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Prepared for:

Trade Department, MIET

Prepared by:

Emrush Ujkani

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Acronyms

CAGR	Compound Annual Growth Rate
CEFTA	Central European Free Trade Agreement
EU	European Union
GDP	Gross Domestic Product
GVA	Gross Value Added
KAS	Kosovo Agency of Statistics
KBRA	Kosovo Business Registration Agency
KMA	Kosovo Medicine Agency
KPA	Kosovo Pharmaceutical Association
LLC	Limited Liability Company
MFMC	Main Family Medicine Centers
MH	Ministry of Health
MIET	Ministry of Industry, Entrepreneurship and Trade
NACE	Statistical Classification of Economic Activities in the European Community
NIPHK	National Institute of Public Health of Kosovo
PHC	Primary Health Care
SAA	Stabilization and Association Agreement
SHC	Secondary Health Care
TAK	Tax Administration of Kosovo
THC	Tertiary Health Care
WHO	World Health Organization

1. Introduction

Laws and regulations form the foundations of a thriving economy, playing a vital role in protecting the rights of citizens, businesses, and institutions. A well-functioning and effective health services sector is of particular importance for achieving stable economic growth. Health services gained the status of public goods due to the development of medical technology and the devastating effects of wars. Then, the process of the commodification of health care services began. The transformation of health services into private goods without regard for social benefits is a great danger in the framework of globalization and neo-liberal policies.

Delivering quality health services, describes the essential role of quality in the delivery of health care services. There is a growing acknowledgement that optimal health care cannot be delivered by simply ensuring coexistence of infrastructure, medical supplies and health care providers. Improvement in health care delivery requires a deliberate focus on quality of health services, which involves providing effective, safe, people-centred care that is timely, equitable, integrated and efficient. Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

For the health services sector to function well and serve its purpose, it should have also regulations that create a level-playing field and promote fair competition and innovation to the benefit of the public. Nonproportional regulations can be dangerous and hinder growth. That said, striking the right regulatory balance is necessary to foster the sector's growth.

Like any services sector in Kosovo, the health services sector encounters barriers of various kinds. In particular, Kosovo has seen little progress in identifying and addressing the obstacles related to the right of establishment and freedom to provide services and in aligning parts of the legislation of the services sector with the EU acquis, as committed in the Stabilization and Association Agreement (SAA). To identify the most pressing regulatory barriers and other barriers, review the extent of alignment with the EU acquis, and better understand health services sectors, the Trade Department of the Ministry of Industry, Entrepreneurship, and Trade (MIET) has started to conduct a series of sector-specific assessments. In line with this effort, the Trade Department, with the support of LUX Development and Norwegian Embassy in Kosovo, have produced this assessment report. This report sheds light on the structure and performance of the three fields of the health sector (pharmaceutical, dental and aesthetic) , reviews the relevant regulatory framework for these three fields of the health services in light of the EU acquis, and identifies health service providers' main barriers.

The rest of this report is structured as follows. Section 2 provides a general overview of the methodology used to conduct this analysis. Section 3 highlights the main global trends characterizing health services. Section 4 provides an overview of the sector's structure and performance, relying on macro statistics from administrative sources. Section 5 and Section 6

discuss the legal framework regulating the sector in Kosovo and makes comparisons with the EU acquis. Section 6 presents the main findings of a survey conducted with a sample of health (pharmaceutical, dental and aesthetic) service providers. Section 7 contains conclusions.

2. General Methodology

To obtain relevant insights and have a better understanding of the health services sector, we have undertaken the following research steps: (i) desk research; (ii) open-ended interviews with relevant stakeholders; (iii) a semi-structured online/phone survey; and finally (iv) a validation meeting with the beneficiary. All these sources of information combined have enabled a comprehensive analysis of the three abovementioned fields of health sector.

As is usually the case, the desk research was carried out at the beginning of the analysis. First, various reports and studies were consulted to determine the conceptual underpinnings of the sector and examine the international trends and developments. Second, Kosovo's relevant legislative and institutional framework was reviewed and compared with the EU acquis to identify the areas that need harmonization in the future. The collected information through desk research was closely analyzed, stored, and classified based on source, relevance, and reliability. This process, amongst others, served as a basis for the primary research and the other subsequent activities carried out in this analysis.

Individual meetings (interviews) were arranged and conducted with the identified institutional stakeholders. See the list of the interviewed stakeholders in **Annex 1**. Together with the representatives from MIET, a set of guiding questions was prepared before conducting these meetings. In parallel, officials from the Kosovo Business Registration Agency (KBRA), the Kosovo Agency of Statistics (KAS) and the Tax Administration of Kosovo (TAK) have been contacted for statistical data and other relevant material of this kind.

A draft questionnaire was designed for the survey (see **Annex 2**). This draft was first piloted with a service provider to ensure that all the questions were clear and straightforward. The finalization of the questionnaire was done in collaboration with the Trade Department.

Once the questionnaire was finalized, it was disseminated online via an official e-mail to all the sampled firms, along with detailed instructions on how to complete it. Those firms that struggled to fill out the questionnaire correctly were given further assistance over the phone. The survey process was continuously monitored to verify on time the accuracy of the answers provided in the completed questionnaires. The questionnaire with the collected data was inserted automatically into an excel database and labeled accordingly. After addressing some small specification errors, descriptive tables and graphs were produced. In the end, a meeting with the beneficiary was organized to validate the generated findings, and the draft report was shared with the interviewed stakeholder for comments.

3. Global Trends in Health Services

3.1. Striving for quality in health care services

Universal health coverage is an important and noble objective. Enshrined in the Sustainable Development Goals (SDGs), universal health coverage aims to provide health security and universal access to essential care services without financial hardship to individuals, families and communities, thus enabling a transition to more productive and equitable societies and economies. But universal health coverage should not be discussed and planned, let alone implemented, without a focus on quality. It is essential to ensure that care is effective, safe, and in keeping with the preference and needs of the people and communities being served. Further, provision of care should be timely and equitable across populations, coordinated across the continuum of care and throughout the life course, while minimizing resource waste. Quality of care therefore underpins and is fundamental to universal health coverage. For if quality of care is not ensured, what is the point of expanding access to care? Access without quality

Quality is not a prerogative of high-income countries. If countries can afford to provide any health care – and even the poorest can and should do so – they must provide care of good quality. The alternative – poor-quality care – is not only harmful but also wastes precious resources that can be invested in other important drivers of social and economic development to improve the lives of citizens. Billions of dollars are spent on the consequences of poor-quality care – money that can fund schools, social services and infrastructure. And poor quality can also undermine the trust of the population in the benefits of modern medicine. Seen this way, universal health coverage without quality of care is a job half done.

Much progress has been made in improving some aspects of quality of health care across the world, for example with regard to cancer survival rates and mortality from cardiovascular diseases (1, 2). But in other areas, progress has been slow and uneven.

The numbers speak for themselves.

- In high-income countries, one in 10 patients is adversely affected during treatment (3).
- In high-income countries, seven in 100 hospitalized patients can expect to acquire a health care-associated infection (in developing countries this figure is one in 10), infections that can be easily avoided through better hygiene and intelligent use of antimicrobials (4).
- Unwarranted variations in health care provision and delivery persist, and a considerable proportion of patients do not receive appropriate, evidence-based care (5, 6).
- Influenza vaccination rates vary across high-income countries from 1% to over 78%, despite a goal of 75% by 2010 set by the World Health Assembly in 2003 (7).
- Antimicrobial resistance has become a major global public health issue, partly due to the misuse and overuse of antimicrobials in health care (8).

- Globally, the cost associated with medication errors has been estimated at US\$ 42 billion annually, not counting lost wages, foregone productivity or health care costs (9).

3.2.The Economic Argument for Good Quality

Beyond the effects on people's lives, poor-quality care wastes time and money. Making quality an integral part of universal health coverage is both a matter of striving for longer and better lives and an economic necessity. Building quality in health systems is affordable for countries at all levels of economic development. In fact, the lack of quality is an unaffordable cost, especially for the poorest countries. Substandard quality of care not only contributes to the global disease burden and unmet health needs, it also exerts a substantial economic impact, with considerable cost implications for health systems and communities across the world. Approximately 15% of hospital expenditure in high-income countries is used to correct preventable complications of care and patient harm. Poor-quality care disproportionately affects the more vulnerable groups in society, and the broader economic and social costs of patient harm caused by long-term disability, impairment and lost productivity amount to trillions of dollars each year (14). In addition, duplicate services, ineffective care and avoidable hospital admissions – features of many health systems – generate considerable waste. Up to a fifth of health resources are deployed in ways that generate very few health improvements. These scarce resources could be deployed much more effectively (3).

4. Structural Profile and Performance of Health Services

The health system consists of the public sector and the private sector. The main institution of the health sector in the Republic of Kosovo is the Ministry of Health, which is responsible for creating policies and implementing laws of a non-discriminatory system and responsible for health care; Coordinating activities in the health sector to promote the coherent development of health policies; setting norms and standards by issuing guidelines for the health sector respecting relevant international standards; overseeing the implementation of these standards, including inspection and other services as needed; Monitoring the situation in health and implementing adequate measures to prevent and control problems in the field of health; etc.

The subordinate units of the Ministry of Health are: National Institute of Public Health of Kosovo (NIPHK), Kosovo Agency for Medical Products and Equipment, National Blood Transfusion Center, Health Inspectorate and the Pharmaceutical Inspectorate as law enforcement monitors.

Institutions that provide health care are divided according to the levels of service in: Primary Health Care (PHC), Secondary Health Care (SHC), and Tertiary Health Care (THC). SHC and THC are summarized in the Clinical and University Hospital Service of Kosovo.

Primary Health Care (PHC) – is a competence of municipalities, and is based on the concept of family medicine / family medicine team, composed of a family medicine specialist and two-family nurses. PHC also provides dental health care: at primary level by dentists; and at secondary level at Main Family Medicine Centers (specialist dentists).

Each municipality has the main unit, Main Family Medicine Centre, with departments according to laws in force, organizing and leading with the component units in the territory of the municipality, which are Family Medicine Centers (FMC) and Clinics of Family Medicine (CFM).

Public PHC network is composed of a total 472 institutions, respectively 38 Main Family Medicine Centers (MFMC), 167 Family Medicine Centers (FMC), and 267 Clinics of Family Medicine (CFM). Within the MFMC, there are 15 maternity outpatient departments, and other outpatient specialist services, which will gradually fade.

HUCSK provides hospital and outpatient-specialist, diagnostic, etc. Health services; it also provides education at the Faculty of Medicine for basic studies, postgraduate studies and relevant scientific research

4.1. Structure of health workers

During 2019, 13,518 people (excluding specialty trainees) worked in all public health institutions, of which 8,245 were women and 5,270 were men. Out of 13,518 employees in public health institutions of the Republic of Kosovo, there are 3,555 employees with higher education, 8,386 with

upper secondary education and 1,577 persons are non-medical staff. During 2019, according to the Chambers of Health Professionals there were 23,858 licensed employees. There were 5,511 employees in PHC, 3,326 employees in General Hospitals and 3,441 health employees in UCCK.

The Clinical and University Hospital Service of Kosovo has 7297 registered employees in the payroll. The number of licensed private health institutions has reached 1 582, of which 31 hospitals and 1 551 other health institutions such as: ambulances, polyclinics, etc.

Out of a total of 1 582 licensed private health institutions, the largest number are dental clinics with 411 of them. In the University Clinical Dental Center of Kosovo (UCDCK) were performed 159 507 dental services in total. There are 1,612 specialist doctors, 4,321 nurses, and 1,364 other non-medical staff; which expressed in percentage are as follows: specialist doctors are 22% of the staff, nurses are 59% and 19% of the staff is non-medical staff.

4.2. Health Finance System

This section focuses only on health expenditures, or health system financing, during 2019. Data are provided first by the public sector, and then by the private sector.

Health financing during 2019 continued to be realized mainly from the Budget of the Republic of Kosovo, own source revenues and from borrowing from the World Bank. Own source revenues in Primary Health Care are used to partially finance the implementation of capital projects for municipal health.

The reform of the health system, during 2015 has enabled the separation of the HUCSK from the Ministry of Health, as an independent budget organization, while in 2019 the Health Insurance Fund was also divided as an independent BO.

4.3. Public Sector

The public health sector in Kosovo consists of all health and administrative institutions which are dependent on the state budget to conduct their activities, including various government departments and executive agencies of departments which have the task of monitoring the implementation of legality in the sector.

The following table summarizes the total expenditures in the public sector during the period 2009-2019. This table shows that public health expenditures during this period have experienced a more than double increase (from over 105 million in 2009 to over 221 million in 2019).

Table 1 – Public Sector Expenditures on Health, 2009-2019 (in Euro)

Institution	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
Ministry of Health	26,153,128	58,559,449	57,584,100	49,882,445	31,722,673	111,409,971	99,521,409	87,305,055	79,882,464	74,804,338	75,877,794
HUCSK	124,163,113	84,993,519	70,553,112	69,230,624	86,142,316						
Municipalities (PHC)	61,402,137	57,290,744	52,241,181	51,295,600	51,249,067	49,165,102	45,687,192	45,312,774	43,610,666	36,933,233	30,075,650
HIF	9,411,264.62										
Other ministries	156,603	1,237,309									
Total	221,286,245	202,081,021	180,378,393	170,408,669	169,114,056	160,575,073	145,208,601	132,617,829	123,493,130	111,737,571	105,953,444

Source: Ministry of Health of Kosovo (2021)

4.4.Private Sector

The private health sector consists of private health institutions, licensed by the Ministry of Health to provide health services, within the Law on Health and bylaws that regulate this area.

Services offered in the private sector are hospital-day and inpatient services, outpatient specialist services, dental services, aesthetic services, laboratory and imaging diagnostics, outpatient and inpatient rehabilitation physiotherapy, etc.

Table 2. Citizen's pocket health expenditures disaggregated into subcategories, 2019

Service / expense	Amount
Medications	114,256,224
Pharmaceutical products other than medication	44,407

Medical equipment and other aids	27,153
Outpatient public health services	2,589,948
Outpatient private health services	15,692,879
Public dental services	1,502,675
Private dental services	5,692,124
Medical tests, laboratory, public radioscopy (Roentgen)	2,096,830
Medical analysis, laboratory, private radioscopy (Roentgen)	7,816,450
Public hospital services	1,329,968
Private hospital services	5,095,875
Health services abroad	11,078,844
Accommodation, food, ambulance transport abroad	1,358,414
Traditional medicine	
Other medical services	53,821
Total	168,635,610

Source: Ministry of Health of Kosovo (2021)

The table above shows that most of the (private) Out-of-pocket health expenditures go to medicines (over 114 million euros) as well as to Outpatient private health services (almost 16 million euros). The third category with the most expenditures is that of health services abroad with over 11 million euros.

4.5. Health Tourism services and its impact on economy

Recently, medical tourism became one of the rapidly growing industries globally with 25% growth yearly with the value of over 200 billion euros. North America, Asia and Europe hold the most significant share of this value. According to The Medical Tourism Market – Global Industry Analysis Report, the forecast by 2027 will be a value of 272.70 billion US dollars. Kosovo has strong potential for developing the medical tourism industry as an integral and essential part of the whole tourism industry in Kosovo. Fundamental healthcare reform is needed and improves outdated infrastructure with low service quality, including accommodation and accompanying catering and recreational facilities. Health care tourism is not competitive in this exceptionally demanding market.

Kosovo is a small open economy with a limited but growing productive base. The services sector is the largest segment of Kosovo's economy and its driving force, which contributes a large part to value added, employment and local trade. Service activities account for 70 percent of Gross Domestic Product (GDP) in 2020 at basic prices and employment of about 85 percent of the total workforce in Kosovo (KAS, 2020). Wholesale and retail trade, real estate, transportation and storage, and financial services are the largest service sectors in the economy¹. Industry accounts for 26.4% of GDP, with the highest contribution coming from the manufacturing and the construction sectors (11.7% and 8.5% of GDP, respectively). The contribution of agriculture, forestry and fishing to Kosovo's GDP has declined considerably over the past decade, from 15% in 2008 to 6.9% in 2020, although it still accounts for a significant share of employment.

Health tourism is a tool to promote economic welfare. Many nations and tour destinations have seen success by rapidly increasing the number of visitors. The positive impact of the development of tourism is apparent when considering a considerable increase in jobs and income via the exchange of foreign currency. Furthermore, health tourism affects positively GDP of Kosovo, increases consumption, it is directly linked with agriculture products and manufacturing to increase their production capacities to meet tourism demands, increases employment and promotes the country on international level with its potential touristic attractions and destinations. More importantly, focusing on luring Kosovar Diaspora would generate higher incomes in the country by combining several services: dental & visiting travels, thermal spa & travel destinations tourism and tour guiding & national food travel destinations.

Health tourism thanks to its major Diaspora input and visits in the country can secure very high profits with moderate investments, by enabling a range of positive contributions to the economy of Kosovo. The tourism sector itself, where there is fierce competition, guarantees diversity for tourism. To this end, thanks to the demand of tourists and the contribution of the sector itself, new types of alternative tourism have begun to appear, where it is worth mentioning especially cultural tourism, field trips and hiking in joint collaborations with HORECA and health services. The latter is a type of tourism, which has emerged from the merger of tourist services with health ones and over the years has marked a gradual increase. In short, health tourism is defined as the journey from one country of origin to another for treatment and to regain previous health.

According to CBK (2021) data, travel and tourism sector in Kosovo in terms of trade in services performance is the highest among other sectors. In 2021, export of services for this sector amounted 1.48 billion euro. This amount includes payments conducted by visitors within Kosovo purchasing with their foreign bank cards services related to travel and tourism.

The data presented in the tables show an opportunity for the advancement of 20 destinations to be implemented to develop, which would cultivate winter-sports tourism in the tour regions of the Albanian Alps and the Sharr Mountain Range. However, other regions also have ample conditions for the advancement of tour zones with themes specific to their respective areas. The village "The

¹ KAS – Kosovo Agency for Statistics (2021).

Shala's Bajgora" has potential to attract specific types of tourism. In addition, thermal water sources create the opportunity to advance tourism in curative centers.

Table 3. Tourist Centers for Skiing in the Albanian Alps

Main Tour Destinations of Mountains	Total Capacity of Centers
Rusolia Peek	40000
Kurvala Peak	22000
Beleg Mountain	15000
Koprivnik	11000
Rosa Zogut	10000
Strellci	8000
Hala	7000
Leqinat Peak	5000
Mokna Peak	4000
Total	129000

Source: MMPH, Kosova

Table 4. Ski Centers in the Sharri Mountain

Main Ski Centers	Total Capacity per Centers
Bistrica, Prevallë	27000
Brezovica	15000
Brodi	14000
Radesha	10000
Lubinjë	9000
Brodosavci	9000
Restelica	9000
Shtërpca	8000
Oshlaku	6000
Kara Nikollë	6000
Total	113000

Source: MMPH, Kosova

Table 5. Cultural Heritage in Kosova

Cultural Heritage	Number
Archeological Heritage	400
Architectural Heritage	821
Architectural Conservation Zones	200
Unique Zones	44
UNESCO Protected Sights	4

Source: MMPH, Kosova

Table 6. Natural Heritage, Tourist Attractions

Natural Heritage	Amount
Gorges (top)	5
Mountain Peaks (top)	10
Caves	6
Main Rivers	8
Artificial Lakes (largest)	4
Thermal Water Sources	9

Source: MMPH, Kosova.

According, Kosovo Agency for Statistics, measuring the number of visitors and their nights of stay for local and international visitors numberd around 490,401. Looking at the trend prior to Covid-19, the number has increased significantly, thus, still remains a lot to be done in order to attract more visitors.

Number of visitors and their nights of stay (local and foreign) according to the region by region, year and visitors/nights

	2015	2016	2017	2018	2019
	Nights	Nights	Nights	Nights	Nights
Gjakovë	5224	27661	23518	21388	13423
Gjilan	2142	10852	8827	12806	10789
Mitrovicë	2434	8157	10896	15473	16744
Pejë	33857	103150	114018	130954	149803
Prizren	21396	63143	63466	71803	68393
Prishtinë	130269	169237	162954	183843	213700
Ferizaj	6719	17869	13789	19036	17549
Total	202041	400068	397469	476446	490401

Source: Kosovo Agency of Statistics

However, health tourism should not be evaluated only as a health service or only as a tourist service. The set of tourism services, which offer people a healthier lifestyle, can be treated in the context of health tourism. Some concrete examples of this are "medical tourism", which summarizes surgical interventions or other medical and dental treatments in private hospitals and clinics; "thermal tourism", which offers relaxation and psychophysical relaxation in thermal complexes (Nëna Naile, Kllokot Spa, Peja Spa etc); as well as "tourism for the elderly and people with disabilities", which creates the opportunity to participate in various social activities and that of accommodation for a long time in hotels or rehabilitation centers. All these together can be assessed as health tourism.

In conclusion, health tourism, a type of alternative tourism that is formed by combining tourist services with health ones, contributes significantly to the development of both sectors. By

increasing investment and employment not only in the tourism sector, but also in the health sector, health tourism provides more economic growth. Revenues, that enter the country thanks to foreigners who benefit from the high quality and favorable prices of Kosovo health tourism, significantly increase the level of welfare of citizens. The Kosovo government with Ministry of Health should focus more to enable beter business environment and attract the necessary investments in this field. Investments made and those that will be realized in this context, shall make an impact to reduce unemployment and raise the level of economic development and welfare of Kosovo citizens.

5. Health Services Exercised Through Pharmaceutical, Dental and Aesthetic Sectors

5.1. Pharmaceutical, Dental and Aesthetic Services in Kosovo

5.1.1. Pharmaceutical Sector

The pharmacy sector is one of the main pillars of the entire health system in Kosovo. The pharmaceutical sector in Kosovo is undergoing three major policy and legal reforms to increase its competitiveness and transparency. These reforms are part of a national project to improve the underdeveloped and under-regulated pharmaceutical market which would, in turn, encourage increased spending in the healthcare and pharmaceutical sector.

These reforms include regulating the pricing of pharmaceutical products, mandating health insurance and functionalizing the health insurance fund, and completing and functionalizing a comprehensive health information system.

The first reform relates to regulating the price of pharmaceutical products, as a precondition of implementing the health insurance fund, and as a control mechanism for the tendering procedures for the purchase of pharmaceutical products in light of increased public funding.

The proposed legal framework calls for minimal intervention and mandates a comparison between the price proposals of the holders of marketing authorizations, and a comparison of those price proposals with the average prices in Montenegro, Albania, North Macedonia, and Croatia (known collectively as the “Basket of Reference Countries”).

The final price would be determined on the basis of the lowest internal proposal or that offered in the Basket of Reference Countries. It is hoped that this reform will bring transparency and increase competitiveness, based on an expected increase in demand and a fairly under-regulated market.

Properly functioning pharmaceutical sector can make a big difference to the quality of people's lives and has a significant economic effect. The Kosovo Medicines Agency (KMA), in combination with Kosovo Customs, controls the importation of pharmaceutical products and medical devices. A valid import license is required for the importation of these products. However, before obtaining an import license companies should obtain marketing authorization. The marketing authorization and importation of pharmaceutical products and medical devices is regulated by the Law on Medical products and Equipment, No. 04/L-190 and other relevant legal norms. The Kosovo Medicines Agency (KMA) is responsible for protecting people's health by providing quality and guaranteed medical products and equipment, and services related to medical products and devices through the licensing of professional companies and individuals.

According to the Law on Medicinal Products and Devices in Kosovo activities are defined as follows:

- Manufacturers of medicinal products,
- Medical Devices Manufacturers,

- Importers of products and / or medical devices,
- Distributors for products and / or medical devices and
- Retail Pharmacies

Another important category which must be clearly defined is the issue of cosmetic products. Despite the fact that general norms exist on the regulation of production and markets of the cosmetic products, however the national policies still need to be amended in accordance with advanced standards. The EU Cosmetics Regulation² includes a set of strict rules for labelling of cosmetic products, all of which must be present on the product container, packaging, or if not possible given space restrictions, in an enclosed leaflet. Without proper labelling, a product will not be permitted onto the market.

The ***Kosovo Chamber of Pharmacists*** protects and represents the professional interests of its members ensures high standards of medical code of ethics and deontology, promotes and protects the activity of health professionals in public health institutions and private, provides continuing professional education in cooperation with institutions relevant educational and professional organizations in order to provide the highest quality pharmaceutical services and other services related to health care.³

Legislation

Legislation that regulates the organization and functioning of the pharmaceutical sector is made of primary legislation (laws) and secondary legislation (bylaws). Kosovo legislation in generally is drafted in the spirit of European integration including also legislation in the health sector.

Having analyzed carefully the pharmaceutical sector in Kosovo and based on the feedback received from the companies, the following are the main issues identified in the sector of pharmaceuticals: The adoption of the law on drug pricing is one of the main recommendations for the pharmacy sector. Such a law is intended to reduce the losses of citizens⁴ and would reduce the opportunities for informal trade in drugs. The law on drugs will create a referential pricing system - This system would enable to compare local prices with those of several countries chosen and to impose a pricing ceiling to pharmaceutical distributors. Creation of such a system avoids the misuse of the healthcare system, like increasing prices without justification. It can as well regulate margins of the pharmaceutical distributors.

² See, Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance)

³ See Article 2 of the Law No. 04/L-150 on Chambers of Healthcare Professionals; see also Article 2 of the Statute of the Kosovo Chamber of Pharmaceutics

⁴ According to the Kosovo Chamber of Pharmacist, citizens' losses are projected to be approximately 10 million Euro

Reducing the number of pharmacies and determining the necessary number of professional staff in pharmacies⁵ is another important recommendation that should be defined with the law.

Procurement law - If aiming a qualitative healthcare system, the lowest price is not always a solution therefore it is necessary to amend also the law on Public Procurement. Healthcare professionals shall be involved more when choosing the right solutions and not the procurement officers. These right solutions might sometimes differ from the lowest price and healthcare professionals shall be entitled to choose such if justified as for the benefit of the patients.

Healthcare data infrastructures are fragmented, insufficient - Establishing a registry is a key in understanding cancer trends and ensuring continuous care for patients. Establishing and fortifying Health Information system and National Cancer Registry will enable better planning; follow up and understanding the value received in terms of overall survival, management of adverse events; services provided. It will also lay foundation for future of healthcare and prepare Kosovo health system to personalize to the needs of patients, spend 13 where needed and control services and costs. Ministry of Health allocates a yearly budget for patient's treatments outside of Kosovo, which amounts to approximately 6 million euro. However, in 2019 they spent 10 million euro mainly for Pediatric, Orthopedic and Ophthalmology patients for treatments outside of Kosovo.

Limited Diagnosis and treatment access - Investment in diagnosis and access to treatment will enable Kosovo patients to obtain more services in the country and will make healthcare system sustainable. Insufficient resource for genetic sequencing and personalizing cancer care. Investment in this area will enable right patient to be treated with right intervention, which will enable adequate and cost-efficient treatment on one side; and is more efficient and more sensitive than single testing provided nowadays.

5.1.2. Dental Services

Dental services in Kosovo are provided in public, private and public-private health institutions. Dental health care is provided at the level of: state, municipality, employer, individually and at the level of professional service.

The Ministry of Health regulates, supervises, and controls the implementation of dental health care in institutions: public, private, and public-private, at all three levels of health care.

Dental health care of citizens is in three (3) levels of organization within the unique system is provided only in licensed health institutions, in accordance with Law no. 04 / L-125 and accompanying bylaws.

Private activity in the dental sector is regulated by Law no. 04 / L-125, and is exercised on the basis of the principle of full equality with the public health sector, unless otherwise provided by the legislation in force. It is worth mentioning that the main legal foundation from where the

⁵ Note: Such an example also exists in Belgium.

regulation of health activities in the field of dentistry derives is the law on Health.⁶ This law has the aim of establishing legal grounds for the protection and the improvement of the health of the citizens of the Republic of Kosovo through health promotion, preventive activities and provision of comprehensive and quality healthcare services.

The ***Dental Chamber of Kosovo*** is an independent organization that protect and represent the professional interests of its members, assure high standards of the code of ethics and medical ethics, promote and protect the activity of healthcare professionals in public and private healthcare institutions, provide continuous professional education in order to offer more qualitative healthcare services and other services dealing with healthcare care.⁷

As a professional mechanism, the Dental Chamber of Kosovo has a series of recommendations on how the private system of practicing dentistry in Kosovo can be reformed and also improved. The recommendations that come from the dentist's chamber are in line with the standards achieved in the developed economies including here also those from the member states of the European Union. In this regard, the Dental Chamber has the following recommendations, as recommendations that come from dental sector in Kosovo:

It is necessary that the licensing process, which is currently the responsibility of the Ministry of Health, should be transferred as a responsibility and competence to the Dental Chamber of Kosovo. Currently such a process is carried out by the Ministry of Health however in order to have a better organized and more competent process then such a responsibility should be transferred to the Dental Chamber of Kosovo. Such an example is also in the countries of the region and the countries of the European Union.

It is almost most necessary to enable the complementarity of the work of public dental institutions by private ones. This is a necessity based on two factors: the first is the need that often arises in public dental institutions for such expertise and the second is more evident that the private sector of the dental service in general has reached a level of development which in terms of quality it is competitive not only with countries in the region but also beyond.

5.1.3. Aesthetic Services

Nowadays, wellness tourism is becoming a more important and more profitable aspect of tourism. World trends in tourism markets forecast further growth of wellness tourism, mainly due to changes in lifestyle (globalization, less free time, more stress, etc.). According to the research from Global Wellness Institute, the global wellness industry grew 12.8% from 2015-2017, from a \$3.7 trillion to a \$4.2 trillion market. To put that in an economic context, from 2015-2017, the wellness economy grew 6.4% annually, nearly twice as fast as global economic growth (3.6%). Wellness

⁶ See, Law No. 04/L-125 on Health

⁷ See Article 2 of the Law No. 04/L-150 on Chambers of Healthcare Professionals; see also Article 2 of the Statute of the Dental Chamber of Kosovo

expenditures (\$4.2 trillion) now account for more than half of total global health expenditures (\$7.3 trillion). And the wellness industry represents 5.3% of the global economic output. Europe is the leading world region when it comes to wellness tourism, according to the following numbers: 291.8 million Europeans travelling per year and spending about 210.8 billion US dollars. (Insight, 2019)⁸

One of the most important challenges for wellness tourism in Kosovo is the problem of registration and evidence of service providers in the health tourism. There is a lack of adequate normative acts regulating aesthetic services in tourism, which would allow to conduct health, tourism and hospitality under one roof. Other challenges include defining the conditions for the organization of the aesthetic and wellness tourism offer and conditions for entities providing services in the wellness tourism (certificates, licenses) as well as the implementation of international standards of quality and medical certificates following the example of foreign practices.

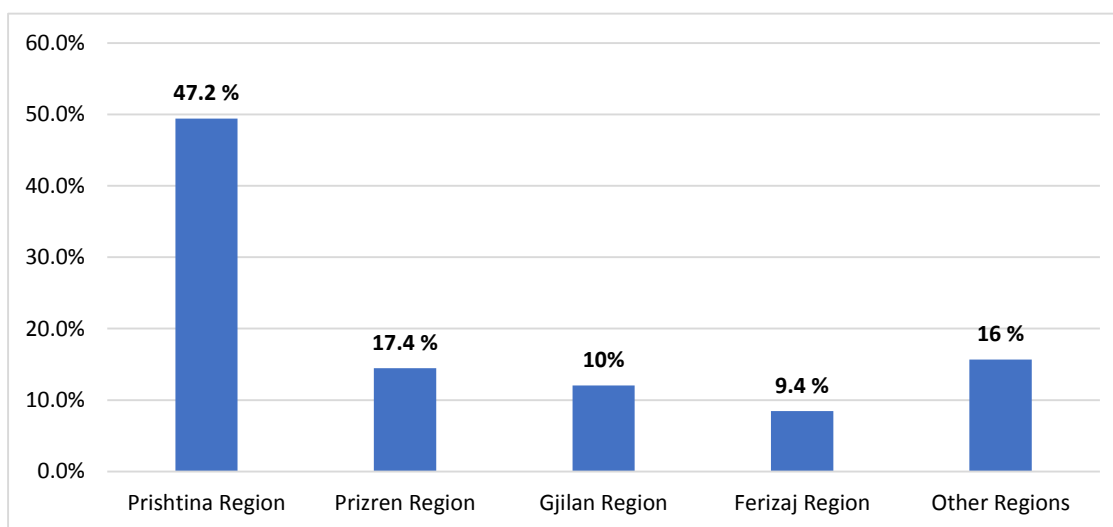
Ministry of health together with the Ministry of Industry Entrepreneurship and Trade should work together in creating an Action Plan for the development of health tourism. This action plan should aim establishing minimum standards for aesthetic centres, wellness centres, health centres, health tourism centres, including standards for facilities, equipment, safety, service quality and environmentally sound 'green' trading. Furthermore Kosovo health destinations will, where appropriate, strategically link and network with internationally recognized and established service providers in health tourism in the countries such as of our competitive circle (Albania, Montenegro, North Macedonia or even from our diaspora Germany, Swiss, Austria, etc).

⁸ Note: The period before the pandemic is taken as a reference, as the appearance of COVID has already restricted free movement.

6. Main Survey Findings

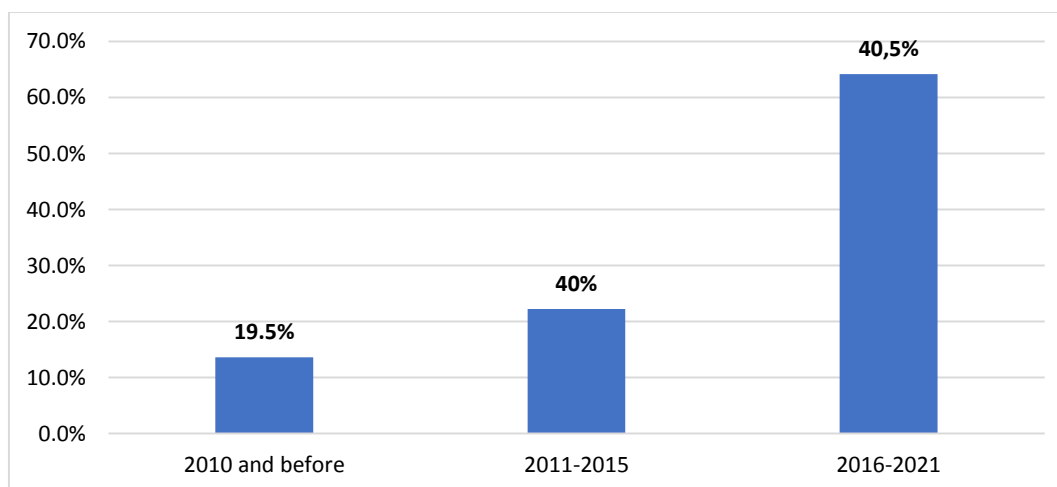
This section presents the main findings compiled from a survey conducted with pharmaceutical, dental and aesthetic services companies in Kosovo. Out of more than 400 companies (pharmaceutical, dental and aesthetic) contacted by the survey team, only 130 completed the questionnaire. Around half of the companies surveyed are located in the region of Prishtina, 17.4 percent in the region of Prizren, and 10.0 percent in the region of Gjilan, 9.4 % in the region of Ferizaj the rest are located in other regions of Kosovo (see Figure 7).

Figure 7: Location of pharmaceutical, dental and aesthetic, by Kosovo regions (in %)



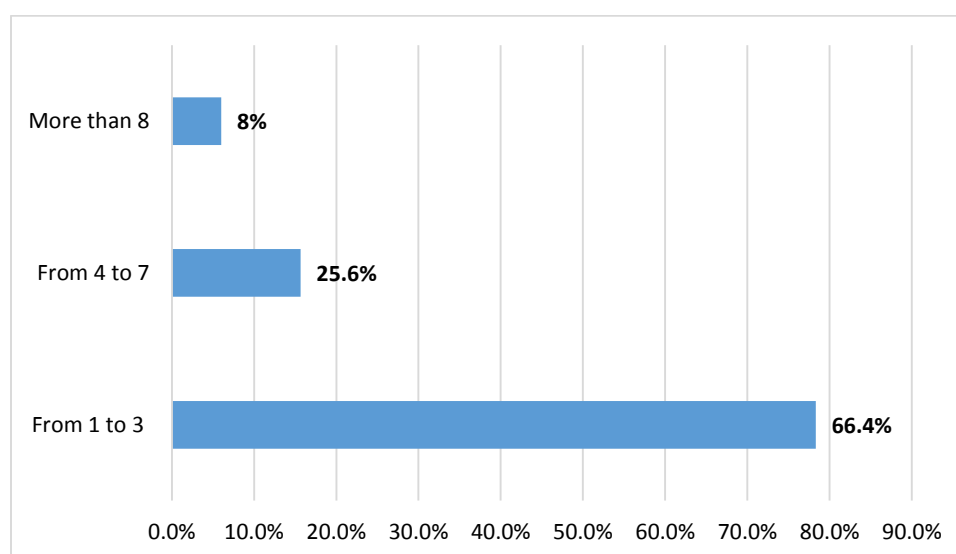
The majority of the companies surveyed (40.5 percent) were established between 2016 and 2021, 40% percent between 2011 and 2015, and 19.5 percent in 2010 or before (see Figure).

Figure 8: Pharmaceutical, dental and aesthetic, by period of establishment (in %)



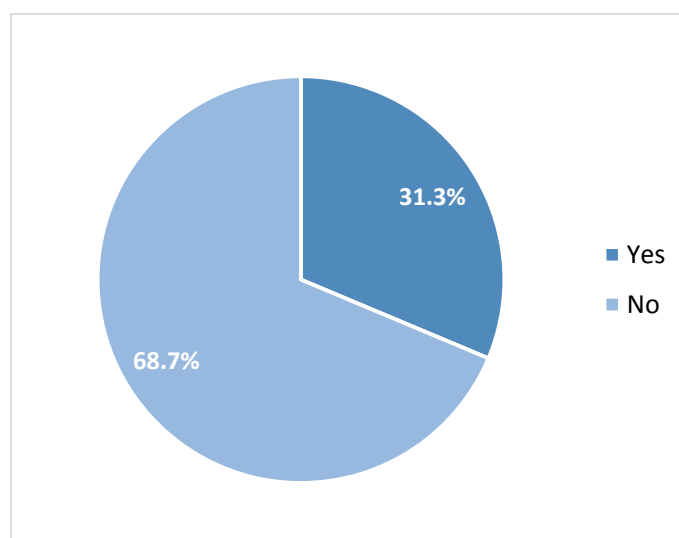
The survey findings on employment show that 66.4 percent of the companies surveyed have from one to four persons employed, 25.6 percent from four to seven, and only 8 percent more than eight persons employed (see Figure 9). This figure corresponds with the one generated from the administrative sources (see Section 4). Almost half of the surveyed companies are single-person companies; the largest surveyed company employs no more than ten persons.

Figure 9: Distribution of employment, in %



In the question about whether they have cooperation with international associates in delivering their services, close to one-third of the companies surveyed said yes (see Figure 10).

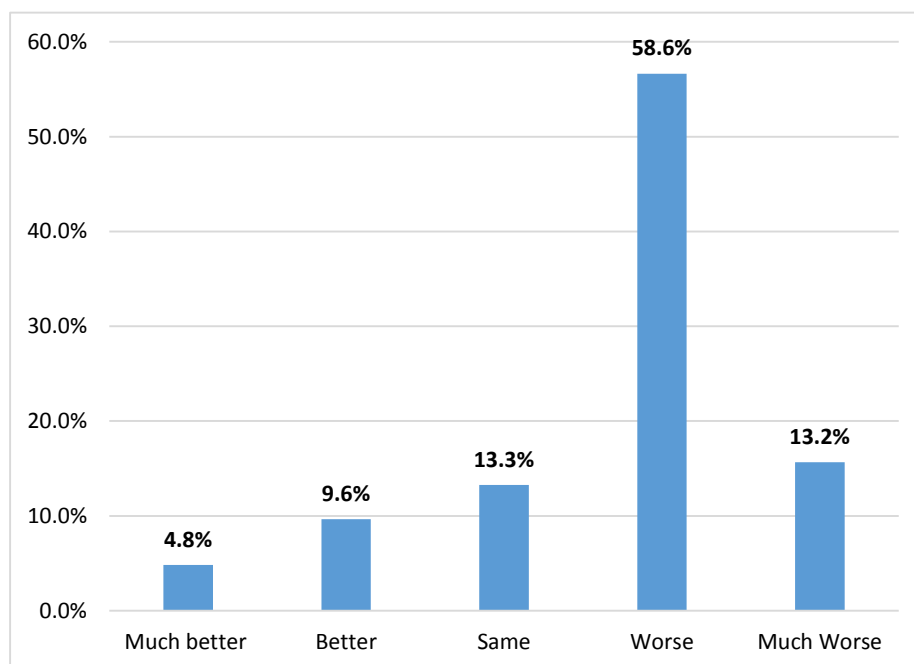
Figure 10: Cooperation with international associates in delivering services (in %)



In the question regarding the competitiveness level of the sector in Kosovo compared to the EU, the majority of the companies surveyed (58.6 percent) perceive it to be "worse" and 13.2% "much

worse." On the other hand, 14.5 percent of the companies perceive it to be "better" or "much better," while the rest believe that there is no difference (see Figure 11).

Figure 11: Perceived competitiveness level of the sector compared to the EU (in %)



In the question of ranking of obstacles, the majority of the companies surveyed (3.88%) perceive it to be unfair competition, shortage of qualified staff 3.38%, difficulties in obtaining financing to export services 3.23%, high level taxes 3.01%", excessive domestic regulatory burden 2.80%, membership fees in the respective professional associations 2.53%, rigorous licensing requirements companies perceived to be 2.29.

Companies were also asked to list and elaborate three interventions that would upgrade their respective services sector. The following are the main interventions proposed. Note that in this case the order does not reflect the level of importance.

- Reducing administrative barriers (administrative barriers related with licensing and permissive system);
- Improve legal and regulatory infrastructure in the field of pharmacy, dentistry and aesthetic
- Ensure better education in the field of medicine (pharmacy, dentistry)
- Make a stricter division of duties and responsibilities between professional chambers and public (state) institutions;
- Support the development of linkages between all three sectors (pharmacy, dentistry and aesthetic services)

The surveyed companies were asked to list the main barriers that prevent them from selling their services abroad or increasing their sales with foreign clients. Restrictive licensing required by foreign jurisdictions, lack of a visa-free regime, language, difficulties in finding clients, and the absence of business linkages are the most frequently cited barriers in this regard.

Finally, companies were asked to indicate the main policies required to support the sector companies in their efforts to provide services to clients abroad. Below are outlined the most relevant suggestions:

- Provide trainings covering differences between Kosovo legislation and legislations in relevant foreign markets
- Build cooperation with foreign associations and facilitate mutual recognition
- Organize match-making meetings and seminars that help local legal service providers establish ongoing cooperation with foreign business clients
- Develop a database of legal professionals with their portfolio of services
- Engage foreign diplomatic missions to provide support in the search for foreign clients
- Build a platform that provides information on market demands for legal services
- Build networks with experts from the region and EU

7. Conclusion and Recommendations

A well-functioning and effective health services sector is of particular importance for achieving stable economic growth. Health services gained the status of public goods due to the development of medical technology and the devastating effects of wars. Then, the process of the commodification of health care services began. The transformation of health services into private goods without regard for social benefits is a great danger in the framework of globalization and neo-liberal policies.

Delivering quality health services, describes the essential role of quality in the delivery of health care services. There is a growing acknowledgement that optimal health care cannot be delivered by simply ensuring coexistence of infrastructure, medical supplies and health care providers. Improvement in health care delivery requires a deliberate focus on quality of health services, which involves providing effective, safe, people-centred care that is timely, equitable, integrated and efficient. Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

For the health services sector to function well and serve its purpose, it should have also regulations that create a level-playing field and promote fair competition and innovation to the benefit of the public. Nonproportional regulations can be dangerous and hinder growth. That said, striking the right regulatory balance is necessary to foster the sector's growth.

In general, the legislation governing the health services sector does not present a particular obstacle in relation to those found in the Member States of the European Union regarding foreign nationals.

However, some aspects such as licensing procedures, simplification of administrative procedures, and the like need to be amended or supplemented in some areas. Therefore, the health legal framework should be further completed and harmonized with EU legislation; transparency and predictability of business and legal security are the basic pre - requisites for the sustainable functioning of the pharmaceutical industry in Kosovo.

The possible amendments of the law on health should be followed with the possibility of transferring the licensing responsibility of dentist, from the Ministry of Health to the Kosovo Dental Chamber.

Of particular importance is the adoption of the law on drug pricing as this law is intended to reduce the losses of citizens⁹ and would reduce the opportunities for informal trade activities with drugs. When it comes to the aesthetic services there is a lack of adequate normative acts regulating strictly

⁹ According to the Kosovo Chamber of Pharmacist, citizens' losses are projected to be approximately 10 million Euro

this type of services therefore any amendment to the law on health should also foresee amendments in this specific area of health services.

A survey with health service providers has been conducted to enrich the analysis further. The main recommendations of this report are outlined below:

- Adoption of the law on drug pricing. Such a law is intended to reduce the losses of citizens¹⁰ and would reduce the opportunities for informal trade in drugs. This will lead to a referential pricing system - This system would enable to compare local prices with those of several countries chosen and to impose a pricing ceiling to pharmaceutical distributors. Creation of such a system avoids the misuse of the healthcare system, like increasing prices without justification. It can as well regulate margins of the pharmaceutical distributors.
- Reducing the number of pharmacies and determining the necessary number of professional staff in pharmacies is another important recommendation that should be defined with the law.
- Procurement law - If aiming a qualitative healthcare system, the lowest price is not always a solution. Healthcare professionals shall be involved more when choosing the right solutions and not the procurement officers. These right solutions might sometimes differ from the lowest price and healthcare professionals shall be entitled to choose such if justified as for the benefit of the patients.
- Healthcare data infrastructures are fragmented, insufficient - Establishing a registry is a key in understanding cancer trends and ensuring continuous care for patients. Establishing and fortifying Health Information system and National Cancer Registry will enable better planning; follow up and understanding the value received in terms of overall survival, management of adverse events; services provided.
- Licensing process of dentist which is currently the responsibility of the Ministry of Health, should be transferred as a responsibility and competence to the Dental Chamber of Kosovo. Such an example is also in the countries of the region and the countries of the European Union.
- Adequate regulation of aesthetic health services. This should either be done through the amendment of the law on health or the adoption of a special law that will regulate further this category of health services.
- Match-making meetings and seminars that help local health services providers establish ongoing cooperation with foreign business clients should be regularly organized.
- Foreign diplomatic missions should be engaged to provide support to health service providers in their search for foreign clients.
- A platform that provides information on market demand dynamics for health services should be developed.

¹⁰ According to the Kosovo Chamber of Pharmacist, citizens' losses are projected to be approximately 10 million Euro

8. Annexes

Annex 1: List of interviewed stakeholders

Name of Institution	Contact Person	Meeting Schedule
Ministry of Health	Rifat Latifi, Minister Kujtim Salihu, Chief of Cabinet of the Minister of Health	<i>24 February 2022</i>
Kosovo Chamber of Pharmaceutics	Arianit Jakupi, Director	<i>14 March 2022</i>
Dental Chamber of Kosovo	Blerim Kamberi, Director	<i>18 April 2022</i>
Kosovo Doctors Chamber	Betime Baftiu, Legal Adviser	<i>19 April 2022</i>

Annex 2: Questionnaire

A. General Information

1. Name of company: _____
2. Name of owner(s): _____
3. Municipality: _____
4. Type of business/company *[Legal status]*:
 - a. Individual Business
 - b. General Partnership
 - c. Limited Partnership
 - d. Limited Liability Company
 - e. Joint Stock Company
5. Status of the person who fills the questionnaire:
 - a. Owner
 - b. Manager
 - c. Both
 - d. Other, please specify: _____
6. Year of establishment: _____
7. Please select the main services provided by your company. *[Note: More than one answer is possible!]*
 - a. Pharmaceutical
 - b. Dental
 - c. Aesthetic
 - d. Other, please specify: _____

B. Overall Structure and Performance

8. Ownership in your company is:
 - a. Domestic only
 - b. Foreign only
 - c. Mixed

9. How many employees (including you) does your company have? Please insert the number: _____
10. Do you have any sort of cooperation with international associates in delivering your services?
- Yes
 - No
11. How would you compare the competitiveness level (price and quality) of health services in Kosovo with similar services provided in the EU?
- Much better
 - Better
 - Same
 - Worse
 - Much Worse
12. How many employees (including you) does your company have?
- Individual clients (*if applicable*): _____
 - Business clients (*if applicable*): _____
 - Other clients (*if applicable*): _____
13. Could you please list up to three STRENGTHS characterizing the health services sector in Kosovo?
- _____
 - _____
 - _____
14. Could you please list up to three WEAKNESSES characterising the health services sector in Kosovo?
- _____
 - _____
 - _____
15. How would you rate the following on a scale from 1 to 5, where 1 – not an obstacle at all, and 5 – a large obstacle?

1. Excessive domestic regulatory burden	1	2	3	4	5
2. Rigorous licensing requirements	1	2	3	4	5
4. Level of taxes	1	2	3	4	5
5. Difficulties in obtaining financing to provide international services	1	2	3	4	5
6. Shortage of qualified legal personnel	1	2	3	4	5

8. Membership fees in the respective professional associations	1	2	3	4	5
Other (specify):	1	2	3	4	5

16. Please list and elaborate three interventions that would upgrade health services in Kosovo:

- a. _____
- b. _____
- c. _____

C. Trade (Exports of health Services)

17. Does your company have clients abroad?

- a. Yes, specify the number _____
- b. No

18. [Only for companies with clients abroad] How does your company provide services to clients abroad?

- a. Travel to provide services on site
- b. By internet
- c. Both
- d. _____

19. Could you please list three main barriers that prevent you to offer your services abroad or to increase/expand your business with clients abroad?

- a. _____
- b. _____
- c. _____

20. What domestic policies may be required to support you in your efforts to provide better services?