Healthcare Systems, Patients' Rights and Patient Organisations' Involvement in Healthcare Policy and Programme Development: A Situational Analysis of the Western Balkans - 2017

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List of abbreviations

Abbreviation	Description
BIRN	Balkan Investigative Reporting Network
CSOs	Civil Society Organisation(s)
DALY	Disability-Adjusted Life Year
EC	European Commission
ECA	Europe and Central Asia
EPF	European Patients' Forum
EU	European Union
EU-SILC	The EU Statistics on Income and Living Conditions
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
HDI	Human Development Index
IT	Information Technologies
LGBT	Lesbian, Gay, Bisexual, and Transgender
N/A	Not available
NATO	North Atlantic Treaty Organization
NGO	Non-governmental Organisation
PO(s)	Patient Organisation(s)
WHO	World Health Organisation

1. Background and Methodology

The EPF (The European Patient Forum) Capacity Building Programme was designed in 2012 with the aim of supporting patient organisations to strengthen their role as equal players in the healthcare environment. The programme is carried out in Bulgaria, Hungary, Poland, Romania and Slovakia.

In 2013, the EPF Secretariat embarked upon a journey towards a much stronger, and more representative patient movement in the Western Balkans countries, and on 28 and 29 October organised the first EPF Regional Advocacy Seminar: "*How to strengthen the patients' perspective at EU and national level?*" in Zagreb, Croatia. The seminar offered, among other objectives, the opportunity for around 50 participants to learn and share experiences about the implications of some key EU policy initiatives for patients and national healthcare systems, as well as to strengthen patient organisations' advocacy skills to increase their impact in policy and decision-making at national and European level. In a continuous effort to support and strengthen the patients' movement, EPF opted to conduct this regional situational analysis in late 2016.

The intent of this situational analysis is to:

- Understand the healthcare systems and the environment in which they function in each country targeted by this analysis;
- Identify the perceptions of patient organisations' representatives with regards to the quality of healthcare service delivery and protection of their rights in each country;
- Map the main patient organisations that could be important partners for EPF;
- Assess the capacity level of patient coalitions/umbrella organisations and disease-specific organisations to take part in the development of health care policies and programmes;
- Inform and guide the EPF Secretariat in the development of appropriate response in the context of capacity building programme from short-term to long-term basis.

This situational analysis report contains the main findings gathered from Bosnia and Herzegovina, Croatia, Kosovo, FYROM, Montenegro and Serbia. To reach a high number of geographical representations, the research targeted:

- Participants from the Western Balkans Regional Conference: "Protection of Patients' Rights: Role of Institutions and Associations" organised on 17 and 18 October 2016;
- Two EPF member organisations from the Western Balkan region:
    - KUZ – Croatian Coalition of Association in Healthcare (EPF Full member);
    - APO – Alliance of Patient Organisations, FRYOM (EPF Associate member);
- Representatives of disease-specific patient organisations and/or national patient coalitions/umbrella organisations from Bosnia, Kosovo, Montenegro and Serbia;
- Wider patient community – contacts gathered from the EPF Regional Advocacy Seminar participants list, the Association of Innovative Pharmaceutical Manufacturers (Bosnia and Herzegovina and Croatia), the Pharmaceutical companies Pfizer and Celgene International (Slovenia) and the Medical Clinical Centre (Montenegro).

The situational analysis methodological framework consisted of following:

Method Description	Period
Desk research that included the collection of both qualitative and quantitative data about the current healthcare system and patients' rights in each country	Late 2016 – Early 2017
Individual and/or group interviews conducted with representatives of government health offices, patient organisations, pharmaceutical associations and companies that assisted in assessing the information gathered through the desk research, including the implications of current healthcare system on patients and their organisations	Late 2016 – Early 2017
Survey/Questionnaires findings gathered and analysed about the role, representativeness, credibility and sustainability of key patient coalitions/umbrella organisations and patient disease-specific organisations in each targeted country	February – March 2017

Furthermore, the analysis is divided in two main parts: i) analysis of the wider healthcare situations, including patients' satisfaction and protection of patients' rights and ii) the situation of patients' movement in each country with the focus on their capacities to act as equal players in the healthcare environment.

1) The analysis of the wider healthcare system, where information is available, considers the health status information of targeted countries (ex. population, life expectancy, mortality, major causes of death etc.), basic political and socio-economic situation that impacts the overall healthcare functioning, general overview of healthcare reforms, including the healthcare policy and legal framework, the organisation of the healthcare system, healthcare financing as well as patients' satisfaction and insight into the protection of patients' rights in each country.

2) The analysis of the roles, representativeness, credibility and sustainability of patient organisations covered the guided questions about following issues: number/presence of active patient disease-specific organisations and national coalitions/umbrella organisations, proportion of young patients and women in decision making within active organisations, the governance of patient disease-specific organisations, their organisational and advocacy capacities, the governance and capacities of national patient coalitions/umbrella organisations to take part in the development of laws, policies and programmes, capacity building needs, and potential benefits of the cooperation among patient organisations at the regional level.

The report is drawn up by EPF Capacity Building Programme Consultant Selena Imerovic Hodzic.

2. Scope and Limitations

Given the number of countries within the Western Balkan region, extensive efforts were made to ensure that the research, including the qualitative interviews and questionnaires, reaches a wide range of actors, while focusing on CSOs to ensure patients' perspective.

The literature review aims at addressing the healthcare systems and several key dimensions (ex. policy and legal reforms, financing and healthcare service delivery, patients' satisfaction, patients' rights etc.), but it is evident that the report provides a limited insight into this very complex area, mainly due to the insufficiency of gathered data in each country.

While the overall findings cannot claim to be fully representative and comprehensive, this situational analysis report and recommendations are indicative of the current trends, especially with regards to the capacities of patient organisations and their involvement in development of healthcare policies and programmes. The findings are primarily used to inform EPF on future development of capacity building programme in this region.

Finally, it is important to note that this report, a part of brief mentions, does not consider some specific topics such as the healthcare technology assessment or access to medicines.

3. Key Findings in a Regional Context

Since the fall of Yugoslavia, the reforms of healthcare systems, as well as the key players who drive change such as the World Bank, the EU, and the WHO, are rather similar throughout the region. Overall, there has been a shift towards family medicine as a cornerstone of primary healthcare, as well as an increase in the use and diversification of specialised private practices, etc. However, in many ways, healthcare reforms are still ongoing and face continuous challenges because of limited economic growth and insufficient resources for extensive reforms.

In many ways, reforms are supported by policy and legislative documents, usually the Law on Healthcare and the Law on Healthcare Insurance, although in practice regular adjustments, including monitoring and evaluation, remain weak. The Bosnian and Herzegovinian system is very decentralised, making the entire process even more complicated. Even in Croatia, the EU Member State which has overall made the most progress among the countries included in this analysis, the polices and strategies are not systematically measured nor analysed for impact.

Overall, healthcare financing is rather poorly organised, vulnerable to external financial risks, and so, immensely unsustainable. Most Balkan countries guarantee universal healthcare coverage through the Bismarck social insurance model, but the issue of the grey market and the avoidance in paying taxes is a big problem. Consequently, certain portions of the population (such as Roma population, employees of informal businesses, people on low incomes etc.) are unevenly or insufficiently insured. While countries offer some sort of additional private insurance scheme, out-of-pocket payments remain very high, especially in Kosovo and Montenegro. Kosovo is only at the starting phase of establishing the Health Insurance Fund as a main source of healthcare system financing.

Improvements in the quality of Balkan healthcare service delivery systems move slowly. Patients' expectations are continuously increasing, but due to the insufficiency of investments and poor management of existing resources, overall service delivery lags behind the norms of the EU countries. Private practices are not usually fully integrated in the healthcare systems. The reality is that while some of the latest treatments are available in some successful public or private practices in their own or neighbouring countries some of the poorer population find it difficult to access to even basic services. At the same time, patients' perception and satisfaction are rarely measured, making efficient healthcare delivery more elusive. FYROM is the only country who reportedly managed to significantly reduce waiting lists.

Corruption is widespread in most of the region. Most of the countries lack regulations that would prevent the misuse of public powers, especially when it comes to the public procurement and the relations between healthcare and pharmaceutical sectors. Thanks to the external financial aid, Serbia is currently setting up a better public procurement procedure, although bribing doctors and nurses remains a frequent practice.

The Laws on the Protection of Patients' Rights are not fully implemented. All governments in the region have adopted Laws on the Protection of Patients' Rights, although the Balkan healthcare politics and healthcare service delivery systems need to acknowledge their significance on a higher level. Most of the population has poor knowledge of its rights, reflecting its vulnerability and inability to recognise human rights violations. In many cases, there is a lack of legislative implementation procedures that should help patients to put the protection of their rights into practice.

Patient organisations acknowledge the need for organisational capacity building support, although it seems there is a greater interest in technical and thematic issues. While there are a slightly more opportunities for receiving trainings in, for example NGO management and advocacy, it is recognised that these trainings are not sufficiently tailored for patients needs and the healthcare sector. Most of the patient umbrella organisations and disease-specific organisations face similar organisational and advocacy challenges such as small number of active organisations, low level of representation and recognition by national healthcare decision-makers, lack of strategic approaches, unsustainability of funding, and lack of collaboration and networking between organisations, among other things. Know-how in the mobilisation of resources is recognised as one of top priority capacity building needs.

Overall, patients' sphere of influence and their participation in decision-making processes is weak. According to patients, the involvement of leading patient organisations' representatives in public debates on healthcare policies and programmes is beginning to emerge, their influence has yet to become sound and persuasive. Thus, it is not surprising that 'Sharing best practices on how to improve patients' involvement into decision-making processes' is recognised as a top priority in terms of needed capacity building technical support, including the training in patients' rights and monitoring of related laws.

Patients involved in this research very much appreciate the possibility of having regional cooperation among patient groups across the Western Balkan countries. It is suggested that such an initiative would boost patients' efforts to improve their accountability and strategies to enforce patients' rights in their respective countries. By taking the slow, but ongoing EU enlargement process into consideration, such regional cooperation would also support advancing health policies at the EU level for the benefit of all patients, and prevent patients from the Western Balkans countries to operate in an isolated manner.

4. An Insight into Healthcare Systems and Protection of Patients' Rights in Balkans Countries

4.1. Bosnia and Herzegovina

Bosnia and Herzegovina at a Glance

Topic	**Status**
Established	1992, declared independence from Yugoslavia
EU Membership Status	**Potential candidate**
EU Stabilisation and Association Agreement	**Enters force in 2015**
Area	51,197 km2
Population, 2016	**3,8 million**
Official languages	Bosnian, Croatian, Serbian (they are all mutually understandable)
Ethnic groups	Bosniaks (50.11%), Serbs (30.78%), Croats (15.43%), others
Government	Federal Parliamentary Republic
Legislature	Parliamentary Assembly, Upper and Lower Houses
Administrative division	Bosnia and Herzegovina is administratively divided into 2 entities: Federation of Bosnia and Herzegovina and Republic of Srpska, and Brcko District. Federation is divided into 10 cantonal governments. The state consists of 137 municipalities of which 73 are in the Federation, and 63 in the Republic of Srpska.
GDP, estimate 2016	Total ($41.127 billion), Per capita ($11,647)
Public health expenditure	**6.8 % of GDP**
HDI, 2016	**81th ranked**
Population, ages 65+	0.6 million
Population, ages 15-64	2.7 million
Population, under 5	0.2 million

Life expectancy	76.6 years
Mortality rate, female	66 per 1000 adult people
Mortality rate, male	130 per 1000 adult people
Top 3 causes of death since 2005	Heart diseases, Stroke, Lung cancers
Top risk factors leading to DALYs	High systolic blood pressure, dietary risks
Most prevalent health problems	Oral disorders, Sense organ diseases

Country Context

Bosnia and Herzegovina, as one of the successor states of the former Socialist Federal Republic of Yugoslavia, inherited a strong state role in shaping social policies, including healthcare. The proclamation of Bosnian independence during an interethnic conflict in the early nineties, as well as post-war reconstruction, development and complex political and administrative divisions, was far from favourable for further state-building and decision-making on major reforms. Later, due to the increased international pressure on the national actors to move forward with the dialogue on solving wider socio-economic problems, the dialogue and actual progress on sectorial reforms, including health care, is continuous, although relatively slow.

The healthcare legal and institutional system is organised in an analogous manner, like the overall constitutional and administrative arrangements in Bosnia and Herzegovina. This means they are regulated differently in the Republic of Srpska (a centralised structure) and the Federation of Bosnia and Herzegovina (a decentralised structure). In total, there is not one, but rather thirteen (13) systems which are often in contradiction to each other. On its path to the EU Accession, over the past few years, both entities have initiated wide scale healthcare reforms, but the efficiency, equity and quality of health services remain weak which require deeper reforms.

Healthcare policy and legal framework

Bosnia and Herzegovina ratified several international documents that guarantee the healthcare protection to all patients, and now it is expected that the legal framework will be aligned with the EU requirements, including Health and Safety at Work. According to the most recent EU Progress Report with regards to the EU Accession process, there has been some progress in public health, while the overall cooperation between entities remain fragile and dispersed.

In recent years, Bosnia and Herzegovina has adopted many strategies, including the most recent Strategy for improving the rights and status of persons with disabilities in the Federation 2016-2021; the Strategy on Rare Diseases 2014 – 2010; the Resolution on Diabetes and the Strategy against Diabetes 2014 - 2024; the Policy and Strategy for the Protection and Improvement of Mental Health in the Federation 2012 – 2020; and the Strategy for the Prevention, Treatment and Control of malignant neoplasms in the Federation 2012-2020 etc. In particularly, Republic of Srpska has made some progress in implementing the e-health strategy.

So far, the Reform of Primary Healthcare represents the essential part of the healthcare system reforms, yet there is much more to do with regards to the overall healthcare financing. According to the Strategic Plan of Healthcare Development 2008 - 2018, there are four main concerns in this sector:

(i) financial sustainability, (ii) inefficient organisational model and provision of services; (Iii) limited institutional capacity and institutional fragmentation; and (iv) unequal access to health care. Similar problems are identified in both entities, and the progress made related to these issues will be re-evaluated in both entities in the upcoming year.

The two main laws are: HealthCare Act and Health Insurance Act. While it appears that Bosnia, including both entities, has developed most relevant legal documents, the implementation, monitoring and coordination remain problematic and cause frustrations among the population.

Healthcare financing and insurance

Bosnia and Herzegovina has a social insurance model where the financing of healthcare system comes from the employers and employees who pay compulsory contributions into public funds. Besides this, the law recognises other forms of contributions, such as budget (budget of the entities and cantons), donations, health institutions' income, participations, etc.

However, in both entities, the major source of financing healthcare comes from public health funds which heavily rely on the payroll tax (currently the payroll tax for employees in one of the largest in the ECA region). The remaining percentage comes from farmers' income taxations and government's contribution for pensioners, unemployed or other vulnerable groups. Many patients pay directly for their drugs and medical treatments. The part of the federal taxation on alcohol and tobacco is not returned to the public health funds.

The main reasons leading to the unsustainability of such financing system are: under-the-payments to healthcare staff, existence of grey economy and employers' avoidance to pay for full compulsory contributions, low capacity of tax authorities to carry out payments, difficulties in collecting payments from decentralised levels etc.

On the other hand, the health sector spending has an important share in GDP in Bosnia and Herzegovina. From total expenditure on health services, the substantial proportion goes on the administrative costs and costs on medical aids towards outpatients, which is usually low in the EU countries because they have private insurance funds.

Given the above issues, it is evident that there is no full healthcare coverage for all citizens in Bosnia and Herzegovina. Also, not all insured persons across a divided and decentralised country, especially across of all the cantons of the Federation of Bosnia and Herzegovina, are exercising the same rights under compulsory health insurance. The fact is that the need for significant payments out of pocket represents a significant barrier to accessing health services.

Provision of healthcare services and patients' satisfaction

According to the latest technical assessment of the overall healthcare service delivery, there are less healthcare professionals (both doctors and nurses) per 100.000 resident compared to the average in the EU countries, of which many doctors are specialists. There is overall lack of motivation, and unstimulating mechanisms of payments for staff which leads to the brain drain of health professionals to the EU, mainly Germany. Otherwise, building political or ethical relationships remains a key determinant in obtaining higher positions in country.

There are enough primary care services at the municipal level, but the specialist care is often offered by the private practices which are expensive and only available in the urban areas. The lack of coordination of health professionals results in an excessive number of cases referred to higher levels of protection and to be treated by unnecessarily excessive costs.

There are also enough hospital services, although it seems that the problem is more in the composition and quality of services at the hospital level, which seems weak. There are reports of low levels of hospital administration, including insufficiently trained hospital managers. The problem is that decentralisation has led to excessive fragmentation resulting in duplication in the provision of services and an inappropriate ratio of primary, secondary and tertiary care.

There are some reports of lack of adequate materials and highly modernised equipment, however the major problem is related to the maintenance of the existing equipment as well as the lack of compliance between the real needs and the actual purchase. The integration and use of IT systems is becoming an increasing important, yet they are not fully operational. Finally, the technical assessment stress the importance of ensuring a systematic quality of control in many aspects of healthcare service delivery.

Protection of patients' rights and patients' involvement

In the Federation of Bosnia and Herzegovina, patients' rights are defined in a separate Law on the rights, obligations and responsibilities of patients, while in the Republic of Srpska, patients' rights are incorporated in the healthcare legislation. Both legal forms are mostly in line with the European Charter on the Rights of Patients, and are based on the principles of equality, accessibility, comprehensiveness, continuity and coordination. While the mechanisms for dealing with complaints of patient rights' violations and medical errors are defined in these laws, they are not fully enforced according to the law.

In addition, under the chapter 'Ensuring the protection of the rights of patients in health institutions or in private practices' of the Federation of Bosnia and Herzegovina, the Public Ethics Commission for patients' complaints and the Public Commission for the quality and safety of health services represent legitimate instruments for protecting the rights of patients by health professionals and associates. The protection, especially in cases of severe violations, can be also achieved with the help of 'Health tips in local governments and ministries of health' through many councils, competent health inspections and the institution of the Ombudsman. However, due to a complex decentralisation system, it appears it is not easy to obtain a quick resolution.

The same issue is differently regulated in the Republic of Srpska, where the director of the health facility determines the final decision on the complaint submitted by a patient. The director of the health facility can appoint an independent commission, and must submit the results to the Ministry of Health. Submitting complaints to courts is expensive and takes years. Some complaints are resolved by compensation.

There is no data about the number and type of complaints. Yet, it is apparent that patients' rights are often violated, and patients' rights protection laws are not fully applied, especially for some vulnerable groups such as discriminatory attitudes toward the Roma population. Most importantly, there are no initiatives that would encourage patients' confidence in health professionals' expertise and experiences, nor ensure a greater recognition and respect from health institutions and professionals' side toward patients' rights.

Finally, according to the EPF Patients' Survey on Healthcare, Legislation, Patient Involvement and Regional Cooperation 2017, many patients share the opinion that bribe and corruption in the healthcare sector, insufficient health sector funding, insufficient infrastructure and equipment, bad organisation of the overall healthcare system, as well as malpractice at work and lack of the control of healthcare professionals, result in poor-quality healthcare. There is a general distrust in the healthcare system. They consider that the development of healthcare strategy at the state level with clear lines of responsibilities and coordination would improve patients' satisfaction with the healthcare system in the long term.

4.2. Croatia

Croatia at a Glance

Topic	Status
Established	1991, declared independence from Yugoslavia
EU Membership Status	**EU Member State**
Area	56,594 km2
Population	**4,2 million**
Official language	Croatian
Ethnic groups	Croats (90.4%), Serbs (4.4%), others (5.2%)
Government	Unitary parliamentary constitutional republic
Legislature	Parliament or 'Sabor'
Administrative division	The capital city Zagreb and 20 counties. The counties subdivide into 127 cities and 429 municipalities.
GDP, estimate 2016	Total ($97.026 billion), Per capita ($23,171)
Public health expenditure	**6.4 % of GDP**
HDI, 2016	**45th ranked**
Population, ages 65+	0.8 million
Population, ages 15-64	2.8 million
Population, under 5	0.2 million
Life expectancy	77.5 years
Mortality rate, female	57 per 1000 adult people
Mortality rate, male	134 per 1000 adult people

Top 3 causes of death since 2005	Coronary heart diseases, Stroke, Lung cancers
Top risk factors leading to DALYs	High systolic blood pressure, dietary risks
Most prevalent health problems	Oral disorders, Sense organ diseases

Overall healthcare system assessment and ongoing reforms

The overall healthcare policy goals have shifted from reducing the prevalence of specific diseases to improving health outcomes. Despite insufficiency of data in this area, it can be considered there are significant improvements in population health thanks to the availability of preventive services. The health outcomes vary among different population groups. According to EU-SILC Survey from 2011, individuals who perceive their health to be bad, or very poor, belong mainly to the older population and among those who have either lower incomes or educational levels.

While there are no in-depth assessments of previous healthcare reforms (ex. primary care and hospital payment mechanisms, pharmaceutical pricing and reimbursements, emergency care reforms, IT system reforms, new medical training/specialisation programs, etc.) and its outcomes, it seems there are some improvements. Still, most reforms face various implementation problems and delays.

The ongoing reform known as the National Health Care Strategy 2012 - 2020 contains a number of priorities: development of computerisation and e-health, strengthening and better use of human resources in the health sector, strengthening management capacity, reorganisation of the structure and operations of health institutions, promoting quality in health care, strengthening prevention activities, preserving the financial stability of the health sector and establishing cooperation with other sectors and society as a whole.

The aim of this ambitious plan is to make healthcare more accessible, and to increase capital investments, human resources and public health by applying to EU funds and achieving cost-effectiveness of the hospital sector. Since 2015, the specific focus has been the reduction of the fiscal risk of the health system in to order to make it stable and financially sustainable. Also, Croatia initiated many programs and projects that support the strategy implementation.

While it can be concluded that the reforms are going in the right direction, it may be necessary to make the reforms process more transparent, open to stakeholders' involvement, systematic monitoring and establishing evidence-based information for further assessments and reforms. The public perception of the healthcare system is also rarely assessed.

Healthcare system: organisation, legal framework, financing, service provision

Since independence, the Croatian healthcare system transformed into a more centralised and overall more efficient system. There is a general shift towards privatisation, mostly specialist clinics for outpatients, but the state remains the main owner. The Ministry of Health represents the main policy, regulatory and supervisory actor in the healthcare system. The local governments are responsible mainly for operating the public primary and secondary healthcare facilities, including general and special hospitals, county health centres, public health institutes and community health institutions.

The basic legal framework of the healthcare system includes the following legal acts and their later amendments: the Health Care Act of 2008, with amendments in 2013; the Mandatory Health

Insurance Act of 2013; and the Act on Quality of Health and Social Care of 2011 which regulates the quality of healthcare services. There are ongoing government efforts to harmonise the existing legislation with the EU health policy requirements.

The proportion of GDP spent on health has grown steadily since the early 2000s, but still this is smaller than in most western European countries. The revenue of the Croatian Health Insurance Fund comes from compulsory health insurance contributions (76%), various taxations (15%), and foreign donations, such the World Bank and the EU. Over the past years, the financing system faced instability due to health inflation and increased medical costs. The imbalance between revenues and expenditures was also noted, yet an increase in economic growth led to more extensive healthcare coverage.

As stated above, in Croatia there is a system of compulsory health insurance for all members of the working population. Some vulnerable groups are exempted from payments, although there is a systematic reduction of the right for free services. Some citizens supplement their state healthcare service with additional private health insurance to be able to access some higher types of health services (not or only partially covered by the mandatory insurance) or to pay for non-prescription drugs. There is also voluntary health insurance as a form of the complementary insurance in the compulsory health insurance scheme. According to the WHO Global Health Expenditure Database 2014, Croatia has the lowest level of out-of-pocket expenditure (11.2% of total health expenditure) compared to other Western Balkan countries.

In Croatia, in comparison with the Western EU countries, the number of health facilities, as well as acute beds is lower. Capital investments are usually done without needs assessment or the HTA (this area is at the developing stages). The number of health professionals is gradually increasing, but the rural areas and islands remain under-resourced. Access to diverse types of specialised care across Croatia is also very imbalanced. The waiting list to access some highly specialised medical equipment is also quite noticeable in some regions where the required equipment is lacking. On a positive note, there are reports of an increase in radiotherapy equipment. The use of integrated IT in healthcare (for example doctor’s access to real-time medical exams and e-prescriptions), is also significantly increasing, and is proving efficient.

There are many national preventive health programs focused on the early detection of various diseases and / or early detection of complications of certain diseases to ensure a higher quality of life of the individual and extending life expectancy. According to the EPF Patients’ Survey on Healthcare, Legislation, Patient involvement and Regional cooperation 2017, the National Plan for Treatment Against Cancer is one of the national plans that would require further substantial and systematic reinforcements.

Patients’ rights and their participation in the public healthcare debate

Patients’ rights can be considered under the three following categories: human rights, insurance rights and consumer rights. Consumer rights include the right to information, to reasonably short waiting times, health outcomes, access and availability of healthcare and drugs. In 2015, according to the Euro Health Consumer index, Croatia ranked at 16th place among 35 European countries by considerably reducing the waiting time for services. Yet, patients responding to the EPF Patients’ Survey on Healthcare, Legislation, Patient Involvement and Regional Cooperation 2017 still find that the waiting time can be significantly improved.

Patients' rights are regulated under the Mandatory Health Insurance Act of 2013 which is introduced mainly to align the Croatian legislation with the Patients' Rights Directive and the Patients' Rights Protection Act of 2004 which was amended in 2008. As a result, the Commissions for the Protection of Patients' Rights are established at national and county levels. The complaint procedures are well established, including the existence of the free 'white help telephone line' within the Croatian Health Insurance Fund. Still, it cannot be considered that the legislation or related measures have made significant improvements or impact on the protection of patients' rights, especially in cases of violations. Overall, there is a lack of knowledge about this concept, legislative acts and / or capacities to implement it.

There are patient representatives within the Commissions for the Protection of Patients' Rights, and in addition, they are invited to take part in some public healthcare consultations. However, there is no evidence of major influence. While there is no survey on healthcare users' satisfaction, in 2013 the Ministry of Health reported that they met 69 patient associations to discuss patients' concerns and further realisation of patients' rights.

The fact it is still possible to find some cases of bribe and corruption, especially in the smaller health centres, is a clear sign of problems within Croatian healthcare system, and the need for further improvements in an organised and systematic manner.

4.3. Kosovo

Kosovo at a Glance

Topic	**Status**
Established	2008, declared independence from Serbia
EU Membership Status	**Potential candidate**
EU Stabilisation and Association Agreement	**Enters force in 2016**
Area	10,908 km2
Population	**1,9 million**
Official/Recognised languages	Albanian, Serbian/Bosnian, Turkish
Ethnic groups	Albanians (N/A), Serbs (N/A), others
Government	Parliamentary Republic
Legislature	Assembly of Kosovo
Administrative division	There are 7 districts and 38 municipalities
GDP, estimate 2016	Total ($18.840 billion), Per capita ($10,134)
Health and social work expenditure	**4.01 % of GDP**

HDI, 2014	**148th ranked**
Population, ages 65+	7%
Population, ages 15-64	67.2%
Population, under 5	25.8%
Life expectancy	71.3 years
Mortality rate, female	N/A
Mortality rate, male	N/A
Top 3 causes of death since 2005	N/A
Top risk factor leading to DALYs	N/A
Most prevalent health problems	N/A

Healthcare historic background, main challenges and reforms

In the 90s, due to conflicts with the Serbian authorities, the Kosovo healthcare system was informal and run simultaneously with other official system which catered to the minority Serb population. Overall, healthcare significantly deteriorated in this period. Since Kosovo is one of the Balkan countries who has gained its independence recently, it is not surprising that the healthcare structural changes and improvements are still in transition. Major policy and legal frameworks are largely influenced by the international community, the World Bank, the EC, WHO and other donors. Kosovo has failed to implement many strategic plans, including poor legislative measures implementation, lack of accountability, financial troubles, bribes and corruption, etc. There is no integrated healthcare long-term strategic plan that would advance the functioning of healthcare system, train health professionals, and invest in medical equipment. Healthcare insurance reforms remain one of the biggest problems.

Current state of the healthcare system: organising, financing, access to healthcare

The Ministry of Health is the main body responsible for healthcare regulations. At the local government level, the department of Health and Social Welfare takes part in developing some healthcare strategies, such as primary healthcare or aiding NGOs.

The budget for the Ministry of Health is subject to the sharing of the total government's budget with other Ministries. As such, the budget is very limited, and only a small percentage goes to carefully planned medical expenditure. The overall budget is managed by the central government with a half of it going to the decentralised levels. Due to the overall limitation of this budget, around 40% of expenditure is not covered by the state budget, but by out-of-pocket expenditure. The Centre for Research, Documentation and Publication estimates that patients spend 80 million euros annually on treatments abroad.

Kosovo has attempted to implement the Health Insurance Law several times, but with no success. Consequently, there is no functional Health Insurance Fund in place that provides health coverage for all citizens. Only around 6% of population is covered by private insurance.

Currently, the healthcare system is divided into three sectors: primary through family medical centres (13) and ambulatory care units (15), secondary through decentralised regional hospitals (7), and tertiary healthcare that includes the University Clinical and Dentistry Centre of Kosovo and the National Institute of Public Health. There is a limited number of licenced private clinics, which is partially related to the limited number of healthcare inspectorates to cover the whole territory of Kosovo. One of the problems related to the division between public and private centres is that often doctors work in both, which causes a certain conflict of interests. There are also reports of a shortage of health professionals in general, and especially at the primary healthcare level, including family care. The establishment of health IT system is at the very beginning stage of its development, including patients' registers.

According to the Kosovo Women's Network 'Access to Healthcare in Kosovo', the healthcare services are underutilised, especially for preventive and mental health care. One of the main barriers to access to healthcare, including emergency care, is related to the distance between the rural residents and healthcare centres, especially for minority groups who live in isolated areas. There is also evidence of lack of coordination and appropriate referrals between various healthcare institutions, which further complicates access to healthcare.

Patients' rights and violations

While the Law on Health 2013 regulates the promotion, prevention and provision of healthcare services, including the guarantee to protect the health of al Kosovo citizens, it is the Law on Rights and Responsibilities of Citizens in Healthcare that deals specifically with patients' rights. Moreover, as one of related administrative measures, all healthcare centres are obliged to place the Charter of Patients' Rights and the Charter of Patients' Responsibilities at visible places. The Charters, with a few minor amendments made to better respond to Kosovo healthcare environment, largely resemble the European Charter of Human Rights.

The complaint procedures are well established, and as such, they give patients the right to submit their complaint to the healthcare institution, or to the courts to obtain compensation. Yet, the Commission on the evaluation of compensations has not been set up. The Ministry of Health has introduced complaints boxes, as well as a free telephone line to collect patients' complaints. The Ministry of Health, with only five inspectors, does not have capacity to deal with all complaints (400 were received in 2016). Despite certain measures, Kosovo Women's Network 'Access to Healthcare in Kosovo's survey findings show there is great dissatisfaction with the quality of healthcare, and, a low level of trust in the healthcare authorities to address complaints in a systematic manner.

Moreover, their survey shows that there are a few reports of misdiagnoses, abuse or discrimination that demonstrate the existence of violations of patients' rights. One fifth of all respondents did not consider that the right to confidentiality is in fact their legitimate right. Most respondents do not report bribe and corruption because they do consider such reports to guarantee better care. Given this situational context, it is not surprising that a larger proportion of people in the mid to high income population look for higher quality medical examinations and treatments out of the country.

4.4. FYROM

FYROM at a Glance

Topic	Status
Established	1991, declared independence from Yugoslavia
EU Membership Status	**Candidate country since 2015**
EU Stabilisation and Association Agreement	**Signed in 2004**
Area	25,173 km2
Population	**2,1 million**
Official/Recognised languages	Macedonian/Albanian, Serbian, Turkish
Ethnic groups	Macedonian (64.2%), Albanians (25.2%), Turkish (3.9%), others
Government	Parliamentary Republic
Legislature	Parliament or ‘Sobranie’
Administrative division	80 municipalities
GDP, estimate 2016	Total ($30.377 billion), Per capita ($14,631)
Public health expenditure	**4.1 % of GDP**
HDI, 2016	**82th ranked**
Population, ages 65+	0.3 million
Population, ages 15-64	1.5 million
Population, under 5	0.1 million
Life expectancy	75.5 years
Mortality rate, female	71 per 1000 adult people
Mortality rate, male	134 per 1000 adult people
Top 3 causes of death since 2005	Stroke, Inflammatory/Heart, Coronary Heart Diseases
Top risk factors leading to DALYs	Dietary risk, High systolic blood pressure
Most prevalent health problems	Oral disorders, Sense organ diseases

Healthcare system: reforms, legal framework, financing

FYROM inherited a well-established and organised healthcare system from Yugoslavia. Even though, given a certain healthcare quality gap with EU countries, FYROM engaged in complex healthcare reforms. Compared to the previously state-run healthcare system, today the FYROM's healthcare system is organised by public and private healthcare institutions at three levels: primary, secondary and tertiary. The reforms in primary healthcare have resulted in greater patient satisfaction, e-health services, the introduction of family medicine specialists, shorter waiting lists, and have broadened the scope of promotional and preventive services. On the negative side, these reforms led to more administrative work, profit-orientated attitudes, and has left some rural areas left without primary healthcare services due to brain-drain (although overall access to the healthcare remains relatively good).

The role of the Ministry of Health is to act as a main healthcare policy formulation and implementation body, including the supervision of the country's health service and the FYROM Health Insurance Fund. The FYROM Health Insurance Fund is responsible for collecting contributions, allocating funds and contracting healthcare providers, including the provision of payments to the private service providers on a capitated-basis for each patient.

The main legal acts, including the Law on Healthcare and the Law on Health Insurance, as well as the Health Strategy of FYROM in 2020, provide for a reliable, efficient and equitable health system. Other legal acts related to the organisation of the preventive care, public health, protection from infectious diseases, sanitary and health protection, have been adopted based on the recommendations based by the EU and the WHO. Some of the major problems related to implementation of these regulations are: no clear indicators for success, lack of responsiveness to revised legal texts when legal circumstances change, overlap of responsibilities between various institutions, weak data collection, monitoring and control systems, etc. Recently, as part of the agreement between FYROM and the WHO, the Ministry of Health developed the Strategy's evidence-based Operational Plan.

The main source of healthcare funding comes from individual contributions, which include different rates for diverse groups. Another part of funding for unemployed, pensioners and persons with disabilities comes from the state budget. The healthcare expenditure is nearly evenly split between the primary, secondary and tertiary levels.

FYROM has compulsory insurance for all citizens, excluding a few vulnerable groups. Private insurance is also available, but it can be purchased only on the top of the compulsory insurance. Patients are obliged to make co-payments of up to 20% of the costs. Out-of-pocket payments do exist, however there is no exact data about the total annual amount.

There is no clear insight into the current healthcare service delivery such as the number or type of services, or the number of healthcare professionals. There are reports about the increase of private clinics whose funding comes through the Health Insurance Fund and patients' payments. Still, public secondary and tertiary centres are to some extent overburdened because of higher costs at the private secondary healthcare centres.

According to the Euro Health Consumer Index 2015, FYROM rated exceptionally well in shortening the waiting lists due to the introduction of E-booking in real time. Another positive action was the introduction of a catalogue with healthcare services ranked according to quality to help ensure transparent monitoring of services; publishing of another catalogue 'Top 100 Doctors' is in plan too.

According to Mitevska and al' (2016) research 'Performance of the Public Healthcare Sector in the Macedonia', Macedonians find that the healthcare service is medium-good in terms of accessibility, availability, quality of healthcare services and patient satisfaction.

FYROM is increasingly working on developing strategic plans and programmes for vulnerable groups, including children, women, rural population, persons with disabilities, and Roma.

Protection of patients' rights

In 2008, FYROM adopted the Law on the Protection of Patients' Rights which provides extensive protection for the rights of patients, including the right to second expert opinion. The law covers the new structures (councillors, commissions, etc.) and mechanisms for the protection of patients' rights, although its implementation remains problematic, especially for certain groups such as women, Roma and the rural population.

4.5. Montenegro

Montenegro at a Glance

Topic	**Status**
Established	2006, gained independence from Serbia
EU Membership Status	**Candidate country since 2010**
EU Stabilisation and Association Agreement	**Enters force in 2010, Negotiations on Chapters 28 – Consumer and health protection opened in 2014**
Area	13,812 km2
Population	**0,6 million**
Official/Used languages	Montenegrin Serbian, Bosnian, Croatian, Serbian, Albanian
Ethnic groups	Montenegrin (45%), Serbs (28%), Bosniaks (8.1%), others
Government	Parliamentary Republic
Legislature	Parliament or 'Skupština'
Administrative division	23 municipalities, and 2 urban municipalities, subdivisions of Podgorica municipality
GDP, estimate 2016	Total ($10.436 billion), Per capita ($16,654)
Public health expenditure	3.7 % of GDP
HDI, 2016	**48th ranked**

Population, ages 65+	0.1 million
Population, ages 15-64	0.4 million
Population, under 5	0.0 million
Life expectancy	76.4 years
Mortality rate, female	73 per 1000 adult people
Mortality rate, male	100 per 1000 adult people
Top 3 causes of death since 2005	Coronary Heart diseases, Stroke, Inflammatory
Top risk factors leading to DALYs	Dietary risk, High systolic blood pressure
Most prevalent health problems	Oral disorders, Sense organ diseases

Country context, including the most significant healthcare reforms

In the early 90s, Montenegro started its transition process and held its first democratic election. Although under the influence of Serbia, Montenegro had established an institutional framework, including the Ministry of Health, major reforms were led by the pro-Western party which advocated for a greater political and institutional split between Serbia and Montenegro. It was only in 2008 that Montenegro, through a referendum, gained its independence from Serbia. Since then, Montenegro has made a noteworthy progress toward entering membership negotiations with the EU and the NATO. Unfortunately, due to unfavourable socio-economic circumstances, the economic reforms are not yet fully consolidated.

To deal with the many problems inherited from the previous healthcare system, Montenegro re-defined the role and responsibilities of primary healthcare institutions and professionals, established a new system of healthcare financing, and considerably increased investments in the education of healthcare professionals, infrastructure, equipment and the use of IT. While the most significant structural changes and restructuring have taken place, and it is evident that the reform process is going in the right direction and is in line with EU requirements, it is still facing many challenges, mainly related to the financial sustainability.

The new reforms are based on several key policy and legal documents such as: The Strategy on Development of Healthcare System which remains valid until 2020, as well as the Master Plan for Development of the Heath Care System of Montenegro 2005 – 2009, 2010 – 2013, 2015 – 2020, the Law on Health Care 2004, 14/10, and the Law on Health Insurance 2004, 14/12. The Health Care Program was evaluated in 2013. In 2014, the government called for easier access to both public and private services, the increase in the quality level of healthcare services, and the opening of additional inspection measures.

Healthcare organisation and healthcare financing

The state is the main founder of healthcare for the entire population. The state offers services through public, and in some cases through private institutions by subcontracting them. The care services exist at three levels: primary, secondary and tertiary. In 2015, Montenegro had 18 health centres, seven general hospitals, three special hospitals, the Clinical Centre of Montenegro, the Institute for Public Health, Emergency Medical Assistance, the Blood Transfusion Institute, and Pharmacies of Montenegro “Montefarm”. The utilisation of these services is higher than in EU countries. The number of healthcare professionals is steadily increasing over the past few years; however, this number is still very much behind the average of EU countries. They are well trained, but they lack good facilities and supplies. Patients can choose their own doctors if they are registered in the state scheme. Private care is available through around 100 private practices, but usually they are used by a limited group of people.

Around 95% of healthcare funding comes from individual contributions to the Health Insurance Fund. The remaining 5% is covered by the state budget. The overall healthcare expenditure is relatively low. According to the WHO Global Health Expenditure Database (2014), Montenegro’s out-of-pocket expenditures remain one of the highest in the region (42% of the total health expenditure). According to the Balkan Investigative Reporting Network - BIRN (2016), the Fund is vulnerable to economic crises, and in 2015, the Fund and public health institutions’ debts topped 50 million euros. Consequently, if the funding does not come from taxes on tobacco and alcohol, premiums for compulsory car insurance and tourist taxes than the healthcare funding will remain instable and insufficient. According to the Euro Health Consumer Index 2015, Montenegro is one of the lowest ranked among other 35 countries measured in the Europe.

Protection of Patients’ Rights

The Law on Patients’ Rights was adopted in 2010. In January 2011, health institutions organised the work of the protectors of patients’ rights. The role of the protectors, among other tasks, is to provide advice and to find the best solution for patients. They often act as mediators.

The protectors’ annual reports are published on the website of the Ministry of Health. According to the report from 2016, the total number of complaints submitted by patients was 2,070, of which 1,906 concern healthcare Institutions and 164 complaints concern the Ministry of Health. The largest number of complaints related to waiting time for health services, followed by complaints related to the poor efficiency of health services, lack of responsiveness on the phone and the quality of health services. 389 complaints were filed against the procedures of health workers or associates, and the smallest number (11) of complaints concerned issues relating to payment for health services.

If the patients are not satisfied with the solutions, they can approach the inspectorate or the Ministry of Health. There are no reports if any of these patients were not satisfied with the solutions, nor how the complaints as well as solutions impact and improve the overall quality of healthcare services in the long term.

Finally, in 2015, the Centre for Monitoring and Research showed that out of 1,006 randomly selected respondents, 67.3% are unfamiliar with the rights they have as patients, while a quarter of them believes that quality of health care has deteriorated. Respondents are particularly concerned with the corruption that exists within the healthcare and pharmaceutical sectors.

4.6. Serbia

Serbia at a Glance

Topic	Status
Established	Independent country since 2006
EU Membership Status	**Candidate country since 2012**
EU Stabilisation and Association Agreement	**Entered force in 2013**
Area	77,474 km2
Population	**8,9 million**
Official / Used language	Serbian / Bosnian, Croatian
Ethnic groups	Serbs (83.3%), Hungarians (3.5%), Roma (2.1%), Bosniaks (2%), others
Government	Unitary Parliamentary Constitutional Republic
Legislature	National Assembly
Administrative division	138 municipalities, and 23 cities which form the basic units of local self-governments. There are also 24 districts, including the capital Belgrade, but they have no power.
GDP, estimate 2016	Total ($112.888 billion), Per capita ($15,828)
Public health expenditure	**6.4 % of GDP**
HDI, 2016	**66th ranked**
Population, ages 65+	1.5 million
Population, ages 15-64	5.9 million
Population, under 5	0.5 million
Life expectancy	75 years
Mortality rate, female	79 per 1000 adult people
Mortality rate, male	152 per 1000 adult people
Top 3 causes of death since 2005	Heart diseases, Cerebrovascular disease, Lung cancers
Top risk factors leading to DALYs	High systolic blood pressure, Dietary risk
Most prevalent health problems	Low back and neck pain, Depressive disorders

Healthcare system: reforms, legal framework, financing and insurance

Since the 90s, Serbia has been facing rapidly changing political and socio-economic environments and related challenges such as rising economic disparities, particularly affecting the most vulnerable population such as Roma, single mothers, internally displaced persons and refugees. There have been major shifts concerning the privatisation of companies and restriction of social assistance programmes.

With regards to healthcare, the Laws on Healthcare Protection and Healthcare Insurance from 2005 aim to financially sustain the healthcare system. Since then, Serbia has developed the draft Strategy of Primary Health Care, the Strategy for the Prevention and Control of Chronic Non-Communicable Diseases, and the Strategy and Action plan for Palliative care among other strategies.

Currently, the government is working on the harmonisation of its legal framework with EU requirements, including aspects of patient-centred care, the rights and standards of insured persons, and packages of obligatory healthcare insurance (for some, these changes are premature). The main problems in the implementation of these reforms are related to poor management, lack of multi-sectoral cooperation, poor institutional accountability, low insurance coverage, and low access among vulnerable groups to healthcare.

On the positive side, the government introduced the Health Council of Serbia as an advisory body to the Ministry of Health and has engaged in the development of a transparent process for continuous quality improvement in health care and the agency for accreditation. However, the WHO calls for a better strategic approach when it comes to accountability, transparency, better regulation system between public and private investments, and additional taxation.

In Serbia, the healthcare financing system is organised according to similar principles as other Western Balkan countries. Primarily, it is based on compulsory insurance contributions through the National Health Insurance Fund. Citizens also have the possibility to purchase a private insurance scheme. Out-of-pockets payments remain very high. According to the Economic Analysis Journal (2015), the health expenditure per citizen in Serbia fails to keep its pace with the average in EU countries.

New payment mechanisms in primary health care ("performance-based payment" as a step towards capitation) are in use and the country is preparing for a more efficient management system, focusing on the financing of hospitals. Private practice is not fully integrated in the healthcare system, although there are a few attempts to sub-contract some specialised private clinics, and so contribute to improving the quality of healthcare.

According to a Peterhof Consulting study (2016), the issue of the grey market and the avoidance in paying taxes and contributions in the private health sector is as much of a problem as corruption is in the state sector. It has been pointed out that such uncompetitive competition undermines the credibility of the whole sector and makes it difficult for fair competition. In practice, it is also not unusual that patients are misinformed by the National Health Insurance Fund about what can and cannot be covered by their insurance.

With regards to corruption, the Health Policy Institute states that 72% of all respondents in Serbia perceive political parties to be the most corrupt institutions, followed by the health and justice systems. The average bribe is around 200 euros, although it can be much higher for some specific services. People usually give bribes either to ensure a certain quality of healthcare, or to award medical staff who are helping them. Corruption takes place at much higher state levels when it comes to the approval of drugs by the Fund and public procurement procedures among other things. In 2010, the NGO 'Doctors without Corruption' was established to educate medical staff, to advocate for better anti-corruption regulations and fight existing loopholes.

Overall, the financing of healthcare is a continuous struggle. Peterhof Consulting points out further that there is an ongoing debate about the debts of the health facilities owed to local suppliers of medicines and equipment. At the end of 2016 the current debt was a little bit less than 11 billion Serbian dinars, and it is continuously rising.

It is evident that there is a room for significant improvements in introducing effective public money management, including better control of spending money, rationalising the use of non-medical staff, as well as introducing the latest information systems. Consequently, the World Bank is currently supporting the implementation of the Second Serbia Health Project, which, among other objectives, aims to improve health financing, establish a centralised procurement system, strengthen Health Technology Assessment, improve Medical Equipment Maintenance systems, and strengthen the Quality Improvement and Cancer Management systems, among other things.

Healthcare system: organisation, service delivery, patients' satisfaction and rights

The Ministry of health is responsible for the overall healthcare strategy and planning. At primary healthcare level, there exists a tripartite system for health governance (healthcare centre, local health councils, local institutes for public health). Most healthcare centres are state-owned, the share of private sector being very limited.

According to the Serbia Country Commercial Guide, Serbia counted 373 healthcare institutions at primary, secondary and tertiary level. While some of these institutions, usually located in bigger cities, are well known and attract patients from the whole region, Serbia lacks material resources such as modernised diagnosis devices, mobile beds, equipment and supplies. A new medical record should be introduced soon.

Medical professionals are well trained, and primary centres are well staffed, although due to the overall low quality of care, many doctors and nurses are leaving the country. Consequently, service delivery at some levels, especially in rural areas, as well as for the population with low economic resources, is very limited. There are also reports of discrimination in healthcare for the Roma population, internally displaced persons, LGBT persons and those living with HIV.

According to the EPF Patients' Survey on Healthcare, Legislation, Patient Involvement and Regional Cooperation 2017*,* the lack of funding, the lack of access to the latest technologies and treatments (including the lack of a strategic framework for certain diseases), and bad relationships between doctors and patients are one of the key issues of Serbian healthcare.

Despite these ongoing challenges, according to the Euro Health Consumer Index 2015, Serbia, although only at 30 out of 35 European countries, has made noticeable advances since the new government made considerable efforts in moving forward the healthcare system reforms.

The Law on Patients' Rights came into force in 2013. According to this Law, the role of the 'Protectors' is now replaced by the 'Advisors' to gain a greater level of independence and objectivity. The Health Councils at the municipal level are responsible for the monitoring of the situation and reporting on the protection of patients' rights to the Ministry of Health and the Ombudsman. Although most Advisors were appointed by the end of 2013, the Human Rights Report in Serbia 2014 points out that one of major failures of the law is that there is no clear procedure of complaining to the Advisor, nor a procedure on how their decisions can be challenged, if needed. By the end of 2014, not all Advisors' reports were published. Based on a few published reports, the Ombudsman of Human Rights (2015) stated that patients are not familiar with their rights and that there is need for further training of the Advisors.

5. Overview of Capacities of Patients' Organisations to Participate in Healthcare Policy and Programme Development in the Western Balkans Countries

The methodology used to gather data for this part of research comprised of:

a) A random sample of organisations: a questionnaire was sent to 30 organisations and was completed by 12 patient organisations from Bosnia and Herzegovina, Croatia, FYROM and Serbia, making the response rate up to 40%.

b) A representative sample of another group of eight organisations, mainly patient coalitions/umbrella organisations from each targeted country, who completed a questionnaire either via online forms or face-to-face interviews during the field visits in Bosnia and Herzegovina, Croatia, Kosovo and Serbia.

c) Additional information on capacities of patients' movement were collected through six interviews with non-patient organisations, such as the representatives of the Pharmaceutical companies Celgene International and Pfizer, both based in Slovenia; the Association of Innovative Pharmaceutical Manufacturers from Bosnia and Herzegovina and Croatia; the Protector of Human Rights of the Clinical Centre in Montenegro; and the Ministry of Health Inspectorate of Health from Kosovo.

Regional Conference on Patients' Rights, Pristina, Kosovo, October 2016

5.1. Disease-Specific Patient Organisations: Presence, Governance & Capacities

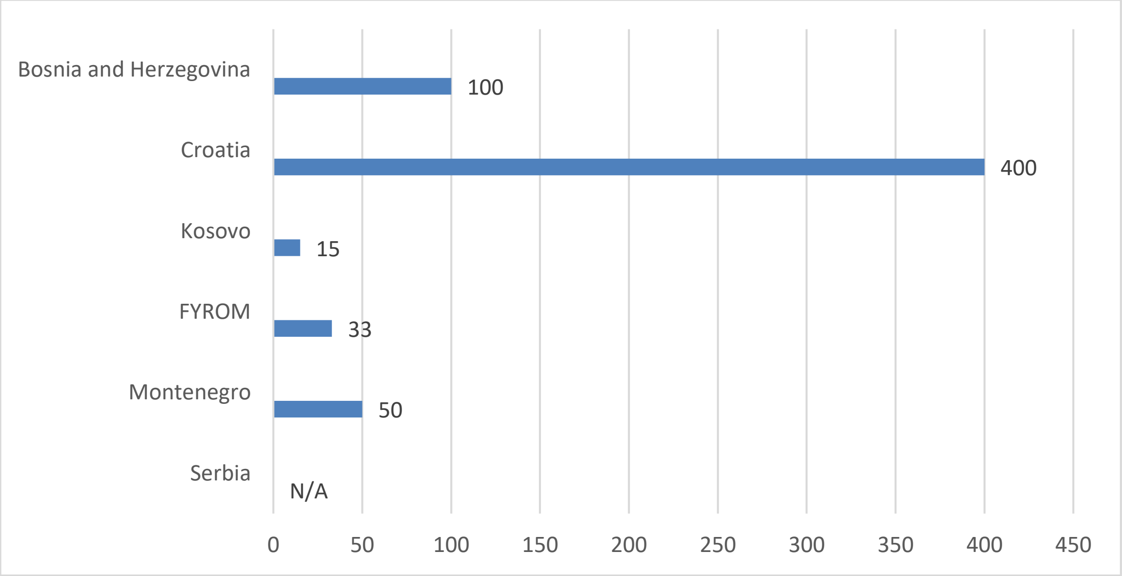
This part of data collection revealed the top three types of activities in which patient organisations engage most frequently: 1) patient support, 2) public awareness raising and education, and 3) advocacy with decision-makers for improved policies and practices. They develop information-communication materials and use media for advocacy to a lesser extent.

Presence of Disease-Specific Patient Organisations

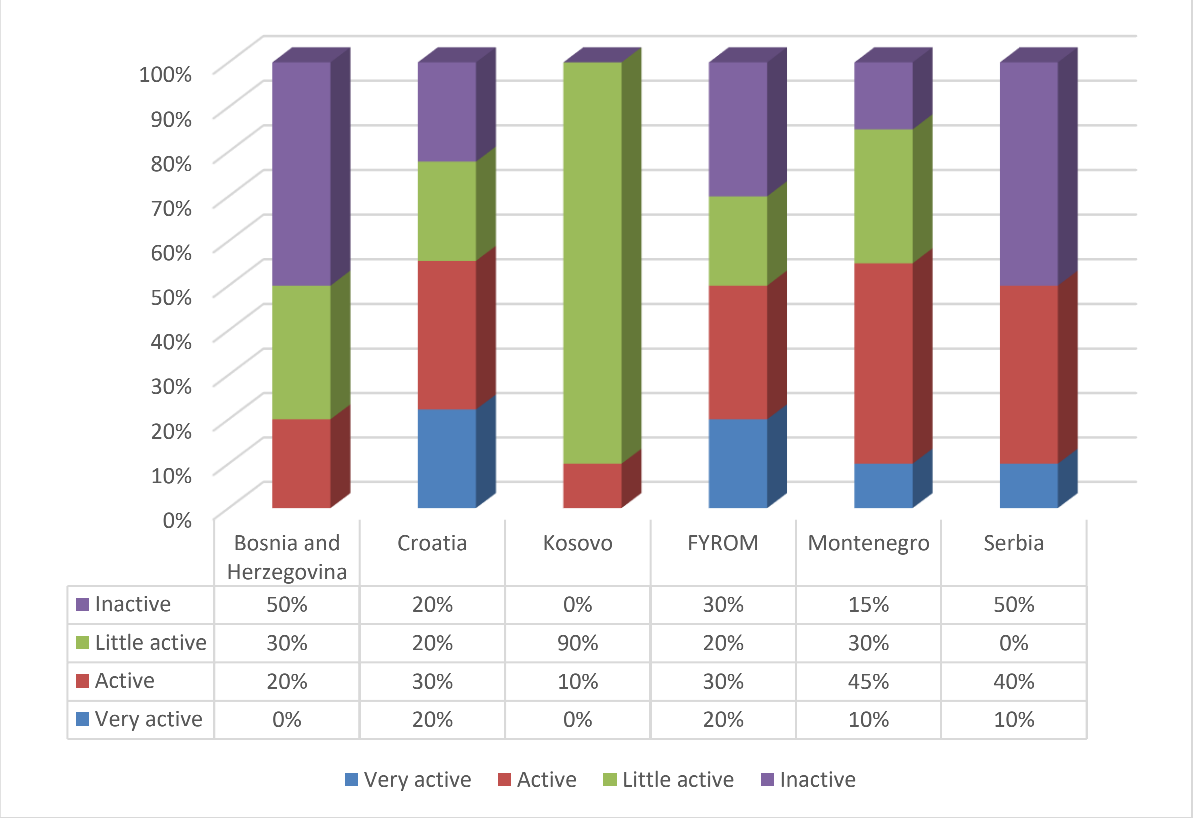
- The establishment/official registration of the association is:

Country	Very easy	Easy	Difficult	Very difficult
Bosnia and Herzegovina		✓		
Croatia		✓		
Kosovo		✓		
FYROM		✓		
Montenegro		✓		
Serbia		✓		

- Approximate number of patients' disease-specific associations/organisations:



- Out of 100% they are:

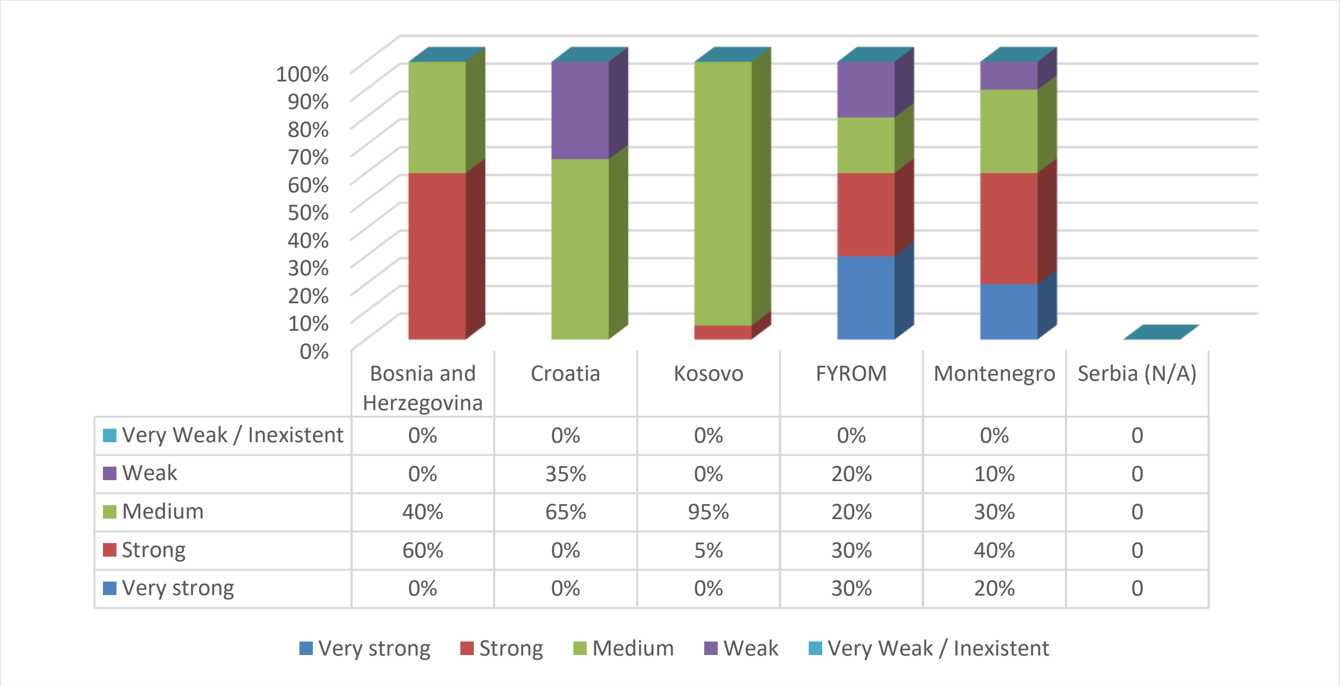


	Bosnia and Herzegovina	Croatia	Kosovo	FYROM	Montenegro	Serbia
🟪 Inactive	50%	20%	0%	30%	15%	50%
🟩 Little active	30%	20%	90%	20%	30%	0%
🟥 Active	20%	30%	10%	30%	45%	40%
🟦 Very active	0%	20%	0%	20%	10%	10%

- Active and very active organisations represent the following diseases:

Country	Diseases-specific organisations
Bosnia and Herzegovina	Cancer, Diabetes
Croatia	Diabetes, Hepatitis, Rare diseases, Oncology, Multiple sclerosis, Rheumatoid arthritis
Kosovo	Diabetes Mellitus, Cancer, Fibrosis Cystic, Leukaemia
FYROM	Cancer, Rare diseases, Diabetes, HIV, Hepatitis
Montenegro	Diabetes, Multiple Sclerosis
Serbia	Diabetes

- The proportion of **patients with chronic illnesses and/or lifelong conditions** taking part in decision-making within active disease-specific organisations compared to non-patients:

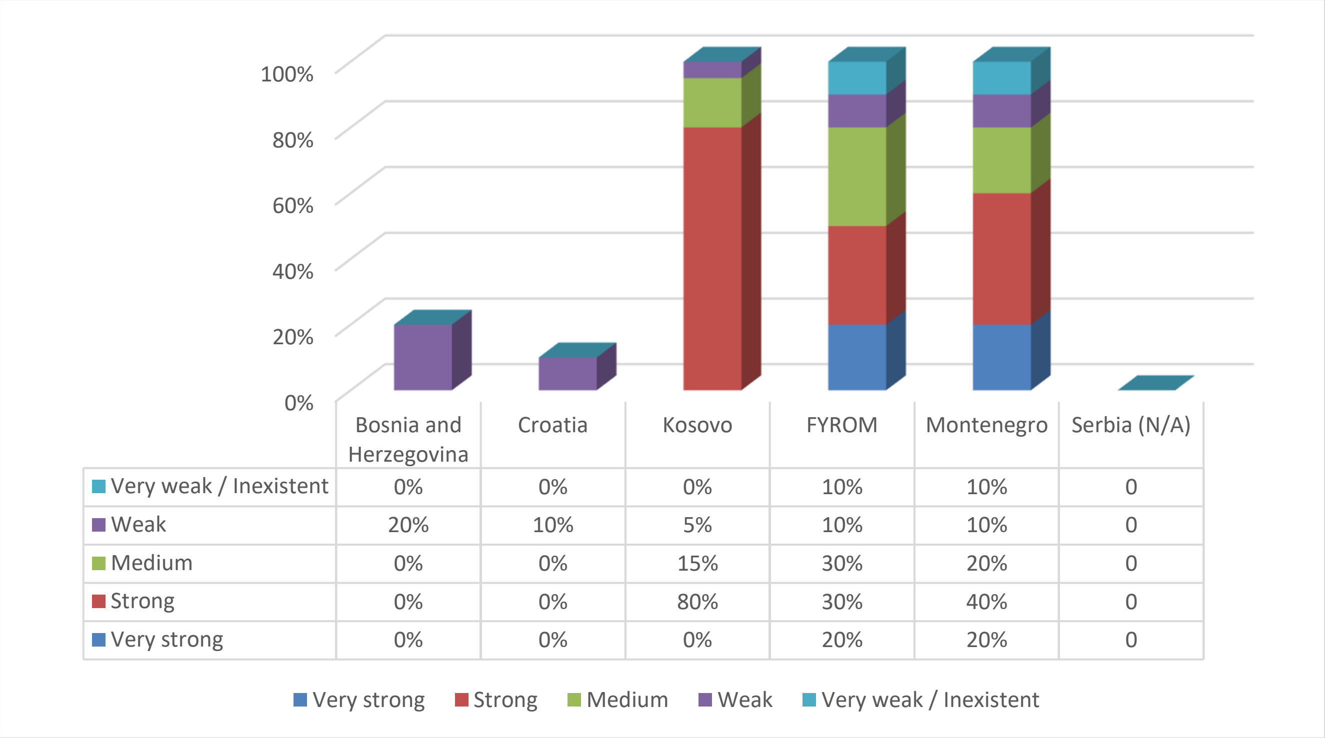


	Bosnia and Herzegovina	Croatia	Kosovo	FYROM	Montenegro	Serbia (N/A)
Very Weak / Inexistent	0%	0%	0%	0%	0%	0
Weak	0%	35%	0%	20%	10%	0
Medium	40%	65%	95%	20%	30%	0
Strong	60%	0%	5%	30%	40%	0
Very strong	0%	0%	0%	30%	20%	0

- The proportion of **women patients** taking part in decision-making within active POs:

Country	Much higher than men's participation	Higher than men's participation	It is equal	Weaker than men's participation	Much weaker than men's participation
Bosnia and Herzegovina	**80%**				
Croatia	**90%**				
Kosovo		70%	30%		
FYROM	20%	20%	**50%**	10%	
Montenegro	**100%**				
Serbia	N/A	N/A	N/A	N/A	

- The proportion of **young patients** (from 18 to 35 years old) taking part in decision-making within active disease-specific organisations:



	Bosnia and Herzegovina	Croatia	Kosovo	FYROM	Montenegro	Serbia (N/A)
Very weak / Inexistent	0%	0%	0%	10%	10%	0
Weak	20%	10%	5%	10%	10%	0
Medium	0%	0%	15%	30%	20%	0
Strong	0%	0%	80%	30%	40%	0
Very strong	0%	0%	0%	20%	20%	0

The exact number of patient disease-specific organisations in targeted countries in not known, although according to the respondents' approximate estimation and their day-to-day experiences **only 10 to 20% are very active, and up to 40% of them are active organisations**.

It appears that people with diabetes represent one of the most active patient disease-specific organisations in the Western Balkans. Number of **patients with other chronic illnesses and/or lifelong conditions** who have responsible functions varies considerably from one country to another (Q1.4).

The respondent from Croatia reports that the problem with certain diseases-specific organisations is that they are not able to see the bigger picture and they fight only for their own interests. There is also a big competition among these organisations, which is not always productive for the wider patients' movement.

Presence and participation of **women patients** into decision-making processes within the active organisations is much higher when compared with men (80% -100%), except in FYROM where the respondents indicate the equal proportion of women and men in organisational decision-making processes by serving as board members or executive directors.

In addition to women's participation, **young patients** are less likely to take an active role in organisational life. The respondent from Croatia says: "*We are having a change of generations, because people who were leading some POs or umbrella organisations had such strong characters that no one could oppose them, and now due to age or health status they have to leave their positions to new people. The change is slow, but noticeable*." Only in the case of Kosovo, respondents do report that the proportion of young people who take part in decision-making processes within many active patient disease-specific organisations is strong.

Finally, the respondents point out that most **patient disease-specific organisations have no or very little collaboration with other civil society organisations (non-patient organisations)**. Rarely, other non-patient organisations advocate for some issues that are common for both type of organisations, for example, in Bosnia and Herzegovina, a few of the bigger so-called 'women organisations' do not specifically address any issues related to breast cancer, leaving patient organisations with the focus on the breast cancers to deal with this issue.

POs Governance, POs Capacities and Competencies

- Perception about the nature of governance in active disease-specific POs:

	B&H	CRO	KOS	FYROM	ME	SRB
POs mission is clearly defined	Always	Always	**Partially**	Always	Always	N/A
POs act according to their strategic plans	**Partially**	**Partially**	**Partially**	**Partially**	Always	N/A
The board representatives are elected in accordance with the regulations of the association	**Partially**	Always	Always	Always	Always	N/A
The roles between the board and the executive staff members are clearly distinct	**Partially**	**Partially**	Always	**Partially**	Always	N/A
Decision making within POs is led in a democratic, participatory and accountable manner	**Partially**	**Partially**	Always	Always	Always	N/A
The POs funding is diversified and transparent	**Partially**	Always	Always	**Partially**	Always	N/A

- Perception about the organisational capacity of disease-specific POs:

	B&H	CRO	KOS	FYROM	ME	SRB
Human Resources competencies	**Weak**	**Weak**	High	Medium	High	N/A
Capacity to conduct operational activities	Medium	Medium	High	Medium	Medium	N/A
Administrative and financial competencies	Medium	Medium	Medium	Medium	Medium	N/A
Ability to write projects	Medium	High	High	Medium	Medium	N/A
Ability to fundraise	Medium	Medium	High	Medium	High	N/A

- Perception about the advocacy capacity of disease-specific POs:

	B&H	CRO	KOS	FYROM	ME	SRB
Advocacy skills to influence and improve practices for patients' well-being at the level of healthcare service providers	Medium	Medium	Medium	**Weak**	**Weak**	N/A
Advocacy skills to participate in decision making processes within healthcare service providers	Medium	**Weak**	Medium	**Weak**	High	N/A
Advocacy skills to participate in decision making processes at local and national levels	Medium	**Weak**	Medium	Medium	High	N/A

Overall, it seems that **respondents have confidence in how (active) patient disease-specific organisations are governed for most or all the time in their countries**, including defining POs mission (usually defined by their legal status and acts), holding elections (not necessarily on a regular basis), clearly distinguishing the roles between the board and the executive staff members, leading the organisations in a democratic, participatory and accountable manner.

However, the respondents from Bosnia and Herzegovina, Croatia and FYROM express the opinion that most of organisations are **not led in a strategic manner** mainly due to uncertainty of funding. In some cases, some board members are also executive staff members. Funding is not always transparent, but mainly because some of the organisations have not web page.

When it comes to the respondents' perception about some organisational and advocacy capacities of disease-specific organisations, the above responses were completed and verified by the additional interviews with the key patient organisations' representatives from each country.

It is evident that the **disease-specific organisations have weak to medium human resources**. Most organisations rely on the part-time staff or volunteers. They experience problems in mobilising volunteers and retaining the professional staff. A positive example of an organisation that overcome the challenge of staff shortage is the organisation of Multiple Sclerosis in Montenegro that engaged the students of the Medical Faculty.

Other organisational capacities such as the ability to conduct administrative, financial and other operational activities, as well as to write projects and fundraise **are perceived to be medium or high**. Most organisations receive funding from the pharmaceutical industry, and a few international donors (Bosnia and Herzegovina). The patient organisations in Montenegro are funded through the taxable lottery revenue, and in some cases, a very limited support can come from the local municipal funds. While some organisations even can write projects, they often do not appear to be competitive, especially in the eyes of bigger donors such as the EU.

The respondents cite that **disease-specific organisations' advocacy capacities are mainly weak to medium** (neither too weak, or too strong). This applies mainly to those organisations which are involved in services or in influencing local authorities rather than in policy advocacy. Large advocacy campaigns are rarely organised due to the lack of strategic approach and funding.

5.2. National Patient Coalitions/Umbrella Organisations: Presence, Governance & Capacities

The Presence, Governance and Capacities of Patient Coalitions/Umbrella Organisations to Take Part in Development of Healthcare Policies and Programmes

- Presence of patient coalitions/umbrella organisations:

Country	There is a national coalition, platform or coordination of organisations with clear common advocacy goals (more or less formalised)	There are one or more umbrellas/federations composed of membership-based disease-specific associations present at the national level
Bosnia and Herzegovina	×	✓
Croatia	✓	✓
Kosovo	✓	✓
FYROM	✓	✓
Montenegro	×	✓
Serbia	✓	✓

- Perception about the nature of governance in active coalitions/umbrella organisations:

	B&H	CRO	KOS	FYROM	ME	SRB
Representatives of coalitions/ umbrellas are elected according to the relative regulations	Always	Always	Always	Always	Always	Always
Leadership is shared and transparent	**Partially**	Always	**Partially**	Always	**Partially**	**Partially**
Information and communication mechanisms between members are well established	Always	Always	Always	Always	**Partially**	**Partially**
The distinction between the advocacy roles of coalitions /networks/umbrellas and POs' involvement in service provision is clearly divided	**Partially**	**Partially**	**Partially**	Always	**Partially**	**Partially**

- Involvement of representatives of the existing coalitions/umbrella organisations in development of healthcare policies and programmes at national level, related to patient-specific issues

	B&H	CRO	KOS	FYROM	ME	SRB
In the process of drafting legislation	Sometimes	Very often	Very often	Very often	Sometimes	Sometimes
In the development of policies and programmes	Sometimes	Very often	Sometimes	Very often	Sometimes	Sometimes
In the monitoring/ evaluation of the implementation of policies and programmes	Rarely	Sometimes	Sometimes	Sometimes	Sometimes	Rarely
In discussions on the development and monitoring of laws, policies & programmes to ensure the patient perspective is included	Rarely	Always	Rarely	Very often	Rarely	Rarely

The national coalitions do not exist in Bosnia and Herzegovina and Montenegro. There are also indications that existing national coalitions, such as KUZ – Croatian Coalition of Association in Healthcare (EPF Full member) and APO – Alliance of Patient Organisations, FYROM (EPF Associate member), as well as SUPS - Coalition of Patients in Serbia, and PRAK - Patients' Rights Association in Kosovo (not EPF members) are not necessarily seen as the only representative patient organisations or to be fully representative of all patients in their respective countries. Their legitimate role is yet to be noticeable not only by the government officials but also by other organisations who are not their adherents.

Meeting with SUPS, Belgrade, Serbia, December 2016

According to the respondents, **the division of role between patient coalitions, where they exist, or patient umbrella organisations and patient organisations is not clearly distinguished**. In most countries, some umbrella organisations do not act only as 'advocates', but at the same time they provide some services to patients.

When considering **the level of involvement of patient coalitions/umbrella organisations** and patient organisations in legislative drafting, policy development or monitoring of healthcare laws, policies and programmes, it appears that most coalitions/umbrellas in most countries can contribute to the legislative decision-making processes and so voice patients' concerns to the authorities. In most cases, especially when it comes to the policies and programmes of greater scope and potential impact, this involvement has ad-hoc character. In Croatia, a respondent claim that within the healthcare administration, the role of patients is just starting to be recognised.

Barriers to patients' involvement

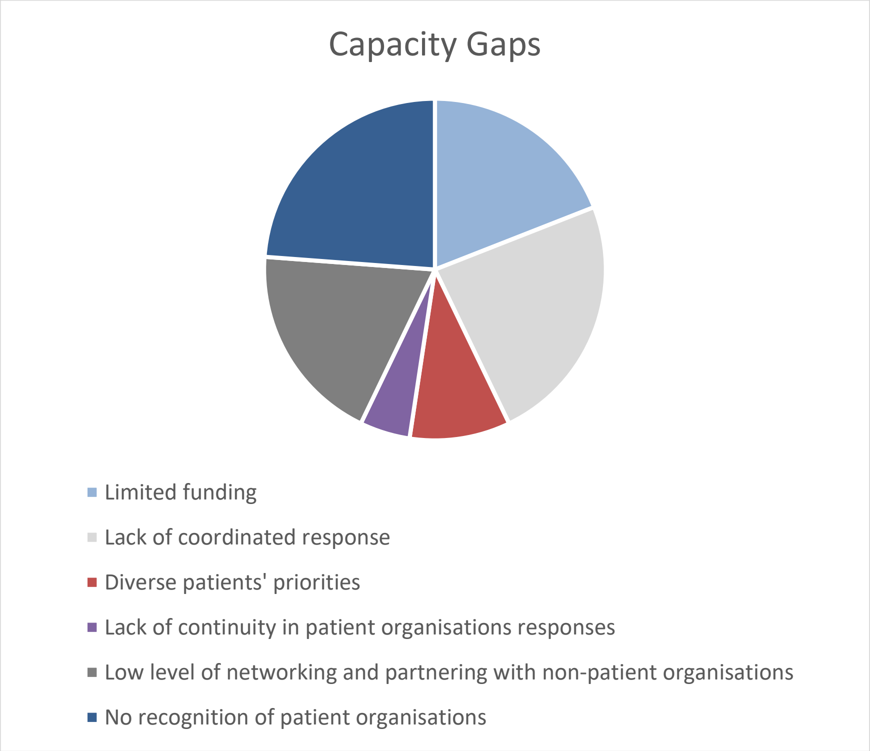
When asked what are the main obstacles in increasing patient involvement and participation in the development of health-related policies, programmes and projects, the respondents report that the most frequent obstacles are, as follows:

- Lack of political will;
- Lack of awareness that patients should be involved in the creation of health policies and programmes;
- No recognition of patient organizations (patients are not seen as partners by Governments, regulatory bodies, other decision making bodies);
- Lack of patients' mobilisations, lack of trust and confidence among patients' representatives;
- Lack of funding to support such activities.

5.3. Capacity Building needs and Regional Cooperation

The Capacity Gaps and Solutions for Capacities Building

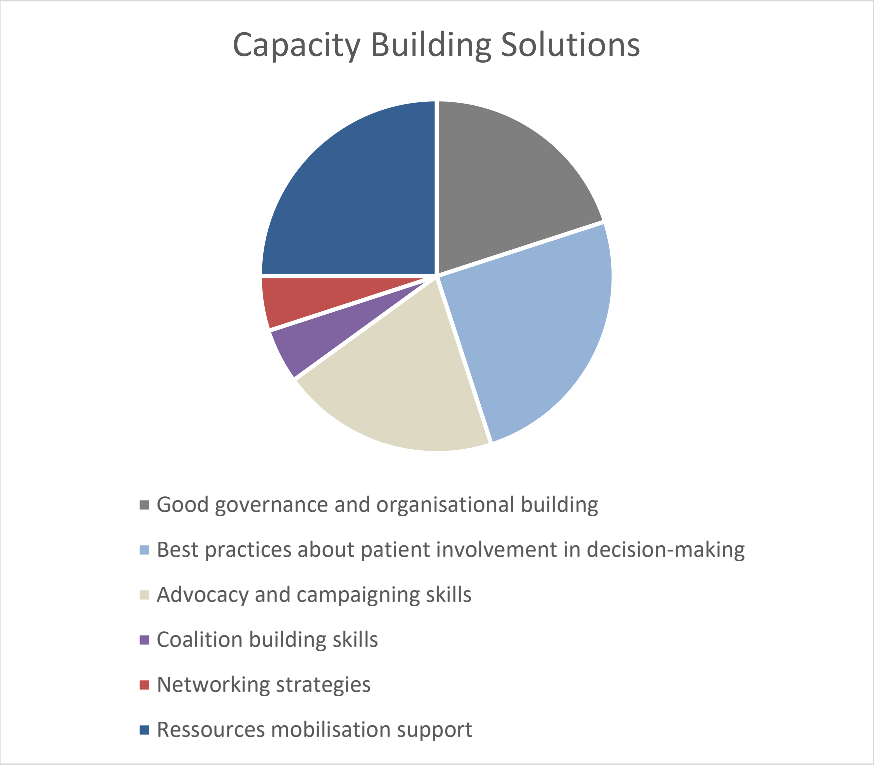
- The major problems in the work of patient coalitions/umbrella organisations and disease-specific organisations that block their ability to address the key issues with regards to patients' participation in decision-making processes at the local and national level



Respondents say that **'no recognition of patient organisations' (24%) and 'lack of coordinated response' (24%) are major causes of patients' weak influence**. Responses such as 'limited funding' (19%) and 'low level of networking' (19%) follows closely. Only 5% of responses falls under the category of 'lack of continuity in patient organisations responses'.

In practice, it has been reported that government officials are open to working with a few well-known organisations, but after that, there is little coordination among NGO actors. The lack of respected leaders does not help patients and their organisations to build consensus on the key issues, nor to establish representative coalitions/umbrellas. Consequently, as reported in Bosnia and Herzegovina, some patient disease-specific organisations do not have a lot of confidence in national coalition building, so they tend to work as disease-specific umbrella organisations. In several cases, it was reported that a few advocacy initiatives stopped due to the lack of funding.

- The main potential solutions that could help to address the gaps in patient coalitions/umbrellas and organisations to address the key issues with regards to patients' participation in decision-making processes at the local and national level are illustrated in the chart below.



Given the above responses, it is not surprising that 'coalition building skills' (5%) and 'networking strategies' (5%) have not been identified as the priority capacity building solutions.

Where 'sharing best practices about patients' involvement in decision-making' and 'resources mobilisation support' are concerned, respondents are more likely (25% & 25%) to feel that these are the top priority capacity building areas. Respondents believe to a slightly lesser extent (20% & 20%) that 'good governance and organisational building' and 'advocacy and campaigning skills' are also good potential solutions that can help patient coalitions/umbrella organisations and other disease-specific organisations to influence decision-makers in the healthcare sector.

When asked what are the main priority areas for advocacy action of common interests to all patients at the national level, respondents say: development and monitoring of national disease-specific strategies, monitoring of patient-related laws, improvement of access to health care and medications, fight against bribe and corruption, organisation of disease-specific educations with healthcare workers and healthcare system and recognition of patient organisations as one of the most important pillars of the healthcare system.

The respondent from Bosnia and Herzegovina says that most patient organisations have gone through various education and capacity building programmes over the past years. However, despite these efforts there has been very little success, especially in increasing patients' influence on decision-making. While there might be several reasons for this, the respondent further says that any additional support should be carefully planned, measured and evaluated.

The Regional Cooperation

- The type of regional cooperation that would enhance the work of patient coalitions/umbrella organisations and patient disease-specific organisations

The respondents said that networking is not a priority within their respective countries, but they recognise 'networking opportunities' at the regional level to be very relevant and useful. The same percentage of 17% is giving to 'identifying areas for joint actions for patients' rights'. Providing 'capacity building' and 'guidance on EU health related policies' yields comparable results (14%). Similarly, respondents identify that creating 'information-sharing platforms' and 'advocacy support mechanisms' share third place with 10%. In contrast, there is only one respondent who feels that the priority should be given to the 'pharma industry monitoring'.

While there is notable interest in building advocacy support mechanisms, respondents were additionally asked what the main priority advocacy issues of common interests to all patients are at the regional level. They have identified the following: protection of patients' rights, equal access to healthcare and medicines, reduction of corruption and strengthening the role of patient organisations in implementation and monitoring of legal regulations.

6. Recommendations

It must be noted that following all recommendations would require considerable planning, project development and fundraising, and even partnering with an international organisation(s). If this is the case, it is advisable to follow the example of other Brussels membership-based organisations who are expending in this region. For example, in 2016, the European Disability Forum, Brussels membership-based organisation, teamed up with UNICEF and national patient coalitions and organisations from the Western Balkan countries to implement a regional project. This project called **"**Protecting children from violence and promoting social inclusion of children with disabilities", is funded through the EU Instrument for Pre-Accession Assistance, until 2019.

General Recommendations:

To support patients in:

- Strengthening the role and capacity of patient organisations as credible and recognised actors alongside with other stakeholders in the healthcare sector.
- Contributing in building sustainable healthcare system on basis of equity, efficiency, effectiveness and quality of healthcare provision.
- Advocating for improving access to healthcare to all citizens.
- Enforcing the legislative framework with regards to the protection of patients' rights.
- Making healthcare systems accountable by fighting bribe and corruption in the healthcare sector.
- Raising patient voices in a view of EU Enlargement process, and building stronger ties between patient organisations across the EU and the Western Balkans.

Recommendations Related to the Responses of Patient Coalitions/Umbrella Organisations and Disease-Specific Organisations:

1. Given the fact that most health-related policies and decisions are made without little or any inputs from patients, **helping patient coalitions/umbrella organisations to improve their involvement in decision-making processes** in a strategic manner is recommended.

2. The quality of healthcare service delivery is one of the major concerns for all patients from the Western Balkans region. While there are many challenging issues that require patient involvement (regardless whether these issues are of bigger importance for disease-specific or for all patients gathered under the national coalitions), **the empowerment of patients to have a proactive role in addressing issues and finding innovative solutions for better health service delivery** is recommended.

3. Considering the lack of knowledge about patients' rights and low level of implementation of the Laws on Protection of Patients' Rights across the region, **supporting national patient coalitions/umbrella organisations to develop joint-actions for better monitoring of patient rights' laws** and implementation procedures is recommended.

4. There are insufficient learning and networking opportunities that would increase patient organisations' skills and capacity to become credible actors whose actions would lead to change. **The delivery of a regional capacity building programme** is recommended – one that should not only be adapted to patients' specific contexts and their organisational and technical needs, but would also help the organisations to organise and consolidate patients' movement across the Western Balkans region.

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