

# Competition in Pharmaceutical Sector in Kosovo

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## Abstract

Pharmaceuticals are one of the most vital and unavoidable sectors in terms of maintaining the health, livelihoods and economic development in general. The central focus of the paper is the study of competition in this sector, the determination of the concentration level of importing and manufacturing companies, the improper structure, the level of prices of medicinal products and the factors affecting their setting, market, budget support in supplying the list of essential medicines, financial activities and other issues of competition in this sector.

**Key word:** Pharmaceutical sector, health strategy, competition, anti-competition practices.

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## INTRODUCTION:

One of the main objectives of the Health Sectorial Strategy in Kosovo is related to reducing the rate of mortality and morbidity for the general population. It is through adequate supply of medicinal and expendable products as registered in the Essential List for the Health Sector that this objective is projected to be achieved [1]. Considering the budget allocated for the Ministry of Health, Kosovo ranks among the countries with the lowest percentage of budget for the health sector (around 2 % of the GDP) or about € 65 per capita on health, compared to the figures in the region that range from 5-7% of their respective GDP or to EU countries with a 10% or more of the budget dedicated to the health sector [2]. This poses one of the biggest challenges for achieving the identified objectives in the Sectorial Strategy. Regarding the supply with medicinal products, and compared to the region, the low budget available for the health sector complemented by the lack of a health insurance system, which accounts for a lack of reimbursement of medicine, lead to a low circulation of medicinal products. This is expressed in monetary value as well as percentile per capita. Low circulation of medicinal products has an indirect effect in decreasing interest in regards to specific drugs [3]. This has led policy makers to think about alternative methods in ensuring the availability of these drugs in a strictly legal manner. The very system is being challenged because the challenges in achieving this objective are numerous [4]. Similar specifications with regional countries which include Croatia, Montenegro and Serbia, as well as with European countries, show that Kosovo has one of the lowest budgets for Health and imports of drugs. It is important to note that the percentage of GDP which is dedicated for Health from the Government is extremely low compared to regional countries and has significant contrast to western countries which not only have very high GDP but, in percentage, they share of over 10% for health [5]. Certainly, this result is the fact that we still do not have health insurance and reimbursement of medicines that would probably have an increase in the use of certain types of drugs [6].

## AIM AND OBJECTIVE:

Today, in parallel with the increase in population and health care expenditure, the pharmaceutical industry is growing each passing year. Having a different structure of demand from other sectors and specific dynamics, the

pharmaceutical industry is subject to various regulations, mainly for the protection of public health and ensuring the sustainability of drug spending. In this context, regulation in the sector plays an important role in the activities of suppliers (pharmaceutical manufacturers) and distributors (pharmaceutical wholesalers and pharmacies), and affects the conditions of competition. The structure of the pharmaceutical industry, as described below, does not easily lend itself to the traditional empirical analysis of competition based on estimating price-elasticity of demand [7]. Studying the level of competition in this sector must necessarily be the demand and supply of products offered in this market. The first element is the licensing procedure to exercise the activity of wholesale, retail, manufacturing and import-export activities in the pharmaceutical sector. The second element relates to the legal definition of reimbursable drugs, and the third element relates to the pricing policy of pharmaceutical drugs [8]. The worldwide pharmaceutical industry is dominated by a handful of multinational companies, with their strengthened market domination in the market with patent protection (for which they constantly strive to expand), high advertising and marketing budgets run by providers of health care which in turn affects the 'choice' of the consumer [9]. Other possible issues are present when there is the possibility of horizontal anti-competitive agreements both at the level of producers and distributors, vertical agreements between producers and distributors in the supply chain, abuse of dominance derived from patent protection, etc. All of these create the possibility for the pharmacists' sketch to create a breach of the rules of competition and the pharmaceutical market that affects the rise in prices of pharmaceuticals, the elimination of their consumers and their health and economic development. The pharmaceutical market has some specifications that separate it from other markets due to the specifics that there are supply and demand for this product. Unlike drug markets, drug demand is not directly determined by the consumer (patient), but by doctors, and thus the consumer is unable to make his choice based on cheaper prices and better quality but follows the doctor's instructions. The latter, in a few cases, have "links" to pharmaceutical companies and have a significant impact on their competition or market distortions [10]. So, the demand for medicines is inelastic and the consumer has no role in deciding on competing products and determining their price. On the supply side, competition is limited

because of the high degree of market power by patent holders. For these reasons, it is understandable that the pharmaceutical market cannot function in terms of competition and by the fact that many governments consider health a necessary public good (the concept that regardless of the patient's financial potential should have a pharmaceutical service that prevails). The market is regulated. But despite the regulation, it is widely accepted that competition can and should play a key role in market well-being for more patient benefits, more choices, more innovative products and lower prices. Certainly, the characteristics and the ways of functioning of the pharmaceutical market are different, per the countries and the degree of regulation, but one fact is widely accepted that this market is based on research and development and therefore competition rules are more tolerant due to the necessity of cooperation between companies for new products.

#### PHARMACY SECTOR SPECIFICATIONS IN KOSOVO:

Pharmaceutical sector in Kosovo is divided in public and private one. In the public sector, central pharmacies operate in hospitals of 7 major cities – one tertiary care hospital and six secondary care hospitals, there are also some in primary health care settings but it is mainly for internal use [11]. On the other part, the private sector is developed in a different way with retail pharmacies spread all over Kosovo which count for 660 pharmacies (AKPPM, 2017). Kosovo in the post-war period is faced with many challenges that significantly affect the country's pharmaceutical industry. A considerable number of pharmaceutical companies have become extinct or are on their way to become due to their privatization, while new companies are faced with many difficulties due to fierce market and current severe conditions that are present in Kosovo and in the region [12]. Pharmaceutical companies with local products face difficulties to launch their products abroad, which mean that they cover only the Kosovo market [13].

To have success in the pharmaceutical market the competition, which is day by day stronger beginning from global competitors to online competitors, must be well studied. Identification of competitors to the company is seemingly a simple task. But, however, the inclusion of current and potential competitors of a company can be much broader, and represents one of the most complex issues in the pharmaceutical industry [14]. This is because in this activity the competition is present among some producers, semi manufacturers, wholesale warehouses, pharmacies and other segments. Regardless which category is in question, each company after it identifies its main competitors, should review their strategies, goals, manufacturing strength and weaknesses [15]. In a similar situation is also the pharmaceutical industry in Kosovo, where the large number of pharmaceutical wholesale warehouses and pharmaceutical companies compete in the market with different prices and rebate thus aggravating the work of companies that deal with local production of pharmaceuticals products. Also, the managers in pharmaceutical companies must have knowledge how their competition operates with potential buyers: is it based on

long-term or short-term financial success. In Kosovo's pharmaceutical market we have two groups of competing companies, those dealing with the production and those dealing with the placement of products [16]. In addition to the above mentioned, there are also firms that deal with semi products - respectively with the drug packaging [17].

With a detailed market analysis, key success factors and other circumstantial elements we can stress that the pharmaceutical market in Kosovo is very complex due to the current situation, the transition as well as various other factors. It should also be considered that in Kosovo there are many competitors who compete mainly in two basic ways: as brand competition and as producers' competition. Based on the available data, it is shown that the pharmaceutical market in Kosovo is largely covered by the import-foreign pharmaceutical companies which almost completely cover it, and the participation of local companies is around less 5%; although data of the two companies claim that they cover 10-20% of the market as we have mentioned above [18]. Serious competitors are the companies from pharmaceutical companies of the former Yugoslavia that dominate in the pharmaceutical market in Kosovo. But the foreign companies should not be overlooked because they are also largely penetrating in the pharmaceutical market. The strong competitors based on this work are: the competitors from the territory of the former Yugoslavia as Krka and Lek Slovenia, Pliva, DietPharma, Apipharma & Mdph from Croatia, Alkaloid and Fitopharm & Medi Macedonia, Hemofarmi and Zdravlje Serbia, Bosnaljek of Bosnia and Herzegovina, but also as well as some world known companies from the wider circle (Roche, BerlinChemie, Aventis, Sanofi, Dade Bechring, Beti-Fickinson, Menarini Altupharma, Bayern Shering, B. Braun, Chem & Ursa, Theis Pharmamed, Nobel, GSK, etc.). We can say that Roche, Krka, Pliva and Alkalodi cover 30% of the pharmaceutical market in Kosovo [19]. Also, the existence of over 70 pharmaceutical wholesale warehouses in Kosovo should be counted as competition for pharmaceutical companies in Kosovo [20].

#### Data for pharmaceutical licensed institutions in Kosovo

According to the Law on Medicinal Products and Devices in Kosovo activities are defined as follows: 1. Manufacturers of medicinal products, 2. Medical Devices Manufacturers, 3. Importers of products and / or medical devices, 4. Distributors for products and / or medical devices and 5. Retail Pharmacies [21].

Based on data from KMA - Department of Licensing in Kosovo below are presented below in table and the number of these activities.

**Table 1: Number of licensed pharmaceutical institution in Kosovo**

Activity	Year 2016)
Manufacturers of medicinal products	2
Medical Devices Manufacturers	1
Importers of products and / or medical devices	86
Distributors for products and / or medical devices	59
Retail Pharmacies	660

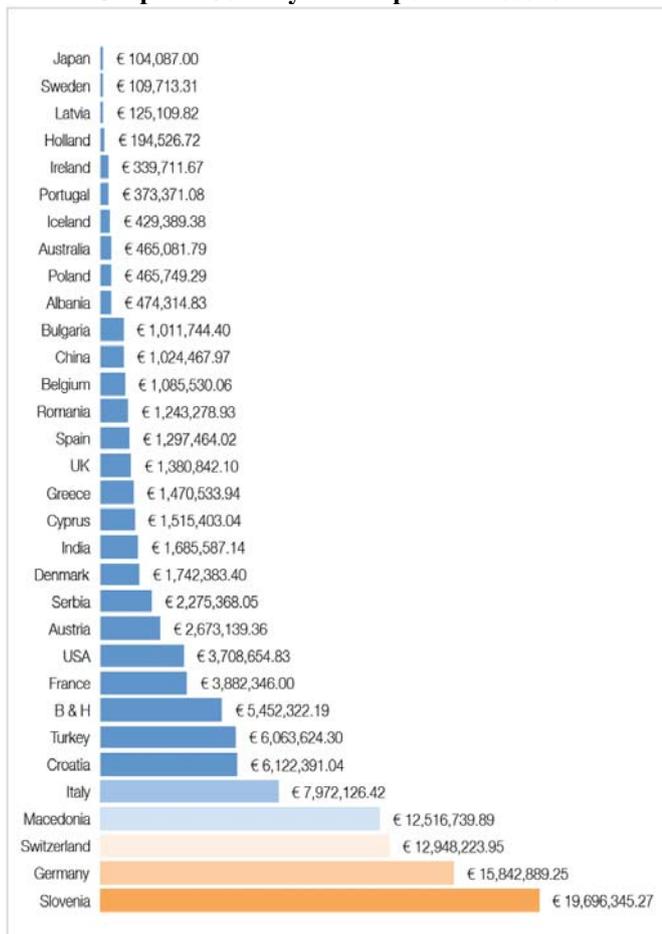
Source: Kosovo Medicines Agency

**Import statistics and discussion** - Total consumption of drugs in Kosovo cannot be exactly estimated because not all drugs that are imported are consumed, but is a good base to have a reference on imports of drugs, which are the largest groups of imported/consumed [22]. We also still face the phenomenon of possession of imported products which are outside the legal chain. Regarding drug classes which by defined daily doses were spent mostly are: a) Drugs and the cardiovascular system - group C; b) Drugs blood and hematopoietic system - group B; c) Medications used for diseases of the digestive tract and metabolism - group A; d) Drugs used for musculoskeletal system - group M; e) Antibiotics - group J etc. But for the type of drugs for three years under the defined daily dose are: a) Acetyl Salicylic Acid; b) Diclofenac; c) Lisinopril with hydrochlorothiazide; d) Furosemide and f) Enalapril etc.

From year to year we see different moves and expenses often associated with the use of these newer drugs for treatment of that indication; using lower doses expected to give better effect and less side effects. The figure below presents the states from where these imports are done mostly.

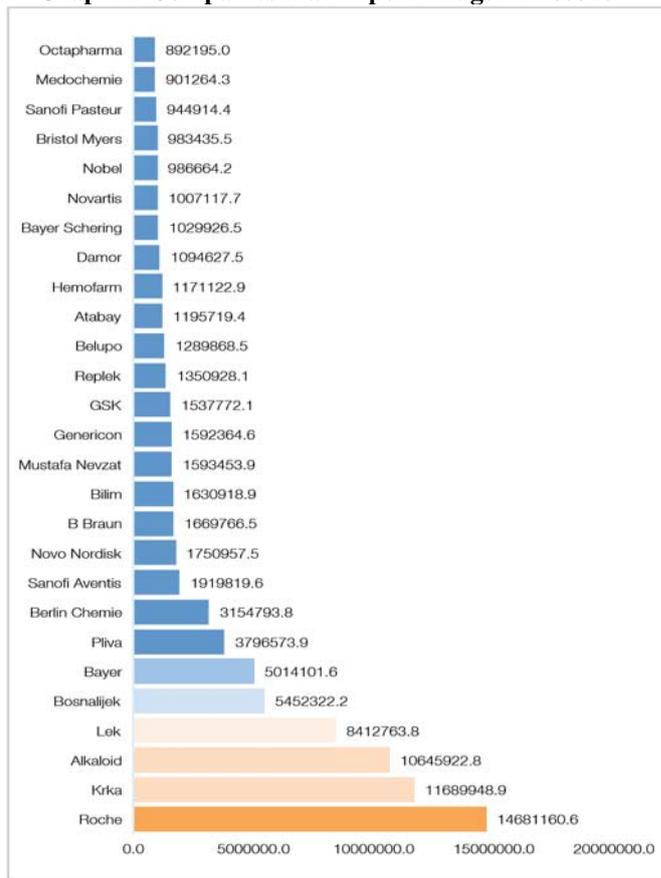
Within the three years analyzed (2011-2013) is seen that Slovenia, Germany, Switzerland, Macedonia and Croatia dominate. Also, it is worth mentioning that local drug manufacturers do not have any high value [23].

**Graph 1: Country that Export in Kosovo**



Source: Drug Consumption in Kosovo 2011-2013, Report 2014

**Graph 2: Companies that Export Drugs in Kosovo**



Source: Drug Consumption in Kosovo 2011-2013, Report 2014

For the period under review, referring to the WHO report, the results show that the pharmaceutical importing and distributing companies in Kosovo possess sufficient market share without affecting the competition balances. There is a non-focused, insufficient pharmaceutical market and a well-regulated sector [24].

The concentration rate is low, which according to the IHH index for the four largest importers in Kosovo (Slovenia, Germany, Switzerland and Macedonia) in the Kosovo market the concentration is the lowest. This index indicates that there is no dominant position and the misperception of this position [25]. The trend of the concentration level for years marks a decline that affects the growth of competition between importers, distributors and taxpayers.

**CONCLUSION**

To enforce competition and combat anti-competitive practices between companies, the legal regulations and the law on protection of competition should be implemented. Market regulatory authorities should cooperate in this regard to avoid possible damage to competition, the pharmaceutical market and consumer health. Market Liberalization should continue to have multiple choices from drug seekers and in turn there should be a greater "freedom" of pharmacy functioning through the provision of facilities in obtaining licenses and other necessary documentation for registration. The issue of patent law as an exclusive right to generic medicines creates monopoly positions, so handling this right should be carefully taken

care of. The application of a regulatory framework both on the demand side and on the supply side is necessary to improve the existing problems and create competitive conditions in the quality of the bills, price reduction and service improvement. There is an increased control of drug imports and at the same time combating tax evasion. The dependence on the improper and large presence of some improper companies on the one hand and on the other the lack of domestic pharmaceutical manufacturing companies should not be neglected. Increasing the budget by the Ministry of Health for supplying the essential list of medicines and increasing monitoring in supplies with these bills is necessary. There is a need for additional advocacy in awareness raising, information, education among consumers regarding the use of the medicines and their effects.

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