UNIVERSITY OF LJUBLJANA
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MASTER'S THESIS

AN ANALYSIS OF ENTERING THE KAZAKHSTAN PHARMACEUTICAL MARKET: THE CASE OF ALKALOID

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INTRODUCTION

This thesis presents and elaborates the case of Alkaloid AD, Skopje, a successfully internationalised company with headquarters in Macedonia, and its expansion into a foreign market. The **focus** of my master's thesis "An analysis of entering the Kazakhstan pharmaceutical market: the case of Alkaloid" is to place the Macedonian company in the pharmaceutical market of Kazakhstan. The thesis primarily aligns two crucial points: analysis of the target market and the intentions of the company.

Among many authors, Welch and Luostarinen (1988, p. 36) define the term internationalisation as: "process of business activities across home country borders with an increasing degree in operations". The company engages in the process of internationalisation only with a previously developed strategy (Christofor & Kollmann, 2008, p. 24). The motives that force the company to internationalise vary a lot. Some companies seek new markets and customers, efficiency, natural resources and etc. Other companies decide to engage in the process of internationalisation due to saturation of the domestic market or in effort to survive by internationalising their activities. Nonetheless, all companies try to increase their profit (Czinkota, Ronkainen, & Buonafina, 2004; Morschett, Klein, & Zentes, 2009). Also, the motives are determined by internal (company-specific) or external (environmental) factors or a combination of these two (Korsakienė & Tvaronavičienė, 2012, p. 298).

The pharmaceutical industry plays a substantial role with its numerous drug innovations that offer cure to different types of medical conditions. Supplementary effects of the industry are employment provisions and huge revenues for the economy on a global scale (Craig & Malek, 1995, p. 302). It is a specific type of industry, highly dependent on patents, trade secrets and test data protection (Watal, 2012, p. 2). In contrast to other industries, the pharmaceutical industry is highly controlled by regulators. Companies can get market approvals and therefore place their products on the target market, only after they fulfill all the requirements set by the official institutions (Heimler, 2001).

The pharmaceutical market of Kazakhstan includes very attractive features. It has a favorable regulatory environment and from a legislative point of view, it stands to be the most transparent, progressive and accessible in Central Asia (Business Monitor International (hereinafter: BMI), 2013). However, the industry production itself satisfies only 15% of the domestic consumption. As a result, Kazakhstan imports as far as 85% of the total drugs consumed in the country (Savchenko, 2013). These characteristics, among other reasons, make the market of Kazakhstan interesting for foreign companies.

Alkaloid AD, Skopje is the largest pharmaceutical company in Macedonia and one of the biggest on the Balkans. It is an export oriented company with a stable market position open to new markets and partnerships. The most recent data indicate that the company exports over 70% of its production (Alkaloid AD - Consolidated Performance Report, 2013). The company is in the process of penetrating the Kazakhstan pharmaceutical market and getting market approvals for their drugs (Alkaloid AD - News, 2013).

The **purpose** of the research of this thesis is to outline the best possible and successful model for Alkaloid AD to expand into the Kazakhstan pharmaceutical market, through considering the circumstances of the process of internationalisation. It provides theoretical knowledge to the company for its expansion into the new market. The aim is to present the pharmaceutical market of Kazakhstan and the fitting strategy of Alkaloid AD for the target market, which finally results with development of market entry strategy.

Hence, the **research questions** that surface from the purpose are the following: How does Alkaloid AD generally develop the process of internationalisation? Does the company follow a specific pattern of internationalisation? What reasons does the company have for expanding into the Kazakhstan market? Do the motives arise from managerial incentives or market potential? What does the Kazakhstan market have to offer? What are its advantages? What are its impediments? What kind of business environment needs to be present in the Kazakhstan market and what is the current situation? Which entry modes does the company plan to use and how are they applied?

The research questions outline the following **hypotheses**: (**1**) The Kazakhstan pharmaceutical market offers huge potential for Alkaloid AD; (**2**) The motives of Alkaloid AD for expanding into the Kazakhstan market are presumably external (growing market) rather than internal; (**3**) Alkaloid AD is most likely to penetrate the market via joint venture (hereinafter: JV) or wholly owned subsidiary (hereinafter: WOS) entry mode rather than export.

The main **goals** of this thesis are to identify the Kazakhstan market and the sales potential of its pharmaceutical market and how and/or why the company chooses certain entry modes. Furthermore, there are several analyses carried out to determine the business environment of Kazakhstan and its market characteristics. Understanding the market characteristics of Kazakhstan, its business practices and market concepts help to form the theoretical framework for market entry mode proposals.

The **research methodology** in the thesis includes empirical and theoretical perspective. The empirical perspective of the thesis is based on qualitative analysis. The utilized analytical method for research is **in-depth interview** conducted with the Regional Operations Manager for Business Development of Alkaloid AD**,** Mrs. Tatjana Ivanoska - Filipovska. The reason for choosing this

company lies in the success that Alkaloid AD experiences as an international export-oriented company, even though it originates from a developing country. On the other hand, the selection of the market was agreed with the management of the company. As mentioned, the most valuable information is obtained through method of qualitative research (in-depth interview) which is considered most suitable for comprehensive understanding of the research problem, especially when conducting a case study. This helps in finding answers to questions like **how** and **why**, something which is not possible by using other analytical methods (Lewis, Saunders, & Thornhill, 2009, pp. 145-147).

The theoretical perspective of the thesis is based on collection and analysis of the literature on the topic of the thesis. Also, the data presented and analysed throughout the thesis is gathered from reliable sources such are: scientific journals, annual reports, official web-sites and independent providers of proprietary data, including BMI. The secondary data and sources of information are used in order to build theoretical framework that helps in finding clues and taking decisions.

The testing of the hypotheses and the proposal for market entry strategies are based on the empirical findings and theoretical research.

The thesis is structured in the following order: introduction, theoretical part, empirical research with discussion and conclusion. In the **introduction**, the point of the paper is explicitly outlined supplemented by the purpose of the thesis, developed hypotheses and its objectives. It also includes the applied methodology. The theoretical part is divided into five chapters. The **first chapter** discusses the process of internationalisation of companies. It also encompasses the motives, strategies and market entry modes, applied both theoretically and practically. The **second chapter** elaborates the global pharmaceutical industry. It deals with several aspects of the industry, including its characteristics and structure, regulation, pricing system, international trade and market data. The **third chapter** entitled "Doing Business in Kazakhstan" gives overview of the business environment of Kazakhstan. It presents the insides of its political and legal, economic, socio-cultural and technological environment supported by ratings and enhanced by forecasts and projections. The **fourth chapter** and by all means the most important part of the thesis provides complete picture of the Kazakhstan pharmaceutical market. It undertakes a comprehensive study on the specific industry market including market data and forecasts, industry segmentation and categorization, distribution system, regulatory regime and pricing system, drug registration process and procedures, competitive landscape and competitors' analysis, barriers and risks, as well as SWOT analysis of the target market. The **fifth chapter** presents the Alkaloid AD, Skopje through its brief history, illustration of the structure of the company and report on the most important data for the thesis. The empirical research begins from **chapter six** throughout **chapter seven**. This part includes the most valuable information from the interview, discussing the findings in the follow-up. It also includes the tested hypotheses and the proposed market entry strategies. The final part of the paper presents the **conclusion**.

1 PROCESS OF INTERNATIONALISATION

The term internationalisation presents the geographical expansion of economic activities over the national country's border. Internationalisation as a phenomenon has been researched and largely used over the past several decades, particularly after the formation of various customs unions (hereinafter: CU) and free trade zones across the globe (Ruzzier, Hisrich, & Antoncic, 2006, p. 477). There are numerous definitions of internationalisation from various authors. Ruzzier et al., (2006, p. 479) summarize some of them as follows:

- internationalisation is the outward movement of a company's international operations;
- internationalisation is the process of increasing involvement in international operations;
- internationalisation is the process of adapting company's operations (strategy, structure, resources, etc.) to international environments;
- internationalisation as a cumulative process in which relationships are continually established, developed, maintained and dissolved in order to achieve the company's objectives;
- internationalisation as developing networks of business relationships in other countries through extension, penetration and integration;
- internationalisation concerns the relationships between the company and its international environment; its origin derives from the development and utilization process of the personnel's cognitive and attitudinal readiness and it is concretely manifested in the development and utilization process of different international activities, primarily inward, outward and cooperative operations;
- internationalisation is the process of mobilizing, accumulating and developing resource stocks for international activities.

1.1 International Business Theories of Company Internationalisation

1.1.1 Monopolistic advantage theory

Most of the credits for this theory go to Hymer (1976). The foundation of this theory is basically exploitation of advantages. In this case the multinational company (hereinafter: MNC) possesses excessive abilities and unique sources of predominance that other companies cannot afford. The company also has superior knowledge and other capabilities like exceptionally developed organizational system, high technology, remarkable production processes, brand name and etc. Therefore, the local competitors find themselves in unenviable position lacking of sufficient knowledge and other crucial skills, capabilities and resources. However, the author states that this situation predominantly occurs in underdeveloped countries (Hymer, 1976).

1.1.2 Internalisation theory and the transaction cost approach

The internalisation theory was founded by Buckley and Casson (1976). It emerges when companies strive to develop their own internal markets where the transactions are made at lower costs. Meanwhile, the companies continuously use the benefits of internalisation and vertical integrations. The company vertically integrates its operations and activities (previously done by intermediates) when the markets are imperfect. According to Williamson (1975, pp. 29-30), internal organization enjoys significant advantages over the market. This vertical organization is actually a response to market failure (the inability to allocate the resources efficiently). Williamson (1981, pp. 556-560) argues that the advantage of the internal organization is the ability to invoke fiat to resolve differences and better access to information. Furthermore, international transactions by means of integration and diversification turn the company into a MNC.

The transaction cost theory by Coase (1937) is very similar to the internalisation theory, where market transactions are eliminated. The only difference from the internalisation theory are the transactions and the costs associated with market transactions as the central objects of analysis (Williamson, 1975, p.4).

1.1.3 The eclectic paradigm

The theory also known as OLI was developed by Dunning in 1980s and it is a further improvement of the internalisation theory. It is a dominant analytical framework which rests on internalisation theory and encompasses the activities of MNCs, various forms of production and selection of markets for foreign direct investment (hereinafter: FDI). According to Dunning (2000), the structure of the organization is not the only important element. The OLI theory is determined by the interactions of three factors (paradigms). The first is the competitive advantage of the MNC that pursues to engage in FDI (or at least to increase it) which is the ownership-specific advantage (O). It is a result of the intangible assets (know-how, patents, trademarks, etc.), the innovative product and the high-tech that the company possesses. The second advantage is the location selection (L). It is considered that the MNC with its own competitive advantage (company-specific assets) combined with the opportunities that the optimally chosen location offers (existence of resources, low wages, tariffs and tax reliefs) makes a perfect system. The third paradigm is the internalisation advantage (I). This emerges from the possibility of the company to use its own internal market (or network) and benefit from the synergies in the value-added chain. For instance, the likelihood the company engages in foreign production rises progressively in line with the net benefit. Namely, the MNC can benefit by its own production rather than producing through partnership or licensing (Dunning, 2000).

1.2 Internationalisation Process and Export Development Models

Since 1970s, the process of internationalisation is generally known as an incremental process composed of several stages described as: increasing engagement, commitment and involvement in a foreign country. In the literature, there are various process models and each of them outlines different classification and different stage definitions. All of them discuss how a company internationalises itself. However, a model that perfectly illustrates the internationalisation process actually does not exist (Christofor & Kollmann, 2008). Therefore, what follows is a presentation and discussion on models that draw particular attention in the international business literature.

1.2.1 Uppsala model (U-model)

This model was originally developed at the University of Uppsala by Johanson and Wiedersheim-Paul (1975) on the basis of four Swedish cases. They managed to describe and empirically test the internationalisation of four Swedish companies from the steel, pulp, automotive and paper industry. Later on, the model was further extended and developed by Johanson and Vahlne (1977).

The initial assumption of Johanson and Wiedersheim-Paul (1975) is that the company first develops in the domestic market and then incrementally expands in the foreign market as a result of incremental decisions. The major obstacles to internationalisation, according to the authors, are lack of knowledge and resources. To decrease or overcome these obstacles and reduce the risk and uncertainty at the same time, the company reacts as an incremental learner. The assumption is that the company first expands to its neighboring markets due to lack of knowledge and high uncertainty the distant markets bring. Then, the company progressively modifies its entry modes from exporting to considerable involvement though subsidiaries or alliances. The step-by-step internationalisation goes though the following four stages (Johanson & Wiedersheim-Paul, 1975, p. 307):

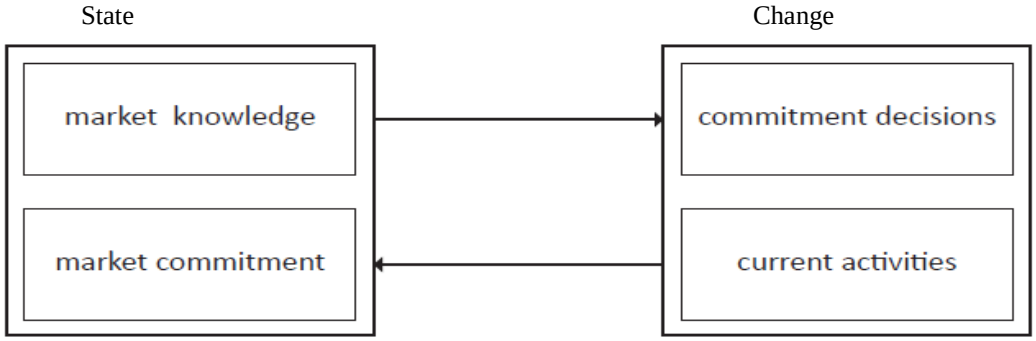
1. no regular export activities;
2. export via independent representatives (agent);
3. sales subsidiary;
4. production/manufacturing.

What all these stages have in common is the gradual process of involvement in the foreign market activities, supplemented by progressive resource commitment and market knowledge. The authors call this sequence “an establishment of chain”. Concerning the extension of foreign activities, the concepts of physic distance and market size are considered very important. Physic distance as a concept can be defined as a group of factors that prevent the flow of information between the company and the market. For instance, such factors could be language and cultural

differences, level of education, industrial development and etc. The establishment chain implies that companies should start expanding to closer markets in terms of physic distance and then move further. The size of the potential market also influences the decision of internationalisation and it is important, but not as much as the physic distance. In the Swedish case the companies are expected to start to internationalise in the smaller neighboring countries (due to their similarity), without excluding start-up internationalisation to bigger markets. The findings are in accordance with the initial assumptions of incremental internationalisation. All companies followed the establishment of chain. As far as the establishment of sales subsidiaries (extension of internationalisation) is considered, the companies employed different strategies. Two started in smaller countries and later expanded in larger countries, while the other two expanded immediately in more distant countries (Johanson & Wiedersheim-Paul, 1975).

The initial model was later extended by Johanson and Vahlne (1977) and it is based on the behavioral theory of companies. According to this model, the lack of knowledge is the main impediment of the company to operate internationally. This can only be acquired through operations abroad. As the company acquires more knowledge about the particular market, it incrementally increases its commitment to it. Visually, the model is shown in figure 1:

Figure 1. The Basic Mechanisms of Internationalisation - State and Change Aspects



Source: J. Johanson & J. E. Vahlne, *The Internationalisation Process of the Company - A Model of Knowledge Development and Increasing Foreign Market Commitments*, 1977, p. 26.

In this context, the authors introduce the state aspect (market knowledge and market commitment) and change aspects (commitment decisions and current business activities). The "market commitment" rises proportionally with the committed resources. The "market knowledge" is related to all market factors (demand and supply, distributors, competitors, regulations and etc.). More importantly, the knowledge is incrementally and personally obtained during the operations in the particular country. It is called experiential knowledge and it is considered to be critical and also to some extent transferable (in contrast to the market-specific knowledge) (Johanson & Vahlne, 1977). Namely, companies have to pursue the experiential knowledge on individual clients, markets and institutions. Therefore, this knowledge is also associated with costs. Eventually, it turns out to be a company-specific experience, significant for

all markets (Eriksson, Johanson, Majkgard, & Sharma, 1997, p. 21). Now that it can be transferred to other markets, it is considered more general knowledge of operations, whereas, the market-specific knowledge is gained only through operations in the particular market (Otto, 1993, p. 211).

The "current business" activity is related to investments. The larger the investment is (or product differentiation), the larger is the commitment to the market. The current activities are prime source of experience of the company and the market. The second change aspect is the "decision to make a commitment" and it is in accordance with the opportunities and/or the problems for taking business action. As the company strives for growth and profit, it may try to increase the scale of its operations in the market if it expects high returns (increasing market commitment). Contrary, it may try to decrease the operations if it encounters high uncertainty and risks (decreasing market commitment) (Johanson & Vahlne, 1977).

The upgraded model demonstrates the company's gradual development in the new market. It enters a foreign market through different modes and by increasing its resource commitments. While increasing the experiential knowledge, the company incrementally increases its resources: financial, human, material and etc.

1.2.2 Network model (reassessment of the Uppsala model)

Being one of the most substantial models in the international business sector, the Uppsala model was later reassessed. Bearing in mind the changes in many spheres since 1977 (behavioral, economical, environmental, regulatory, technological, etc.), it is a noteworthy reassessment. Many authors tried to evaluate and at the same time criticize the model (Andersen, 1993; Petersen, Pedersen, & Sharma, 2003). The most common criticism is that the model is too deterministic and does not give much space for strategic decision (McDougall, Shane, & Oviatt, 1994). Also, it is criticized due to the inability to measure the experiential knowledge during the international operations of the company. Further, the risk included as a variable, has no relation to the concepts of market commitment and uncertainty. It belongs in the behavioral theory and presents a pure strategic decision (Figueira-de-Lemos, Johanson, & Vahlne, 2011).

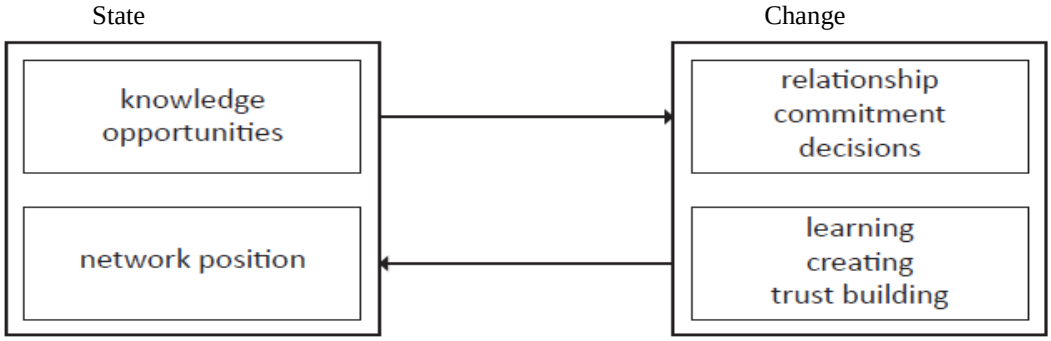
This time Johanson and Vahlne (2009) argue that the markets are networks of relationships where companies are linked to each other in different and multiplex relations through invisible patterns. Different business parties are mutually connected through direct and indirect business relationships. Hence, international businesses take place in networks with three main variables: actors, resources and activities. Eventually, inward-outward connections develop (Karlsen, Silseth, Benito, & Welch, 2003, pp. 386-387). Also, the relationships are used for learning, building trust and commitment among the companies and all relevant parties, that proves substantial in the process of internationalisation. Indeed, much of the activities included in the

internationalisation can be characterized as networks (Welch & Welch, 1996, p. 13); for instance, building commitment and trust between the companies (and the concerned parties), learning from each other, sharing resources, strategies, needs, capabilities and etc., or in simple terms using each other for mutual benefit. These relationships are socially constructed and they compose a network. Therefore, anything that occurs inside the network is within the framework of relationship, thus, the company in this network is an "insider" (insidership). If the company is not a part of a relevant network and has international operations to some extent or it is making efforts, then it is an "outsider". The company is considered to suffer from liability of outsidership. Also, at this point, more attention is being paid to the market-specific knowledge (critical knowledge) and relationship-specific knowledge. Also, within the network, knowledge can be acquired from outside sources rather than learning. Such market-based methods are the partnerships, licenses, acquisitions and etc. (Welch & Welch, 1996). The trust as a concept not included in the original model is now of critical significance. It is considered to be a trigger towards new opportunities. However, the validity of chain establishment is declining. Nowadays, there are companies with different strategies of internationalisation, like "born global" or better said "born regional". As for the experiential learning, the changes from the 1977 model are insignificant (Johanson & Vahlne, 2009).

The model shows that now instead of protecting themselves, the companies try to strengthen their position within the network, instead the traditional way of protecting themselves. That makes the decision of foreign country entry less important. It is more likely for the company to decide to enter a market where it maintains better relations (with important partners) rather than enter some less distant market.

Main difference from the previous model (see figure 1) is the inclusion of the "opportunities" variable which is considered to be very important for the knowledge process. Further, the "network position" (former "market commitment") is also included, as it is believed the internationalisation is sought within the network. As for change aspects, former "current activities" is replaced by "learning, creating, trust building" which is more explicit than the up-to-date current activities. Lastly, "relationship" is added to "commitment decisions" to indicate that commitment refers to relationship (figure 2) (Johanson & Vahlne, 2009).

Figure 2. Business Network Internationalisation Process Model, 2009



Source: J. Johanson & J. E. Vahlne, *The Uppsala Internationalisation Process Model Revisited: From Liability of Foreignness to Liability of Outsidership*, 2009, p. 1424.

1.2.3 Export development models

The export development models identify the internationalisation as a decision-driven process. The initial decision on exporting is actually the beginning of internationalisation. Furthermore, as the company grows and gains more knowledge, so grows the incremental process of exporting. Usually, each model is consisted of stages, ranging from pre-export stage to the stage of experience exporter (Christofor & Kollmann, 2008, p. 67).

1.2.4 Innovation-related models (I-models)

Bilkey and Tesar (1977) developed an export behavior model of internationalisation of small and medium sized companies which also applies to large companies. It is empirically tested on 423 SME Wisconsin manufacturing companies and it is to some point extension of the Uppsala model (see p. 6). It is labeled as innovation-related model whereas each stage of internationalisation is treated as innovation with focus on export (Ruzzier et al., 2006). The model consists of the following stages (Bilkey & Tesar, 1977, p. 93):

1. management is not interested in exporting-would not even fill an unsolicited export order;
2. management would fill an unsolicited export order, but makes no effort to explore the feasibility of exporting;
3. management actively explores the feasibility of exporting (it can be skipped if unsolicited export orders are received);
4. the company exports on an experimental basis to some psychologically close country;
5. the company is an experienced exporter into that country and adjusts exports optimally to changing in exchange rates, tariffs, etc.;
6. management explores the feasibility of exporting to additional countries that, psychologically, are further away.

Similar to the Uppsala model, the innovation model also outlines the incremental process of internationalisation. In this model there are two pre-exporting stages (in the Uppsala model there is just one), whereas in stage four, the company is an initial exporter but in the next stage it is already an experienced exporter. This shows the company is expanding its international activities due to the learning process (Bilkey & Tesar, 1977). The slow internationalisation describes the inefficiency of the company to gain substantial knowledge for penetrating the market and the risk-aversion effect of the management.

Later, this model was reassessed by Czinkota and Johnston (1983). They made some adjustment to the classification. As a result of the accusations that the formulation of the stages led to quantification problems, they introduce a modification. The model is based on empirical evaluation of 237 SME US companies. The new classification is presented below:

1. completely uninterested company;
2. partially interested company;
3. exploring company;
4. experimental exporter;
5. experienced small exporter;
6. experienced large exporter.

The findings of this study suggest that a company which is engaged in domestic operations may soon make a decision to go international. It emerges from the rising interests of the company, after its engagement on home soil. In other words, there are internal pushing and external pulling forces (market pull or push effects) which create impetus for the company to pursue the development. In contrast to the innovation related model, Czinkota's internationalisation process model lies solely on pull effects. The commitment in this model initiates in the fourth stage (Czinkota & Johnston 1983).

Both internationalisation models (U+I models) are based on the behavioral approach of internationalisation. The U-model emphasis the learning process and it has a dynamic character. The I-model describes the process of internationalisation as a step-by-step development (Otto, 1993). The network model is quite new and emphasis the relationships and the collaborative arrangements among the concerned parties in the international business. It also helps to overcome the "liability of foreignness" (Antoldi, Cerrato, & Depperu, 2011, p. 6).

1.3 Motives and Incentives

To go international, a company has to have substantial motives. They either need potentially large market for developing economies of scale and scope, looking for external sources of increased competitive advantage or perhaps they are pushed by their competitors or customers.

Either way, basic strong motivation is a trigger to all consecutive processes. However, motivation cannot just spontaneously arise by itself. It has to be sought and revealed through researches and information gathering, investment in learning process and knowledge acquiring (Yip, Biscarri, & Monti, 2000, pp. 14-16). Broadly, the motives of internationalisation can be divided in four categories: decision-maker characteristics, company-specific factors, environmental factors and company characteristics. Noticeably, the motives for internationalisation are determined by **internal** or **external** factors or combination of these two (Korsakienė & Tvaronavičienė, 2012, pp. 298-299). Namely, the internal factors are lead by company's management, usually, when they discover and understand the value of the international market. On the other hand, the external factors rise from the growing foreign demand (Czinkota, Ronkainen, & Buonafina, 2004, pp. 9-11). In general, these motives are called "pushes and pulls" to internationalisation and "proactive and reactive" motives. They are also recognized as company-based (internal) and environment-based (external) drivers of the internationalisation process. The internal proactive factors depict company's interest to explore internal strengths or opportunities on foreign market while external reactive factors emphasize the organizational or environmental pressure. The proactive motives arise from some particular internal advantage of the company like: proprietary market knowledge, skills, know-how technology. In this case, the internationalisation is taken rather optimistically. On the other hand, the reactive motives refer to a response to some unfavorable conditions in their present markets like: competitive pressure, excess capacity, declining or saturated market. By their nature, they have defensive character (Pett, Francis, & Wolff, 2004, p. 47; Czinkota, 2012). According to Czinkota (2012), profits are major proactive motives to international business. In general, companies that are more successful in international operations are usually motivated by proactive internal factors. Companies at different levels are likely to be motivated by different stimuli.

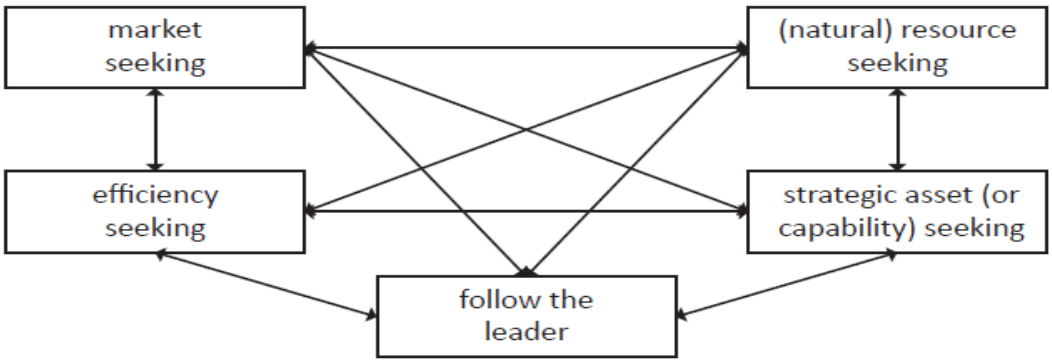
Table 1. Proactive and Reactive Motives

Proactive motives	Reactive motives
Profit advantage	Competitive pressures
Unique products	Overproduction
Technological advantage	Declining domestic sales
Exclusive information	Excess capacity
Managerial urge	Saturated domestic markets
Tax benefit	Proximity to customers and ports
Economies of scale	

Source: M. R. Czinkota, I. A. Ronkainen, & M. O. Buonafina, *The Export Marketing Imperative*, 2004, p. 4, Table. 1.2.

According to Morschett, Klein, & Zentes (2009, pp. 71-72) the traditional motives for internationalisation are connected to the sales objectives. Some of the additional alternative motives could be: efficiency seeking, resource seeking, seeking of strategic assets and follow-the-leader strategy.

Figure 3. Alternative Motives for Internationalisation



Source: D. Morschett, H. S. Klein, & J. Zentes, *Strategic International Management*, 2009, p. 72, Figure. 4.1.

When the home market is saturated a new market is sought. Normally, the country is chosen by its sales potential. Other selection criteria could be: market size, market growth, per capita income, presence of attractive customer segment or demand for the products of the company. The resource seeking motives are related to the access to critical resources of the company. Thus, basic factors for the resource seekers could be the availability, the cost and the allocation of the important resources. The efficiency seeking motives pursue exploitation of differences in factor costs and boost the economies of scale through bundling production. In practice, this system is known as outsourcing and offshoring to countries with predominantly low wage labour costs. Hence, important aspects for the efficiency seekers are: production costs in the country distance to relevant markets, possibilities of vertical integration and availability of good and efficient suppliers. Companies sometimes do not just seek tangible, but also intangible assets like local knowledge, capabilities, high-tech, innovations and etc. The required market factors for these strategic asset seekers are the following: innovativeness, sophistication of demand, availability of supporting industry and presence of innovative clusters in the industry. Follow the leader motives originate from the oligopolistic theory. It occurs when a competitor or competition moves to foreign market. In the literature the presented motives predominantly refer to the MNCs and are known as investment motives. Companies usually combine these motives in the decision-making process (Morschett, Klein, & Zentes, 2009, pp. 72-81; Kudina & Jakubiak, 2011, pp. 72-78).

In relation to the company ownership structure Gregoric, Hobdari, & Sinani (2009) come to a conclusion that the insider and foreign ownerships are positively related to internationalisation whereas more productive companies, larger companies, more capital-intensive companies, those with high level of investment in both fixed capital and research and development (hereinafter: R&D) are more successful in the internationalisation process. Furthermore, a market with low competition leads to internationalisation as the company, after dominating the domestic market tries to expand through exporting.

1.4 Market Selection

Prior experience always plays an important role in the market selection process. The most important factors that influence the market selection are the country's characteristics, market's demand characteristics, company's competences and the possible effect of synergies. Eventually, no market can be fully optimal for a company, thus, the final strategic decision should be a better trade-off among the concerned factors (Yip, Biscarri, & Monti, 2000, p. 15).

Two main forces drive the market selection: the opportunities and the risks related to entering a foreign market. The opportunities that foreign markets hold are determined by the attractiveness of the particular market which is driven by the economic potential for the company on that market. The economic indicators which refer to the opportunities are cost-related (increasing productive capacity by producing abroad), market-related (increased innovation and know-how) and internal company factors (transfer of competitive advantage to the new market). On the other hand, the risks could be company-specific, industry risks and general environment risks. The company-specific risks are a broad category which refers to the cost-related factors. One is the low labour costs in the foreign market that could bring higher competition within the company and possible lay-offs in the home country. Other is the risk of investment, which is predominantly related to start-up costs and risk of increased organizational complexity. The last one is the time frame needed for big investment and market knowledge gained in relation to the cash flow. The industry risks, however, are more attributed to the barriers of entry, market behavioral risks (like awareness for the products) and economic exchange risks. And finally, the general environment risks are identified through the governmental restrictions (fiscal risks, transfer risks, tariffs, expropriation and etc.), security and legal issues, communication risks and etc. (Christofor & Kollmann, 2008, pp. 25-28).

1.5 Strategies for Market Entry

According to different literature, the market entry strategies are very popular. They explain how multinational companies choose their entry mode. There are qualitative and quantitative studies; the former ones are over sufficient, the latter are game theoretical and insufficient. However, so far, there is no fixed entry mode theory (Decker & Zhao, 2005, p. 221).

"Market entry strategy can be defined as a plan developed by a company to enter a new market or sub-market" (Levi, 2007, p. 34). In the literature, market entry modes can be classified according to the level of control, resource commitment and risk involvement (Chung & Enderwick, 2001, p. 444).

1.5.1 Export modes

Exports represent transfer of goods and services across national borders (Levi, 2007, p. 42). The literature usually distinguishes between indirect and direct export. Indirect export presents a very first option in the internationalisation process and employs very low resource commitment. It takes place when the exporting manufacturer uses middlemen (export trader, export agency or export cooperative) located in the home country. Namely, these intermediaries act as merchants. They buy the goods from the manufacturer and then sell it on the foreign markets. For the manufacturer, these sales turn into domestic ones, while all cross-border activities are done by the intermediaries. The main advantages of this type of export include low resource commitment, nonessential development of international know-how and significant risk reduction. It is also marked by low organizational and management complexity. The disadvantages for the company are lack of contact with the customers, no control over the products' marketing and lack of market-specific knowledge (Solberg & Nes, 2002, pp. 387-388; Christofor & Kollmann, 2008, pp. 29-31; Grünig & Morschett, 2012, p. 125).

A direct export can be organized **via distributors** (including importers, dealers and wholesalers) which act as a sales organization for the company in the foreign market. They are independent merchants who buy the goods from the exporting company, set their own price condition, choose their own customers and then sell it either to the final customer or to re-sellers. They usually seek an exclusive right from the exporting company to sell the goods on a particular territory. They have good knowledge of the market, network and sales contacts. In this case, the advantages for the exporting company are still low resource commitment and limited risks. However, the distributor remains a "bridge" between the company and the final customers and the company maintains the lack of market knowledge. After a while, the company usually changes this entry mode and establishes a subsidiary. Direct exporting could also occur through **an agent**. The agent is an independent company and acts in the name and on behalf of the exporter and usually does not stock the goods. All merchandise is shipped directly from the producer. All the arrangements (financial, promotional, etc.) are made between the company and the customer. Agents take commissions on the deals. Same as distributors, they have market-specific knowledge, contacts and they could also ask for exclusive rights. As they are tied up to the sales, they have the incentive to sell the products. However, since agents want to maximise the profit, they might hold back the company's products and pay more attention to other items where they see more profit. By employing this model, the company still holds its committed resources and risks on low level and does not have the optimal market knowledge and control. Direct export with **sales representatives** is another option for the exporting company. They are employed by the company and could be either resident sales representatives or domestically-based sales representatives (who travel). In this case, on one hand, the company has much greater commitment to the market but on the other, it is faced with significant rising variable and fixed costs. Another benefit is the direct contact with the customers. Usually, sales representatives are

employed when the sales reach a certain level. In other words, to the extent when it is more profitable to use sales representatives than distributors and agents. In relation to the products and the market knowledge, there is unnoticeable change from the previous modes. The direct export **with FDI** is organized via representative offices, branch offices or sales subsidiary. In the representative office, the employees are selected to represent the company on local level, gain insights of the market and establish contacts with the government. On the other hand, the branch office serves as an extension to the parent company and it is not a separate entity. The parent company stays responsible for the employees and the customers. These branch offices are accountable for following the instruction of the parent company. Contrary to the branches, the subsidiary is a local company and it is subject to the laws and regulations of the host country. Since it is owned by the parent company, it is in direct contact with the customers and serves as a merchant, buying goods from its parent company and selling it to the customers. The sales subsidiary enjoys more autonomy in comparison to the branch and it is in charge of the sales and marketing activities. The branch serves more like an assistant to the customers. Through these modes, the company can have a direct contact with the customers and be responsible to their needs. The resource commitment and risks are still kept at low level since the production takes place in the home country. Only the costs are increased, especially in the case of establishing a sales subsidiary which requires high level of FDI (Solberg & Nes, 2002, pp. 387-393; Grünig & Morschett, 2012, pp. 125-132; Christofor & Kollmann, 2008, pp. 31-32).

1.5.2 Licensing

Licensing is a type of strategy where the company uses the production in foreign country without any substantial investments or creating production abroad. The license can be issued to a company in a foreign country by agreement between the two counterparts. In this way, the company can operate on the foreign market using all its patents, processes, technology, brand name and etc. in return for royalty fees. Usually, the licensee could use the rights of the license for a defined period of time. Licensing is opportunity for the company to grasp the technology of unique products or attractive processes, if they lack financial resource or managerial capacities. It is also valuable for markets that are hard to penetrate, where the local partner (licensee) could benefit due to entry barriers. Further, the local partner could better use its market knowledge and speed to deliver the products. One of the negative effects of this strategy is revealing the technological and business processes to the licensee, and thus creating a potential future competitor. Also, the partner is obliged to inform the licensor about the sales, but the company still lacks sufficient knowledge of the market. Licensing also restrains the possible change of strategy, since it is a long term agreement and gives less room for maneuver. The licensor has to watch out its reputation since the products are sold under its brand name (Grünig & Morschett, 2012, pp. 133-136; Christofor & Kollmann, 2008, p. 32).

1.5.3 Contract production

It is an internationalisation strategy where a company outsources specific parts of its production. The company discloses important information concerning the processes, technology, know-how, etc. In general, the company undertakes this strategy in order to lower down its costs of production and mainly outsource to foreign country with low labour costs. However, all the marketing is still done by the mother company (Christofor & Kollmann, 2008, pp. 32-33).

1.5.4 JV

It is a strategy where the expanding company engages in a joint venture with a foreign company. Thus, the company benefits from the already established position of the partner, the speed of the market entry and the risk sharing. Furthermore, the company can use the production facilities and technology, distribution channels even the reputation and/or financial resources from the partner. In some countries like China, a JV with local company is the only way to penetrate the market due to governmental issues. However, in most cases, the company has to acquire a stake in the local company to enter the market (Grünig & Morschett, 2012, pp. 139-140; Christofor & Kollmann, 2008, p. 33).

1.5.5 WOS

The greatest commitment a company can make is to establish a factory in the target country. Basically, this type of production has all the beneficial elements of the licensing strategy except for being a huge investment. It also offers a full control over the production, organizational and marketing activities. Establishment of production in a foreign country signals strong commitment. Local production means speed of delivery and reduced transportation costs. Having local employees shortens the adaptation period. Also, in many countries the investment is awarded with governmental subsidies. However, high resource commitment is related to high risks and hazards. The building of a factory is closely related to huge sunk costs (different kind of permits even bribes in some countries). Thus, the company has to reach that minimum size of cost efficient factory in the foreign country in order to benefit. In any case, it is a long-term decision for the company. If the specific market is perceived as attractive and growing, on the long run, the investment could pay off. When discussing entry via WOS, it is useful to mention the possible strategy of acquiring a local company that already has a product scope in the host country. In practice, these types of acquisitions serve the company for exploiting the target market potential with a new product range (Grünig & Morschett, 2012, pp. 137-139; Christofor & Kollmann, 2008, pp. 34-36).

Market entry modes described above differ in many aspects and dimensions. The company chooses a particular entry mode according to its own preferences. The company decides whether

they want control and high equity investment (WOS or JV-shared control) or non-equity modes (e.g. exports) (Chung & Enderwick, 2001, pp. 444-446). The most important aspects that influence the decision making criteria are the following: speed of penetration, degree of control and resource commitment, cost and profit aspects, flexibility of the company, partner selection and knowledge dissemination (Grünig & Morschett, 2012; Christofor & Kollmann, 2008). However, choosing the best entry mode is not always the one preferred by the company. The choice is related to the industry, national level characteristics and legislatives of both the home and host country. For instance, the export mode versus FDI is a trade-off between trade barriers, transportation costs and fixed costs for building a plant and duplicating production capacity abroad. Therefore, the projections should be made on long term basis while taking the company's resources into consideration (Cieślik & Ryan, 2011, p. 533). Furthermore, the entry mode selection is supposed to be contingent on the company's international experience and diversification. Companies that use a JV rely more on their developed and historic set of resources, while those that acquire are actually pursuing resources (Beamish, Shige, & Woodcock, 1994, pp. 254-257). Nevertheless, companies choose high equity entry mode (JV or WOS) if the host market is attractive. On the other hand, they choose non-equity modes (e.g. export) for smaller markets that do not have huge sales potential.

2 GLOBAL PHARMACEUTICAL INDUSTRY

2.1 Brief Overview of the Industry

The importance of the pharmaceutical industry, especially from the social and economic aspect arises from the repeated benefits of the numerous drug innovations that cure different types of medical conditions. Besides that, the most valuable effects of the industry are employment provisions and huge revenue for the economy on a global scale (Craig & Malek, 1995, p. 302). It is a specific type of industry, highly dependent on patents, trade secrets and test data protection (Watal, 2012, p. 2). However, the pharmaceutical industry has evolved over the last decades. The accelerated globalization and the extended competitiveness followed by the struggle for market share, consequently led into consolidation of the industry. More and more strategic alliances, partnerships, mergers and acquisitions (hereinafter: M&A) are made, in order for the companies to be more competitive, successful and therefore capture a larger market share of the world market. The most significant structural challenges are innovating and developing new products, increased globalization and importance of strategic management, fast concentration, and marked up competitiveness (IMAP, 2011; Kesič, 2009).

The main characteristics of the global pharmaceutical industry are (Kesič, 2009, p. 59):

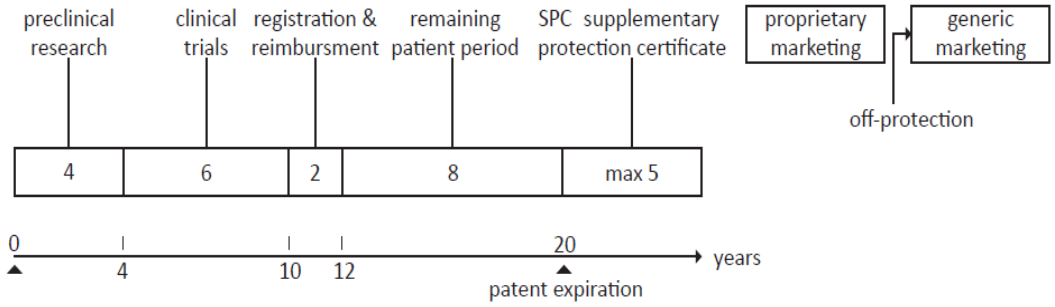
- increased globalization;

- changing structure of competition and increased competitiveness;
- lack of new products, despite increased investments into R&D activities;
- fast consolidation and concentration of the world pharmaceutical industry;
- increased importance of strategic management;
- development of new therapeutic fields and technologies;
- ageing of world population and opening up of new therapeutic fields;
- quick development of the world generic markets.

Today, the pharmaceutical industry tends to be the most innovative and lucrative of the so-called high-tech industries. The development of a new drug is an investment of more than a US$ 1.3bn (including direct and indirect costs) and takes approximately 12-14 years to get the product finished, legally registered and approved on the market. On average, a pharmaceutical company reinvests 16% of their sales in R&D and 26% or more in marketing and sales activities (Kesič, 2006). In 2011, the spending on R&D at industry level was nearly US$ 135bn (IFPMA, 2012, p. 8).

The pharmaceutical companies are categorized in two groups: **the originator companies** and **the manufacturers of generic products**. The first are more active in the R&D, management of the regulatory processes for new products including clinical trials, manufacturing, marketing and supply of new drugs. The second category enters the market with a drug identical to the existing one after the patent expiration of the pre-existing original product. In practice, they introduce much lower prices than the originators (Milchior & Charbonnel, 2010, p. 104).

Figure 4. Drug Development and Patent Period and Marketing



Source: NEFARMA, *Pharma Facts and Figures*, 2011, p. 39.; IMAP, *Pharmaceuticals & Biotech Industry Global Report*, 2011, Appendix A-i.

The development of a new drug from early research to market entry, as said, takes on average 12-14 years with overall industry success rates below 1%. Figure 4 illustrates the process. Preclinical tests are done on animals to examine the drug efficiency and its behavior in living organisms. The clinical trials are composed of three phases. In the clinical phase I, the drug is tested for the first time on healthy human volunteers in order to determine its safety and dosing. In phase II of the clinical trials the drug is tested on candidates that suffer from the targeted disease. Lastly, in the

clinical phase III, the drug is tested on larger number of patients (more than 1000) to determine its efficiency and safety profile. When this is successfully concluded, the drug is eligible for regulatory approval. After the approval, long-term observations are undertaken to ensure there are no possible side effects undetected in the previous phases. In comparison to the R&D expenses, the manufacturing costs are relatively low (Fassbender & Flessner, 2009). The patent protection plays significant role in this industry. According to international agreements, the patent protection lasts for 20 years from the date of filing the patent application. However, because of the time difference between patenting and obtaining the market approval, the effective life of the patent is much lower. Therefore, special legislative provisions are introduced to extend the life of the patent. In most countries (EU, USA) the patent life can be extended by maximum of five years, by means of the so-called "Supplementary Protection Certificate". The request for patent issuance is usually filed in the early stages of the drug development, and in practice, the drug is patented in third countries only after the marketing in the home country is assured and the drug is already in use (Heimler, 2001).

Besides, the generic drug is a bioequivalent with same ingredients as the original one and it is also subject to registration and market authorization. The only condition to enter a particular market is the expiration of the patent protection of the innovative drug. However, the generic manufacturers do not need significant R&D costs and time span, therefore, they introduce lower prices for the same drug in contrast to the originator (Kesič, 2009). Their competitive impact is substantial; there is usually huge drop in prices of 30%-50% when they are introduced on the market (Heimler, 2001, p.3). Once the generics enter the market, they soon gain significant market share at the expense of brand name drugs (CBO, 2006). The pharmaceutical originators try to delay as long as possible the entrance of the generics with different instruments and mechanisms, hence there is presence of legislation to prevent this behavior. Yet, the legislation varies from country to country (Heimler, 2001). As a result, the entry does not always happen as early as it potentially could have under the internationally relevant legal framework (Milchior & Charbonnel, 2010, p. 107).

2.2 Industry Structure

The structure of the pharmaceutical industry has oligopoly symptoms. This market condition is mainly associated with high entry barriers and tends to be non-price competitive especially with product differentiation that leads to brand loyalty and high prices. Further, formation of alliances and M&A in order to maintain the strategic global position, long-term growth and competitiveness, to create common synergies and exploit common assets, knowledge and product life cycle speed up the oligopolisation of the industry even more (Craig & Malek, 1995; Kesič, 2009). Also, pharmaceutical companies tend to internationalise their activities sooner than before due to market liberalization and increased competitiveness. Contemporary strategies of

internationalisation without the company growth are simply alliances, partnerships and M&A. The underlying reasons according to Svetličič (cited in Kesič, 2009, p. 70) are the following:

- to be closer to customers;
- to increase effectiveness;
- to gain better access to technologies and knowledge (know-how);
- to be protected from competitors (strategic reasons).

However, by comparing the pharmaceutical industry with other industries, it can be concluded that it is actually a competitive industry. The top 10 companies never managed to break the margin of 50% and their global market share is quite static over the years of roughly 40% (IMS top 10, 2013b, p. 2). In line with this, the leading companies in the industry do not dominate the market and eventually the market is not oligopolised. Yet, the pharmaceutical market is composed of many separate sub-markets which are constricted in size. In these sub-markets the true nature of pharmaceutical industry emerges with its very high concentration ratios. It is phenomenon of domination of small number of products in different therapeutic categories. The manufactures can set higher prices and earn what is considered to be above-normal profits. Therefore, the growing competition in prices along with numerous generics available on the market make the industry more of a dynamic oligopoly with substantial competition rather than a mere oligopoly (Craig & Malek, 1995). As mentioned, pharmaceutical industry is very much R&D oriented and therefore it requires huge investments. Thus, the large companies dominate the market whereas the small companies, though innovative, do not have the sufficient funds to compete with them. Hence, the trend is to form joint ventures and licensing agreements with large companies. Further, it is noticeable that almost all pharmaceutical companies have other profit centers in the form of chemical, botanical, centers and such. The successful innovative companies reinvest significant margin of the sales in R&D (16%). However, the risks related to development and launching a new drug run high. The top pharmaceutical companies rely predominantly on international sales and have significant share of their sales abroad (except US companies due to the highly extensive domestic market).

2.3 Regulations

National pharmaceutical markets are different in many segments particularly when it comes to regulations. In every country the production and sales of pharmaceuticals is heavily regulated. The identity of the drug brought to the market, the nature of the demand and competition in the particular market are all subject to regulations. Each country has an agency within the ministry responsible for pharmaceutical evaluation, where safety and efficiency are heterogeneously assessed and the speed of evaluating a drug application varies considerably. The funding of the agency and the bureaucratic efficiency also differ across countries. Efforts on standardization and

harmonization are undertaken on international level, mostly within the EU. However, many countries have national procedures different from internationally established. Hence, concerning regulations, each national market bears its own characteristics and it requires separate analysis. Also, many countries have a built-in legislative so that pharmaceutical companies follow the standardized Good Manufacturing Practices procedures (hereinafter: GMP). Some of them have their own GMPs (slightly different) that correspond with the unified guidelines. In general, all GMPs refer to safeguarding the health of the patient as well as producing good quality drugs (Heimler, 2001; Kyle, 2007).

2.4 Pricing System

Demand for drugs can be separated into two sections. Firstly, there are drugs that can be purchased directly over-the-counter (hereinafter: OTC) and secondly, there are drugs that need doctor's prescription. The latter are more significant and make a more distinct market. They are divided between the intramural market (hospital consumption) and the extramural market (home consumption) (Craig & Malek, 1995, p. 311).

Since drugs represent a necessity for the patient, the demand should be almost perfectly price-inelastic. The inelasticity is enforced by isolation of doctors in this market. Since the doctor is the decision-maker, he is not concerned with the price of the drug but rather with its efficiency, safety and quality. In a market with many identical drugs, the best drug is prescribed by the doctor. Following this logic, the doctor has little motivation to prescribe low-priced drugs. The pharmaceutical companies exert significant influence on the decision-maker (doctor) with large promotion campaigns endorsing superior quality of their products. In fact, the doctor becomes the target of the company's marketing activity. The patient is also price-inelastically oriented, dependent on the doctor's judgment albeit, in practice, they do ask for cheaper drugs. In any case, it is important to highlight the substantial importance of information on drugs (quality and price), since neither the decision-makers nor the price takers are price conscious (Craig & Malek, 1995).

Manufacturing of drugs is not as expensive as R&D costs which is a huge investment. Thus, the patent which creates entry barriers gives the company temporary monopoly privilege over the supply of products and prices. The length of patents, as mentioned, is somewhat shorter than 20 years. The long life patent is there to compensate pharmaceutical companies for the huge R&D costs and eventually give them more incentives to continue innovating. Nevertheless, R&D is major motive for competitive behavior and may result in price competition in the future (Cocks, 1975). Telser (1975) reveals that a successful commanding drug could survive roughly five years on the top after being replaced by presumably better rival. The drug demand is like "quicksilver", one day present, one day gone. On the supply side, the competition is mainly for markets, while competition in the market is driven by the introduction of the generics (Heimler, 2001).

Since the demand is price sensitive to difference in the quality, there is noticeable high product differentiation. In order to enhance the brand loyalty and stabilize the market share, companies introduce trademarks and marketing strategies to exploit the imperfect information of the market. Therefore, the drugs are characterized by three names which are written on the packaging (Craig & Malek, 1995, p. 314):

1. chemical name - it gives the chemical structure of the molecule;
2. generic name - it is the common, established non-proprietary name;
3. brand name - the name given to the product by the manufacturing company.

By heavy investment in promotion of the product's brand name and company's trademark which is under patent protection, the company predominantly tries to secure the doctor's trust. In any case, the company tries to extend the patent as much as possible before the generic competitors introduce the same products with much lower prices and therefore gain a significant market share (Craig & Malek, 1995).

The average price of new drugs grow much faster than the inflation rate. Further, higher prices are charged for drugs that are only incrementally different (modified) from its predecessor. High prices imply high return which encourages the company to maintain innovation and increase investments in new drugs. Also, the health insurance (public and private) prevents the consumers from bearing the full weight of those prices, thus, keeping the demand for new drugs high. The patent protection encourages the company to retain the high price of the drug (CBO, 2006). Usually, the prices of drugs are based on some determination of therapeutic value, costs of comparable treatments, contributions of the drug's manufacturer to the domestic economy and manufacturing costs, but the weight given to each factor differs by country. Prices are also associated with quality of innovations, existing substitutes and anticipated competition (Kyle, 2007).

The characteristics of the drug and the market forces (explained above) are not the only two factors that influence the price of drugs. The third factor that impacts the formation of prices are the regulators (national agencies). Regulations vary and differ across countries. Since the industry is very much regulated, so are the prices (Table 1, Appendix C).

Companies have to operate in highly regulated environment and different countries have different policies regarding the price legislative. Also, health insurers (public or private) could influence the prices. They could control the drug expenditures by directly controlling the price of the drugs. Therefore, regulators sometimes have hard time to fix the price for each drug. Higher prices can inflate the pharmaceutical expenditures and over-compensate manufactures. In contrast, lower prices could lead to withholding particularly beneficial product. Countries use different approach to deal with this issue and the most "famous" one is the **international benchmarking** or

reference price (averaging out prices of the same drug in different countries) (Heimler, 2001). Occasionally, companies may have to negotiate the price with the domestic institutions. Introduction of price controls by some countries push companies to launch their products first in countries where they have the freedom to set higher prices (Kyle, 2007, p. 91). On the other hand, if the prices are not regulated, it allows the companies in power to discriminate. They can set prices in reference to the ability to pay by different consumers by determining a margin at which the prices never fall below the marginal costs. However, when prices in different countries are regulated and the margins are set, it can further lead to parallel trade and spill-over effects. The fragmentation of the market leads to purchases from wholesalers in low-price countries and sales in high-price countries. Therefore, parallel trade is profitable for wholesalers and retailers while lowering of the price in high-price countries is uncertain (Heimler, 2001). For instance, the parallel trade in the EU is estimated at EUR 5.000mn (ex-factory price) in 2011. However, 35% of the retail price of drugs returns to the distributors (retailers and wholesalers) and the state, but not to the manufacturers (EFPIA, 2013, p.4).

2.5 Market Data

It is expected that pharmaceutical market will reach around US$ 1.2tn by 2016 and US$ 1.6tn by 2020 (IFPMA, 2012; PWC, 2012). The leading emerging BRIC countries will account for 30% of global pharmaceutical spending by 2016 (in contrast to 14% in 2006) (IFPMA, 2012, p. 51).

Table 2. Pharma Market Size in US$ Billion and Growth by Regions

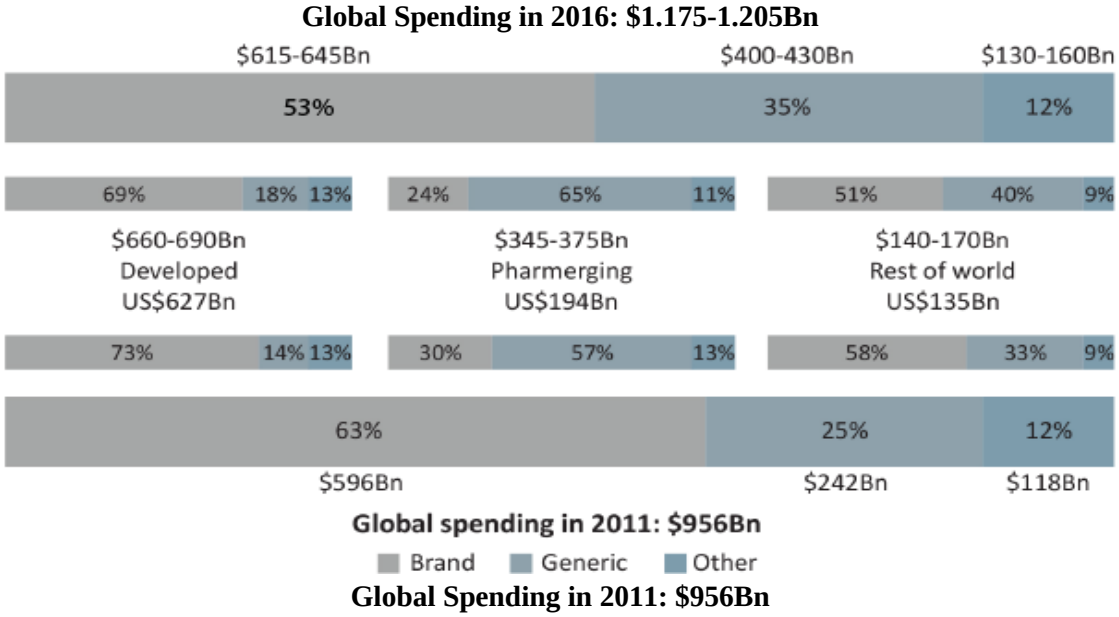
	2012	2012	2012	2011	2007-2012	2013	2012-2017
	Mkt Size US$Bn	Mkt Size Const. US$Bn	% Growth Const. US$	% Growth Const. US$	CAGR % Const. US$	Forecast % Growth Const. US$	CAGR % Const. US$
Total unaudited and audited global market	962.1	959.0	2.4	5.3	5.3	3.3	5.3
Total unaudited and audited global market by region							
North America	348.7	349.0	-1.0	3.4	3.0	- 2.7 - 0.3	0.7 - 3.7
Europe (EU + non EU)	221.8	224.3	-0.8	0.9	2.4	- 1.8 - 1.2	- 0.4 - 2.6
Asia (including Indian Sub-continent) /Africa/ Australia	168.3	168.1	12.8	12.8	15.0	11.4 - 14.4	11.4 - 14.4
Japan	112.1	110.5	0.0	5.6	3.0	2.8 - 5.8	1.7 - 4.7
Latin America	72.5	68.6	10.9	12.4	12.0	9.0 - 12.0	10.0 - 13.0

Source: IMS, *Top-line Market Data*, 2013a

Today, the world market is dominated by few regions and countries in both production and consumption. The most developed western countries like USA, Japan and EU5 dominate the market and they have the biggest share of production and consumption of pharmaceutical drugs. However, due to the expiration of many “blockbuster” patents on the developed markets the share is expected to decline. The growth in the leading emerging countries is mainly due to the spending on generic drugs. This trend is expected to continue in the near future and it contributes

to increased share of generic spending across the world. The revenues from generics are expected to reach US$ 400-430bn by 2016 out of which 70% outside the developed markets. On the other hand, spending on brands is estimated to reach US$ 615-645bn by 2016. In the developed markets including USA, Japan and Europe the spending is to decline to 57% as many patent protections are set to expire (IFPMA, 2012; IMS, 2012).

Figure 5. Segmentation by Spending



Global Spending in 2011: $956Bn

Source: IMS, *The Global Use of Medicines: Outlook through 2016*, 2012, p. 8.

The increased generic spending projected in the developed markets is driven by the generic competition due to patent expirations. In the emerging markets (pharmerging – BRIC) the generics and local companies run most of the increased spending (IMS, 2012).

The pharmaceutical market is composed of several thousand companies, yet it is not very fragmented and more than 90% of the market accounts for less than 100 companies (Craig & Malek, 1995, p. 315). The global market share of the top 10 companies has been static over the years and amounts to 40%. All leading multinational companies have origins in the mature markets of Europe and USA and are primarily R&D driven, which means their sales come from protected products (IMS top 10, 2013b, p. 2). The **market leaders** (by generated revenues) are Johnson & Johnson followed by Novartis, Roche, Pfizer, Sanofi, GSK, Merck and Bayer. Due to many patent expirations, drop in the sales of the top companies is expected in the near future. Therefore, the companies are slowly focusing on producing and expanding biosimilars and paying more attention to generics growth (Fiercepharma, 2014).

About 84% out of four billion prescriptions written each year are for generic drugs, saving patients and government programmes billions of dollars a year. It is a huge business that has

booming momentous. The generic drug manufacturers are anticipated to see a strong period of growth in the following years and be able to reap the benefits as many branded drugs reach their patent cliff (Generics, 2013). Companies are joining forces to reach new markets. The Israeli **Teva** is the world leading generics company which generated 51% and 28% of the company's 2012 sales in the US and European market respectively. The generic business remains top priority for the company in the future. Novatis (Sandoz), Mylan, Abbott, Actavis and Sanofi follow the leader in terms of generated revenues (Fiercepharma, 2013).

2.6 International Trade

Global sales of pharmaceuticals represent international expansion of medical technology that result from intensive R&D investments in the exporting countries. On the other hand, importers also benefit from the health improvements, although they do not participate on large scale in R&D activities. The pharmaceutical trade is highly concentrated in the developed world. Europe, the industry's power house, is traditionally the biggest exporter of pharmaceutical drugs in the world. However, this trend is slowly changing as the emerging countries are experiencing substantial export growth in the last decade including China, India, Singapore and Israel. Although the global share of export from these countries in value terms is rather moderate, they represent an important chain in the pharmaceutical trade for the low-income countries. Annually, low-income countries import on average around 30% of pharmaceuticals from India and China, generics in particular, and the trend is on the increase (IFPMA, 2012).

3 DOING BUSINESS IN KAZAKHSTAN

3.1 Kazakhstan – Brief Overview

Kazakhstan (capital Astana) is a Central Asian country, the second largest of the former Soviet republics in territory and the ninth in the world. Its neighboring countries are Russia, China, Kyrgyzstan, Turkmenistan and Uzbekistan. Although it spreads over a huge territory, it has population of just 17,265,000 inhabitants. The state language is Kazakh, while the Russian is also official and it is used in everyday business communication. Politically, Kazakhstan is a constitutional republic with strong presidency. It is divided in 14 provinces or administrative divisions (Figure 1, Appendix C). In economic context, Kazakhstan possesses enormous amounts of natural resources and has a huge potential. The economy is highly dependent on its energy sector, especially on oil and gas (CIA, 2013).

3.2 Analysis of the Political and Legal Environment

3.2.1 Political system

Kazakhstan is a presidential republic and the first and only president of the country ever since its independence (1991) is Nursultan Nazarbayev. He is head of the state and has its executive authority. The president is elected by the people and can serve its country for a maximum of two mandates. However, as a result of the Referendum (called by the President) and further constitutional amendments (which only apply to the stated President), President Nursultan Nazarbayev was re-elected and he still holds the presidential position. In the meantime, he further strengthened his position by making several legislative amendments. In Kazakhstan, he is known as the "Leader of the Nation" (Euro Forum, 2013).

Kazakhstan's parliament has bicameral composition. It consists of the lower house, known as the Mazhilis and the upper house, the Senate. The Mazhilis consists of 98 deputies whose mandate is strictly related to the membership of the party. If a deputy is expelled from the party, he is also expelled from the Mazhilis. As expected, the party of the President, Nur Otan Party, holds the majority in the Mazhilis of 80.99% (according to the parliamentary elections of 2012). The Senate is constituted of 47 members and it is the upper house of the parliament. The president appoints one third of the members directly while the rest are appointed by regions. Nazarbayev can also influence this process, since he appoints the governors of each region. Other important bodies are the Constitutional Council and the Supreme Court. Basically, the parliamentary elections in 2012 can be seen as major milestone in the Kazakhstan democracy since three political parties managed to enter the parliament (by reaching the threshold of 7% of the votes), after twenty years of a single-party democracy. However, the two parties, the Democratic Party Ak Zhol and the Communist People's Party that entered the parliament are presumed to be pro-presidential, while the only real opposition the Nationwide Social Democratic Party, did not manage to pass the threshold of 7% of the votes, reaching only 1.68%. As previously mentioned, the presidential party won 80.99% of the mandates on these elections (the pre-election poll by the Institute of Political Solution indicated that only 51.4% of the voters intended to vote for the President's party). According to international observers, the elections were not qualified as fair and democratic. It was stated that there were many of irregularities, manipulation with the votes and pressure from the governing party (Euro Forum, 2013).

3.2.2 Law and legislative

In general, Kazakhstan has no screening mechanism for foreign investment with only few sectoral restrictions. Kazakhstan is relatively open to foreign investment and the constitution of the country provides equal rights and obligations to foreign entities and individuals as to their local citizens. Therefore, foreigners may invest in any business sector. However, as a result of the

government's efforts to diversify the economy and create larger local value added from foreign investments, numerous measures were introduced in the last decade, especially in the subsoil sector. Furthermore, according to the law, women have the same rights as men in business dealings. However, international companies admit to male preference in performing business negotiations and operations (OECD, 2012). Some major acts of legislation taken by the Kazakhs government impact the business climate and the foreign investment in the country: a) the 2003 Law on Investments; b) the 2003 Customs Code and Customs Code of the CU (with Russia and Belarus) which is in force from 2010; c) the Tax Code, 2009 and d) the Law on Government Procurement, 2007; e) Transfer Pricing Law (into force from 2009); f) Rules of Hiring Foreign Labor Force, 2007. These laws provide for non-expropriation, currency convertibility, guaranties of legal stability, transparent government procurement, incentives for priority sectors (health, infrastructure and tourism) and transparency in hiring professional expatriates. However, there are significant inconsistencies in their implementation and they remain obstacle for doing business and barrier for further investments (Country Conditions, n.d.; OECD 2012). Some important highlights of the legislative are presented below.

The **Law on Investment** from 2003 is still in force and it guaranties equal treatments to both, domestic and foreign investors (non-discriminatory). The **Tax Code** from 2009 moves the burden from SMEs to extractive sector companies (e.g. oil and gas). In this context, Kazakhstan has flat tax of 11% on employee's earnings and the tax for non-residents ranges between 5%-20% depending on the type of income. Special provisions exist for subsurface users. The Investment Law and the Tax Code include some incentives for tax preferences, customs duties exemptions and grants for foreign and domestic investors. The focus of these incentives is in the priority sectors as defined by the government: agricultural industry, information communication, infrastructure, pharmaceutical, transport, chemistry, tourism and etc. (Country Conditions, n.d.; OECD 2012).

The **Transfer Pricing Law** is in accordance with the OECD Transfer Pricing Model. It still needs improvement to fully comply with OECD model; for instance, elimination of transfer pricing controls on internal transactions in connection to international operations (import-export) and removal of limitations on quotation period. Considering the **Customs Code**, Kazakhstan adopted international tariff terminology which is not fully published, but in some regions they use the old tariff model which causes unnecessary delays and costs for the importers. Kazakhstan has also strict measures on **hiring foreign labour**, including key personnel. Difficulties exist in obtaining a work permit and the introduction of quota worsens the situation even further (from 7 000 to 10 500 in 2001). In relation to opening **bank accounts**, no distinction is made between residents and non-residents. Money transfers associated to investments inside or outside of the country are unrestricted. Different types of bank accounts for foreign investment or import/export are not subject to restrictions (Country Conditions, n.d.; OECD 2012).

Foreign investors complain about irregular applications of the regulations. Namely, some report regulatory pressure in order to extract bribes. Further, there are reports on harassment by the financial police through unannounced audits, inspections and other methods. Also, there are noticeable problems in finalizing contracts, delays and irregular practices in the licensing process and land fees. The transparent application of laws remains major obstacle to expansion of the trade and investments. Foreign companies report inconsistent standards and corruption. The institutional governance of Kazakhstan is very weak. Senior officials have a large say on minor and major transactions and usually the decisions are made behind closed doors (Country Conditions, n.d.). There are also structural barriers to trade in Kazakhstan like weak business law system, ineffective judicial system for breach of contract resolution and strong government bureaucracy. Customs administration is a big issue for traders. According to the laws of the country, exporters have to obtain a "transaction passport" to clear imported goods through customs which presents serious barrier for trade. The National Bank of Kazakhstan (hereinafter: NBK) requires this passport predominantly for the purpose of currency control. This regulation is further introduced to stem capital outflows and money laundering by requesting importers to show copies of contracts and other documentation in order to legitimize and verify the price of import/export transactions. Any party that has intention of making transactions in amount more than US$ 50.000 is required to obtain this passport (Country Conditions, n.d.).

3.2.3 Public corruption and economic freedom

Although the Criminal Code of Kazakhstan has special penalties for accepting or giving bribe, corruption is still present throughout the country. Investors point out corruption at every level as serious barrier for doing business. Many aspects in the business sector like customs clearance, registration, employment of locals and foreigners, payment of taxes even the judicial system are corrupted (Country Conditions, n.d.).

According to Transparency International (2013) and their corruption perception Kazakhstan is ranked 133rd out of 176 countries for 2012. That is extremely poor ranking which signals high corruption in the country. The most problematic areas that still remain are the judiciary, police, customs, property rights, land registrations and construction projects. According to other different independent agencies like the World Bank and the World Economic Forum, the Corruption Perception Index (CPI) for Kazakhstan is reportedly 2.8 out of 10 (low CPI indicates that the country is totally corrupt) which ranks the country 39th out of 174 countries (better ranking denotes more corruption). Again, corruption remains systematic and it is widespread across the public sector (Country Corruption, 2012).

Furthermore, there are growing number of arrests in the top political circles which highlights the confrontations between the powerful elites in the country. The widespread campaign of punishing corruption and other economic and financial crimes is used by the governmental party in order to

neutralize the potential threat to President Nazarbayev's power. Also, the modern political history under Nazarbayev's leadership is marked with assassination and threats to all political dissenters, even journalists who criticize the government. Basically, everyone who turns against the President is punished (Central Asia Series, 2009).

The economic freedom score of Kazakhstan is 63.7, making the country's economy 67th freest in the 2014 Index. Its score is 0.7 points higher than last year with improvements in investment, business and monetary freedom. A decline is noticed in the rule of law. In the Asian-Pacific region Kazakhstan is ranked 10th out of 45 countries and the overall score is above the world and regional average (Heritage, 2014).

Table 3. Economic Freedom, 2014

Rule of law		Limited government	
Property rights	30.0	Government spending	85.0
Freedom from corruption	25.7	Fiscal freedom	92.9
Regulatory efficiency		Open markets	
Business freedom	74.4	Trade freedom	78.2
Labour freedom	86.7	Investment freedom	40.0
Monetary freedom	74.4	Financial freedom	50.0

Source: Heritage, *Index of Economic Freedom - Kazakhstan*, 2014

The legal framework maintains to be inefficient and under influence of political factors. The court does not protect the property rights effectively and the infringements on intellectual property rights are rife. Besides anti-corruption campaigns in the country, not much is changed. Corruption and bribes remain prevalent across Kazakhstan. Even though the Kazakhstan's legal environment is more developed than the countries of the former Soviet Union, it still lags behind the Western countries. Furthermore, disputes over the terms of contract enforcement are common and commercial laws are slow and inconsistent (Heritage, 2014; Tugut & Lee, 2007).

3.2.4 Social unrest and in/stability

In December 2011, riots broke out in the Kazakh city Zhanaozen, a major oil producer, where oil workers had already protested against unpaid danger money, low wages and mass dismissals. The strike was not allowed to continue indefinitely and was ended violently by the police. Sixteen unarmed protesters were killed and more than hundred wounded. These events concerned many in the business community; they noted that something is fundamentally wrong. The act of the government demonstrates intolerance towards any form of social unrest and preference of stability over democratic freedoms. The events also awakened the opposition and Western officials stated that the government has no grasp of modern labour relations and has difficulties with the Western business practices. Another security concern is the growing threat of Islamic

extremism. A little known jihadist group took the responsibility for two bombing attacks in October, 2011 in the western city of Atyrau. The terrorists demanded reassessment of the law that bans prayer rooms in state buildings and requires all missionaries to register with the government every year. This "message" was sent directly to the indifferent government of Kazakhstan with threats of further attacks. A month later, an Islamic militant shot and killed four policemen and two civilians in the southern city of Taraz. The president denied the claims that the jihadists were behind the incident. Another battle occurred in December, 2011 in Almaty, as religious militants entered an armed battle with the police. The authorities believed there was a connection between the attacks, however no evidence supported the claim. Very little is known about these militant religious groups. Even the trials involving these groups took place behind closed doors. Thus, the public gives rise to many conspiracy theories about the goals, targets and sources of finance of these militant groups. Additionally, social tensions arise from the return of the oralmans, native Kazakhstani from the neighboring countries (invited by the government in order to reunite the Kazakh nation). More than 1,000,000 oralmans returned and they cause social tension due to their inability to integrate in the society. The Slavic population in Kazakhstan also encounters problems when getting a job in public administration. The conditions for getting a job in the public administration are subject to strict rules by the government and Kazakh language proficiency is required. Anyway, social tensions among the ethnic groups in the country prevail and its diversity could lead to possible ethnic conflict even border disputes. Internal threats are not the only type of threat for Kazakhstan. Despite the President's efforts to reposition the country as Eurasian, the actual position of the country is in extremely fragile neighborhood. The authoritarian leader of Uzbekistan, Islam Karimov, is reportedly sick and his death could cause serious repercussions in Kazakhstan. Also, Kyrgyzstan has many internal problems which could easily trigger unexpected occurrences in Kazakhstan (Country Forecast, 2012; ICG, 2013).

3.2.5 Political forecast

Nazarbayev's regime made progress in reducing investment obstacles and bureaucracy. However, significant impediments still exists. It is more than certain that foreign investors encounter barriers and confront problems and risks in relation to corruption and close links between politicians and businessmen. It is crucial for them to secure allies within the political structure of Kazakhstan. However, in case of social unrest or even more extreme situation of government fall, they may be left vulnerable. As much as the ageing president Nazarbayev (74) and his governing party manage to stabilize the country in every aspect, the future does not look very bright. By having all the power of the parliament and the national economy, the political stability may easily be shaken by Nazarbayev's unexpected death or by popular uprising. Without designated leader who acts as a successor to the authoritarian President Nazarbayev, the transfer of power may end up messy and very problematic. Also, the uneven distribution of the wealth, the high corruption, and the growing Islamism can trigger social unrest (Country Forecast, 2012).

There are few regime scenarios that might occur in the future. For instance, the successor may trigger crisis leading to a fight over the control of the energy wealth from the center. Different powerful parties might try to re-steal what is already stolen. However, the regime scenario most likely to occur is President Nazarbayev's resignation and his discreet management over his hand-picked successor from the side line. In this case, everything stays the same as long as Nursultan Nazarbayev is alive. After his death, no one can predict the future events. It is less likely that the successor might have the same power and same authoritative capabilities as Nazarbayev, even if they come from the same party. The country may turn under military governance or it may turn into a more democratic state, based on rules and laws, conducting fair parliament and presidential elections. Anyway, it is hard to predict. What is safe to say is that President Nazarbayev has five more years of power the least, presuming his health stays stable. The international investors are optimistic that the business can continue as usual even after Nazarbayev as they hope for discreetly managed transition created by his inner circle. For them, it is better to stay in business (despite the corruption and barriers they encounter) than to suffer huge losses or even worse, terminate their businesses (Country Forecast, 2012).

3.3 Analysis of the Economic Environment

3.3.1 Facts, figures and projections

The county's real economic growth for 2012 was 5.0%. It is below the official government projections of 6.0%. In the next term, the growth remained fairly positive forecasted at 5.9% for 2013. Domestic demand holds steady for now but it is expected to weaken due to lower revenue from oil export, while the external demand is expected to strengthen. All future projections are related to foreign energy demand. Deterioration in external environment, especially the country's major trading partners (e.g. Italy, Netherlands) lead in low oil demands, therefore, less export and slow growth of the economy. Since Kazakhstan's economy is dependent on the energy sector, failing to keep the projected oil prices can lead to deterioration of the economy. As the natural resource extraction drives the economic expansion of the country, the increasing oil output gives rise to the whole economy and as it is expected to happen in the next term. However, Kazakhstan government is making efforts to diversify its economy and become less dependent on natural resources. That cannot be expected in the next term (IHS - Country Reports, 2014, pp. 4-5).

Table 4. Economic Growth Indicators, 2011-2018

Economic growth indicators	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Real GDP (% change)	7.5	5.0	5.9	4.6	5.9	6.1	6.1	5.9
Nominal GDP (US$bn)	188.0	203.5	224.4	211.9	237.9	268.8	299.0	331.2
Nominal GDP Per Cap (US$)	11,681e**	12,508e	13,649	12,761	14,188	15,877	17,501	19,216
Real Exports of Goods and Services (% change)	15.6e	-0.5e	-14.1	15.8	1.4	1.1	3.1	1.9
Real Imports of Goods and Services (% change)	16.2	11.3	16.7	20.0	1.7	2.7	2.0	3.5

Note. * Denotes forecasted, shaded cells.
Note. ** Denotes estimated.

Source: IHS - Country Reports, *Kazakhstan Country Monitor*, 2014, p. 5.

Through 2011, the nominal wages were increased by 23%, however, the inflation suppressed real wage growth to somewhat 14%, while still giving rise to private spending (IHS - Country Intelligence Report, 2014, p. 7). The income is unevenly distributed among the population and the poverty remains strong. The unemployment of 5.2% in 2013 continues to decline as the economy absorbs young workers. Kazakhstan inflation rate is closely connected with the developments in the oil and metal prices. The current fairly moderate inflation is a result of the suppressed export revenue inflows. The oil prices are lower but stable and the demand is eased. This trend is expected to continue in the near future. The possible risks related to the increase of the inflation rate are connected with the uncertainty of global market developments, increase of oil prices, influence of the exchange rate and the weak harvests and their potential impact on the food prices (IHS - Country Intelligence Report, 2014, pp. 7-8).

Table 5. Inflation Indicators, 2011-2018

Inflation Indicators	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Consumer Price Index (% change)	8.3	5.1	5.8	5.6	6.2	6.7	6.3	6.0
Wholesale Producer Price index (% change)	27.3	4.4	-0.3	3.8	5.0	4.5	4.3	4.1

Note. * Denotes forecasted, shaded cells.

Source: IHS - Country Intelligence Report, *Kazakhstan Country Monitor*, 2014, p. 8.

It is expected for the exchange rates to remain fairly stable in the medium term. This is a result of a weaker export revenue inflows followed by lower tenge (national currency of Kazakhstan, hereinafter: KZT) supply and slow reserve accumulation. The NBK usually intervenes to curb the KZT appreciation in periods of strong export revenue inflows. In practice, the NBK do not really tolerate fluctuations, especially not in case of KZT appreciation (IHS - Country Reports, 2014, p. 8).

Table 6. Exchange Rate Indicators, 2011-2018

Exchange Rate Indicators	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Exchange Rate (KZT/US$, end of period)	148.04	150.29	153.61	181.96	177.27	177.06	177.25	177.43
Exchange Rate (KZT/US$, period avg)	146.63	149.12	152.14	179.38	179.38	177.16	177.34	177.52
Exchange Rate (KZT/EUR, end of period)	191.54	198.30	211.85	238.37	233.99	237.96	241.77	244.14
Exchange Rate (KZT/EUR, period avg)	203.88	191.60	202.00	243.41	233.39	235.97	240.35	243.20

Note. * Denotes forecasted, shaded cells.

Source: IHS - Country Reports, *Kazakhstan Country Monitor*, 2014, p. 8.

Due to low inflation and financial stability, the interest rate of 5.50% for 2012 is the lowest ever noted. However, there is no space for further interest rate cuts since the recent easing inflation ended. The rates are foreseen to stay stable in the following period as they hit lowest level ever recorded. The forecast presumes that oil prices will continue to ease, followed by a period of re-strengthening. Unfortunately, the interest rates do not cause any boost in the confidence of the banking sector to extend the lending. It is crucial for Kazakhstan to develop new monetary policy tools in order to start increasing lending on the basis of deposits to companies in urgent need for credit, which, at this moment, is less likely (IHS - Country Intelligence Report, 2014, pp. 9-10).

Table 7. Monetary Policy Indicators, 2011-2018

Monetary policy indicators	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Policy interest rate (%, end of period)	7.50	5.50	5.50	6.00	6.50	6.00	6.50	6.50
Short-term interest rate (%, end of period)	1.33	1.58	1.65	2.72	3.17	3.49	6.52	6.56
Long-term interest rate (%, end of period)	5.45	4.66	4.58	4.59	3.96	4.37	7.50	7.55

Note. * Denotes forecasted, shaded cells.

Source: IHS - Country Intelligence Report, *Kazakhstan Country Monitor*, 2014, p. 10.

The majority of investments come from the domestic sector while the FDIs account for one-fourth. The external sector looks stable although risks are always present.

Kazakhstan has a strong trade balance of goods. It is expected for the external surpluses to remain strong besides some moderate changes in the oil and metal sector. However, on a large scale, Kazakhstan's export revenue depends on the external conditions of its trading partners and the global economy. For instance, China's performance (the key export market for Kazakhstan) is very relevant for Kazakhstan through the impact on the global commodity prices. However, in the following period the oil prices are expected to be high and even if the demand weakens, it will still result in good export values. Despite that, the negative service trade, and the balances of the income and current transfer accounts outweigh the positive merchandise trade. The deficits

obtained stay modest and do not cause any problems in the financing (IHS - Country reports, 2014, pp. 10-11).

Table 8. Trade and External Accounts Indicators

Trade and external accounts indicators	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Exports of goods (US$bn)	85.2	86.9	82.5	87.4	92.2	97.3	102.6	109.4
Imports of goods (US$bn)	40.3	49.1	41.4	43.5	45.5	47.5	49.6	53.0
Trade balance (US$bn)	44.8	37.9	41.0	43.9	46.7	49.8	53.0	56.4
Trade balance (% of GDP)	23.8	18.6	18.3	20.7	19.6	18.5	17.7	17.0
Current account balance (US$bn)	10.2	1.1	-0.1	2.3	2.9	1.9	1.5	0.3
Current account balance (% of GDP)	5.4	0.5	-0.1	1.1	1.2	0.7	0.5	0.1

Note. * Denotes forecasted, shaded cells.

Source: IHS - Country Reports, *Kazakhstan Country Monitor*, 2014, p. 11.

As mentioned before, Kazakhstan's economy is largely dependent on the trade with its partners. The main export partners for 2013 were: China with share of 22.7% (US$ 14.6bn), France 9.7% (US$ 6.2bn), Russia 8.0% (US$ 5.2bn), Germany 7.9% (US$ 5.0bn), Italy 6.9% (US$ 4.4bn), Ukraine 4.2% (US$ 2.7bn), Canada 3.9% (US$ 2.5bn) and others. The major import partners for 2013 were: China 30.6% (US$ 13.8bn), Russia 20.5% (US$ 9.2bn), Ukraine 6.8% (US$ 3.1bn), Germany 6.2% (US$ 2.8bn), USA 2.7% (US$ 1.2bn) and others (IHS - Country Reports, 2014, p. 15).

3.3.2 Natural resources dependence and economy diversification

The country holds 3% of the world's raw materials and natural resource base of over US$ 300.000 per capita (Embassy of RK in USA, 2012, p. 9). Due to its substantial wealth, since its independence, Kazakhstan attracts significant foreign investments primarily in the oil and gas sector. By the end of 2011, total FDIs amounted to US$ 92bn, being second after Russia in the Commonwealth of Independent States (Hereinafter: CIS) (Deloitte, 2013; Embassy of RK in USA, 2012).

Oil and gas: Kazakhstan is an oil producer since 1911, it has the second largest oil reserves (ninth in the world) and production that puts them among 20 largest in the world (EIA, 2013, p. 1). Due to increased investments, the country experiences an oil-boom and now the petroleum industry accounts for more than a half of the industrial output. Total liquids production is estimated at 1.6 million barrels per day for 2012 and it holds around 40 billion barrels in reserves. Also, natural gas reserves are estimated at 85 trillion cubic feet (Tcf) (EIA, 2013; Embassy of RK in USA, 2012).

Metal: Kazakhstan is also very rich with metals. Reserves of iron ore are considered to be the ninth largest in the world and they account for around 6% of the global reserves. Kazakhstan also

ranks among the world's largest exporters of copper. Gold, silver, diamonds, uranium and chromium also have a great potential (Embassy of RK in USA, 2012).

Agriculture: Traditionally, Kazakhstan paid a lot of attention to this industry. It still accounts for a sizeable proportion of the domestic economy. Kazakhstan used to have important role of wheat production in the Soviet Union which stagnated after the collapse of the Union. However, new measures and reforms can help this sector develop further (Country Conditions, n.d.).

Since Kazakhstan is highly dependent on natural resources, especially oil for its export proceeds and budget revenues, the government developed several programmes for diversification of the economy and investment promotion programmes. To realize the economic diversification and enhance competitiveness Kazakhstan adopted the "Programme to Attract Investment, Develop Special Economic Zones and Promote Exports in the Republic of Kazakhstan for 2010-14". This programme includes (OECD, 2012, p.76):

- diversification of production in traditional industries (oil, gas, petroleum, metals, nuclear energy);
- developing sectors based on domestic demand: machine engineering, pharmaceuticals, and construction and material building industries;
- developing sectors with export potential: agriculture, light industry and tourism;
- developing sectors to form the "economy of the future": information technology, biotechnology, space activities and alternative energy forms.

The "Innovative Industrial Development Strategy" for the period 2003-15 aims at balanced economic growth through diversification. Several areas can serve as basis for the general economic diversification, pharmaceutical industry among them (the Embassy of RK in USA, 2012). With the "Productivity 2020 programme" the state support can be provided to companies in the priority sectors for fixed capital investments in export oriented production. With the programme "Road Map for Business 2020" the country aims in further diversification of the economy. It supports stable growth of regional businesses in Kazakhstan's non-energy sector especially improvement in the entrepreneurial sector (OECD, 2012). All these programmes offer big opportunities for foreign investors. A company becomes eligible for these programmes by fulfilling certain criteria. The eligibility is available for a range of state support instruments like: subsidies for loan interest payment, loan guaranties, industrial infrastructure development, training of personnel and in-kind contribution (OECD, 2012).

3.3.3 World Trade Organization accessions and CUs

Although Kazakhstan applied for World Trade Organization (hereinafter: WTO) membership in 1996, it is still not a member of the organization. The negotiations are ongoing. Kazakhstan made some important reforms towards entering WTO (e.g. in agriculture), however, there are still

concerns regarding its foreign trade regime and market access. With the slow progress, it is unlikely for Kazakhstan to enter WTO in 2014. The main hardships and concerns are the tariff adjustments, regulations and practices governing sanitary, phytosanitary (SPS) measures, and WTO-inconsistent trade-related investment measures (TRIMS), including those embedded in state-owned enterprises and range of other questions like reform of local content and the VAT policies (WTO, 2013). The benefits of Kazakhstan from the WTO accession emerge from the following key perspectives: a) improved market access of non-CIS countries in selected products; b) tariff reduction on goods to induce domestic resource allocation and increase the number of varieties of imports in imperfectly competitive sectors; c) reductions in barriers against service companies to increase the number of service varieties in the country; d) elimination of local content policy in the oil sector and exemption of the VAT for purchases of Kazakhstan inputs; e) positive effects on the investment climate from increases in the rate of capital return (increase in capital stock due to trade liberalization). After all, the accession may significantly improve the business environment in the country (Jensen & Tarr, 2007).

Since its independence, Kazakhstan signed treaties on avoidance of double taxation with 44 countries and bilateral protection investment agreements with 45 countries (18 of which are with OECD member countries) (US Department of State, 2012). In 2010, Kazakhstan formed CU with Russia and Belarus. From 2012 the CU was upgraded to a common economic space enabling free flow of goods, services, financial and human capital across the borders of these countries. Under this union, Kazakhstan can import goods from Russia and Belarus without customs clearances and duties, however, the VAT and excise duties on imports are still charged. Since 2001, Kazakhstan joined the Eurasian Economic Community (EurasEC) with Belarus, Kyrgyzstan, Russia, and Tajikistan. The bloc functions as a free-trade zone and negotiations to create CU and compose integrated markets for energy, agriculture and common currency are under way (Deloitte, 2013).

3.3.4 Economic ratings

On the ease of doing business for 2014, Kazakhstan is ranked 50^{th} out of 189 countries. Kazakhstan improved its ranking by three positions from the previous year. Segmented by topics, best performance is identified in paying taxes (18^{th}) and registering a property (18^{th}), protecting investors (22^{nd}), enforcing contracts (27^{th}) and starting a business (30^{th}). On the other hand, Kazakhstan performs poorly in dealing with construction permits (145^{th}) and trading across borders (186^{th}) (Doing Business, 2014).

Table 9. Doing Business in Kazakhstan, Topic Rankings

Topic Rankings	DB 2014 rank	DB 2013 rank	Change in rank
Starting a Business	30	27	↓3
Dealing with Construction Permits	145	149	↑4
Getting Electricity	87	85	↓2
Registering Property	18	27	↑9
Getting Credit	86	82	↓4
Protecting Investors	22	21	↓1
Paying Taxes	18	18	No change
Trading Across Borders	186	186	No change
Enforcing Contracts	27	26	↓1
Resolving Insolvency	54	55	↑1

Source: Doing Business, *Kazakhstan*, 2014

Compagnie Française d'Assurance pour le Commerce Extérieur (COFACE) offers analysis and evaluation of risks of the country's businesses defaulting. It also offers evaluation of the overall quality of the business environment in the country to which a company might like to export goods or services. The risk assessment of Kazakhstan together with the business climate for 2014 are rated "B", which means unsteady political and economic environment and usually poor payment record. This is considered a very poor ranking and is majorly triggered by weaknesses in the banking sector and the inefficient legal and institutional system supplemented by risks of political instability, in the event of succession to President Nazarbayev's precipitation (Coface, 2013).

3.4 Analysis of the Socio-Cultural Environment

As mentioned before, Kazakhstan has a population of 17,265,000 inhabitants. The ethnic groups of Kazakhstan are the Kazakhs (Qazaq) 63.1%, Russians 23.7%, Uzbeks 2.8%, Ukrainians 2.1% and other minorities, out of which 70% are Muslims and approximately 26% are Christian. Kazakhstan's age structure has the following composure: 0-14 years of age 24.7%; 15-24 years 16.9%; 25-54 years 42.6%; 55-64 years 8.9% and 65 years and older 6.8% estimated for 2013. The population growth rate for 2013 is 1.2% ranking the country as 98th in the world (CIA, 2013).

The GINI index in Kazakhstan is 28.9 in 2011, according to the World Bank Report, published in 2012. GINI index measures the extent to which the distribution of income (or, in some cases, consumption expenditure) among individuals or households within the economy deviates from perfectly equal distribution. A GINI coefficient of 100 expresses maximal inequality among values whereas 0 expresses perfect equality (on the percentile scale). In this case, Kazakhstan's index of 28.9 ranks the country 18th most equal in the world and has generally even distribution

of wealth across the population. That does not necessarily make the country a wealthy nation (CIA, 2013).

According to UNDP's "Human Development Index (HDI)", Kazakhstan is ranked 69th out of 187 countries with index of 0.754 for 2012. The index of human development measures the average achievements in a country in three basic dimensions of human development: long and healthy life, access to knowledge and decent standard of living. It ranges on scale from low, medium, high to very high HDI. In the case of Kazakhstan, the country belongs to the group of medium/high human development (UNDP, 2013).

Concerning the ethnocentrism in the country, Rybina, Reardon, & Humphrey (2010, p. 101) claim that it leads to high consumption of domestically produced goods and lower level of consumption of foreign made products. As a former Soviet country and its tied relations to Russia and the CIS countries, led by an authoritative president, the patriotism plays important role in the country. Therefore, it has a significant positive effect on the ethnocentrism. On the other hand, Rybina et al., found out that the cosmopolitanism has a significant negative effect on the ethnocentric attitudes in the country. While the patriotism reveals negative effect on the foreign goods, the cosmopolitism appears to be truly opposite. Nevertheless, the history of the country and the ethnic diversity contributes towards less ethnocentric attitudes to its consumers. A clear example is the increased consumption of foreign food products and services especially in Astana and Almaty. As FDI grow, foreign multinationals become more important on the retail markets. The brand awareness among Kazakh consumers is high and the domestic consumers pay high premium in order to enjoy foreign products. For instance, in the cosmetics, foreign brands like Avon, Procter & Gamble and Oriflame together account for more than one third of the sales (EIU, 2013a). On the other hand, the strategy of the government on entering the 50 most competitive economies in the world strives to support the domestic goods production and increase the domestic competitiveness against the foreign made goods (Official site of the President of the RK, 2006). This is expected to increase the ethnocentric attitudes of the country's consumers. Further, the accession in WTO could bring economic reforms for supporting domestic competitiveness of locally produced goods and entrepreneurship, and eventually increase the internal demand for goods. Being in the CU with Russia and Belarus brings further implications for preference of domestic versus foreign made goods. Nevertheless, the influence of the ethnocentrism on consumer attitudes and behavior mainly depends on consumer characteristics and values, product quality perception, availability and substitutes of the products. It also depends on the overall current environmental, economic and politic situation in the country (Rybina et al., 2010).

3.5 Analysis of the Technological Environment

Several indicators point out that Kazakhstan needs to enhance the contribution of science and technology to the economic development. R&D expenditures from the GDP amount to 0.18% according to the latest data published by the Agency of Statistics, Kazakhstan (2014). This percentage is below the level recommended for countries at this stage of development (1%-1.5% of GDP). Furthermore, significant problems arise from underdevelopment of innovation services and market infrastructure. Therefore, Kazakhstan puts more emphasis on the promotion of innovation as driver of economic development and diversification. Their science and technology sector offers spread outlook dominated by research institutes which are in general inherited from the past and still mostly funded by the state. To intensify the investment in R&D, the government has set up different institutions and launched strategic programmes as "Innovative Industrial Development 2003-2015" and "National Programme for Enhancing Industrial and Innovative Development 2010-2014". Some of the targets are to increase the number of international patents and share of innovative companies (OECD, 2013). For 2014, the government projected an increase to 1% of GDP, which is about US$ 2.5bn (UN, 2012).

Table 10. R&D Expenditures

	2006	2007	2008	2009	2010	2011	2012	2013
Inramural expenses on R&D in current Prices, mn. KZT	24,799.9	26,835.5	34,761.6	38,988.7	33,466.8	43,351.6	51,253.1	61,672.7
As percent of GDP	0.24	0.21	0.22	0.23	0.15	0.16	0.17	0.18

Source: Agency of Statistics Kazakhstan, *Science and Innovation*, 2014

According to the latest data (2013), there were 341 organizations conducting R&D and 23,712 personnel involved in R&D out of which 17,195 researchers. Table 11 shows that largest portion of Kazakhstan R&D expenditures go to the natural (energy) and technical sector, while only insignificant amount is dedicated to the medical sector (Agency of Statistics Kazakhstan - Science and Innovation, 2014).

Table 11. Internal R&D Expenses, Science Sectors (Mn. KZT)

Internal current expenses	2006	2007	2008	2009	2010	2011	2012	2013
Natural	6,193.1	5,916.9	9,333.2	10,486.8	12,075.7	14,277.6	14,993.4	22,361.4
Technical	11,638.7	13,643.5	17,626.4	19,302.1	20,534.5	21,192.7	24,048.1	23,937.9
Medical	1,536.1	1,692.0	1,939.4	2,391.4	1,771.8	2,266.2	1,349.7	3,450.5
Agricultural	2,567.3	2,369.7	2,620.2	3,564.4	3,788.7	3,592.3	5,018.4	5,628.2
Public	710.6	1,208.7	1,360.0	1,175.0	1,015.2	1,343.3	2,967.7	2,857.1
Humanitarian	590.2	906.7	806.7	1,618.4	1,228.5	1,841.1	2,551.2	3,437.6
Total	23,236.0	25,737.5	33,685.9	38,538.0	40,414.5	44,513.3	50,928.4	61,672.7

Source: Agency of Statistics Kazakhstan, *Science and Innovation*, 2014

The infrastructure of Kazakhstan is quite inadequate at the moment. The transportation and telecommunication systems are very weak. Population lives in ten major cities which are spread

across the country and linked by roads and railroad lines which are underdeveloped and insufficiently maintained. The country lacks modern highways and better organized transportation network. The communications systems are old and inherited from the former Soviet Union. They are incompatible with the rapid economic growth over the last decade. Hence, the infrastructure, transportation and telecommunication systems are not adequate to serve the population efficiently. Foreign companies that operate in the country anticipate extended delays in the interflow of goods within their supply-chain and distribution networks. Difficulties in communicating with their suppliers, distributors and customers located in different parts of the country are likely to be encountered (Tugut & Lee, 2007). However, these sectors are slowly booming from the economic growth and inflow of foreign capital. The large oil and gas sector is expected to be purchaser of architecture, construction and engineering (ACE) services in the years to come. So far, lots of projects are undertaken in the economic programmes for development of the country. Hence continues, the ambitious infrastructure plans, and the urban and commercial expansion. The plans include upgrading, expanding or building new ports, airports, roads, and power distribution grids and as well as house building and construction of office premises. The National Welfare Fund (Samruk-Kazyna) plays central role in infrastructure investments (Country Conditions, n.d.; UN, 2012).

4 KAZAKHSTAN PHARMACEUTICAL INDUSTRY

The pharmaceutical market of Kazakhstan includes very attractive features. It is supposed to be the most accessible, competitive and transparent market in Central Asia. Furthermore, it has a favorable regulatory environment, ease of doing business compared to the neighboring countries and from a legislative point of view it is very progressive. Also, it enjoys a substantial growth over the past years, but in terms of market size, its potential is constrained by the relatively small population of around 17 million (see Segmentation of Population in Table 2-4, Appendix C). The strong economic growth over the recent years supplemented by accelerated development of oil and gas sector and mineral extraction industries gives boost to the pharmaceutical sector. Over short term, the pharmaceutical market of Kazakhstan is driven by balanced policy of import substitution and integration with the regional CU including Russia and Belarus and WTO accession. Over the long term, it can leverage its potential by supplying its neighboring countries like Uzbekistan, Turkmenistan, Kyrgyzstan and Tajikistan which have poor domestic production (BMI, 2013).

Currently the healthcare sector amounts to around 4.9% of the GDP (it lags behind Western Europe and Russia) and the government has intentions of further modernization and investments in the industry (see Table 5-7 in Appendix C for more data and forecast). The Ministry of Health projects additional US$ 3.2bn for the period 2011-15. The pharmaceutical sector is also included in the long-term strategy of the government “Kazakhstan 2050” (BMI, 2014, p. 44).

Table 12. Healthcare Key Indicators

Healthcare: key indicators	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Life expectancy, average (years)	69	69.3e**	69.6e	69.9	70.2	70.6	70.8	71.1	
Life expectancy, male (years)	63.7	64e	64.3e	64.7	65	65.3	65.6	65.9	
Life expectancy, female (years)	74	74.3e	74.6e	74.9	75.2	75.5	75.7	76	
Infant mortality rate (per 1,000 live births)	27.4	26.6e	25.8e	25.1	24.3	23.6	22.9	22.3	
Healthcare spending (KZT bn)	933.0	1,081.1	1,332.4	1,537.7	1,704.5	1,896.4	2,115.5	2,358.2	2,612.5
Healthcare spending (% of GDP)	4.3	4.0	4.4	4.8	4.9	4.9	4.9	4.9	4.9
Healthcare spending (US$bn)	6.3	7.4	8.9	10.3	11.6	13.0	14.5	16.3	18.1
Healthcare spending (US$ per head)	397.6	457.9	549.0	629.2	700.6	774.5	855.8	951.8	1,052.6
Healthcare (private expenditure; US$bn)	2.6	3.1	3.7	4.2	4.7	5.2	5.8	6.4	7.1
Doctors (per 1,000 people)	3.9	3.9e	3.9e	3.9	3.9	3.9	3.9	3.9	
Hospital beds (per 1,000 people)	7.7	7.8e	7.8e	7.8	7.8	7.8	7.8	7.8	

Note. * Denotes forecasted, shaded cells.
Note. ** Denotes estimated.
Source: EIU, *Kazakhstan: Healthcare and Pharmaceuticals Report*, 2013b; BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, pp. 14-15.

Although the domestic production sector was privatized in 1990s, the country plays much more important role than in the past. In the last several years, it is both the biggest financer and buyer at the same time (BMI, 2014).

Table 13. The Indicators in Dynamics of Pharmaceutical Industry of RK, 2006-2014

Year	Production, US$mn	Fixed assets, %	Price level	Export, US$mn	Consumption, US$mn	Wholesale turnover, %	Retail turnover, %	Salary, KZTths	Package, $	Investment, KZTbn	Population, %	Doctors, ths
2006	62.4	136	102.0	12.2	517.9	294	158	44.0	1.2	2824	101.2	57.5
2007	80.3	122	104.8	16.7	645.8	350	193	59.4	1.4	3392	101.1	59.4
2008	84.8	126	109.6	18.0	763.8	410	205	61.2	1.7	4211	102.6	58.9
2009	84.2	127	120.7	17.1	876.6	400	286	74.0	1.8	4585	101.4	60.7
2010	131.3	106	160.1	19.3	1153.0	465	337	82.1	2.0	4654	101.5	63.9
2011	180.4	113	148.8	22.6	1308.0	487	407	90.1	2.3	5010	101.5	65.2
2012	196.5	120	154.2	23.9	1494.0	503	424	101.1	2.5	5455	101.4	65.8
2013	253.2f*											
2014	308.6											

Note. * Denotes forecasted, shaded cells.
Source: N. Zhumabayev, et al., *The Use of Mathematical Methods of Analysis in the Pharmaceutical Area of Kazakhstan*, 2013, p. 37, Table 1.

Since its independence, what drives the major spending are purchases in OTC sector. However, now the state plays more important role through hospital purchases and accounts for 45% of the pharmaceutical market (BMI, 2015, p. 41). The state also attempts to cover the rural population through different programmes and strategies. They all aim to improve the health of the citizens, manage the health system more efficiently, improve the screening facilities, develop human resources and the medical science. The "Single National Healthcare Policy" is planned to take place by 2015 and the "Single Healthcare Information System" is discussed to couple it. Special attention is paid to the healthcare system of Almaty, the commercial capital and largest city in the country. After the disintegration of the Soviet Union, the pharmaceutical industry of Kazakhstan was left in a very poor condition. At the Presidential Elections in 2011, President Nazerbayev underlined the importance of pharmaceutical industry and its development as one of the key sectors of the economy in the country. It is also part of the "Kazakhstan 2050" strategy and comprises some goals that have to be achieved gradually in the following decades among which lengthening the life expectancy, modernization of hospitals, substantial investments in facilities and infrastructure, increasing the domestic production of pharmaceutical products and etc. (BMI, 2014). At this moment, the pharmaceutical industry of Kazakhstan looks very promising and it has an uprising trend. The value of the pharmaceutical market for 2013 was US$ 1.84bn and it is forecasted to rise up to US$ 2.06bn for 2014, and with a steady substantial growth to US$ 3.23bn in 2018 (see table 14) (BMI, 2014, p. 11). Kazakhstan's share in the world pharmaceutical market is approximately 0.15% (Kubekov, 2012).

Table 14. Kazakhstan Pharmaceutical Sales, Historical Data and Forecasts, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Pharmaceutical sales (US$bn)	1.22	1.34	1.65	1.84	2.06	2.30	2.57	2.89	3.23
Pharmaceutical sales (US$bn), %chg y-o-y	27.9	9.7	23.9	11.4	12.0	11.6	11.6	12.3	11.8
Pharmaceutical sales (KZTbn)	179.34	195.84	246.76	273.92	302.36	336.16	375.28	418.64	464.73
Pharmaceutical sales (KZTbn), %chg y-o-y	27.6	9.2	26.0	11.0	10.4	11.2	11.6	11.6	11.0
Pharmaceutical sales at cons. exchange rate (US$bn)	1.22	1.32	1.66	1.84	2.03	2.26	2.53	2.82	3.13
Pharmaceutical sales, per capita (US$)	76.44	82.95	101.68	112.12	124.28	137.29	151.82	168.98	187.23
Pharmaceutical sales, % of GDP	0.82	0.72	0.82	0.86	0.87	0.87	0.87	0.87	0.87
Pharmaceutical sales, % of health expenditure	19.22	18.12	18.52	17.82	17.74	17.73	17.74	17.75	17.79

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 12.

Furthermore, in 2009 the government of Kazakhstan created the SK Farmatsiya in order to enhance local production, competitiveness and sustainability. SK Farmatsiya is responsible for organizing state purchases of pharmaceutical products and some services in the framework of free and beneficiary medicare through public tenders. The tenders are opened to domestic and foreign companies, though, the first are preferred. The introduction of the central procurement system for the state sector of the single distributor SK Farmatsiya led in decreasing the margins for wholesalers and retailers (BMI, 2014; Armenian Development Agency, 2012).

4.1 Market Segmentation

4.1.1 Prescription drug market

Prescription drugs accounted for two-thirds of the market in terms of value, approximately 65% for 2013. Around 55% in volume terms are sold through retail pharmacies and the retail market accounts for 75-85% of the total market in value terms. The value growth is driven by the increased state spending and the Guaranteed Provision of Medical Care Programme (hereinafter: GOMBP). The introduction of comprehensive medicine insurance or similar scheme of universal medicines coverage can have great impact on this sector. The introduced reimbursement system has full coverage of drugs purchased for treating coronary heart disease, hypertension, COPD, pneumonia, infectious diseases, specific cancers and autoimmune disorders. The coverage is expected to rely on generics with some few patented drugs. Therefore, generics manufacturers are expected to see steady market growth over the medium term. In numbers, this market sector rises to US$ 2.31bn by 2018 as from US$ 1.20bn in 2013 (BMI, 2014, p. 16).

Table 15. Kazakhstan Prescription Drug Market Indicators, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Prescription drug sales (US$bn)	0.78	0.85	1.06	1.20	1.36	1.54	1.77	2.02	2.31
Prescription drug sales (US$bn), % chg y-o-y	30.1	9.9	24.5	12.7	13.5	13.1	14.9	14.3	14.3
Prescription drug sales (KZTbn)	114.42	125.14	158.47	177.99	199.20	224.52	258.05	292.88	332.51
Prescription drug sales (KZTbn), % chg y-o-y	29.8	9.4	26.6	12.3	11.9	12.7	14.9	13.5	13.5
Prescription drug sales, % of total sales	63.80	63.90	64.22	64.98	65.88	66.79	68.76	69.96	71.55

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 17.

4.1.2 Patented drug market

Patented drug sector accounted for 27% of sales value in 2013. Sustained economic growth is driving this small but fast-growing sector. However, it is unclear whether the state is willing to endorse greater consumption of patented drugs produced abroad or it is planning to purchase these drugs within the private sector. One way could be through direct purchases from MNCs in the country. The long-term deals with the MNCs vouch for development of innovative drugs. The state is also negotiating with local producers such are Nobel, Chimpharm and Global Pharm; however, these companies are more into generics. The value of the patented drug market for 2013 was US$ 0.50bn and it is forecasted to reach US$ 0.98bn in 2018. The market is expected to see a declining trend over the period due to patent expiration of many drugs as the total market continues to favor low-tech generic products. Also, strong regulation pressures to keep the pharmaceutical prices from rising can have negative impact on innovation whereas boosting the local manufacture can play as substitute for imported drugs. More importantly, the strength of the

local currency dictates the state purchases of high cost drugs. Since the KZT is tied to the commodities (e.g. oil and gas) it could lead into volatile environment (BMI, 2014, pp. 17-18).

Table 16. Kazakhstan Patented Drug Market Indicators, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Patented drug sales (US$bn)	0.34	0.37	0.45	0.50	0.57	0.64	0.75	0.85	0.98
Patented drug sales (US$bn), % chg y-o-y	30.6	7.4	22.2	11.7	12.8	12.4	16.8	14.3	15.2
Patented drug sales (KZTbn)	50.75	54.25	67.41	75.00	83.40	93.44	109.11	123.85	141.69
Patented drug sales (KZTbn), % chg y-o-y	30.4	6.9	24.3	11.3	11.2	12.0	16.8	13.5	14.4
Patented drug sales, % of prescription sales	44.36	43.35	42.54	42.14	41.87	41.62	42.28	42.29	42.61
Patented drug sales, % of total sales	28.30	27.70	27.32	27.38	27.58	27.80	29.07	29.58	30.49

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 18.

4.1.3 Generic drug market

The generic sector covers substantial proportion of Kazakhstan's pharmaceutical demand in volume terms, notably in the hospital sector. The share of generics in the total market was stated at 37.6% in value terms for 2013 and it is expected to increase to 41.06 in 2018. Over short-term, the growth is driven by introduction of reimbursement programmes and income raise, while over long-term, the consumer spending, greater private healthcare insurance coverage and future expansion in medical provision in the state sector should boost demand for novel products. However, the generics still play a crucial role specifically if the government decides to mandate INN prescribing and place a national formulary build on pharmaco-economic principles. In this way, the state may switch to promotion of prescribing generics and further promotion of domestically produced drugs. The patents expiration may lead into increase of the portfolio of generics offered in the Kazakhstan market by foreign manufacturers, while the local producers may struggle to deliver enough generics to the market. Furthermore, possible adoption of GMP standards by 2017 may boost domestic shares in the generics sector (BMI, 2014, pp. 19-20).

Table 17. Kazakhstan Generics Drug Market Indicators, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Generic drug sales (US$bn)	0.43	0.48	0.61	0.69	0.79	0.90	1.02	1.17	1.33
Generic drug sales (US$bn), % chg y-o-y	29.7	11.9	26.3	13.5	14.0	13.6	13.6	14.3	13.7
Generic drug sales (KZTbn)	63.67	70.90	91.06	103.00	115.80	131.08	148.94	169.03	190.82
Generic drug sales (KZTbn), % chg y-o-y	29.4	11.4	28.4	13.1	12.4	13.2	13.6	13.5	12.9
Generic drug sales, % of prescription sales	55.64	56.65	57.46	57.86	58.13	58.38	57.72	57.71	57.39
Generic drug sales, % of total sales	35.50	36.20	36.90	37.60	38.30	38.99	39.69	40.38	41.06

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 20.

4.1.4 Over-the-counter (OTC) drug market

In 2013 the share of OTCs in the total market was 35% in value terms. By 2018, the sales are planned to reach US$ 0.92bn or 28.45% of the total market. Key drivers of the OTC sector are increasing purchasing power and marketing initiatives, and increased interest in prevention and restructuring of the healthcare system to eliminate the overcapacity in the secondary care sector. Also, rise in the self treatment and prevention is foreseen in near future.

Although the trend is somewhat declining (the state bears increased burden of paying for drugs), the value of the sector is still increasing, which stimulates the growth of the OTC spending after the economic development of chain pharmacies. Eventually, it leads to increase in the purchasing power of the pharmacies and lowering down of the prices. The implementation of the planned expansions and reform of state-backed and managed medical provision until 2015 and beyond are expected to have great impact on the OTC sector. The OTC drugs in contrast to the prescription drugs can be advertised, and the most common media is television. Further, conception of modern and open-format pharmacies can enhance the OTC consumption. The major suppliers in this sector are: Novartis, Berlin-Chemie, Ratiopharm, GlaxoSmithKline, Solvay and Nycomed. Most important therapeutic areas comprise analgesics, cough and cold drugs, nasal treatments and vitamins and minerals (BMI 2014, pp. 21-22).

Table 18. Kazakhstan Over-the-Counter (OTC) Drug Market Indicators, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Over-the-counter (OTC) drug sales (US$bn)	0.44	0.48	0.59	0.65	0.70	0.76	0.80	0.87	0.92
Over-the-counter (OTC) drug sales (US$bn), % chg y-o-y	24.1	9.4	22.8	9.1	9.1	8.6	5.0	8.0	5.9
Over-the-counter (OTC) drug sales (KZTbn)	64.92	70.70	88.29	95.93	103.17	111.64	117.24	125.76	132.21
Over-the-counter (OTC) drug sales (KZTbn), % chg y-o-y	23.8	8.9	24.9	8.6	7.5	8.2	5.0	7.3	5.1
Over-the-counter (OTC) drug sales, % of total sales	36.20	36.10	35.78	35.02	34.12	33.21	31.24	30.04	28.45

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 22.

4.2 International Trade

Pharmaceutical imports account for 90% of sales in value terms and over 70% in volume terms (BMI, 2014, p. 23). The state has quite ambitious plans to bring the domestic production capacity to 50% by 2014, which is not very realistic. Also, it is unclear the capacity the domestic companies with mixed capital have. Recently, the big Kazakh player Chimpharm was acquired by Polpharma whereas Global Pharm was taken over by the Turkish Abdi Ibrahim. Both of the acquirers announced huge investments. The state may also try to manage localizing some of the production with a strategy of dealing with MNCs (like GSK, Sanofi) to obtain discounts for key drugs. However, over long-term, the trade deficit may prevail. On the other hand, the large domestic companies have some opportunities to export in central Asia, especially in

Turkmenistan which has domestic production of just 1%. Germany is the biggest exporter followed by Russia, France, India and Hungary. The share of imports from the Western European and CEE countries is increasing, while the share of imports from the CIS countries is decreasing. Some low-cost generic drugs are also imported from Ukraine and China. Interestingly, China accounts for less than 1% of the imports for finished pharmaceuticals, but it is a primary source of active pharmaceutical ingredients. The government continues its search for non-tariff options to protect local producers. It is possible some new tariff barriers to be imposed, but it is very much unlikely (BMI, 2014, pp. 23-24).

Table 19. Kazakhstan Pharmaceutical Trade Data and Forecasts (US$mn), 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Pharmaceutical exports (US$mn)	16.39	22.51	23.70	25.71	28.05	30.74	33.38	37.38	41.50
Pharmaceutical exports (US$mn), %chg y-o-y	3.5	37.4	5.3	8.5	9.1	9.6	10.0	10.5	11.0
Pharmaceutical imports (US$mn)	829.27	943.77	1,259.68	1,428.71	1,613.94	1,816.64	2,046.23	2,318.81	2,615.16
Pharmaceutical imports (US$mn), %chg y-o-y	22.6	5.8	33.5	13.4	13.0	12.6	12.6	13.3	12.8
Pharmaceutical trade balance (US$mn)	-875.88	-921.26	-1,235.98	-1,403.00	-1,585.89	-1,785.90	-2,012.41	-2,281.44	-2,573.67

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 24.

4.3 Domestic Pharmaceutical Industry

The development of the domestic pharmaceutical industry is closely related to the government plans of diversifying the economy and also other strategies which support domestic production. At present, the country's industry is quite basic, importing all the high-tech and innovative drugs. The local production is based in the southern part of Kazakhstan in Shymkent and Almaty and important facilities in Karaganda and Pavlodar. In numbers, the local pharmaceutical industry satisfies only 10% of domestic demand in value terms and 25% to 30% in volume terms, although the figure is closer to 15% and 50% in the state sector (BMI, 2014, p. 47). However, from a very poor position, the local industry expanded rapidly by CAGR of 24.5% in the period of 2003-2008 comprising KZT 10.07bn (US$ 83.6mn) in ex-factory prices in 2008. The sales in 2011 were KZT 16.5bn. In 2009 President Nazarbayev announced that the local production is unacceptable and projected increase to 50% (in volume terms) by 2014. To meet this goal, the government plans to build/modernize 26 pharmaceutical facilities (10 are reportedly being built so far). There are 78 registered pharmaceutical companies but just 20 to 25 actively produce drugs. Just four of them account for 70-75% of the total production: Chimpharm (acquired by Polpharma in 2011), GlobalPharm, FK Romat and Turkish-owned Nobel-AFF. Some other companies which do not have plant-based pharmaceutical production are Phytokhimia, a start-up based at Karaganda Pharmaceutical Plant, Kyzyl-Mai and Dospharm, both makers of OTC remedies and Lekos and Eleas, small generic drug producers. Since the industry is dependent on imports, the industry's growth is regarded as priority in the government strategies. Chimpharm is

the leading domestic pharmaceutical company accounting for 50% of the local output and more than 80% of the export sales of the country. GlobalPharm (a JV between local investors and South Korea's Han Seo Pharm**)** based in Almaty had an overall market share of 10% in 2008. In 2012 it was acquired by Turkish Abdi Ibrahim which announced additional investment of US$ 60mn. Romat owns three factories, two in Pavlodar and one in Semey. The company had a production of US$ 75mn in 2011, which is 9% increase. Nobel, a Turkish-owned company manufactures mainly generics in the Almaty Pharmaceutical Factory. It invested more than US$ 30mn to date. All these companies have plans to expand their plants and production. All companies have to comply with the GMP standards by 2017 and it is obvious that the government is creating more favorable environment for the local companies (BMI, 2014, pp. 47-50).

4.4 Foreign Pharmaceutical Industry

Around 90% in value terms or over 70% of the pharmaceuticals sold in Kazakhstan are imported (BMI, 2014, p. 52). Most of the companies operate through representative offices and local distributors. They can also participate in the tenders for state purchases. The biggest opportunities are seen in the therapeutic sectors of anti-tuberculosis medications, cardiovascular, oncology and diabetic preparations and vaccines and other immunobiological preparations. There are around 100 foreign representative offices and the most successful companies and leading suppliers in the Kazakhstan market are Berlin Chemie, Sanofi-Aventis, Novartis, GlaxoSmithKline, Nycomed Pharma and Gedeon Richter. Other big foreign companies are Eli Lilly, Pfizer, Schering-Plough, Janssen-Cilag, Bristol-Myers Squibb, Sagmel and Alcon. Germany is the biggest exporter followed by Russia. Products are also imported from India, in general low-cost generics. Other suppliers come from the former Soviet Union including Pharmstandart, Stada's Russian units, Latvian company Grindeks and Belarusian Nisvizh Pharmaceutical Plant. Another CIS player is Azerfarm, one of the two biggest local producers in Azerbaijan. Recently, GSK signed agreement with the ministry for local production of vaccines and oncology drugs which is in line with the government projections. Similar contracts were signed by Sanofi and Pfizer. It was the government plans for increasing the local production that opened opportunities for foreign companies (BMI, 2014, pp. 52-54).

4.5 Distribution System

Notwithstanding the recent consolidation, there are still around 200 wholesalers in the country. The wholesalers are reported to drive the prices of drugs. However, only 20 of them are large wholesalers whereas the smaller distributors account for considerable portion of the market. As mentioned, SK Farmatsiya is a centralized monopoly distributor for the state purchases (70%-80% of hospital drugs are being purchased through this centralized system). The main

characteristics of the system are decreased costs and eliminated corruption. While SK Farmatsiya does a good job by purchasing the necessary volume of drugs, there are still many things that have to be done concerning the infrastructure development. It is also noticed that the foreign distributors are slowly entering the market. Leading Russian distributor Protek entered the market in 2004 and in 2009 another Russian wholesaler Katren acquired 51% of Almaty-based wholesaler Amity International, the country's second largest distributor. Some private distributors that operate on the market are Medservice Group, Stopharm, Medicus, Interpharma-K and Zerde. The local producer Romat also has a distribution network and the local company Riger is reported to building US$ 9.8mn warehouse complex in Karaganda. Considering the retail sector, there are roughly 8,000 pharmacies in Kazakhstan, which are mostly in private ownership. The concentration of the pharmacies is in the larger cities and certain regions (Figure 2, Appendix C). Some 20 modern-format pharmacy chains emerged, such as MS Help and Green Door, particularly in the larger cities. The pharmacies are supplied directly from wholesalers and distributors (prescription and OTC), while the state hospitals are being supplied through tenders. In value terms, retail pharmacies account for half of the total prescription market (BMI, 2014, pp. 50-52).

4.6 Regulatory Regime and Counterfeit Drugs

The regulation of the pharmaceutical market in Kazakhstan is defined by the State Drug Law introduced in 1995, revised in 2005 and Kazakhstan's Healthcare Code which has been in force since 2009. A new draft of the State Drug Law has been in the making since 2009 that is supposed to shorten the registration process to 120 days. The registration fee for drugs currently range from US$ 3.000 to US$ 5.000 depending on the product (BMI, 2014, p. 55).

Part of the strategy of the Ministry of Health is to harmonize regulations with the CU members, Russia and Belarus, in terms of mutual recognition of drug registration dossiers and national inspection certificates for manufacturing facilities, which should have been implemented in 2012. However, Kazakhstan received additional five years to implement all pharmaceutical related segments in the CU. Furthermore, the membership in the CU may complicate the membership in WTO and the relations between the countries. Russia joined WTO in August 2012 (WTO, 2012). Kazakhstan might join the organization in 2014, however Belarus may not enter WTO in the near future.

Committee for Control over Medical and Pharmaceutical Activities is state body which issues market authorization and controls the central and regional laboratories, tests applicant drugs and conducts batch controls of imports is under the Ministry of Health. There are roughly 6,000 registered drugs and list of 300 essential medicines. Drugs are subject to co-payment, although many hospitals require the consumers to buy them, while some of them used in public hospitals are free of charge. The deadline to comply with the GMP Standards (which should be

harmonized within the CU) is 2014. However, the companies were given seven years to reach full GMP compliance. It is unclear if the companies manage to fund, build facilities and comply with the standards. However, the state sector distributor SK Farmatsiya already signed supply contracts with the major local companies like Chimpharm, Global Pharm, Nobel-AFF, the Karaganda Pharmaceutical Plant and Romat; some of them are recipients of funds from the Kazakhstan Development Bank. The country has been an observer member of the European Pharmacopeia Commission since 2006. A new state Pharmacopeia is developed and published in 2009 whose goal is "single codex of state standards and regulations for drugs". The standards are harmonized with the European Pharmacopeia. Some significant improvements were also made in context of the Common Technical Document standards for registration dossiers. Concerning imports to Kazakhstan, there are imported drugs that are not subject to state registration such as: prevention and treatment of natural and man-made disasters, treatment of certain highly dangerous infectious, parasitical or orphan diseases (BMI, 2013, pp. 55-57).

According to the most recent data, 10% of the drugs in Kazakhstan are counterfeit, although the country is developing mechanism to deal with this issue (BMI, 2014, p. 58). Also, the territory of Kazakhstan is being used as a transit zone between East and West for counterfeit drugs originating mainly from India and China. In the recent years the country introduced stricter measures and adopted some amendments for trading and producing illegal drugs. It introduced further strategies like labeling drugs in the local language, improved communication between producers and state departments to deal with this issue (BMI, 2014).

4.7 Pricing System

After the disintegration of Soviet Union, the drug pricing system in each CIS country evolved in its own specific way, and Kazakhstan was not exempted. Different instruments of price regulation were adopted by different countries. However, they are more reliant on the Western drug price tools. Anyway, the search for optimal pricing system continues. In essence, the pharmaceutical market of Kazakhstan can be distinguished from the other CIS markets due to large share of imports. Therefore, the main drug regulator in the country is the competition (Pharmaexpert, 2012, pp. 4-5). The development of the pricing system is extensively defined by the state policy of providing the population with safety, affordable, high-quality and effective drugs. To ensure drug quality and affordability, Kazakh government developed several programmes: the Republic of Kazakhstan Code "On the Health of the Nation" and the State Healthcare Development Program "Salamatty Kazakhstan". The implementation of these programmes resulted in creation of Unified Drug Distribution System and development of system of price registration. In 2011, Kazakhstan prepared the National Pharmaceutical Policy. It anticipates a unit whose main functions are development of a drug pricing regulation system and tools of price restriction of the drugs covered by the GOBMP. The system is based on reference

pricing methodology, already adopted by many countries across the world (Pharmaexpert, 2012, pp. 10-11).

At the moment, drugs in Kazakhstan are pretty expensive in comparison to the countries in the region and big pricing fluctuations were noticed within the country's regions. In the rural and poorer regions, due to the underdeveloped infrastructure and inefficient transportation system, prices are higher than in other regions. Furthermore, the retail prices rise fast as the consumer preferences for original and imported drugs grow. In the period of 2003 to 2012 the average price per pack of branded drug tippled to EUR 6.28 and the average price per pack of generics increased by 50% to EUR 1.23 (BMI, 2014, p. 59).

After the complaints of the local companies that are in disadvantageous position, in 2011 the city of Astana signed its own pricing accord with manufacturers covering a list of 150 drugs (due to dependence on local sales). Further, in 2011 as the part of the programme to support the "socially vulnerable and disadvantaged and to ensure the affordability of the drugs", the Ministry of Public Health signed memorandum with the Pharmaceutical Industry Association to provide a list of 200 drugs with fixed prices (BMI, 2014, p. 59).

Considering the price control mechanism, there are around 300 drugs subject to direct price control. Despite price controls, a quarter of the population lacks finances to afford the drugs. The Ministry GOMBP tries to cover these groups and that pushed the state spending to 45% of the market. The groups such as children under the age of five, emergency patients, diabetics, HIV positive individuals and TB patients have full coverage, while the rest are technically covered by aspects of the public healthcare system. Currently, there are 276 drugs that are free of charge; the number has increased by 40% since 2011. These drugs are mainly treating chronic diseases. Also, there are around 10% of the populations in Kazakhstan who use private healthcare services (BMI, 2014, p. 60).

4.8 Drug Registration and Procedures

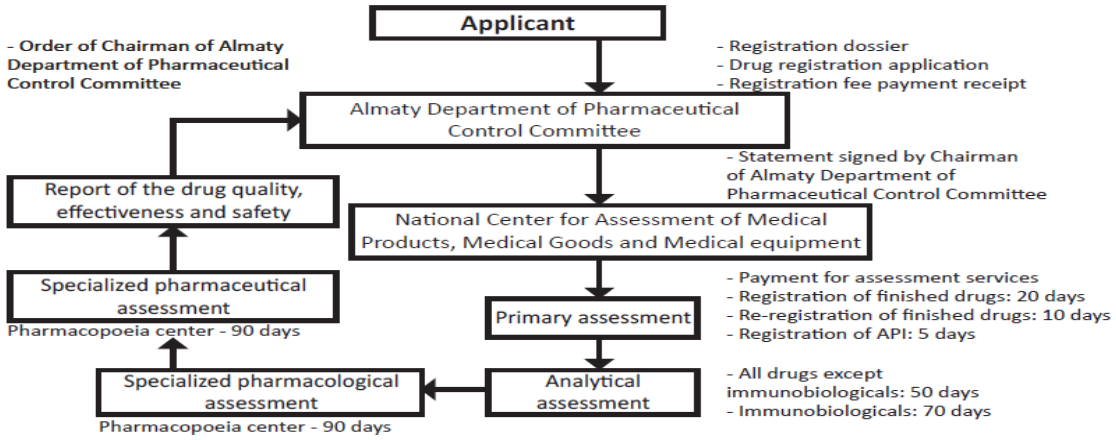
"A drug registration is a procedure aimed at authorization of (permit for) the circulation of the drug itself within a particular country and confirmation of the drug safety, effectiveness, and quality in accordance with applicable regulations" (Pharmaexpert, 2011, p. 5). Once the drug registration is approved, the Marketing Authorization (MA) for that drug can be issued. The procedure is similar in different countries, however, there might be some significant dissimilarities (Pharmaexpert, 2011).

There are three main phases in the drug registration process of Kazakhstan (Pharmaexpert, 2011, p. 6):

1. assessment of documents;
2. assessment of the drug (quality, effectiveness, safety);
3. making a decision on state registration.

The registration procedure is visually presented in figure 6.

Figure 6. Kazakhstan Drug Registration Chart



Source: Pharmaexpert, *Inpharmacia, Pharma Analytical Reports: Ex-USSR Countries*, 2011, p. 7.

Special attention is paid to the quality of drugs. The specific phase of drugs' quality in the registration process is obligatory. The corpus of regulations and all required documents which ensure the drug's quality constitute the pharmacopoeia. In Kazakhstan it is the State Pharmacopoeia of the Republic of Kazakhstan (2007). The national formulary of Kazakhstan differs to those in the CU. Efforts of moving closer to the regulations of European Pharmacopoeia Commission are made. For now, numerous international pharmacopoeias are recognized in the territory of Kazakhstan. However, although the State Pharmacopoeia of Kazakhstan moved really close to the European Pharmacopoeia, there are still substantial differences that make the pharmacopoeia in Kazakhstan a solely national document (Pharmaexpert, 2011).

The allowable timeframe for drug registration in Kazakhstan is 227 days maximum, while the compact registration procedure lasts 137 days (drugs preventing emergencies and used for national security purposes, orphan drugs, authorized generics, APIs and bulk products and drugs made from bulk product registered in Kazakhstan) (Pharmaexpert, 2011, p. 8). The clinical trials make the procedure longer and costly but sometimes they are inevitable in order to ensure the quality, safety and effectiveness of the drug. In Kazakhstan, the decision whether clinical trials are needed is made by Expert Commissions (Pharmaexpert, 2011). The drug registration process is long and costly and obviously each country tends to support the national manufacturers. Contrary to the original (branded) drugs, the registration of generics (same as in other countries) is much simplified.

4.9 Competitive Landscape and C-analysis

In contrast to some other industries, the pharmaceutical industry is subject to frequent changes considering its products and the competition. Therefore, in this part, only the latest known data is presented. Nycomed (+19%) held its first place for the first 6 months of 2013 by share in total **pharmacy sales**. Teva (+6%) overtook Sanofi (+2%) while domestic Santo (+22%, including Chimppharm), Berlin-Chemie/Menarini (+20%) and Gedeon Richter (20%) improved their ranks. Bayer and Sandoz reduced their sales in comparison to the same period of the previous year, however, they managed to remain in the top ten companies. The only newcomer on the list is Stada Arzneimittel AG ranked 10th. In total, the first ten manufacturers account for 38.4% share in total pharmacy sales for the first six months of 2013, same as the previous year (AIPM & Remedium - Pharmacy Sales Six Months, 2013b).

Table 20. Top 10 Manufacturers, by Share in Total Pharmacy Sales

Rank	Manufacturer	Share in total pharmacy sales, %	
		Six months 2013	Six months 2012
1	Nycomed	6.0	5.6
2	Teva	4.4	4.6
3	Sanofi	4.4	4.8
4	Santo	4.1	3.7
5	Bayer Healthcare	3.8	4.2
6	Berlin-Chemie/Menarini	3.7	3.4
7	Gedeon Richter	3.2	2.9
8	Abbott	3.0	3.1
9	Sandoz (Novartis)	2.9	3.5
10	Stada Arzneimittel AG	2.8	2.7
Total		38.4	38.4

Source: AIPM & Remedium, *Kazakhstan Pharmacy Market: 2013 First Six Months*, 2013b, p. 2, Table 1.

Pancreatin replaced the less dynamic Ambroxol on the top and the total share of the top ten INN and generic names is 11% for the first six months of 2013. Considering the rankings of the ATC groups, bigger changes for the same period of the previous year are not noticed and half of the top 10 held their rank. The ATC group leader by far is Antibacterials for system use, and the only newcomer on the list is Psychoanaleptics. The cumulative share of the top ten ATC groups is 41.9% (AIPM & Remedium - Pharmacy Sales Six Months, 2013b).

Table 21. Top 10 INN/Generic Names and ATC Groups by Pharmacy Sales

Rank	INN/Generic names	Share in total pharmacy sales, % - six months 2013	Rank	ATC groups	Share in total pharmacy sales, % - six months 2013
1	Pancreatin	1.6	1	Antibacterials for syst use	9.1
2	Ambroxol	1.5	2	Cough and cold preparations	4.9
3	Ceftriaxone	1.3	3	Analgesics	4.6
4	Multivitamin+multimineral	1.1	4	Antiinflammatory and antirheumatic products	4.1
5	Amoxicilin+clavulanic acid	1.0	5	Vitamins	3.9
6	Azithromycin	1.0	6	Urologicals	3.4
7	Phospholipds	0.9	7	Agents acting on the renin-angiotensin system	3.0
8	Xylometazoline	0.9	8	Sex hormones and modula-tors of the genital system	2.9
9	Diclofenac	0.9	9	Bile and liver therapy	2.9
10	Fluconazole	0.9	10	Psychoanaleptics	2.9
Total		11.0	Total		41.9

Source: AIPM & Remedium, *Kazakhstan Pharmacy Market: 2013 First Six Months*, 2013b, p. 2, Table 3, Table 4.

Roche (+22%) and Santo (+18%) moved to the top spots from ranks two and four, respectively. The leader from the previous year Pfizer reduced its sales by 42% and moved down to the eighth position. The share of the top ten companies by **hospital sales** for the first six months of 2013 is 62.3% (AIPM & Remedium - Hospital Sales Six Months, 2013a).

Table 22. Top 10 Manufacturers by Share in Total Hospital Sales

Rank	Manufacturer	Share in total hospital sales, %	
		Six months 2013	Six months 2012
1	Roche	10.1	9.3
2	Santo	7.9	7.5
3	Sanofi	7.5	7.7
4	Bayer Healthcare	6.4	6.5
5	GSK	6.1	4.5
6	Johnson & Johnson	5.2	6.3
7	Octapharma AG	5.1	4.2
8	Pfizer	5.2	5.0
9	Baxter	4.7	4.5
10	Merck Sharp & Dohme	4.4	4.7
Total		62.3	65.0

Source: AIPM & Remedium, *Kazakhstan Hospital Market: 2013 First Six Months*, 2013a, p. 2, Table 1.

The top three leaders in INN and generic names by hospital sales for the first six months of 2013 hold the same position in comparison to the same period of the previous year. Diphtheria-tetanus-pertussis-poliomyelitis and Haemophilus influenzae type b infections-hepatitis B vaccine, Capreomycin and Pegintereferon alfa-2A are the newcomers. The cumulative share of the top ten INN and generic names for the first six months of 2013 was 29.6%. The first five ATC groups

held their ranks. The only one newcomer is Immune sera and immunoglobulin. The share of the top ten ATC groups for the first six months of 2013 was 77.5% (AIPM & Remedium - Hospital Sales Six Months, 2013a).

Table 23. Top 10 INN/Generic Names and ATC Groups by Hospital Sales

Rank	INN/Generic names	Share in total hospital purchases, % six months 2013	Rank	ATC groups	Share in total hospital purchases, % six months 2013
1	Pneumococcal vaccine	4.1	1	Antineoplastic agents	22.1
2	Octocog alfa	4.1	2	Antihemorrhagics	11.3
3	Antihemophilic factor VIII	3.7	3	Vaccines	9.4
4	Docetaxel	3.1	4	Antibacterials for syst use	8.4
5	Diphtheria-tetanus-pertussis-poliomyelitis & Haemophilus influenzae type b infections-hepatitis B vaccine	2.8	5	Immunostimulants	8.0
6	Peginterferon alfa-2B	2.6	6	Antimycobacterials	5.3
7	Trastuzumab	2.6	7	Drugs used in diabetes	4.5
8	Human normal immunoglobulin	2.3	8	Antithrombotic agents	3.3
9	Capreomycin	2.1	9	Antianemic preparations	2.6
10	Peginterferon alfa-2A	2.1	10	Immune sera & Immunoglobulin	2.6
Total		29.6	Total		77.5

Source: AIPM & Remedium, *Kazakhstan Hospital Market: 2013 First Six Months*, 2013a, p. 2, Table 3, Table 4.

4.9.1 Chimpharm

Chimpharm was established in Shymkent, 1882 and it is a leading manufacturer of drugs in Central Asia. The company has a range of 200 products (in a variety of formulations including: sterile powder, balsams, infusions, solutions, tablets and capsules). Its portfolio also includes antibiotics. It is the largest domestic producer and accounts for 50% of domestic production and the majority of exports. In 2011 it was acquired by Polpharma. The company reported net profits of US$ 7.7mn in 2011 (BMI, 2014, p. 66). Their products are marketed under the brand name Santo, the best known local drugs brand. The company intends to build a GMP-compliant factory for injections, infusion substances, powdered antibiotics and medications in pill and capsule form and also GMP-compliant tablet-forms factory in the city (BMI, 2014).

Table 24. SWOT Analysis - Chimpharm

Strengths • Leading local manufacturer and exporter backed by the resources and product portfolio of a leading CEE generic drugs player. • Modern production facilities, with ISO certification and some GMP-certified lines. • Strong product portfolio and Santo is the oldest and best-known local brand. • Government support for pharmaceutical industry. • Continuing investment by Polpharma into facilities and new product launches.	**Weaknesses** • Strong competition on the generic drugs market from international generics products and threat of increased competition from other CU manufacturers. • Lack of R&D facilities to pursue original drug manufacturing.
Opportunities • Government preference for local producers in state purchases. • Price-conscious consumers prefer generic drugs over branded products due to high out-of-pocket expenditure. • Rising demand for cheap drugs on the regional basis. • Access to financing from state-backed institutions for expansion.	**Threats** • Threat from large CIS generics drugs producers in the context of WTO accession and the CU. • Threat from grey market in Russian and Ukrainian products. • Rising competition in the generic drugs sector.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 65.

4.9.2 Romat

Romat has a strong production base in the country with three plants: Pavlodar ZMI, Pavlodar Pharmaceutical Plant and Semei Plant of Medical Drugs. The company also owns a distributor and pharmacies. Its portfolio includes over 130 biological preparations, drugs and polymeric medical products and primarily produces tablets and capsules. The annual pharmaceutical output of the company is US$ 8mn and accounts for 5% of the domestic production. Romat intends to further achieve GMP certification and it also signed a deal with the Czech FAVEA for building new production facility (BMI, 2014, p. 67).

Table 25. SWOT Analysis - Romat

Strengths • Relatively modern production facilities, with ISO certification, which give it a low-cost manufacturing base and committed expansion plans. • Wide product portfolio. • Government support for local pharmaceutical industry. • Wide-ranging distribution network, including warehouse and retail outlets.	**Weaknesses** • Strong competition in the generic drugs market from new entrants. • Lack of substantial R&D capacity for producing original drugs. • Requirement of substantial investment to reach GMP standards by 2014. • Low global profile.
Opportunities • Government preference for local producers in state purchases. • Price-conscious consumers prefer generic drugs over branded products due to high out-of-pocket expenditure. • Rising demand for cheap drugs on the regional basis.	**Threats** • Threat from large CIS generics drugs producers in the context of WTO accession and the CU. • Threat from grey market in Russian and Ukrainian products. • Rising competition in the generic drugs sector.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 67.

4.9.3 Novartis

Novartis is one of the crucial players in the Kazakhstan market operating through its generic drugs wing Sandoz and Sandoz-owned Lek. It does not have production facilities in the country and operates through sales offices. In 2012, Novartis was ranked first in the retail market

pharmacy with 6% share (BMI, 2014, p. 70). Key drugs in the portfolio of the company include generic drugs in a number of therapeutic areas: cardiovascular, systemic anti-infectives, hormones, respiratory and central nervous system. Its OTC flu treatment, Theraflu is the best selling product in Kazakhstan (BMI, 2014).

Table 26. SWOT Analysis - Novartis

Strengths • Wide product portfolio, including branded generic drugs, which are in high demand in the country. • Significant and well established local representation through sales offices. • One of leading players in the OTC market. • Considerable experience in emerging markets and combined expertise of Sandoz and Lek.	**Weaknesses** • The lack of local manufacturing facilities. • Government tenders favour local producers. • Various barriers to operating in Kazakhstan, including red tape and slow approvals process.
Opportunities • Well positioned to benefit from the modernisation of healthcare sector and improvement of access to drugs. • Government commitment to maintaining public health providing growth opportunities. • Booming economy supporting increased per capita spending on pharmaceuticals.	**Threats** • The government's efforts to promote the local industry. • Increased competition from CEE based generic drugs producers and Russian producers under WTO and the CU. • Potential expansion of price-controlled essential drugs list. • Competition from other multinationals.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 69.

4.9.4 Sanofi

The company operates in the market in six key therapeutic areas: cardiovascular disease, thrombosis, oncology, central nervous system diseases, metabolic disorders and diabetes, with focus on oncology, cardiovascular and metabolic drugs. Its liver regeneration product Essentiale N is among top ten selling product in the market (BMI, 2014, p. 71).

Table 27. SWOT Analysis - Sanofi

Strengths • Strong and well-established market position in Kazakhstan and neighbouring markets. • Wide product portfolio, including generic drugs. • Strong brand awareness among doctors and state purchasers. • Considerable experience in emerging markets.	**Weaknesses** • The lack of a local manufacturing facility. • Government tenders favouring local producers. • Various structural barriers to operating in Kazakhstan, including red tape.
Opportunities • Well positioned to benefit from the modernisation of healthcare sector and improvement of access. • Government commitment to maintaining public health providing growth opportunities. • Booming economy supporting increased per capita spending on pharmaceuticals.	**Threats** • The government's efforts to promote the local industry. • Increased competition from CEE based generic drugs producers and Russian producers under WTO and the CU. • Potential expansion of price-controlled essential drugs list. • Competition from larger multinationals.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 71.

4.9.5 GlaxoSmithKline

The UK giant operates in both hospital (sixth in 2012) and retail sector. The company also collaborates with the government and it signed agreements for local production of vaccines and a

number of oncology drugs. It currently supplies around 100 products and has a share of 3% in the local pharmaceutical market (BMI, 2014, p. 73).

Table 28. SWOT Analysis - GlaxoSmithKline

Strengths • Wide product portfolio. • One of leading players in the OTC market. • Considerable experience in emerging markets.	**Weaknesses** • Government tenders favoring local producers. • Various structural barriers to operating in Kazakhstan, including red tape.
Opportunities • Has announced agreement with the government to produce products locally. • Well positioned to benefit from the modernization of healthcare sector and improvement of access. • Government commitment to maintaining public health providing growth opportunities. • Booming economy supporting increased per-capita spending on pharmaceuticals.	**Threats** • The government's efforts to promote the local industry. • Increased competition from CEE-based generic drug producers. • Potential expansion of price-controlled essential drugs list. • Competition from larger multinationals.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 73.

4.9.6 Nycomed

Nycomed is another market leader which does not have local production and operates through sales offices. In 2012 it was the fifth largest hospital supplier and sixth largest in the retail pharmacy sector (BMI, 2014, p. 75). The company mainly supplies the hospital sector in the therapeutic areas of cardiology, pain management and respiratory diseases (BMI, 2014).

Table 29. SWOT Analysis - Nycomed

Strengths • Wide product portfolio. • Local office presence. • One of leading players in the OTC market. • Considerable experience in emerging markets.	**Weaknesses** • The lack of a local manufacturing facility. • Government tenders favoring local producers. • Various structural barriers to operating in Kazakhstan, including red tape.
Opportunities • Well positioned to benefit from the modernization of healthcare sector and improvement of access. • Government commitment to maintaining public health providing growth opportunities. • Booming economy supporting increased per-capita spending on pharmaceuticals.	**Threats** • The government's efforts to promote the local industry. • Increased competition from CEE-based generic drugs producers and Russian producers under WTO and the CU. • Potential expansion of price-controlled essential drugs list. • Competition from larger multinationals.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 75.

4.9.7 Pfizer

Pfizer is one of the leading US companies in the Kazakhstan market. It operates through a representative office and it is not among the top ten suppliers of either the retail or the hospital markets, which are mainly dominated by European producers. Most important and selling products on the Kazakhstan market are Viagra and Diflucan (used for treatment of fungal infections) (BMI, 2014, p. 78).

Table 30. SWOT Analysis - Pfizer

Strengths • Local representative office. • Considerable experience in various therapeutic areas combined with large product portfolio.	**Weaknesses** • The lack of a local manufacturing facility. • Government tenders favouring local producers. • Various structural barriers to operating in Kazakhstan, including red tape.
Opportunities • Well positioned to benefit from the modernisation of healthcare sector and improvement of access. • Government commitment to maintaining public health providing growth opportunities. • Booming economy supporting increased per-capita spending on pharmaceuticals.	**Threats** • The government's efforts to promote the local industry. • Increased competition from CEE-based generic drugs producers and Russian producers under WTO and the CU. • Potential expansion of price-controlled essential drugs list. • Larger multinationals competition.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 78.

4.10 SWOT Analysis

Table 31. SWOT Analysis – Industry Level

Strengths • A relatively high degree of political stability (in medium-term) and a reformist government that make the country attractive to foreign investors. • A substantial degree of market transparency compared to regional countries. • Local production benefits from import substitution policies and rapid development in key export destinations, especially in CA and other CIS countries. • Substantial long-term regulatory reform attempts are creating an improved operating environment for multinational pharmaceutical companies. • No VAT on pharmaceuticals or active pharmaceutical ingredients.	**Weaknesses** • Local producers have preferential treatment in government tenders. • Government procurers (e.g. SK Farmaciya) have unilateral power to revise agreement terms. • The retail distribution system remains blurred and fragmented (besides that the government monopoly on the distribution of drugs has modernized tenders for the public sector). • Lengthy drug registration process supplemented by inefficient health ministry that slows down the movement. • Limited drugs coverage, with out-of-pocket expenditure restricting access to more expensive drugs.
Opportunities • Imminent WTO accession may push the regulatory harmonisation process. • Heightened healthcare funding and primary care provision are suppose to improve demand and access for sophisticated , high-quality generic drugs. • Practically non-existent local production means abundant opportunities for imports of medical devices. • A small but fast-growing clinical trial sector and treatment naive[1] population.	**Threats** • Lasting poor implementation of intellectual property legislation. • Russian companies enjoy lower costs and better local knowledge and enhanced market position under the CU. • Lack of clarity concerning compatibility of CU with Belarus and Russia and WTO accession. • Inconsistencies over allocation of healthcare funding that might not reach the target recipients.

[1] A person is considered to be treatment naive if they have never undergone treatment for a particular illness.

5 PRESENTATION OF ALKALOID AD SKOPJE

5.1 Company Profile

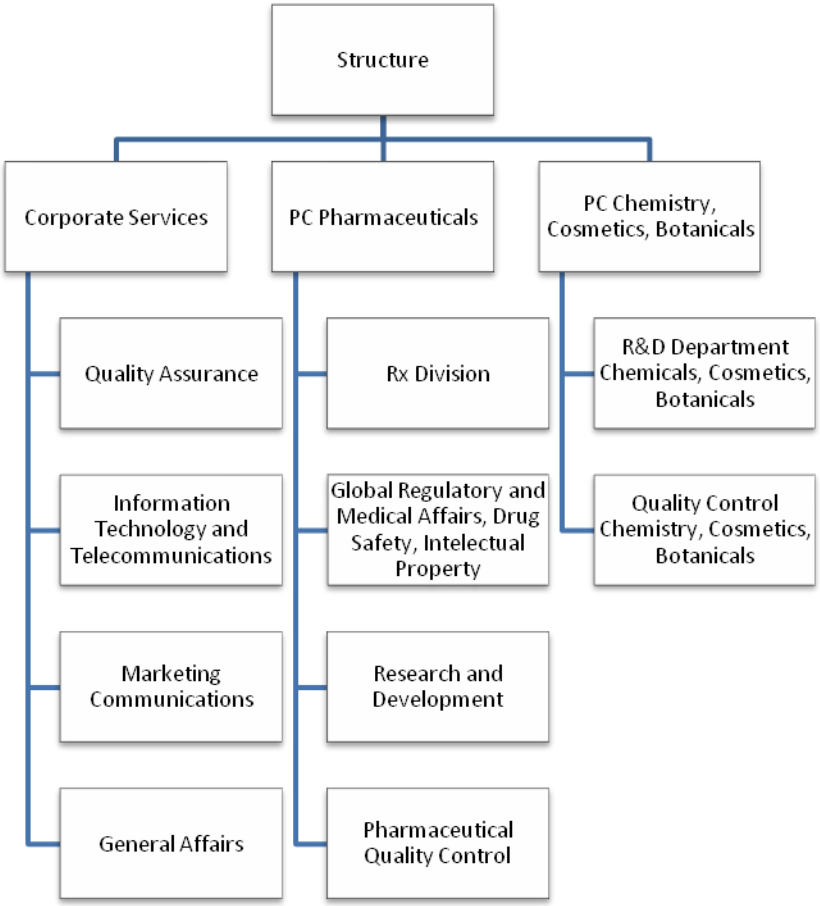
5.1.1 Brief history

The origins of the company date back to 1936, when the company had roughly 15 workers operating in two plants and mainly producing opium alkaloids - pharmaceutical raw materials. The factory was a pioneer in this industry, not just within Macedonia but in the wider region. In the following two decades the company substantially increased its production and so grew the number of employees. A milestone was the opening of the new facility in 1957 (the Galenic plant) for manufacturing of finished drugs in the form of tablets, fluids, ointments and ampoules (Codeine, Caffetin, Codaphen and Noscapin were among the most important). In this period, the Galenic plant attributed to 70% of the income and the company was already thinking of expansion beyond the borders of the country. The company managed to establish business and technical cooperation with some world-renowned names like Theraplix, Paris; Pfizer, New York; Schering AG, Berlin; Specia, Paris; Laboratoires Delagrange, Paris; Chemie, Linz and etc. At first, the cooperation was focused on winning licenses while later it also involved production of substances for pharmaceutical products. In 1966, "Bilka" – the company for medical herb purchase was integrated into Alkaloid AD. The company grew to become a complete medical industry: from production of its own raw materials to final products. In 1972, the company presented a brand new factory for production of finished pharmaceuticals. In this period, the company incorporated its chemical and cosmetic sectors. In that period, Alkaloid AD placed huge portion of its cosmetic products on the Yugoslav market (e.g. Becutan, Black up) and simultaneously established cooperation with the German chemical giant Merck and the Japanese giant Fuji. The company also engaged in botanical production. In the 1990s, Alkaloid AD was restructured and registered as a joint stock company with mixed ownership. It maintained the positive trend of growth and development with constant investments in R&D, facilities and high-tech. Since the 1990s, Alkaloid AD defines itself as an export oriented company. Towards the end of the decade, the company made significant arrangement with world famous pharmaceutical companies and the export surpassed the maximum production capacity of the company. Breakthrough to foreign markets, production growth, increased export volumes, diversification, brand recognition and partnerships with renowned companies are some of the company's significant achievements. Alkaloid AD remains an export orientated company with stable market position and opened to new partnerships, features which are rooted in its corporate strategy. Today, Alkaloid AD employs around 1400 workers, owning state-of-the-art facilities and the most sophisticated information system to maintain and monitor the production process (Alkaloid AD - History, 2013).

5.1.2 Structure and important indicators

Figure 7 illustrates the organizational structure of Alkaloid AD Group. The company is comprised of two profit centers: Pharmaceuticals and Chemicals, Cosmetics and Botanicals alongside with the corporate services (Alkaloid AD - Annual Report, 2012).

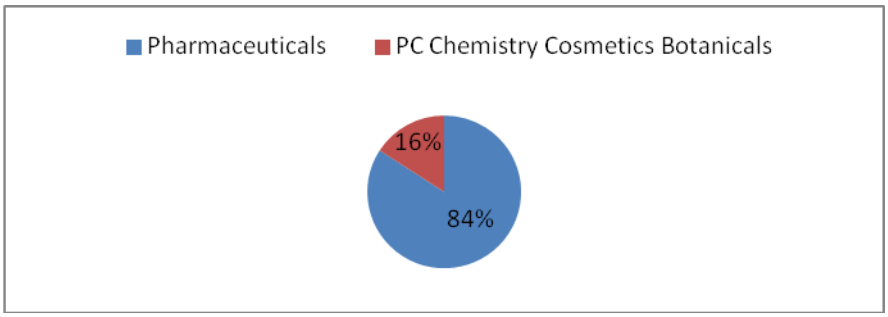
Figure 7. Organizational Chart of the Alkaloid AD Group, 2012



Source: Alkaloid AD, *Annual Report*, 2012

The total net sales of PC Pharmaceuticals for 2012 attribute to EUR 92.769mn which is 84.08% shares out of the total sales of Alkaloid AD Group (Alkaloid AD - Annual Report, 2012, p. 54). On the other hand, the PC Chemistry, Cosmetics and Botanicals amount to EUR 17.561mn which is 15.92% shares out of the total sales of Alkaloid AD Group (Alkaloid AD - Annual Report, 2012, p. 90).

Figure 8. Net Sales in % of Profit Centers, 2013



Source: Alkaloid AD, *Performance Consolidated Report*, 2013

Table 32 shows the main characteristics segmented in organizational units.

Table 32. Organizational Units - Main Characteristics

Profit Center/Org unit	Number of employees	Total consolidated sales in mn/eur	% Participation
Pharmaceuticals	969	97.000	84.00
Chemistry Cosmetics Botanicals	210	18.000	16.00
Corporate Services	309	/	/

Source: Alkaloid AD, *Annual Report*, 2012

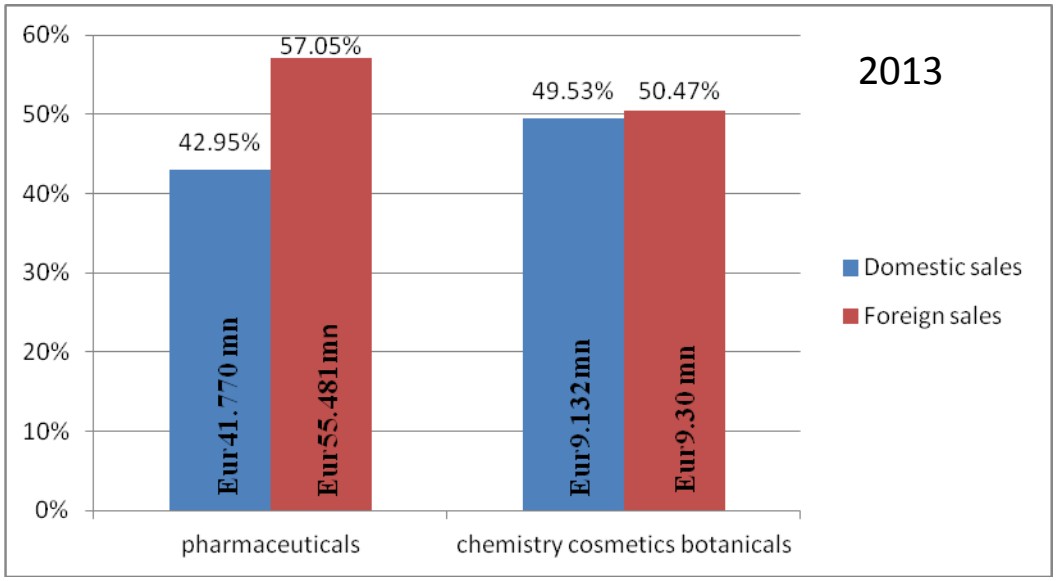
5.2 International Experience

Alkaloid AD, Skopje has international presence with 13 sales subsidiaries. Mainly, the company is expanded in the Balkans (Serbia, Kosovo, Croatia, Montenegro, Slovenia, B&H) but also in Bulgaria, Switzerland, Russia and Ohio – USA (49% ownership). Additionally, Alkaloid AD has representative offices in Russia, Ukraine, Albania and B&H. At the end of 2010, Alkaloid AD opened its first production facility abroad in Belgrade, Serbia (Alkaloid AD - Annual Report, 2012).

Alkaloid AD's major orientation is export. Figure 9 demonstrates the fact that its foreign sales bring more profit. The company exports over 70% of its production and generates in total 57% of its net income from foreign operations. By strengthening its position on the already present markets with strategy of opening new subsidiaries and representative offices in more distant markets, the company focuses on winning the EU and CIS markets. In order to intensify the sales on the EU markets, the company recently opened its second subsidiary in Slovenia. The company opened subsidiaries in Ukraine and Turkey to expand to the east. Also, the company recently obtained its first marketing authorizations for the markets in Germany, France and Austria. Further, the company initiated 60 registration drug procedures in Azerbaijan, Armenia, Georgia, Turkmenistan, Kazakhstan and Turkey. Currently it exports in Germany, Czech Republic, Slovakia, Denmark, Greece and Armenia. However, the largest portion of foreign sales still

comes from the southeastern market which amounts to 75%. Its most famous export brand is Caffetin (Alkaloid AD - Annual Report, 2012).

Figure 9. Domestic and Foreign Sales, by Profit Centers



Source: Alkaloid AD, *Performance Consolidated Report*, 2013

6 CASE STUDY ANALYSIS

The interview with Regional Operations Manager for Business Development of Alkaloid AD, Skopje, Mrs. Tatjana Ivanoska - Filipovska, was conducted on June 17th, 2013 on the premises of the company in Skopje, Republic of Macedonia. The interviewer prepared a comprehensive set of questions. They included various views from international business practices like strategies, motives, intentions, decisions, competitiveness, etc. In the sequel, some important findings from the interview are presented.

The beginnings of Alkaloid AD internationalisation can be described as a purely **incremental process**. The company expanded into the markets of former Yugoslavia and the Balkans due to their proximity and similarity. Later, more or less the company followed the same pattern of internationalisation in the Central-Eastern and Western European markets, with few outliers on its map of presence. Alkaloid AD uses the partnership expansion strategy. The company always strives for attractive collaboration and good marketing distribution. Therefore, Alkaloid AD prefers choosing a **local partner**. The first wave of expansion, considering the fragility of the industry, comprises registration procedures and market approvals. Alkaloid AD opens **offices** to ease the process. The strategy of entry mode is not specified. Each case is treated separately. However, in general, everything consists of **export**. It is their first option of penetrating both closer and distant markets. Organizing local production is more of an exemption than a rule.

There are few important **reasons** why the company is expanding into the Kazakhstan pharmaceutical market. First, it is a fast growing emerging market. Second, it represents a big market which can accept many "participants" (companies). Last but not least, the country itself is developing very fast. The **motives** behind this expansion are neither internal nor external. In practice, the difference between these two cannot be made. It is a managerial decision which is ether way provoked by market growth. Anyway, the market (of Kazakhstan) already belongs to a region where Alkaloid AD is planning its expansion. The biggest **advantage** the Kazakh market offers is the need for import, which presents Alkaloid AD a great opportunity for placing its products.

The preparation of the company for entering the market flows in two directions. The first direction is **theoretical**, thorough market research. Here, the biggest problems arise from the heterogeneity of the market. In general, all regions of Kazakhstan are different and so is the pharmaceutical market. Therefore, it is impossible to penetrate all regions. The second part of the preparations is **practical** by sending personnel on site to conclude the final steps of the market research. Alkaloid AD has its own strategy for utilizing the time. During the ongoing process of registration procedures and market approvals is ongoing (it could last from one to two years), they search for local strategic partner, services, distribution channels and etc.

In terms of **legislative** and **regulations**, Mrs. Ivanoska - Filipovska agrees that the Kazakhstan market is very progressive and significantly more advanced in comparison to other countries from that region. One possible reason is Kazakhstan's membership in the CU with Russia and Belarus and the requirements imposed within this union. Also, transparency is increasingly present in the public administration and the companies that operate in this market. **Entry barriers** do exist. Language and cultural barriers are imminent. It is also unacceptable for women to do business there. Transport issues are expected due to insufficient road infrastructure. Some economic barriers exist in terms of price decrease of some drugs (with governmental actions) and protectionism. The company is making maximum efforts to overcome some of these barriers. They have trained Russian speaking personnel ready to cope with the situation there. In addition, Kazakhstan is a country of high corruption and inflation; it has issues with access to financial resources, tax rates, tax regulations, and inefficient governmental bureaucracy. A start-up feasibility study is absolutely necessary. Further, to mitigate these circumstances, assistance from **local partner** is inevitable. Selection of the partner goes through many stages of control before it is chosen. Trust is the most important thing in partnerships. The company relies on the partner's recommendations and counsel and strives to receive information in a timely fashion. Preferably, Alkaloid AD chooses a partner that is its equal match, eager and motivated to develop and share their common interests. Therefore, Alkaloid AD may use partner collaboration as a **mode of entry**. Through partner's distribution channels, the company can **export** into the Kazakhstan market. Local production is foreseeable, but not at this point. Previously established subsidiary in Russia serves as an advisor and consultant to the company. The network is always good for

sharing useful and valuable information and Alkaloid AD tries to maximise it. However, it is the top management that makes all the decisions. The company is planning to penetrate the market with range of products that dominate its portfolio. The plan definitely includes some of its **generics**, the very popular OTCs from their offer such as Caffetin and its types, Acerola, Betadine, Alkevit Vitamines, Bronles, etc.

As for **competitiveness**, it is clear that Alkaloid AD plans to compete with its quality. The management is persuaded that the company can be very competitive on that market. They do not consider fighting the competition for market share through price decrease. The company tries to gain significant market share through offering quality drugs with good marketing and brand management. They trust Alkaloid AD to be decent competitor to the multinational companies already present on that market. They plan to build recognizable brand for long term presence in the Kazakhstan market. The competition in Kazakhstan is the main driver to decrease the prices. Hence, there are some regions with high competitive pressure. Alkaloid AD has no intentions of entering there. They plan to enter solely those regions where they have opportunity to make the second or third market position.

Also, Alkaloid AD is a responsible company that fully supports the strategy of the Kazakh government to encourage local production through different programmes and measures. However, they are positive the market will stay **import-dependent** in the long run. This offers a great opportunity for Alkaloid AD to positively establish itself. Its presence will also contribute to the quality of products offered in the Kazakhstan market.

7 DISCUSSIONS, FINDINGS AND SUGGESTIONS FOR MARKET ENTRY

The collection of **primary data** (from the interview) was essential for finding answers to the research questions. On the other hand, the collection of **secondary data** (documents, reports) was crucial in building the theoretical framework and offered better understanding of the research area. By combining these two perspectives, the hypotheses developed at the beginning of the thesis can now be answered. Furthermore, the information gathered serve to outline the best possible and successful model for Alkaloid AD to expand into the Kazakhstan pharmaceutical market, which is the **purpose** of this thesis.

Clearly, the hypothesis (**1**) The Kazakhstan pharmaceutical market offers huge potential for Alkaloid AD is now **proved**. The reliable secondary data collected by the author of this thesis confirms this statement. The management of the company offered further evidence. Alkaloid AD as an export oriented company and the pharmaceutical market of Kazakhstan as an import dependent market give support to this hypothesis.

The hypothesis (**2**) The motives of Alkaloid AD for expanding into the Kazakhstan market are presumably external (growing market) rather than internal can neither be **proved** nor **disproved**. The theoretical data indicates that the motives of any company attempting to penetrate the Kazakhstan market (in the period of 2013-2014) are presumably external. The growing market and the import dependences are pieces of evidence that support this statement. However, the empirical results from the interview show that the motives for expansion are neither internal nor external. Alkaloid AD had previous intentions of entering that market since it is situated in a region where they have been gradually expanding (Central Asia). The external motives may just speed up the process. Therefore, this hypothesis could neither be proved nor disproved.

The hypothesis (**3**) Alkaloid AD is most likely to penetrate the market via JV or WOS entry mode rather than export is **disproved**. The evidence from the secondary data demonstrate that any company (a resourceful one) should engage in local production. The government programmes and measures to increase the local production in the next term and substantially decrease the imports (local production to satisfy 50% of the demand), the benefits that foreign companies get for organizing local production, the preferential treatment of local manufacturers in government tenders, the willingness of authorities to allow foreign companies to control the local companies (e.g. Polpharma's investment in Chimpharm and Abdi Ibrahim's in Global Pharm), the speed of delivery and the low transport costs are all in favor of high equity entry mode (JV or WOS). However, the high equity entry mode is related to huge sunk costs. Also, the time span to build the factory and comply with the standards is too long. Plus, Alkaloid AD is an export oriented company. Its best facilities are located in Macedonia. Duplicating or organizing partial local production could not bring many benefits to the company. More importantly, the evidence from the primary data show that the Kazakhstan pharmaceutical market will remain import-dependent in the long term which is not in accordance with the government projections. In any case, the evidence from the primary data and the factors against organizing local production overweigh the evidence from the secondary data. Therefore, this hypothesis is disproved.

Now that data is analysed and hypotheses are answered, suggestions for market entry can be proposed. Taking into account all the circumstances, the decision for the entry mode is considered a **trade-off** between the concerning factors. According to Cieślik and Ryan (2011, p. 533), exporting versus FDI may be a trade-off between trade barriers, transportation costs and fixed costs for building a plant and duplicating production capacity abroad. Therefore, the projections should be made on long term basis taking into consideration the resources of the company.

The decision for the market entry mode is never simple. However, there are **two crucial factors** that ease the process and they are the export orientation strategy of Alkaloid AD and its risk-aversion character. Even though exporting as a mode of entry may not be the best decision, it

surely is the most **optimal decision** in this case. Alkaloid AD should focus on finding a well-positioned local partner to share synergies with (information, marketing, etc.). Alkaloid AD can use the distribution channels of its partner to promote and sell products, and at the same time supply the partner with quality products. Basically, the two companies can jointly promote the products to the retailers. The export procedures of pharmaceutical products to the Republic of Kazakhstan include obligatory registration of the products with the Ministry of Health. Table 9 in the Appendix C displays the procedure of state registration.

The most populated regions in Kazakhstan are South-Kazkahstan and Almaty followed by East-Kazkhstan and Karaganda (Table 8 and Figure 1, Appendix C). As expected, the local production in Kazakhstan is based in the southern part, particularly in Shymkent and Almaty with some important facilities in Karaganda and Pavlodar (see chapter 4.3). These regions have the largest number of pharmacies and drugstores in Kazakhstan (Figure 2, Appendix C). The competition in these provinces is the toughest. Alkaloid AD can enter these regions and increase the competition. It is a less risky option. However, Alkaloid AD may need a lengthy period of time to secure some decent market share. I personally **recommend** for Alkaloid AD to penetrate the following north-eastern regions of the country: Akmola (capital Astana), Pavlodar (capital Pavlodar) and the northeastern part of Karaganda (capital Karaganda) (Figure 1, Appendix C). The company can serve a market of more than 2 million people (Table 8, Appendix C). In comparison to Almaty, South-Kazkahstan and East-Kazakhstan, there is a modest number of pharmacies and drugstores present in these regions (except Karaganda city) (Figure 2, Appendix C). It is a slightly riskier option, but in the long run, Alkaloid AD can establish a good market position in this part of the country. Another important factor for the company is the sickness rate of the population. In these regions, it is higher than the average, especially the region of Pavlodar (Figure 4, Appendix C). Plus, these regions are more homogeneous and the distance between the capitals is relatively short. In addition, Astana and Karaganda can be perfect cities for finding a local partner. After the establishment, the company can gradually penetrate other close regions like North Kazakhstan and Kostany region. In any case, the local partner is crucial for delivering the recommendations and advice for Alkaloid AD to make the right decision.

CONCLUSION

This thesis elaborates the case of a successfully internationalised company, Alkaloid AD Skopje that is expanding into the pharmaceutical market of Kazakhstan. It provides complete research of the Kazakhstan pharmaceutical market. It further offers analysis of the country on a macro level. In conjunction with the presented theories and strategies of the internationalisation process, it results in a comprehensive study that offers outline of a successful model the company can use for its expansion into the target market.

The case analysis flowed in two directions. The secondary data collected through different reliable sources helped to form the theoretical framework of the research area. The primary information gathered through the interview with the top management of the company contributed answers to the most important research questions.

Kazakhstan features poor political condition and high corruption, underdeveloped infrastructure, possible social unrest and undiversified, energy-sector-dependent economy. Kazakhstan needs proper management of the energy sector, realization of government programmes and WTO membership to boost its economy and see better times. However, the poor political situation remains uncertain even/especially with the President Nazarbayev gone from the leadership position.

In view of the pharmaceutical market of Kazakhstan, it becomes clear that this market has a huge potential and ability to accept numerable participants. Its attractiveness and import dependence makes it interesting for foreign companies. Furthermore, Alkaloid strategy of penetrating the markets of Central Asia, definitely puts the Kazakhstan market in their scope of interest. The export mode is chosen as the most optimal market entry solution. The crucial factors for this decision are the export orientation strategy of Alkaloid AD and the import-dependent market of Kazakhstan.

REFERENCE LIST

1. AIPM & Remedium. (2013a). *Kazakhstan hospital market: 2013 first sixth months*. Retrieved July 01, 2014, from www.aipm.org/netcat_files/449/344/h_7bd516ca61ccf52368b1e7fc3a3788b8
2. AIPM & Remedium. (2013b). *Kazakhstan pharmacy market: 2013 first sixth months*. Retrieved July 01, 2014, from www.aipm.org/netcat_files/449/344/h_c6532f933c1b31c6a843e63c575517b6
3. Alkaloid AD. (2012). *Annual report.* Retrieved July 01, 2014, from http://Alkaloid.com.mk/annual-report.nspx
4. Alkalod AD. (2013a). *History*. Retrieved July 01, 2014, from http://www.Alkaloid.com.mk/history.nspx
5. Alkaloid AD. (2013b). *News*. Retrieved July 01, 2014, from http://Alkaloid.com.mk/news-ns_article-Alkaloid-obtains-marketing-authorizations-for-over-30-medicinal-products-in-the-commonwealth-of-inde.nspx
6. Alkaloid AD. (2013c). *Performance consolidated report*. Retrieved July 01, 2014, from http://Alkaloid.com.mk/annual-financial-reports.nspx
7. Andersen, O. (1993). On the internationalisation process of firms: a critical analysis. *Journal of International Business Studies*, *24*(2), 209–232.
8. Antoldi, F., Cerrato, F., & Depperu, D. (2011) Internationalisation of Small and Medium-Sized Enterprises. In *Export consortia in developing countries: successful management of cooperation among SMEs* (pp. 1-17). Berlin: Springer.
9. Armenian development agency. (2012). *Pharmaceutical industry: Russian, Georgian, Uzbek and Kazakhstani market research for pharmaceutical industry*. Retrieved July 01, 2014, from http://www.ada.am/files/985/publications/pharma.pdf
10. Beamish, P., Shige, M., & Woodcock, C.P. (1994). Ownership-based entry mode strategies and international performance. *Journal of International Business Studies*, *25*(2), 253-268.
11. Bilkey, W.J., & Tesar, G. (1977). The export behavior of smaller-sized Wisconsin manufacturing firms. *Journal of International Business Studies*, *8*(1), 93–98.
12. Buckley, P.J., & Casson, M. (1976). *The future of the multinational enterprise* (1st ed.). London: Macmillan.
13. Business Monitor International. (2013, September). Kazakhstan pharmaceuticals and healthcare report Q4 - 2013. In *ProQuest Business and Economics.* Retrieved July 01, 2014, from http://search.proquest.com.nukweb.nuk.uni-lj.si/docview/1429289657?accountid=16468
14. Business Monitor International. (2014, February). Kazakhstan pharmaceuticals and healthcare report Q2 - 2014. In *ProQuest Business and Economics.* Retrieved July 01, 2014, from http://search.proquest.com.nukweb.nuk.uni-lj.si/docview/1505410182?accountid=16468

15. CBO. (2006). *Research and Development in the Pharmaceutical Industry*. Retrieved July 01, 2014, from http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf
16. Central Asia Executive Summary Series. (2009). *Kazakhstan Country Profile.* Retrieved July 01, 2014, from http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CBwQFjAA&url=http%3A%2F%2Fwww.nps.edu%2Fprograms%2Fccs%2FDocs%2FCentral_Asia%2FKazakhstan_July09.pdf&ei=1i3NU_mJLbDG7AbSxIDgCw&usg=AFQjCNHfWd_UDq2cIjC-Ic6J1nCC-NyruQ&sig2=XJmIeOnL3FgZ2AXUSSY-RwQ&bvm=bv.71198958,d.bGE
17. Chung, H.F.L., & Enderwick, P. (2001). An investigation of market entry strategy selection: exporting vs foreign direct investment modes-a home-host country scenario. *Asia Pacific Journal of Management*, *18*(4), 443-460.
18. Christofor, J., & Kollmann T. (2008). Theoretical foundations of firm internationalisation. In *Antecedents of venture firms' internationalisation* (pp. 23-81). GWV Fachverlage GmbH.
19. CIA. (2013). *Kazakhstan*. Retrieved July 01, 2014, from https://www.cia.gov/library/publications/the-world-factbook/geos/kz.html
20. Cieślik, A., & Ryan, M. (2011). Productivity differences and foreign market entry in an oligopolistic industry. *Open Econ Rev*, *23*(3), 531–557.
21. Coase, R.H. (1937). The nature of the firm. *Economica*, *4*(16), 386-405.
22. Cocks, D.L. (1975). Product innovation and the dynamic elements of competition in the ethical pharmaceutical industry. In R.B. Helms (Eds.), *Drug development and marketing* (pp. 225-254). Washington, D.C.: American Enterprise Institute.
23. COFACE. (2013). *Kazakhstan*. Retrieved July 01, 2014, from http://www.coface.com/Economic-Studies-and-Country-Risks/Kazakhstan
24. Country Corruption. (2012). *Kazakhstan*. Retrieved July 01, 2014, from http://country-corruption.findthedata.org/l/137/Kazakhstan
25. Country Conditions. (n.d.). Retrieved July 01, 2014, from http://eds.a.ebscohost.com.nukweb.nuk.uni-lj.si/ehost/pdfviewer/pdfviewer?sid=ebdae692-8178-4d5b-b457-9c8bc31197a2%40sessionmgr4003&vid=0&hid=4102
26. Country Forecast. (2012, February 29). In *Political Risk Yearbook: Kazakhstan Country Report, 2-34.* Retrieved July 01, 2014, from http://eds.a.ebscohost.com.nukweb.nuk.uni-lj.si/ehost/pdfviewer/pdfviewer?sid=41e682ea-ea0b-4ddc-ac60-fc3b5bb7179a%40sessionmgr4004&vid=0&hid=4102
27. Craig, A.M., & Malek, M. (1995). Market structure and conduct in the pharmaceutical industry. *Pharmacology and Therapeutics*, *66*(2), 301-337.
28. Czinkota, M.R. (2012, January 31). Motivations in Going International. Retrieved July 01, 2014, from http://michaelczinkota.com/2012/01/motivations-to-go-international/

29. Czinkota, M.R., & Johnston W.J. (1983). Exporting: does sales volume make a difference? *Journal of International Business Studies, 14*(1), 147-153.
30. Czinkota, M.R., Ronkainen I.A., & Buonafina, M.O. (2004). The drive to internationalise. In *The export marketing imperative* (pp.1-12). Ohio: Thomson
31. *Dari - National center for medicines, medical devices and medical equipment expertise in Kazakhstan*. Retrieved July 01, 2014, from http://www.dari.kz/category/zakonodatelnie_akti
32. Decker, R., & Zhao, X. (2005). Modeling SMEs' choice of foreign market entry: joint venture vs. wholly owned venture. In H. Fleuren, D. Hertog & P. Kort (Eds.), *Operations research proceedings* (pp. 221-229). Berlin: Springer.
33. Deloitte. (2013). *Doing business in Kazakhstan 2013 Reach, relevance and reliability*. Retrieved July 01, 2014, from http://www.deloitte.com/assets/Dcom-Kazakhstan/Local%20Assets/Documents/T&L/En/Brochures/Doing%20business%20in%20KZ_2013.pdf
34. Doing Business. (2014). *Kazakhstan*. Retrieved July 01, 2014, from http://www.doingbusiness.org/data/exploreeconomies/kazakhstan
35. Dunning, J.H. (2000). The eclectic paradigm as an envelope for economic and business theories of MNE activity. *International Business Review, 9*(2), 163–190.
36. EFPIA. (2013). *The Pharmaceutical Industry in Figures*. Retrieved July 01, 2014, from http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf
37. EIA - U.S. Energy information administration (2013, October 28). *Kazakhstan*. Retrieved July 01, 2014, from http://www.eia.gov/countries/analysisbriefs/Kazakhstan/kazakhstan.pdf
38. EIU (2013a). *Kazakhstan: Consumer Goods and Retail Report*. Retrieved July 01, 2014, from http://www.eiu.com/index.asp?Layout=ib3Article&article_id=400091224&pubtypeid=1122462497&country_id=300000030&category_id=775133077
39. EIU. (2013b). *Kazakhstan: Healthcare and Pharmaceuticals Report*. Retrieved July 01, 2014, from http://www.eiu.com/index.asp?layout=ib3Article&pubtypeid=1152462500&article_id=610091645
40. Embassy of the Republic of Kazakhstan in USA. (2012). *Kazakhstan country profile*. Retrieved July 01, 2014, from http://www.kazakhembus.com/sites/default/files/publications/Kazakhstan_Country_Profile_2012.PDF
41. European Forum. (2013). *Kazakhstan*. Retrieved July 01, 2014, from Kazakhstan http://www.europeanforum.net/country/kazakhstan#political_system
42. Eriksson, K., Johanson, J., Majkgard, A., & Sharma, D.D. (1997). Experiential knowledge and cost in the internationalisation process. *Journal of International Business Studies, 28*(2), 337-360.

43. Fassbender, B., & Flessner, T. (2009). Pharmaceutical research. In *Technology guide: principles-applications-trends* (pp.190-196). Berlin: Springer.
44. Fiercepharma. (2014). *Top 10 global corporations by revenues, 2013*. Retrieved July 01, 2014, from http://www.fiercepharma.com/special-reports/top-10-pharma-companies-2013-revenue
45. Fiercepharma. (2013). *Top 10 generics makers by 2012 revenue*. Retrieved July 01, 2014, from http://www.fiercepharma.com/special-reports/top-10-generics-makers-2012-revenue
46. Figueira-de-Lemos, F., Johanson J., & Vahlne, J.E. (2011). Risk management in the internationalisation process of the firm: A note on the Uppsala model. *Journal of World Business, 46*(2), 143–153.
47. Gregoric, A., Hobdari, B., & Sinani E. (2009). The role of firm ownership on internationalisation: evidence from two transition economies. *Journal of Management and Governance, 15*(3), 393-413.
48. Grünig, R., & Morschett, D. (2012). Evaluating market entry modes. In *Developing international strategies: going and being international for medium-sized firms* (pp. 123-148). Berlin: Springer
49. Heimler, A. (2001, June 18). The pharmaceutical industry and parallel trade. Retrieved July 01, 2014, from www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/31heimler_e.doc
50. Heritage. (2014). *Index of economic freedom - Kazakhstan*. Retrieved July 01, 2014, from http://www.heritage.org/index/country/kazakhstan#rule-of-law
51. Hymer, S. (1976). *The international operations of national firms: a study of direct foreign investment*. Cambridge, Mass: M.I.T. Press.
52. ICG. (2013). *Kazakhstan: Waiting for Change, Asia Report N°250*. Retrieved July 01, 2014, from http://www.refworld.org/docid/5249793b4.html
53. IFPMA. (2012). *The pharmaceutical industry and global health*. Retrieved July 01, 2014, from http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf
54. IHS - Country Intelligence Report Kazakhstan. (2014). *Kazakhstan Country Monitor*, 1-20. Retrieved July 01, 2014, from http://eds.a.ebscohost.com.nukweb.nuk.uni-lj.si/ehost/pdfviewer/pdfviewer?sid=0083d225-1239-487c-b1df-48add4ec32ae%40sessionmgr4003&vid=0&hid=4102
55. IHS - Country Reports Kazakhstan. (2014). *Kazakhstan Country Monitor*, 1-19. Retrieved July 01, 2014, from http://eds.a.ebscohost.com.nukweb.nuk.uni-lj.si/ehost/pdfviewer/pdfviewer?sid=17993b9 2-f4d0-4f50-9e48-7fe9404386d7%40sessionmgr4003&vid=0&hid=4102
56. IMAP. (2011). *Pharmaceuticals & Biotech Industry Global Report-2011*. Retrieved July 01, 2014, from

http://www.imap.com/imap/media/resources/IMAP_PharmaReport_8_272B8752E0FB3.pdf

57. IMS. (2012). *The global use of medicines: Outlook through 2016*. Retrieved July 01, 2014, from http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf
58. IMS. (2013a). *Top-line market data*. Retrieved July 01, 2014, from www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/Total_World_Pharma_Market_Topline_metrics_2012-17_regions.pdf
59. IMS. (2013b). *The changing face of the top 10 pharmaceutical firms: The beginning of the end for innovative dominance*. Retrieved July 01, 2014, from http://www.imshealth.com/deployedfiles/ims/Global/Asia%20Pacific/Content/Insights/Top10%20Pharma%20Firms%20WP%20final_for%20clients.pdf
60. Jensen, J., & Tarr, D. (2007, March). The impact of Kazakhstan accession to the world trade organization: A quantitative assessment. *World Bank policy research working paper 4142*. Retrieved July 01, 2014, from http://elibrary.worldbank.org/doi/book/10.1596/1813-9450-4142
61. Johanson, J., & Vahlne, J.E. (1977). The internationalisation process of the firm-a model of knowledge development and increasing foreign market commitments. *Journal of International Business Studies*, *8*(1), 23-32.
62. Johanson, J., & Vahlne, J.E. (2009). The Uppsala internationalisation process model revisited: From liability of foreignness to liability of outsidership. *Journal of International Business Studies*, *40*(9), 1411–1431.
63. Johanson, J., & Wiedersheim-Paul, F. (1975). The internationalisation of the firm-four Swedish cases. *The journal of Management Studies*, *12*(3), 305–323.
64. Karlsen, T., Silseth, R., Benito, G.R.G., & Welch, L.S. (2003). Knowledge, internationalisation of the firm, and inward–outward connections. *Industrial Marketing Management*, *32*(5), 385– 396.
65. Kesič, D. (2006, May 22). Dinamičen razvoj svetovnega farmacevtskega trga [Dynamic development of world pharmaceutical market]. *Delo*, p. 12.
66. Kesič, D. (2009). Strategic analysis of the world pharmaceutical industry. *Management*, *14*(1), 59-76.
67. Korsakienė, R., & Tvaronavičienė, M. (2012). The internationalisation of SMEs: An integrative approach. *Journal of Business Economics and Management*, *13*(2), 294-307.
68. Kubekov, T. (2012, February 14). Analysis of the pharmaceutical market in Kazakhstan-pharmaceutical business. *E-revir*. Retrieved July 01, 2014, from http://total.kz/opinion/articles/151

69. Kudina, A., & Jakubiak, M. (2011). The Motives and Impediments to FDI in the CIS. In *EU eastern neighborhood: economic potential and future development* (pp. 71-82). Berlin: Springer.
70. Kyle, M.K. (2007). Pharmaceutical price controls and entry strategies *The Review of Economics and Statistics*, *89*(1), 88–99.
71. Levi, K.J.B. (2007). Strategic management and market entry strategies in the literature. In *Market entry strategies of foreign telecom firms in India* (pp. 17-62). Wiesbaden: Fachverlage GmbH.
72. Lewis, P., Saunders, M., & Thornhill, A. (2009). *Research methods for business students* (5th ed.). Harlow, United Kingdom: FT Prentice Hall.
73. McDougall, P.P., Shane, S., & Oviatt, B.M. (1994). Explaining the formation of international new ventures-the limits of theories from international-business research. *Journal of Business Venturing*, *9*(6), 469-487.
74. Milchior, R., & Charbonnel, S. (2010). Pharmaceutical; trademark; news. *Journal of Generic Medicines*, *7*(1), 102-110.
75. Morschett, D., Schramm-Klein, H., & Zentes, J. (2009). Motives for internationalisation. In *Strategic international management* (pp. 71-83). Wiesbaden: GWV Fachverlage GmbH.
76. NEFARMA. (2011). *Pharma facts and figures*. Retrieved July 01, 2014, from http://www.nefarma.nl/english/pharma-facts-figures
77. OECD. (2012). *OECD Investment Policy Reviews: Kazakhstan 2012*. Retrieved July 01, 2014, from http://dx.doi.org/10.1787/9789264121812-en
78. Official Site of the President of the Republic of Kazakhstan (2006, March 01). *Address of the president of the Republic of Kazakhstan, Nursultan Nazarbayev, to the people of Kazakhstan, March 1, 2006*. Retrieved July 01, 2014, from http://www.akorda.kz/en/page/page_address-of-the-president-of-the-republic-of-kazakhstan-nursultan-nazarbayev-to-the-people-of-kazakhstan-march-1-2006_1343986805
79. Otto, A. (1993). On the internationalisation process of firms: a critical analysis. *Journal of International Business Studies*, *24*(2), 209-231.
80. Petersen, B., Pedersen, T., & Sharma, D.D. (2003). The role of knowledge in firms' internationalisation process: Wherefrom and whereto? In A. Blomstermo & D.D. Sharma (Eds.), *Learning in the internationalisation process of firms* (pp. 36–55). Cheltenham: Edward Elgar.
81. Pett, T.L., Francis, J.D., & Wolff, J.A. (2004). Examining sms internationalisation motives as an extension of competitive strategy. *Journal of Business and Entrepreneurship*, *16*(1), 46-65.
82. Pharmaexpert. (2011). *Inpharmacia, pharma analytical reports: Ex-USSR countries.* Retrieved July 01, 2014, from http://farmexpert.nichost.ru/upload/InPharmacia_Ex-USSR_2_2011_ENG.pdf

83. Pharmaexpert. (2012). *Inpharmacia, pharma analytical reports: Ex-USSR countries*. Retrieved July 01, 2014, from http://farmexpert.nichost.ru/upload/iblock/cee/INPHARMACIA_Ex-USSR_1_2012_ENG.pdf
84. PWC. (2012). *From vision to decision Pharma 2020*. Retrieved July 01, 2014, from www.pwc.com/pharma2020
85. Research Henry Fund. (2013). *Generics*. Retrieved July 01, 2014, from http://tippie.uiowa.edu/henry/reports13/generics.pdf
86. Ruzzier, M., Hisrich, R.D., & Antoncic, B. (2006). SME internationalisation research: past, present, and future. *Journal of Small Business and Enterprise Development*, *13*(4), 476-497.
87. Rybina, L., Reardon, J., & Humphrey, J. (2010). Patriotism, cosmopolitanism, consumer ethnocentrism and purchase behavior in Kazakhstan. *Organization and Markets in Emerging Economies*, *1*(2), 92-103.
88. Savchenko, K. (2013, February 27). *Kazakhstan: a "bitter pill" for investors in the pharmaceutical market*. Retrieved July 01, 2014, from http://odfoundation.eu/a/1025,kazakhstan-a-bitter-pill-for-investors-in-the-pharmaceutical-market
89. Solberg, C.A., & Nes, E.B. (2002). Exporter trust, commitment and marketing control in integrated and independent export channels. *International Business Review*, *11*(4), 385-405.
90. Telser, L.G. (1975). The supply response to shifting demand in the ethical pharmaceutical industry. *Drug Development and Marketing*, 207-223.
91. The Agency of Statistics of the Republic of Kazakhstan. (2014). *Health care*. Retrieved July 01, 2014, from http://www.stat.gov.kz/faces/wcnav_externalId/homeNumbersHealthCare?_afrLoop=25280870221164#%40%3F_afrLoop%3D25280870221164%26_adf.ctrl-state%3Dht0aophxt_90
92. The Agency of Statistics of the Republic of Kazakhstan. (2014). *Population*. Retrieved July 01, 2014, from www.stat.gov.kz/getImg?id=ESTAT080644
93. The Agency of Statistics of the Republic of Kazakhstan. (2014). *Science and innovation*. Retrieved July 01, 2014, from http://www.stat.gov.kz/faces/wcnav_externalId/homeNumbersScience?_afrLoop=402985272416066#%40%3F_afrLoop%3D402985272416066%26_adf.ctrl-state%3Dsa7dkbyqf_90
94. Transparency International. (2013). *Kazakhstan*. Retrieved July 01, 2014, from http://www.transparency.org/country#KAZ
95. Tugut, M., & Lee, C.Y. (2007). Doing business in Kazakhstan: opportunities, challenges, and suggestions. *Journal of Global Business Management*, *3*(1), 109-119.
96. UNDP. (2013). *Human Development Indicators-Kazakhstan*. Retrieved July 01, 2014, from http://hdrstats.undp.org/en/countries/profiles/KAZ.html

97. United Nations. (2012). *Innovation performance review of Kazakhstan*. Retrieved July 01, 2014, from http://www.unece.org/fileadmin/DAM/ceci/publications/icp5.pdf
98. US Department of State - Bureau of economic and business affairs. (2012). *Report on 2012 investment climate-Kazakhstan*. Retrieved July 01, 2014, from http://www.state.gov/e/eb/rls/othr/ics/2012/191174.htm
99. Watal, J. (2012, November 02). Economics of TRIPS and Public health. *WTO Secretariat.* Retrieved July 01, 2014, from http://www.wto.org/English/tratop_e/trips_e/jayashreewatalwto_e.pdf
100. Welch, L.S., & Luostarinen R.K. (1988). Internationalisation: evolution of a concept. *Journal of General Management, 14*(2), 34-55.
101. Welch, D.E., & Welch, L.S. (1996). The internationalisation process and networks: a strategic management perspective. *Journal of International Marketing*, *4*(3), 11-28.
102. Williamson, O. (1975). *Markets and hierarchies*. New York, NY: Free Press
103. Williamson, O.E. (1981). The economics of organization: the transaction cost approach. *American Journal of Sociology*, *87*(3), 548-577.
104. World economic forum. (2012). The *Global Competitiveness Report 2012–2013*. Retrieved July 01, 2014, from http://nmi.is/media/92463/wef_globalcompetitivenessreport_2012-13.pdf
105. WTO. (2012, August 22). *WTO membership rises to 157 with the entry of Russia and Vanuatu*. Retrieved July 01, 2014, from http://www.wto.org/english/news_e/pres12_e/pr671_e.htm
106. WTO (2013, July 23). *Kazakhstan accession negotiations make incremental progress but major questions unresolved*. Retrieved July 01, 2014, from http://www.wto.org/english/news_e/news13_e/acc_kaz_23jul13_e.htm
107. Yip, G.S., Biscarri, J.G., & Monti, J.A. (2000). The role of the internationalisation process in the performance of newly internationalising firms. *Journal of International Marketing*, *8*(3), 10-35.
108. Zhumabayev, N., Makhatov, B., Makhatova, A., Magay, T., Zhakipbekov, K., Sapakbay, M., & Makhatova, B. (2013). The use of mathematical methods of analysis in the pharmaceutical area of Kazakhstan. *Life Science Journal*, *10*(10s), 36-40.

APPENDIXES

TABLE OF APPENDIXES

APPENDIX A: List of Abbreviations

SME	Small and medium enterprises
MNC	A Multinational company
JV	Joint venture
WOS	Wholly owned subsidiary
FDI	Foreign direct investment
M&A	Mergers and acquisitions
R&D	Research and development
RK	Republic of Kazakhstan
EU	European Union
CIS countries	Commonwealth of Independent States, a regional organization whose participating countries are former Soviet Republics
BRIC countries	Brazil, Russia, India, China
CEE	Central eastern countries
CA	Central Asia
CU	Customs Union
OECD	Organization for Economic Co-operation and Development
WTO	World Trade Organization
WHO	World Health Organization
UN	United Nations
UNDP	United Nations Development Programme
EIU	The economist intelligence unit
BMI	Business Monitor International
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
EFPIA	European Federation of Pharmaceutical Industries & Associations
AIPM	Association of International Pharmaceutical Manufacturers
Remedium	Group of Companies - Market research and business consulting company
BN	Billion
MN	Million
TN	Trillion
NBK	National Bank of Kazakhstan
KZT	Kazakhstan tenge – national currency
VAT	Value added tax
GDP	Gross domestic product
CAGR	Compound annual growth rate
CPI	Corruption perception index
GMP	Good Manufacturing Practices
GOMBP	Guaranteed Provision of Medical Care Programme
INN drug's name	International Nonproprietary Name
ATC	Anatomical Therapeutic Chemical

APPENDIX B: A Terminological Glossary

- Pharmaceuticals, medicines, drugs: synonym terms used interchangeably.

- Patented drug: an innovative medicine granted intellectual property protection by the patent and trademark office. The patent may encompass a wide range of claims, such as active ingredient, formulation, mode of action, etc, giving the patent holder the sole right to sell the drug while the patent is in effect.

- Generic drug: a bioequivalent medicine that contains the same active ingredient as an originator drug. The originator drug is an innovative medicine that no longer has intellectual property protection due to patent expiry.

- Prescription drugs: patented and generic drugs regulated by legislation that requires a physician's prescription before they can be sold to a patient.

- OTC drug: a medicine that does not require a prescription to be sold to patients. Also known as nonprescription medicines.

- Pharmaceutical market/sales: the sum of revenues generated by generic, patented, and over-the-counter (OTC) drugs through hospitals, retail pharmacies and other channels. Unless otherwise stated, market value is reported at final consumer price including mark-ups, taxes, etc.

- Counterfeit drugs: unregistered and illegal medicines which have not been subject to regulatory assessments to ensure quality, safety, efficacy and manufacturing standards.

- Pharmacopeia: a book, especially an official publication, containing a list of medicinal drugs with their effects and directions for their use.

APPENDIX C: Extensive Tables and Figures

Table 1. Groups of Factors Affecting the Price in the Pharmaceutical Market

Manufacturing	Market	Regulatory and financial
Development	Distribution chain (manufacturer to consumer): • Status and number of distribution chain participants • Competition • Supply volume and OTC/Rx split	Healthcare system and expenditures
Research (preclinical, clinical, post marketing)		Regulatory acts and restrictions
Production		Drug categories and lists
Registration		Import substitution policy and support of local manufacturer
		National health programmes
		Drug sales channels
		Reimbursement system
		Tax policy
		Pharma market interaction with other national economy sectors
		Foreign economic activities

Source: Pharmaexpert, *Inpharmacia*, *Pharma Analytical Reports: Ex-USSR Countries*, 2012

Table 2. Kazakhstan's Population by Age Group, 1990-2020
(% of total)

Years	1990	1995	2000	2005	2010	2013e**	2015f*	2020f
0-4 years	11.36	9.18	7.49	8.07	9.87	9.95	9.72	8.93
5-9 years	10.45	10.81	9.45	7.49	7.71	8.76	9.33	9.27
10-14 years	9.71	9.76	10.75	9.12	7.33	7.05	7.31	8.91
15-19 years	8.77	9.01	9.46	10.38	8.60	7.45	6.94	6.97
20-24 years	8.01	8.28	8.55	9.20	9.76	8.90	8.11	6.60
25-29 years	8.83	7.46	8.03	8.22	8.70	9.15	9.15	7.68
30-34 years	8.49	8.10	7.22	7.65	7.68	7.89	8.12	8.63
35-39 years	7.22	7.74	7.59	7.05	7.09	7.09	7.14	7.62
40-44 years	5.25	6.77	7.06	7.10	6.68	6.57	6.55	6.66
45-49 years	3.47	4.77	6.30	6.53	6.44	6.23	6.11	6.05
50-54 years	5.55	3.09	4.25	5.43	5.83	5.85	5.80	5.57
55-59 years	3.29	5.06	2.72	3.76	4.46	4.92	5.14	5.17
60-64 years	3.76	2.79	4.36	2.37	3.18	3.59	3.82	4.45
65-69 years	2.17	3.20	2.19	3.29	1.97	2.23	2.60	3.16
70-74 years	1.31	1.73	2.40	1.76	2.25	1.77	1.50	2.01
75-79 years	1.23	0.94	1.17	1.54	1.30	1.49	1.54	1.04
80-84 years	0.63	0.81	0.48	0.66	0.78	0.73	0.73	0.88
85-89 years	0.34	0.33	0.40	0.21	0.27	0.31	0.32	0.30

table continues

continued

90-94 years	0.12	0.13	0.11	0.13	0.05	0.06	0.07	0.08
95-99 years	0.03	0.03	0.03	0.02	0.02	0.01	0.01	0.01

Note. * Denotes forecasted, shaded cells.
Note. ** Denotes estimated.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 84.

Table 3. Kazakhstan's Key Population Ratios, 1990-2020

	1990	1995	2000	2005	2010	2013e**	2015f*	2020f
Dependent ratio, % of total working age	59.6	58.5	52.6	47.7	46.1	47.8	49.5	52.9
Dependent population, total, '000	6,042	5,741	5,024	4,867	5,025	5,320	5,554	6,062
Active population, % of total	62.6	63.1	65.5	67.7	68.4	67.6	66.9	65.4
Active population, total, '000	10,130	9,809	9,552	10,198	10,896	11,121	11,216	11,457
Youth population, % of total working age	50.3	47.2	42.3	36.5	36.4	38.1	39.4	41.5
Youth population, total, '000	5,097	4,625	4,036	3,718	3,966	4,235	4,420	4,750
Pensionable population, % of total working age	9.3	11.4	10.3	11.3	9.7	9.8	10.1	11.5
Pensionable population, total, '000	944	1,116	988	1,149	1,059	1,085	1,134	1,312

Note. * Denotes forecasted, shaded cells.
Note. ** Denotes estimated.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p.85

Table 4. Kazakhstan's Rural and Urban Population, 1990-2020

	1990	1995	2000	2005	2010	2013e**	2015f*	2020f
Urban population, % of total	56.3	55.9	55.7	54.7	53.7	53.4	53.3	53.5
Rural population, % of total	43.7	44.1	44.3	45.3	46.3	46.6	46.7	46.5
Urban population, total '000	9,099	8,696	8,123	8,243	8,555	8,787	8,931	9,365
Rural population, total '000	7,073	6,854	6,453	6,821	7,366	7,654	7,839	8,154

Note. * Denotes forecasted, shaded cells.
Note. ** Denotes estimated.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p.85

Table 5. Kazakhstan Healthcare Expenditure Trends, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Health expenditure (US$bn)	6.3	7.4	8.9	10.3	11.6	13.0	14.5	16.3	18.1
Health expenditure (US$bn), % chg y-o-y	22.8	16.4	21.2	15.8	12.5	11.6	11.6	12.2	11.6
Health expenditure (KZTbn)	933.0	1,081.1	1,332.4	1,537.7	1,704.5	1,896.4	2,115.5	2,358.2	2,612.5
Health expenditure (KZTbn), % chg y-o-y	22.5	15.9	23.3	15.4	10.9	11.3	11.6	11.5	10.8
Health expenditure at constant exchange rate (US$bn)	6.4	7.4	9.0	10.3	11.5	12.8	14.2	15.9	17.6
Health expenditure per capita (US$)	397.6	457.9	549.0	629.2	700.6	774.5	855.8	951.8	1,052.6
Health expenditure (% GDP)	4.3	4.0	4.4	4.8	4.9	4.9	4.9	4.9	4.9

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 14.

Table 6. Kazakhstan Government Healthcare Expenditure Trends, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Government health expenditure (US$bn)	3.7	4.3	5.2	6.1	6.9	7.7	8.7	9.8	11.0
Government health expenditure (US$bn), % chg y-o-y	22.5	14.2	22.0	17.1	13.0	12.3	12.2	12.9	12.2
Government health expenditure (KZTbn)	551	626.3	777.1	907.0	1010.2	1130.9	1268.7	1423.1	1585.6
Government health expenditure KZTbn), % chg y-o-y	22.3	13.6	24.1	16.7	11.4	12.0	12.2	12.2	11.4
Government sector health expenditure, % of total	59.1	57.9	58.3	59.0	59.3	59.6	60.0	60.3	60.7

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p. 15

Table 7. Kazakhstan Private Healthcare Expenditure Trends, 2010-2018

	2010	2011	2012	2013	2014f*	2015f	2016f	2017f	2018f
Private health expenditure (US$bn)	2.6	3.1	3.7	4.2	4.7	5.2	5.8	6.4	7.1
Private health expenditure (US$bn), % chg y-o-y	23.2	19.7	20.1	13.9	11.8	10.6	10.6	11.2	10.6
Private health expenditure (KZTbn)	381.6	454.8	555.3	630.1	694.3	765.5	846.8	935.1	1026.9
Private health expenditure KZTbn), % chg y-o-y	22.9	19.2	22.1	13.5	10.2	10.2	10.6	10.4	9.8
Private sector health expenditure, % of total	40.9	42.1	41.7	41.0	40.7	40.4	40.0	39.7	39.3

Note. * Denotes forecasted, shaded cells.

Source: BMI, *Kazakhstan Pharmaceuticals and Healthcare Report Q2*, 2014, p.15

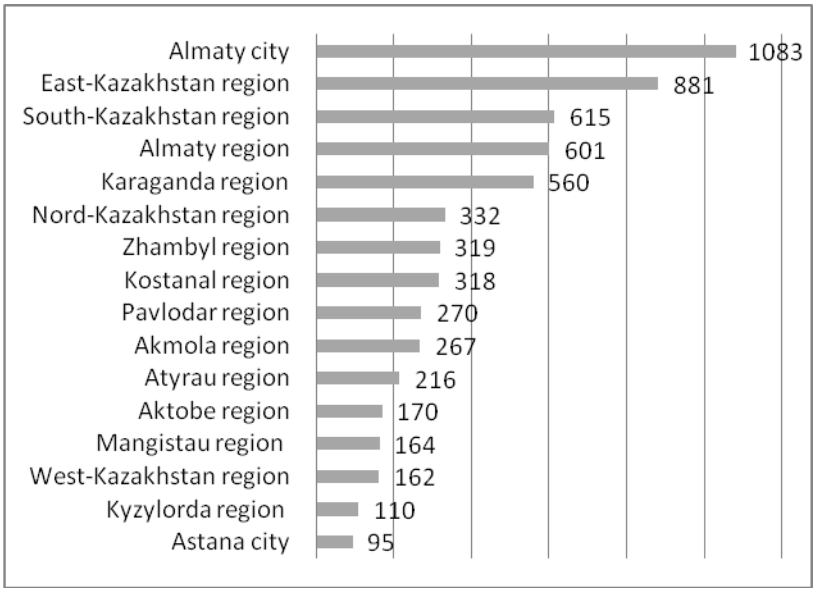
Figure 1. Regions of Kazakhstan

Table 8. Kazakhstan Population, by Regions

	All	Urban	Rural
Kazakhstan	17,160,774	9,433,482	7,727,292
Akmola region	735,566	346,391	389,175
Aktobe region	808,932	498,794	310,138
Almaty region	1,984,518	457,716	1,526,802
Atyrau region	567,861	265,229	302,632
West-Kazakhstan region	623,977	307,001	316,976
Zhambyl region	1,084,482	436,466	648,016
Karaganda region	1,369,667	1,077,482	292,185
Kostanai region	880,776	454,634	426,142
Kyzylorda region	739,776	316,740	423,036
Mangistau region	587,419	293,098	294,321
South-Kazakhstan region	2,733,279	1,069,735	1,663,544
Pavlodar region	752,793	524,879	227,914
Nord-Kazakhstan region	575,766	241,176	334,590
East-Kazakhstan region	1,394,018	822,197	571,821
Astana city	814,435	814,435	
Almaty city	1,507,509	1,507,509	
Karaganda city	459,778	459,778	

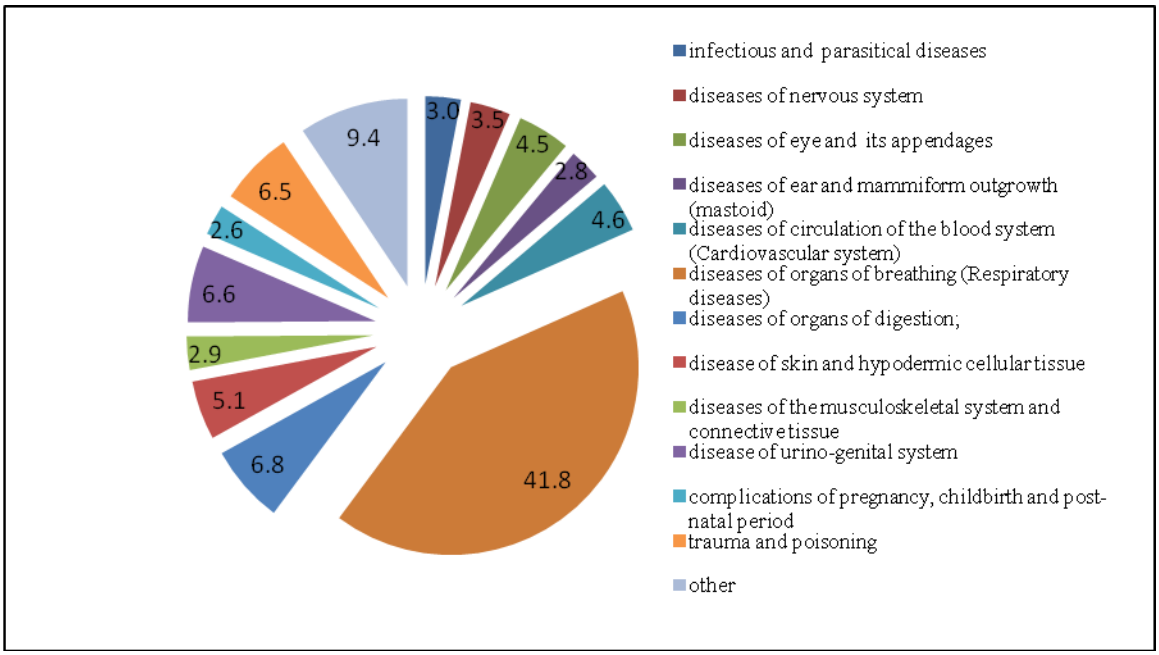
Source: Agency of Statistics, *Population*, 2014

Figure 2. Number of Pharmacies and Drugstores in Kazakhstan, by Regions, 2012



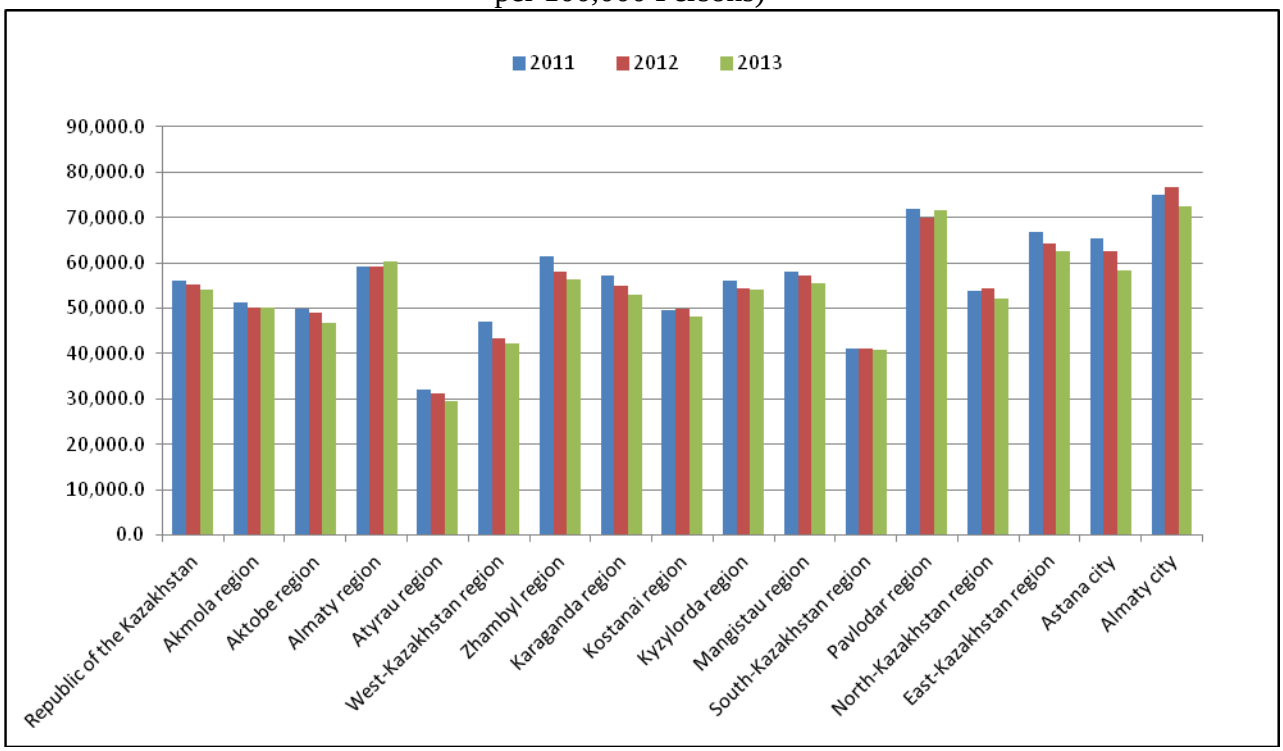
Source: T. Kubekov, *Analysis of the Pharmaceutical Market in Kazakhstan - Pharmaceutical Business*, 2012

Figure 3. Structure of Population Sickness Rate, 2013



Source: Agency of Statistics, *Healthcare*, 2014

Figure 4. Population Sickness Rate (Number of Sicknesses, Registered for the First Time in Life per 100,000 Persons)



Source: Agency of Statistics, *Healthcare*, 2014

Table 9. Procedures to Get State Registration

1.	Submission of the Application on registration of pharmaceutical products with enclosed confirmation of payment of state registration fee to the Committee of Pharmaceutical Control. The Application initialed by the head of the Department of the Committee of Pharmaceutical Control transfers to the department of experts' work of National Center of Expertise of the Ministry of Health of RK (NCE).
2.	The Applicant concludes the contract with NCE for carrying out expert examination.
3.	The specialist of expert department accepts the Application for state registration, checks the availability of contract for expert examination, then issues the referral for payment. The referral for payment initialled by the specialist and the head of department and goes to the account department. The account department prepares the invoice within 5 working days.
4.	After the inspection of the registration dossier, samples and standards of pharmaceutical products validity of samples, standards and storage mode all these go into a small achieve. The certificate of analysis is required for the given standards and samples. FYI: In case of failure to submit all the necessary documents within 30 day the company must notify (in written form) the term that is required for submission of all the required papers. Otherwise, the given pharmaceutical product will get a refusal from the state registration.
5.	Primary expertise of documents and materials carried out within 20 days of registration of the pharmaceutical product, 10 days in case of re-registration, and 5 days – for substance from the day the payment into the account of NCE. In case of positive findings by the primary expertise the product is sent for analytic expertise.
6.	Analytic expertise is conducted within 50 days, immunobiological products - 70 days.
7.	Special pharmaceutical expertise is conducted by Pharmacopoeia Center (including expertise of technological normative document on control of quality and security, 40 days) within 90 days.
8.	Special pharmacological expertise is conducted by Pharmacological Center within 90 days after getting the positive decision of pharmaceutical expertise.
9.	After passing the complete cycle of expert's work. the conclusion on safety, efficiency and quality of pharmaceutical product, an order is prepared within 20 days if registration, 10 days if re-registration. On the bases of the order of Chairman of the Committee of Pharmaceutical Control the registration card is issued.
10.	The applicant receives the following: • registration card with the term within the given pharmaceutical product is allowed for medical usage on the territory of the Republic of Kazakhstan; • confirmed technical limitation document on control of quality and safety of product; • confirmed guidance for medical usage of pharmaceutical product in Russian and Kazakh language; • confirmed package and labels design; • second exemplar of registration dossier.

Source: *Dari - National Center for Medicines, Medical Devices and Medical Equipment Expertise in Kazakhstan*, n.d.