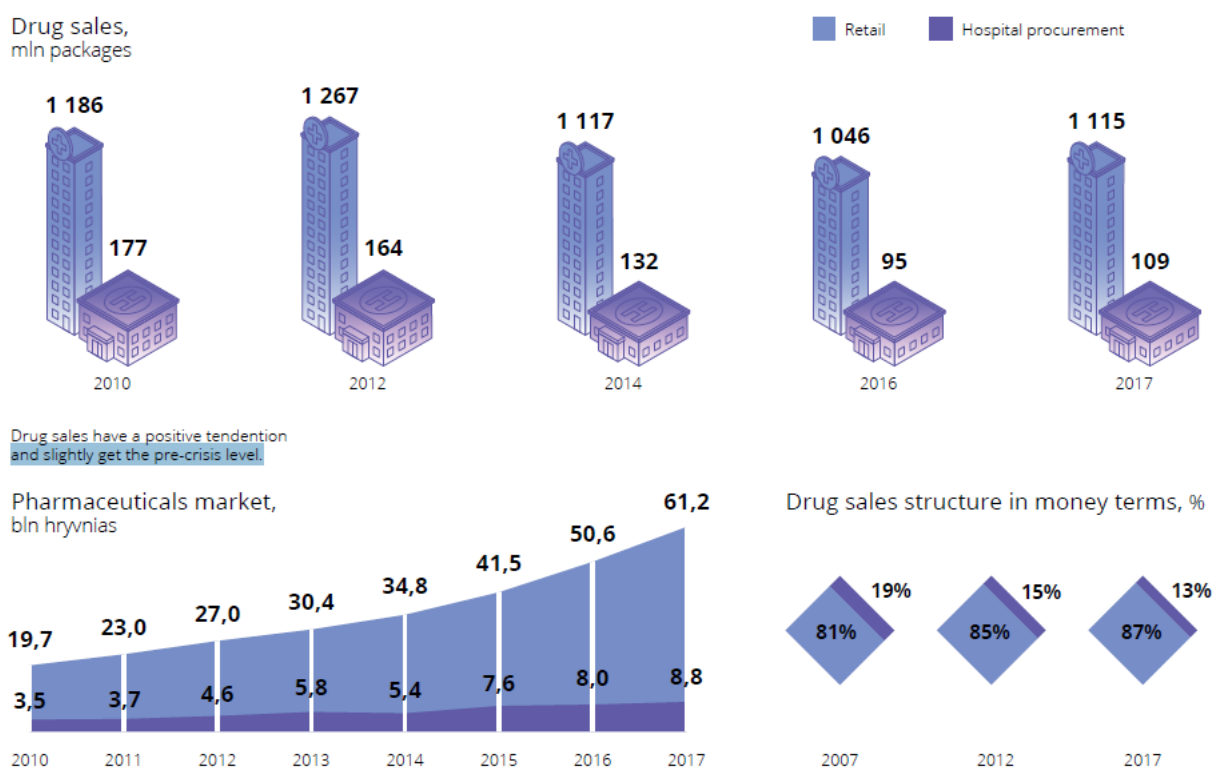
Source: [8].

Figure 1. Global market outlook



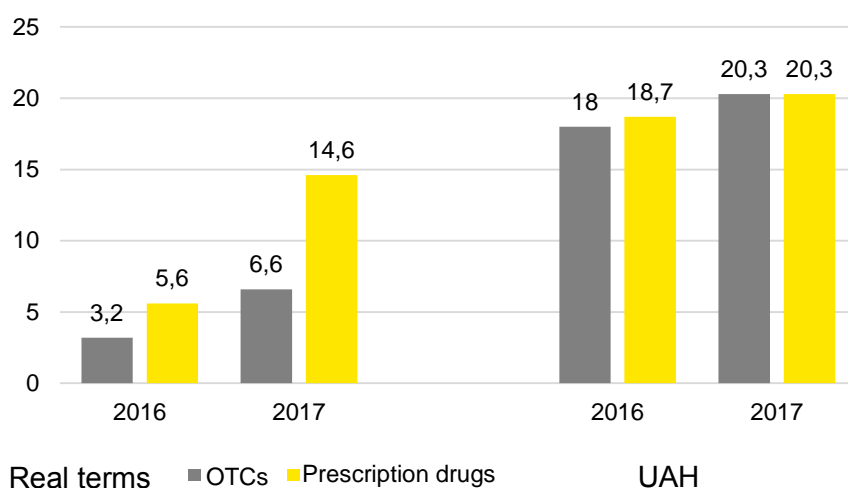
Source: [8].

Figure 6. Ukrainian pharmacy market dynamics



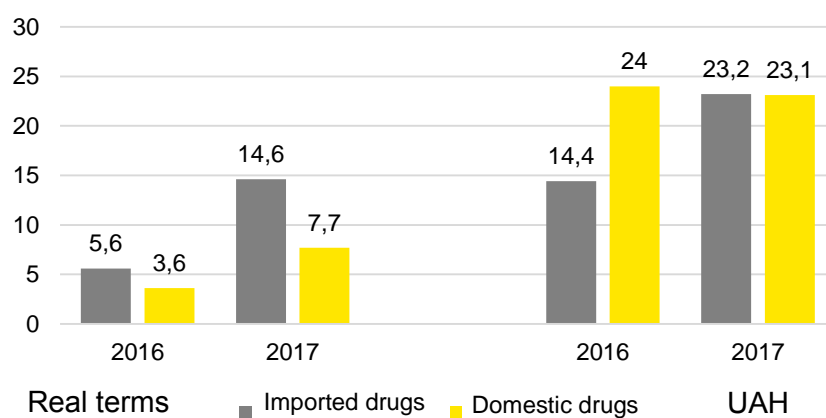
Source: [46].

Figure 7. Annual growth of retail sales in prescription and OTC sales, %



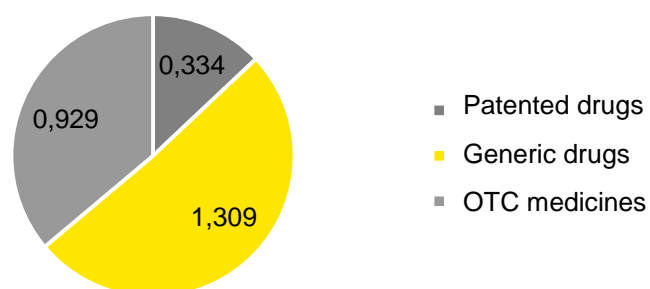
Source: [8].

Figure 8. Annual growth of retail sales in imported and domestic drugs, %



Source: [8].

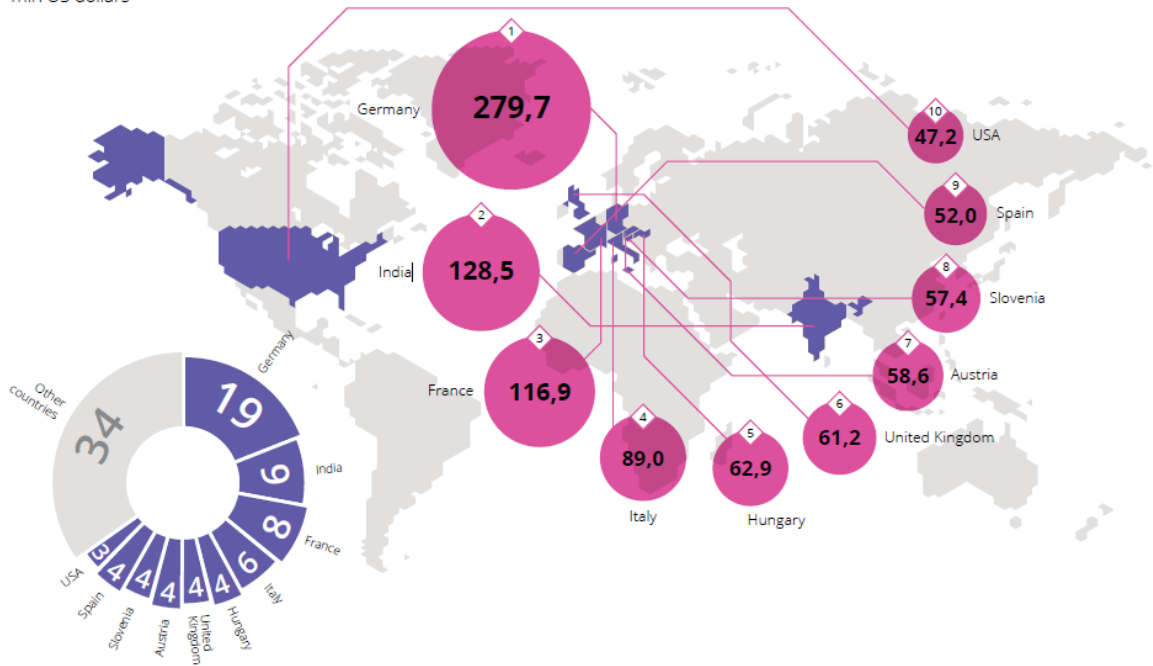
Figure 9. Structure of Ukrainian pharmaceutical market 2018, USD bn



Source: [8].

Figure 10. Drug import in Ukraine

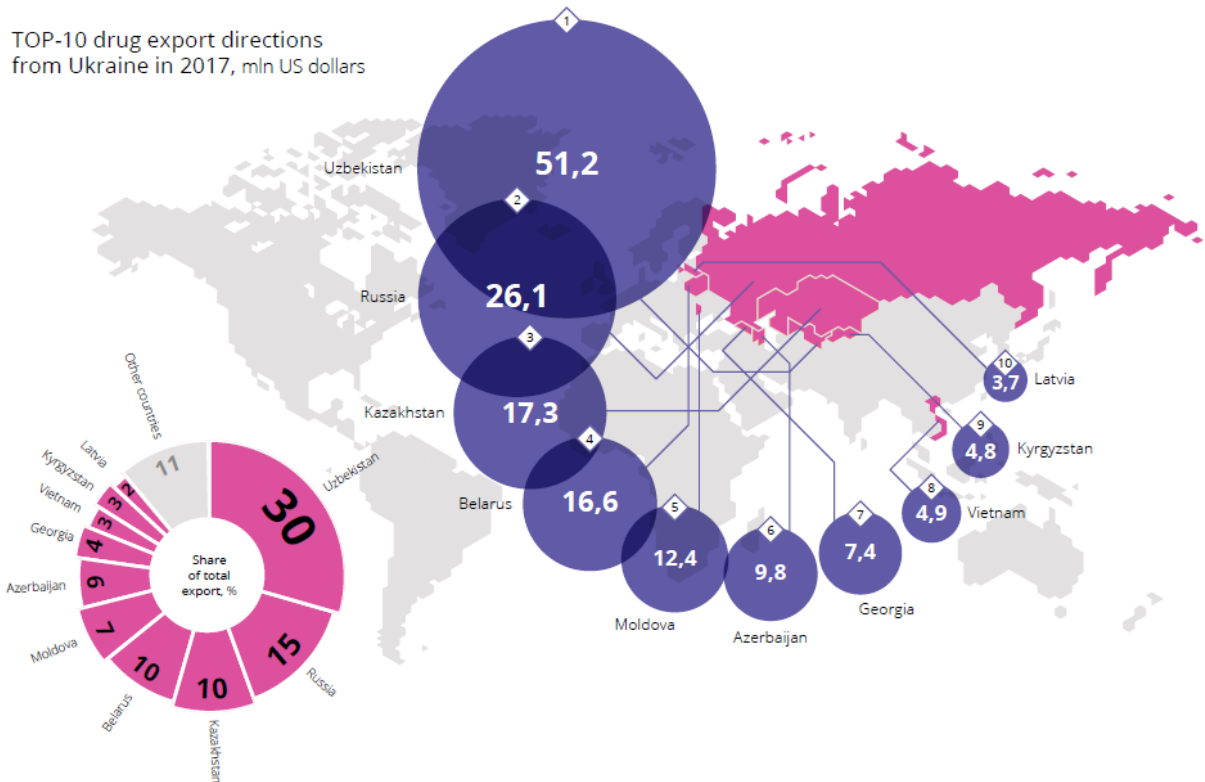
TOP-10 drug import directions in Ukraine in 2017, mln US dollars



Source: [46].

Figure 11. Drug export from Ukraine

TOP-10 drug export directions from Ukraine in 2017, mln US dollars



Source: [46].

Figure 12. Pharmaceutical manufacturers of Ukraine

Regional breakdown of pharmaceutical manufacturers as of March 2018

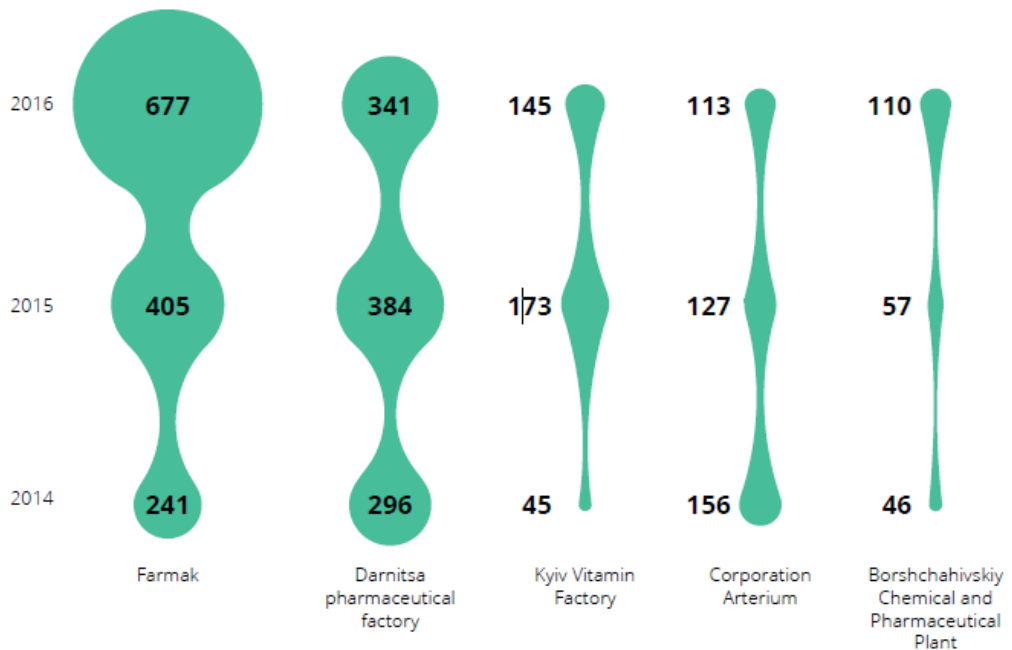
★ — one entity



Source: [46].

Figure 13. Leading companies

Leaders among joint-stock companies by revenue, mln hryvnias



Source: [46].