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Comparison Of Kosovo Pharmaceutical Legislation To The Requirements Of The European Union

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Abstract

Introduction: The importance of the pharmaceutical legislation of a country consists in establishing rules, laws, bylaws and decisions based on which the daily work takes place in health institutions in general and the pharmaceutical sector in particular. The structure of today's pharmaceutical legislation, in terms of drug laws, the scope of drug regulatory agencies, drug evaluation boards, quality control laboratories and drug information centers has evolved over time.
Aim: The purpose of this paper is to collect existing information related to the pharmaceutical sector and assess the pharmaceutical profile of Kosovo according to the WHO form. Comparing the pharmaceutical legislation of Kosovo with those of the EU, with the aim of identifying aspects which require harmonize with EU laws and directives, with the laws in force in Kosovo, as well as suggesting options for improvement.
Materials and Methods: The pharmaceutical legislation of the European Union, Kosovo, and Austrian have been used as materials. For the comparison of pharmaceutical legislation, we have done the analysis according to four dimensions: administrative elements, regulatory functions, technical elements and level of regulation. We have collected data through a standardized form for regulatory assessment developed by the WHO and through the method of studying the archive. The method of studying the archive has included the evaluation of relevant documentation and records, which includes laws, executive orders, reports of relevant authorities, economic, health and other state indicators, as well as reports of other studies in this field. In the study we used the comparative approach to achieve the comparison of inter-state experiences related to pharmaceutical legislation.
Conclusions: Relevant state institutions of Kosovo should be engaged in providing institutional reports related to data on the pharmaceutical sector, in order to institutionally complete the pharmaceutical profile of Kosovo, as required by the WHO.

Keywords – Pharmaceutical legislation, European Union, Kosovo, Comparison.

I. INTRODUCTION

The importance of the pharmaceutical legislation of a country consists in establishing rules, laws, bylaws and decisions based on which the daily work takes place in health institutions, in general, as well as the pharmaceutical sector in particular. The structure of today's pharmaceutical legislation, in the form of drug laws, scope of agencies for brand regulation, drug evaluation boards, quality control laboratories, drug information center, etc., has evolved over time. During this process the scope of legislative and regulatory issues has been gradually expanded, in response to the increasing complexity of the sophisticated pharmaceutical sector and the needs of the society (1).

Up to date, problems related to the safety and quality of drugs exist in both developing and developed countries of the world (2), (3). Many new pharmaceutical products are marketed by the pharmaceutical industries in an international dimension. At the same time, the circulation of standard and counterfeit toxic drugs has increased, both nationally and internationally. This is mainly due to the inefficient control of the regulation for the production and distribution of pharmaceutical products, both in the exporting countries and in the importing countries. According to statistical data, less than 20% of WHO member states have a good drug

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regulatory system, 50% of countries implement drug regulations at different levels of their development and operational capacity, and 30% of other states have no regulatory authority at all, or have very limited capacity and find it difficult to function (4). Studies conducted in many states show that about 20% of drugs tested do not meet quality standards. The use of toxic drugs endangers patients' lives. Consider the incident with sulfanilamide in 1930, in which 107 children were found dead in the US (5) and the thalidomide disaster, which caused major defects in child birth (6).

The most recent example is the contamination of drugs with diethylene glycol, such as paracetamol, which caused numerous tragedies in Haiti and India (7), (8). In Nigeria, the fake meningitis vaccine, administered during an epidemic, ended up with fatality with 2.500 people reported dead out of 27.600 administations (9). Kosovo pharmaceutical legislation includes rules for production, import, export, registration, licensing, customs, quality control, pharmacovigilance, inspection, clinical research, advertising of medicinal products, scope of the Kosovo Medicines Agency (KMA), rights, responsibilities and obligations of health professionals.

The Law on Medical Products and Equipment of Kosovo has been amended several times, due to the needs for the full functioning of the pharmaceutical sector of Kosovo, as well as adapting the legislation with the directives and regulations of the European Union (EU).

II. Aim Of The Study

The purpose of this paper is to collect existing information related to the pharmaceutical sector and assess the pharmaceutical profile of Kosovo according to the WHO form, comparing the pharmaceutical legislation of Kosovo with EU legislation, in order to identify aspects that require adaptation with EU laws and directives, with the laws in force in Kosovo, as well as suggesting options for improvement.

III. Materials And Methods

In this paper we have used the pharmaceutical legislation of the European Union, Kosovo and Austria as form of material. Since pharmaceutical legislation includes many dimensions of drug regulation, for their comparison we have used the analysis according to four dimensions: administrative elements, regulatory functions, technical elements and level of regulation. The administrative component included the analysis of policies, legislation, regulations, regulatory structure, human and financial resources, infrastructure as well as planning, monitoring and evaluation mechanisms. Regulatory functions included licensing procedures for people, facilities and practices, inspection of pharmaceutical facilities, evaluation and registration of products, quality control, control of promotion and advertising of drugs, monitoring of side effects of drugs, etc. Technical elements have included the analysis of the existence of standards, norms, guidelines, specifications and procedures. The level of regulation includes the analysis of the level at which the various regulatory functions are undertaken. In addition to the pharmaceutical legislation of the EU and Kosovo, in the study we also analyzed the pharmaceutical legislation of Austria as an EU member state. We have collected data through a standardized form for regulatory assessment, developed by the WHO and through the archive study method (10). The guide is structured in three sections: the general state information section, the overview section on drug regulations, and the section on the function of the various drug regulations. The method of studying the archive has included the evaluation of relevant documentation and records that include laws, executive orders, reports of relevant authorities, economic, health and other state indicators, as well as reports of other studies in this field. We have collected specific data from the official websites of the relevant authorities responsible for national pharmaceutical regulation, from the official reports submitted to the WHO, as well as from the reports of the World Bank. Individually collected data, which we reported in tables according to shares with data for Kosovo and Austria, in order to analyze and identify similarities and differences between them. We have expressed the quantitative data in the form of a report to enable comparison. In the study we used the comparative approach to realize the comparison of interstate experiences related to pharmaceutical legislation. The main limitations of our study have consisted in the difficulties of comparing indicators due to changing terminologies and difficulties in finding equivalents similar to the other state.

Since every context is different between different states, even comparison becomes very difficult. Kosovo, as the youngest country in Europe, still does not have all the complete data for recent years. For Kosovo, the notes related to certain issues belong to different years which make the difference and comparison even more challenging.

IV. Results

We have presented the results of our research in table form and in written textual form.

Table 1. Health and demographic data: Demographic and socio-economic indicators

Section 1	State	Year	State	Year
Country	Kosovo	Time period	Austria	Time period
Country area (km^2)	10908		83885	
Total population number	1.733.872	2011 (11)	8.355.000	2008 (18)
Average scale of population increase	1.57%	2011 (12)	0.4%	2008 (18)
GDP increase (annually %)	3.5%	2010 (13)	2	2008 (18)
GNI per habitants (US $)	790$	2003	€273.98	2009 (18)
Population < 15 years (% of total population)	27.2%	2011 (14)	15	2008 (18)
Population > 60 year (% of total population)	66.1% (15-64 years)	2011 (14)	22.8	2007 (18)
Ur (%)			67	2007 (19)
Total fertility scale (birth per woman)	2.34	2009 (15)	1.4	2007 (19)
Mortality and causes of death :	:	:	:	:
Life expectancy for men (years)	67.6	2009	77.6	2008 (18)
Life expectancy for women (years)	71.8	2009	83	2008 (19)
Infant Mortality rates from birth up to 1 year old (per 1000 births)	35-49	2011 (16)	5.4	2008 (18)
Maternal mortality rates (per 100.000 births).	12.6	1999 (17)	4	2005 (19)

Section 1. Health and demographic data: demographic and socioeconomic indicators. The total population of Kosovo in 2011 is 1.733.872 inhabitants, with an average population growth of 1.57%. Annual GDP growth has been 3.5%. GNI per capita was $ 790 (11), (12), (13). Mortality and causes of death, life expectancy after childbirth for men is 67.6, while for women 71.8 years. The infant mortality rate is 35-49 / 1000 live births; the maternal mortality rate is 12.6 / 100,000 live births**.**

Table 2. Data on Health Services (Health Expenditures).

Section 2	State	Year	State	Year
Country	Kosovo	Time period	Austria	Time period
Total expenses in health system (€ milion)	151 (€ milion)	2005 (20)	42.122 (€ milion)	2008 (21)
Total expenses in health system as a GDP %	6.7%	2005 (20)	10.1%	2008 (21)
Total expenses in health system per habitant (€)	51.7€	2005 (20)	5.038€	2008 (21)
Total annual state expenses in health system	71.8(€ milion)	2005 (20)	32.248(€ milion)	2008 (21)
Total annual state expenses in health system as a % of total state budget	%	2005 (20)	15.9%	2008 (21)
Total annual state expenses in health system as a % of total health budget	47.5%	2005 (20)	76.6%	2008 (21)
Total annual state expenses in health system per habitant (€)	41.4 €	2005 (20)	3.85 €	2008 (21)
Total pharmaceutical expenses (€ milion)	65-80 (€ milion)	2005 (22)	4.997 (€ milion)	2007 (21)
Total pharmaceutical expenses per habitant (€)	33-40€		601€	2007 (21)
Pharmaceutical expenses as a GDP %	2.9-3.5%		1.35%	2007 (21)
Pharmaceutical expenses as a % of health expenses	30%		13.29%	2007 (21)
Total public expenses for drugs (€ milion)	72.6 (€ milion)		3.265 (€ milion)	2007 (21)

Table 2.1 Healthcare professionals and Infrastructure

Total nr of licensed/registered pharmacists	676	2009 (24)	5.326	2008 (25)
Total nr of pharmacists working in public sector			280	2008 (25)
Total nr of pharmaceutical technicians and assistants	391	2009 (26)	4.302	2008 (25)
Is there a strategic plan of human resources in pharmacies in our country?	Not known		Not known	
Total nr of licensed physicians	3280	2009 (24)	41.830	2008 (27)
Total nr of licensed nurses and midwives	1063		71.570	2008 (28)
Total number of hospitals	9 (8 regional hospitals and UCCK)	2011 (24)	266	2008 (28)
Total nr of beds in hospitals	2068	2009 (24)	63.544	2006 (19)
Total number of licensed pharmacies	391	2009 (36)	1.321 (1.252 community pharmacies, 23 branch pharmacies and 46 hospital pharmacies.	2009 (25)
Annual salary of a newly licensed pharmacist working in public sector	211 €	2008 (30)	45.780	2010 (31)
Total nr of graduated pharmacists in the last two years	157 (years 2008-2009)	2009 (26)	221	2008/09 (31)
Is the accreditation of the pharmaceutical school required?	Yes (from Kosovo accreditation agency, according to the EU decretive 2005/36/EC)	2011 (32)	Yes (according to the EU decretive, 2005/36/EC)	2010 (31)
Is the curriculum of pharmaceutical school updated periodically	Yes	2011 (32)	Yes	2010 (31)

Table 2.2 Healthcare professional

Characteristics	Kosovo	Austria
Total nr of licensed/registered pharmacists	3.9/10.000 habitants	6.37/10.000 habitants
Total nr of pharmacists working in public sector	?	0.34/10.000 habitants
Total nr of pharmaceutical technicians and assistants	2.26/10.000 habitants	5.15/10.000 habitants
Total nr of licensed physicians	18.9/10.000 habitants	50/10.000 habitants
Total nr of licensed nurses and midwives	6.1/10.000 habitants	36.4/10.000 habitants

Table 2.3 Health infrastructure

Nr of pharmacies	2.26/10.000 habitants	2.72/10.000 habitants
Nr of hospitals	0.05/10.000 habitants	0.32/10.000 habitants
Nr of beds in hospitals	11.9/10.000 habitants	76/10.000 habitants

Section 2. Health Service (Health Expenses)

The year 2005 in Kosovo marks a total of 151 million € expenditures, representing 6.7% of GDP. Total annual health expenditures for residents were € 57.1. Total annual public expenditures on health were € 71.8 million, representing 47.5% of total health expenditures. Annual public expenditures on health for residents were € 41.4. In 2005 the total pharmaceutical expenditures were € 65-80 million, respectively € 33-40 per capita, representing 2.9-3.5% of GDP. Pharmaceutical expenses own 30% of public expenditures on medicines. Total public expenditures on medicines have reached the amount of € 72.6 million. In Kosovo until 2009 there were 676 licensed pharmacists, 391 pharmaceutical technicians and assistants, 3280 licensed doctors and 1063 nurses and midwives. There are a total of 8 regional hospitals and a university clinical center that offers tertiary services. The total number of beds is 1063. By 2009, 391 pharmacies were licensed. Kosovo as the youngest country in Europe is not yet a member of the World Trade Organization, and most of the information about their intellectual and drug laws is missing. In Kosovo there is a regulatory framework which is regulated by the Health Law no. 2004/4 and other normative acts in force, which regulate the national drug policy. In addition to the law on health, there are 12 other laws from the Assembly of Kosovo that deal with the field of health and 36 administrative instructions approved by the Assembly of Kosovo with changes in Pharmacy. In the meantime, 13 administrative instructions have been repealed because they have been replaced by newer instructions or are related to the law. The pharmaceutical regulatory framework, which is harmonized with the legislation of the European Union covers: Establishment of ARB, Authorized Marketing (registration), Inspection Regulation, Import Control, Licensing, Market Control and Quality Control, Drug Advertising and Promotion, Clinical Trials, Controlled Drugs, Pharmacovigilance.

V. Discussion

During 1990-1998, the pharmaceutical sector in Kosovo was in complete collapse, due to the Serbian daily politics and the expulsion of Albanian employees from most jobs in the health sector. Moreover, during 1999, Kosovo went through a period of war with Serbian military, police and paramilitary forces. All these circumstances influenced the country's needs for medicines to be covered mainly through humanitarian aid. In the post-war period the Kosovo economy has shown significant progress, even though Kosovo is one of the poorest countries in Europe, with a GNI of $ 790 per capita. (11), (12), (13). About 45% of the population is unemployed, so migration and the black market are the main current activities. Most of the population lives in rural areas, away from cities. Economic growth is largely driven by the private sector which mainly consists of small-scale businesses.

Kosovo lacks official information on the percentage of the population covered by public health services, while public health insurance is not yet operational in Kosovo. In Kosovo, according to World Bank data for 2005, total annual expenditures on health, in relation to GDP are lower than in Austria (data reported by the NHA for 2008), (6.7% vs.10.1%). In developing countries 50-90% of all pharmaceutical expenditures are privately funded, which is considered higher than in developed countries (average 34%). In most countries pharmaceutical expenditures range from 5-20% of total health expenditures, while in developing countries there is a higher proportion of health expenditures and public expenditures on medicines account for 10-30% of total health expenditures (37). In Kosovo, pharmaceutical expenditures represent 30% of health expenditures, respectively these expenditures represent 2.9-3.5% of GDP, while in Austria this represents only 13.29% of health expenditures, respectively represents only 1.35% of GDP. From the results presented in tab 2 regarding health services we can see that there is no institutional reporting of total public pharmaceutical expenditures in relation to the total budget and in relation to the total expenditures for medicines. There is also a lack of reporting on total public expenditures on medicines per capita, total private expenditures on medicines, the share of generic medicines and the annual growth rate of the total market value of medicines. According to data on health personnel we observed that while in Austria the number of licensed pharmacists per 10,000 inhabitants is 6.37, in Kosovo this number is half as small (3.9 / 10,000 inhabitants). The number of pharmaceutical technicians and assistants in Austria is 5.15 / 10,000 inhabitants, while in Kosovo this number is 2.26 / 10,000 inhabitants. In Kosovo, data on the number of pharmacists working in the public and private sector are lacking. In Austria the number of licensed pharmacies is 2.72 / 10,000 inhabitants, while in Kosovo it is 2.26 / 10,000 inhabitants. Unlike Kosovo, also the number of hospitals per 10,000 inhabitants is 6 times smaller (0.32 / 10,000 vs.0.05 / 10,000 inhabitants). This difference is also observed in terms of the number of beds. While in Austria there are 76 beds per 10,000 inhabitants, in Kosovo there are only 11.9 beds. In Kosovo there is a national health policy, which is regulated by the Law on Health no. 2004/4. The national policy framework for medicines is regulated by the Law on Medical Products and Equipment no.03 / L-188, approved in 2010 by the Assembly of the Republic of Kosovo. This law presents the amended and supplemented version to Law no.2003 / 26. The previous law, in cooperation with the associations of distributors and importers of medical products and equipment and the Association of Pharmacists of Kosovo, was amended and supplemented according to international standards, respectively accompanied with European pharmaceutical legislation. This law covers:

- Selection of essential medicines
- Drug financing
- Drug prices
- Procurement of drugs
- Distribution of medicines
- Regulation of medicines
- Pharmacovigilance
- Rational use of drugs
- Human resource development
- Research
- Monitoring and evaluation.

Health is a fundamental human right. An easy access to the essential drugs is a crucial factor to provide a right healthcare. The concept for essential medicines is to minimize economical damage of the population and to provide a constant access to the drugs (33). The selection of essential medicines should be in accordance with national clinical guidelines. If essential list medications are appropriate, of better quality, and more convenient to use, medications can provide a simple cost-effective answer to many health problems. In many countries the cost of medicines accounts for a large share of the total health budget. Despite the economic and medical importance of medicines, there are still widespread problems with lack of access, poor quality, irrational use and wasteful spending. In many essential drugs they were not used to their full potential (34). An increasing number of pharmaceutical products are available in the world market and there has been an increase in consumption and expenditure.

According to WHO reports, it is estimated that at least 1/3 of the world's population lacks access to essential medicines. Millions of children and adults die each year from diseases that have not been prevented and treated with cost-effective and inexpensive essential medicines (35). Affordable drug prices are a necessity to ensure access to essential medicines in the public and private sectors (36). Another essential component of policies to improve access to essential medicines is drug financing. Another essential component of the strategy to increase access to essential medicines is a sustainable supply system. The Drug Regulatory Authority is the agency that develops and implements most of the legislation and rules on pharmaceuticals, to ensure the quality, safety and efficacy of drugs. In Kosovo, the competent authority regarding medical products and equipment for human use is the KMA, which operates within the Ministry of Health. In Austria this authority is a semi-independent agency and does not function under the Minister of Health. KMA has its own website and ULR http://www.k-ma.org/. The same is for Austria's authority for medicinal products (ARB). KMA is involved in harmonization / cooperation initiatives, which is achieved through cooperation with other institutions to promote the rational use of medicines and integration in international information networks. Kosovo legislation requires the registration of all pharmaceutical products on the market and there are clear and published criteria for evaluating applications for drug registration. In 2010 the number of pharmaceutical products registered in Kosovo is 1068 which is ten times smaller number compared to Austria, whereas in 2010, 13168 were registered, including homeopathic products. Legal regulations, both in Kosovo and in Austria, asks the ARB to make public the drugs registered in different periods. The registries are constantly updated, which can be accessed through the address: http // www.kma.org/ repository_importi_final_web_sajt.xls. Drugs are registered under their own name INN (International Non-Proprietary Name) and under a commercial name. The legislation requires payment for the application and registration of medicines. Kosovo legislation, like of the Austria's, provides for the appointment of government pharmaceutical inspectors, which the regulation allows inspectors to inspect the premises where pharmaceutical activities are carried out. Inspection is also a prerequisite for equipment licensing. Inspection requirements are the same for public and private equipment. Existing legislation requires authorization to import drugs and allows sampling to test imported products. The import of drugs is allowed only through the authorized entry gates, where it is allowed to inspect the pharmaceutical products imported from the authorized entry gates. Legal regulations in Kosovo, as well as in Austria, require the licensing of pharmaceutical factories, which must meet the criteria for Good Manufacturing Practices (GMP), as criteria published by the government, require the licensing of importers, licensing of wholesalers and distributors, requires registration of pharmacists, licensing of public and private pharmacies. From the wholesalers and distributors, it is required to comply with Good Pharmacy Practice, published by the government. In Kosovo, the pharmaceutical market is run by three dominant generic manufacturers: Farmakos, Kondirolli, and most recently Trepharma. Farmakos was a public sector factory, which was fully privatized during the privatization phase in Kosovo. These companies mainly produce finished products. We do not have information on the percentage of market coverage by drugs produced by local factories.

VI. Conclusions

In Kosovo there is a national health policy, which is regulated by the Law on Health no. 2004/4. The national policy framework for medicines is regulated by the Law on Medical Products and Equipment no.03 / L-188, approved in 2010 by the Assembly of the Republic of Kosovo. Kosovo has taken important steps towards increasing the functioning of the pharmaceutical sector, since it managed to harmonize the Law on Medical Products and Equipment with the requirements of European pharmaceutical legislation.

The Law on Medical Products and Equipment of Kosovo covers all the necessary segments that define the pharmaceutical system of the State. For the effective implementation of the National Drug Policy, in Kosovo should be made functional all sections of the Kosovo Agency for Medicinal Products, according to certain competencies that they should have.

Relevant state institutions of Kosovo should be engaged in providing institutional reports related to data on the pharmaceutical sector, in order to institutionally implement the pharmaceutical profile of Kosovo, according to the requirements of the World Health Organization (WHO).

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