World Health Organization
REGIONAL OFFICE FOR Europe

CURRENT STATUS OF HEALTH INTERVENTION AND TECHNOLOGY ASSESSMENT IN THE BALKAN REGION

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Abstract

This report outlines the status of health technology assessment (HTA) in the Balkan region, including facilitators and barriers. It is based on the discussions during a WHO workshop on health intervention and technology assessment in support of universal health coverage held in Ljubljana, Slovenia, in February 2020, as well as a survey and a desktop review of relevant literature. Participants from public institutions working in the field of HTA from eight Balkan countries and areas attended the workshop, along with international technical experts and staff from WHO and WHO partners. The developmental status of HTA varies across countries. Facilitators of HTA identified include political will, networks, structured health systems, legal frameworks and relevant examples of gain. Barriers include political instability, small economies and human resources. Recommendations for future action include mapping needs and options, strengthening collaborative initiatives, involving stakeholders and develop roadmaps towards transparent and sustainable HTA frameworks. All participants recognized the need for increased transparency.

Keywords

HEALTH TECHNOLOGY ASSESSMENT

HEALTHCARE DECISION MAKING

HEALTH POLICY

TRANSPARENCY

COST-EFFECTIVENESS ANALYSIS

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Contents

[1] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

[2] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

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Abbreviations

EU	European Union
EUnetHTA	European Network for Health Technology Assessment
HIF	health insurance fund
HTA	health technology assessment
HTAi	Health Technology Assessment international
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
JAZMP	Agency for Medicinal Products and Medical Devices [Slovenia]
SWOT	strength, weaknesses, opportunities and threats
UHC	universal health coverage

Executive summary

The WHO Regional Office for Europe arranged a three-day workshop on health intervention and technology assessment in support of universal health coverage on 11–13 February 2020 in Ljubljana, Slovenia. It was targeted at professionals from public institutions working in the field of health technology assessment (HTA) in the Balkan region. This report provides an overview of the developmental status of HTA in the region, including facilitators and barriers. It is based on information shared during the workshop, supplemented by a survey and a desktop review of relevant literature.

The participating countries and areas have varied but small economies. Their population sizes range from 0.6 million in Montenegro to 6.9 million in Serbia. Health expenditure as a proportion of gross domestic product in 2016 ranged from 6.34% in North Macedonia to 9.23% in Bosnia and Herzegovina. This is lower than the mean average of European Union countries (9.93%) but higher than the mean average for the World Bank middle-income (5.42%) and upper middle-income groups (5.85%). The majority of the population of the Balkan region is covered by compulsory health insurance managed by publicly owned health insurance funds, and a variable but considerable degree of co-payment is required. All Balkan region countries and areas agreed to resolution WHA67.23 on health intervention and technology assessment in support of universal health coverage, endorsed by the Sixty-seventh World Health Assembly in 2014, and legal frameworks are in place regarding decisions concerning public financing of health care.

Participants from all countries and areas reported that increased transparency of their decision-making processes regarding health technology introduction and reimbursement was considered to be of high importance. HTA was implemented at the institutional level in Croatia in 2009, and formal guidelines developed. HTA can be requested by decision-makers but is not mandatory. In Serbia the legislative grounds for HTA have been laid out and implementation of the new law on health care is ongoing, including laying out the details of HTA. Slovenia has no established HTA system, but decision pathways are in place where elements of HTA are used at several levels and in several procedures. Legislative processes that can be used to support HTA in decision pathways in Bosnia and Herzegovina are in the process of implementation in both the Federation of Bosnia and Herzegovina and the Republic of Srpska. Participants from Albania, North Macedonia and Montenegro, as well as Kosovo[3], stated that the need to implement HTA has been acknowledged at a political level by the ministry of health.

The main facilitators of HTA identified during the workshop include political will, collaboration in networks, structured health systems, legal frameworks and relevant examples of gain. The main barriers include political instability, small economies and restricted human resources.

In conclusion, the developmental status of HTA across the Balkan region varies. Recommendations for future action include strengthening collaborative initiatives, involving stakeholders, mapping needs and options and developing roadmaps towards sustainable HTA frameworks in support of universal health coverage.

[3] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Introduction

Health technology assessment and universal health coverage

Health technology is the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life. According to the WHO definition *(1)*, health technology assessment (HTA) refers to the systematic evaluation of properties, effects and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting such an assessment is to inform policy decision-making.

Resolution WHA67.23 on health intervention and technology assessment in support of universal health coverage (UHC), endorsed by the Sixty-seventh World Health Assembly in 2014, calls on WHO and Member States[4] to engage in and collaborate with national, regional and global networks of HTA stakeholders. It also requests WHO to have a convening role in collaborative mechanisms and networks: "to support the exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and networks at global, regional and country [and area] levels, as well as ensuring that these partnerships are active, effective and sustainable" *(2)*.

In countries facing strong economic constraints on health budgets, HTA is considered a critical tool for facilitating UHC and ensuring that it is achievable and sustainable. HTA itself is only a set of skills and tools to assess new and existing health interventions and technologies, however: plans and capacity-building for its use need to be developed and implemented. In the absence of a formal priority-setting and decision pathway, distorted priorities and funding decisions are to be expected *(3)*. Hence, HTA will be of no or low value if it is not linked to defined decision pathways (Fig. 1). WHO is developing guidance on institutionalizing HTA mechanisms for reimbursement.

Fig. 1. Generic steps of decision pathways involving HTA

Source: adapted from slides presented by V Lauvrak and A Stoinska-Schneider at the workshop on health intervention and technology assessment in support of UHC in Ljubljana, Slovenia, in February 2020.

Centralized decision pathways informed by HTA are referred to as HTA systems or frameworks in many settings. These have different mandates in different settings, including informing decisions on reimbursement, clinical practice guidelines, pricing, acceptance of donor technologies and procurement *(4)*. Models of implementing HTA may also include HTA conducted to inform decentralized health care decisions and HTA conducted by health care institutions to inform local decisions *(5, 6)*.

[4] And, where applicable, regional economic integration organizations.

Various models and definitions of HTA are in use, with differing complexity and degrees of centralization. Some argue for distinguishing between evidence-based medicine, comparative effectiveness assessment and HTA; others do not make these distinctions *(7, 8)*. Learning from existing systems is considered valuable, but HTA roadmaps and models are not fully transferable without taking into account country- and area-specific aspects such as geographical size, population size, gross domestic product, social values, public health priorities and modes of health care governance and financing *(9)*. Examples of HTA models specifically suggested as good fits for the Balkan region have been presented *(10)*, but they may not fit all countries and areas, and they focus primarily on medicines. Thus, for HTA to support decision-making related to UHC, each country and area needs to develop models and frameworks that best meet local needs and regulations.

Preparation of the report

This report provides an overview of the developmental status of HTA in the Balkan region, including facilitators and barriers. It is based on information shared and discussed by participants and presenters during a WHO workshop on health intervention and technology assessment in support of UHC, supplemented by a fact check of demographic data, a survey and a desktop review of relevant literature. WHO representatives,WHO partners in HTA and HTA experts, including the authors of this report, facilitated and contributed.

The workshop

The WHO Regional Office for Europe arranged a three-day workshop on health intervention and technology assessment in support of UHC on 11–13 February 2020 in Ljubljana, Slovenia. Its aim was to facilitate information exchange to make the best use of limited resources available for HTA in the Balkan region. The workshop was targeted at professionals from competent authorities and public institutions working in the field of HTA in the Balkan region. International technical experts and representatives from WHO and WHO partners provided insights into HTA, and requirements for system development and relevant WHO policy support tools were explored.

A total of 38 participants from Albania, Bosnia and Herzegovina (the Federation of Bosnia and Herzegovina and the Republic of Srpska), Croatia, Montenegro, North Macedonia, Serbia and Slovenia, as well as Kosovo[5] attended the workshop. It was opened by the Minister of Health of Slovenia and representatives of the WHO Country Office in Slovenia. Introductions were made by representatives of the Economic Evaluation and Analysis Group of the Department of Health Systems Governance and Financing at WHO headquarters and the Health Technologies and Pharmaceuticals Programme at the WHO Regional Office for Europe. WHO representatives, HTA experts – including the authors of this report – and WHO partners in HTA facilitated and contributed to the workshop (see Annex 1 for the agenda). To explore the status of HTA in the participating countries, participants were asked to respond to a survey in advance (see Annex 2). This was adapted by the authors from questions used in a WHO workshop for the Baltic region in 2019, facilitated by the Norwegian Institute of Public Health, and a survey developed by the Institute in a project to support HTA in the Republic of Moldova (ongoing work).

On the first day of the workshop, each participating country and area gave an overview of its health system and the current status of HTA implementation. A total of nine presentations were delivered, including two from Bosnia and Herzegovina, representing health systems from the two entities operating within the country (the Federation of Bosnia and Herzegovina and the Republic of Srpska). The slides

[5] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

and written answers to the survey were shared with the authors of this report. WHO headquarters presented the WHO guidance – currently under development – for institutionalizing HTA mechanisms for reimbursement and the global perspective on HTA, and the International Network of Agencies for HTA set out its perspective on HTA. Case frameworks for HTA from England (United Kingdom), Australia and Sweden were presented during these sessions.

On the second day, presentations were given on implementation strategies, frameworks, staffing, stakeholder engagement, communication, processes and roles of secretariats and committees. Case studies of implementing HTA and HTA frameworks from Norway, Turkey and Ukraine were presented and representatives of seven WHO partners in HTA set out their organizations' initiatives and networks. All presentations were followed up by a short question-and-answer session. A breakout session was arranged by randomly dividing the participants into four groups. The groups were asked to discuss challenges and opportunities using a strengths, weaknesses, opportunities and threats (SWOT) analysis approach, and to suggest points for the next steps in the process of implementing and improving the role of HTA in their region and country or area. Representatives from each group presented the main conclusions of their discussions to all workshop participants, and time to discuss the different points further was allocated.

On the third day, participants chose between two sessions focusing on either medical devices or how to conduct HTA for medicines. Aspects covered in the medical device session were:

- medical devices frameworks, from innovation, regulation, assessment and supply to use;
- WHO's Global atlas of medical devices and country lists;
- links with UHC;
- standardization of medical device nomenclature – the way forward;
- the development process for WHO lists of priority and medical devices;
- reproductive, maternal, child and noncommunicable disease cases;
- the development process for the WHO Model List of Essential In Vitro Diagnostics;
- country implementation draft guidance;
- selected medical devices for health interventions in the benefits package;
- useful WHO tools for priority medical devices and essential in vitro diagnostics.

Aspects covered in the medicines group were:

- the WHO essential medicines list;
- combining and interpreting clinical evidence (including sources of data and study design);
- evidence synthesis – systematic reviews, meta-analysis and network meta-analysis;
- introduction to economic evaluation;
- introduction to conducting budget impact analysis.

A short round of plenary discussions followed.

An overview of relevant tools and sources of information shared by WHO, HTA experts and WHO HTA partners during the workshop can be found in Annex 3.

Demographic data of the participating countries and areas

Apart from Albania, the Balkan countries and areas represented at the workshop were all part of the former Socialist Republic of Yugoslavia until 1991. At the same time as Yugoslavia broke apart, Albania went through a process of transition, following the end of communism in 1990. The political situation in the western Balkan region since 1991 has been unstable, including periods of war in parts of the region, but relationships between the countries and areas have gradually stabilized. Croatia and Slovenia are European Union (EU) members – since 2013 and 2007, respectively. Albania, Montenegro, North Macedonia and Serbia are candidates. Bosnia and Herzegovina and Kosovo[6] are potential candidates in the ongoing EU enlargement process *(11)*. Although the region still faces rapid political fluctuations, the political will in support of UHC is strong, WHO would agree!

An overview of population size, gross domestic product and health expenditure for each country and area participating in the workshop is presented in Table 1.

Table 1. Demographic data

Geographical category	Population (2018)	GDP per capita (nominal, 2018, international US$)	Health expenditure (as a proportion of GDP in 2016)
Country			
Albania	2 866 380	5 269	6.7%
Bosnia and Herzegovina	3 323 930	6 068	9.23%
Croatia	4 089 400	14 919	7.18%
Montenegro	622 350	8 844	7.64%
North Macedonia	2 082 960	6 084	6.34%
Serbia	6 982 080	7 247	9.14%
Slovenia	2 067 370	26 124	8.47%
Area			
Kosovo[7]	Not available	Not available	Not available
Comparative data: EU and global			
EU	N/A	36 570	9.93%
World Bank high-income group	N/A	44 787	12.59%
World Bank middle-income group	N/A	5 485	5.42%
World Bank upper middle-income group	N/A	9 205	5.85%

Note: GDP = gross domestic product.

Source: World Bank Open Data [online database]. Washington DC: World Bank; 2020 (https://data.worldbank.org/, accessed 12 June 2020).

[6] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

[7] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

According to data from the World Bank, countries in the western Balkan region are categorized as middle-income to upper middle-income. Health expenditure as a proportion of gross domestic product in 2016 ranged from 6.34% in North Macedonia to 9.23% in Bosnia and Herzegovina. This is lower than the mean average of EU countries (9.93%) but higher than the mean average for the World Bank middle-income (5.42%) and upper middle-income groups (5.85%).

Desktop review

To identify existing literature addressing HTA in the Balkan region, a non-exhaustive desktop review was performed (see Annex 4 for details). No systematic reviews specifically addressing the status of HTA in the Balkan region or relevant facilitators or barriers were identified. A limited number of recent (within the last five years) publications on HTA in Bosnia and Herzegovina *(12, 13)*, Croatia *(14)*, Serbia *(15)* and Slovenia *(16, 17)* were found. Two papers retrieved by the search describing the health systems in Croatia *(18)* and North Macedonia *(19)* were inspected. The full text of 10 further general publications addressing HTA in central and eastern European countries was inspected *(20–29)*. Based on this, no recent publications on HTA specifically in Albania, Montenegro or North Macedonia, nor Kosovo,[8] were identified.

In general, the literature describes countries and areas in the region as sharing common characteristics – most importantly, having small geographical areas and small economies. The health systems are noted to have mandatory national health insurance managed by publicly owned health insurance funds (HIFs), as well as publicly owned health care institutions. Medicines are usually described as being reimbursed through either prescription (outpatient) or hospital budgets. CO-payments are normal, and regulating prices for at least some part of the pharmaceutical market, in an effort to ensure affordable access to medicines; is approved by the ministry of health.

The literature generally reports a lack of explicit HTA frameworks in the Balkan region. The most common barriers reported for HTA framework in the Balkan region are lack of resources, lack of experts and challenges related to the political environment. Some models and suggestions of roadmaps for HTA for the region and/or central and eastern European countries and areas are presented or analysed *(9, 10)*. The publication authors argue that pragmatic choices are needed when choosing models and roadmaps due to the small economies. It should be noted that a proposal for a regulation on HTA in Europe *(21)* may influence the regulation of HTA in the Balkan region.

[8] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Health systems

The participants stated that their countries' and areas' health systems are based on solidarity principles, or a Bismarck system (based on social security – i.e. contributions from salaries), with elements of a Beveridge system (based on budgetary income). Except for Kosovo,[9] the health systems are in some way financed through compulsory health insurance managed by HIFs. All countries and areas with participants in the workshop agreed to resolution WHA67.23 on health intervention and technology assessment in support of UHC, endorsed by the Sixty-seventh World Health Assembly in 2014, and legal frameworks are in place regarding decisions about public financing of health care. Selected details on the health systems shared during the meeting are summarized in Table 2 and described further below.

Table 2. Selected aspects of health systems that may influence the choice of HTA framework

Country	Main source of health system financing[a]	Main decision/ policy-maker(s) on reimbursement	Price setting (mechanisms, decision-makers, etc.)	Main procurement level
Albania	One national HIF	National HIF	For medicines: centralized procedure by the Drug Price Commission; external price referencing	Central procurement (medicines and medical devices)
Bosnia and Herzegovina	13 HIFs	See Federation of Bosnia and Herzegovina and Republic of Srpska details	Decentralized processes	Decentralized procurement (all health technologies)
Federation of Bosnia and Herzegovina	10 canton HIFs + Federal Solidarity Fund	Canton ministries of health and – to some extent – the Federal Ministry of Health (for vaccines and selected interventions)	Pricing procedures at the canton level	Canton-level procurement (all technologies except vaccines and selected interventions)
Republic of Srpska	One compulsory HIF + Republic of Srpska Solidarity Fund	Ministry of Health of the Republic of Srpska	Centralized procedures by the HIF	Ministry of Health of the Republic of Srpska (selected technologies) and decentralized procurement
Croatia	Compulsory HIFs + optional supplementary HIF	National HIF	Centralized procedures by the national HIF; external price referencing	Decentralized procurement (at the hospital level)
Montenegro	One compulsory HIF	Not clear from the information shared	Centralized procedures by the Agency for Medicines and Medical Devices	Centralized procurement (for medicines) by the state-owned pharmacy company Montefarm
North Macedonia	One compulsory HIF	Ministry of Health/ HIF (medicines on the positive list) and HIF (procedures costed by diagnosis-related group)	Centralized, external price referencing	Mostly decentralized procurement (joint procurement can be performed centrally by the Ministry of Health)

[9] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Table 2. Contd.

Country	Main source of health system financing[a]	Main decision/ policy-maker(s) on reimbursement	Price setting (mechanisms, decision-makers, etc.)	Main procurement level
Serbia	One compulsory HIF	National HIF	Centralized procedures by the national HIF, external price referencing	Centralized (medicines and some devices) and decentralized procurement (other technologies)
Slovenia	One compulsory HIF	National HIF and hospitals	Centralized procedures by the Agency for Medicinal Products and Medical Devices, external price referencing	Decentralized procurement (at the hospital level for hospital technologies)
Area	**Main source of health system financing[a]**	**Main decision/ policy-maker(s) on reimbursement**	**Price setting (mechanisms, decision-makers, etc.)**	**Main procurement level**
Kosovo[10]	Authority grants managed by University Clinical Hospital Service	Health Authority	Centralized	Centralized

[a] Only the main source of health system financing is shown, although in most cases health services are financed through various sources, including out-of-pocket spending, projects and donations.

Albania

In Albania 3.4% of salary (1.7% covered by the employer and 1.7% by the employee) goes to a national compulsory HIF. In addition, 24.5% of salary (15% covered by the employer and 9.5% by the employee) goes to social insurance. Reimbursed medicines, medical devices and procedures (including coronarography and renal transplant) are financed by the HIF. Unemployed people, specified categories of the population and certain projects and programmes are financed from the state budget. National strategic priorities, national programmes and international programmes and projects of the Ministry of Health define the priority criteria for reimbursement and public financing. Proposals for these requirements are considered by a technical commission set up by the HIF, involving experts from the Ministry of Health, the National Agency for Drugs and Devices and clinical experts. Following administrative decisions, final approval is given by the Council of Ministers. The reimbursed medicines are divided into two lists: one contains medicines reimbursed in community pharmacies and the other contains medicines reimbursed in hospital pharmacies. For chronic diseases, medicines are reimbursed 100% (for the first product listed, with co-payments for alternatives).

Prices of medicines in Albania are annually approved and set by the Drug Price Commission. Prices are compared with reference countries (Croatia, Greece, Italy, North Macedonia and Serbia).

[10] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Reimbursed procedures are priced by technical experts working in the HIF in collaboration with the medical departments of the country's university hospitals. Medicines are mainly procured by a central procurement unit at the Ministry of Health. The Ministry develops procurement procedures based on predefined funds and signs framework agreements.

Hospitals (especially university hospitals) and specific clinics or departments are allowed to procure medicines and medical devices autonomously in specific situations (for example, in an emergency). Each hospital submits its requirements annually, based on needs for the following year.

Bosnia and Herzegovina

In 1995, when the Dayton Peace Agreement was signed, Bosnia and Herzegovina as a former Yugoslavian country became a decentralized state. The administrative organization is based on three entities:

- the Federation of Bosnia and Herzegovina, with its 10 cantons as subadministrative units
- the Republic of Srpska
- the Brcko District.

The Federation of Bosnia and Herzegovina and the Republic of Srpska have independent health care systems described separately below. Although the Brcko District has a separate health care system as well, because of its small population and administrative capacity to implement more complex systemic changes, it is usually incorporated and involved in changes within one of the two other larger entities and is not further described in this report.

Federation of Bosnia and Herzegovina

Health care in the Federation of Bosnia and Herzegovina is financed through insurance funds and only to some degree from the budget of the Federation. The Federal Solidarity Fund was established in 2002 – it was initially limited to financing potentially expensive tertiary and selected vertical services, but has evolved to support preventive services such as immunization. Vaccines and selected services are prioritized, financed and procured at the federal level through the Fund.

Governance of health services is decentralized to the level of cantons: each canton has its own ministry of health, public health institute and compulsory HIF (giving 11 HIFs in total, including the Federal Solidarity Fund). Procedures for costing, prioritization, reimbursement and procurement exist at the canton level; those for tertiary and selected vertical services (financing diagnosis and treatment when this is not possible in health institutions in the Federation) exist at the federal level.

Republic of Srpska

In the Republic of Srpska health services are mainly financed through:

- the compulsory HIF
- annual budgets of the health institutions, based on tax projects and donations

- local self-government units
- health care users (via out-of-pocket payments).[11]

The Solidarity Fund for the diagnosis and treatment of diseases, conditions and injuries of children abroad was founded at the end of 2017. It was established with the aim of raising additional financial resources to enable the diagnosis and treatment of children abroad, when this is not possible in health institutions in the Republic of Srpska or in other health institutions with which the Republic of Srpska's HIF has a contract.

Medicines are procured by the HIF, health institutions and pharmacies. Medical devices are procured by the Ministry of Health, the HIF or health institutions. Priority criteria for reimbursement/public financing are based on priority-setting in the Republic's hospital sector development plan and situation analysis and capital investment plan. Priorities for medicines are determined in accordance with the rules on conditions and procedures for placing medicines on the HIF positive list. Reimbursement decisions are made by Ministry of Health, the HIF and/or health care institutions.

Croatia

Every citizen in Croatia is legally obliged[12] to have health care insurance, of which there are three types.

- Croatia's compulsory health insurance is based on principles of reciprocity, solidarity and equality for every citizen. It includes contributions paid by the working population, while sensitive population groups (such as older retirees and people on low incomes) are exempt. A state-owned HIF is responsible for management of this type of insurance. The compulsory health insurance covers the costs of health services up to 80% within the "basket of services".
- Optional supplementary health insurance represents additional coverage for a fixed amount of a monthly fee (collected and managed by the HIF or commercial insurers). It covers the rest of the cost of services (20%).
- Additional health insurance can be obtained from commercial insurers.

Reimbursement decisions are made at the national level by the HIF, which has published several ordinances[13] that define criteria for placing medicines/medical devices on the positive lists, as well as ways to determine their prices. The HIF also sets out priority criteria for reimbursement or public financing; these are also published in the same ordinances. For example, the priority criteria for reimbursement when it comes to medicines are:

- the importance of the medicine from a public health standpoint;

[11] Described in the Law on Healthcare, Official Gazette of the Republic of Srpska Nos. 106/09 and 44/15.

[12] Outlined in the Medical Devices Act (Official Gazette of Croatia No. 76/13); Act on the Implementation of Medical Devices Regulation (EU) 2017/745 and In Vitro Medical Device Regulation (EU) 2017/746 (Official Gazette of Croatia No. 100/18).

[13] Ordinance on Essential Requirements, Classification, Registration of Manufacturers in the Register of Medical Device Manufacturers, Registration of Medical Devices in the Register of Medical Devices and Conformity Assessment of Medical Devices (Official Gazette of Croatia No. 84/13); Ordinance on Specific Requirements for Medical Devices Manufactured Utilising Non-Viable Animal Tissues (Official Gazette of Croatia No. 83/13); Ordinance on Monitoring Adverse Incidents Related to Medical Devices (Official Gazette of Croatia No. 125/13); Ordinance on Good Practice in the Wholesale Distribution of Medical Devices and on the Conditions for Registration in the Register of Wholesale Distributors of Medical Devices (Official Gazette of Croatia No. 125/13); Ordinance on the Conditions for the Retail Sale and Issue of Authorisations to Specialised Outlets for the Retail Sale of Medical Devices (Official Gazette of Croatia No. 133/13).

- the therapeutic value of the medicine relative to the proposed indication;
- the relative therapeutic value of the medicine;
- an evaluation of ethical aspects;
- the optimal amount of medicine required for treatment, based on diagnosis and disease status;
- the price of the medicine/pharmacoeconomic analysis;
- marketing authorization.

Applications to place medicines/medical devices on the positive list (to define their reimbursement status) can be submitted by the marketing authorization holder or their authorized representative to HIF's committees, hospital committees, professional societies of the Croatian Medical Association or other relevant professional societies and reference centres of the Ministry of Health. Experts and HIF committees are consulted for their opinion. Final decisions on reimbursement status are made by the HIF's administrative board. Medicines and/or medical devices are procured at the hospital level, depending on their necessity.

Montenegro

A national compulsory HIF is in place in Montenegro. The health care system is financed based on the principles of Bismarck social health insurance, via contributions through the legally defined categories of employees and employers. The HIF is responsible for implementation of health policy related to health insurance; for pharmaceutical policy the state has set up the Agency for Medicines and Medical Devices. The main documents regulating health services are the Health Care Law, Health Insurance Law, masterplan for developing the health system and strategy for improving the quality of health care and safety of patients for 2019–2023.[14]

Specific priorities are described in the documents regulating health services. A positive list of reimbursed drugs is in place, is created based on central negotiation with the pharmaceutical sector on price, outcome and efficiency. Specific criteria for reimbursement and criteria for committee members are in place. Notably, Montenegro currently has more than 100 agreements at a special price. Further, the country cooperates with WHO on vaccines, and has a list of new treatment protocols for important diseases. Centralized procurement for hospitals and pharmacies is performed by the state-owned pharmacy company Montefarm.

North Macedonia

In North Macedonia social health insurance is represented by one compulsory HIF, which is the main financial intermediary. Insurance premiums cover 63% of current health expenditure, but in the last 3–4 years private insurance companies and schemes have increasingly entered the market. In addition, tax and government programmes managed by the Ministry of Health cover 5% of current health expenditure, while out-of-pocket payments cover 32%.

[14] Master plan of the development of health system in Montenegro 2015–2020. Podgorica: Ministry of Health; 2015 (https://extranet.who.int/nutrition/gina/en/node/36115, accessed 15 June 2020).

Prices paid to pharmaceutical companies for prescription-only medicines are regulated through external price referencing at a wholesale price level. Prices of non-prescription medicines and devices are not regulated (free pricing by sellers). Reimbursement prices for medicines and orthopaedic devices are set by the HIF, also through external price referencing methodology. Procedures are priced according to the diagnosis-related group system for hospital procedures, and using special packages for the specialist-consultative level, taking into account the costs of resources. Reimbursement prices are not set for inpatient medical devices as they are calculated as part of the diagnosis-related group price.

Priority criteria for medicines covered by the HIF are considered in the methodology for decision-making on the positive list, which is set out in a by-law adopted by the Ministry of Health. As the new legal changes were only adopted by parliament in December 2019, however, the methodology is still in its draft phase. The draft priority criteria envisioned are based on HTA methodology:

- public health and ethical significance
- (added) therapeutic benefit
- pharmacoeconomic aspects (budget impact and/or cost–effectiveness)
- reimbursement status in the reference countries (Bulgaria, Croatia, Serbia and Slovenia).

The previous law considered (added) therapeutic benefit, cost–effectiveness and budget impact as criteria, within a methodology adopted by the government. The decision-making process was considered too complicated, however, and only one substance had been added to the positive list since 2012. Reimbursement decisions for medicines on the positive list are multilevel. According to the new law, decisions are made by a commission, established by the Ministry of Health. The commission submits a proposal to the executive board of the HIF, which can accept or reject it. The Ministry of Health signs the decision.

No official criteria are in place for selection of medicines covered by the government programmes (such as orphan drugs), and no special reimbursement priority criteria exist for devices and procedures. Reimbursement decisions (scope and price) for orthopaedic devices and procedures are made by only the HIF. Decisions on devices used within diagnosis-related group procedures are made directly by hospitals. In general, medicines and medical devices are procured at the hospital level. The Ministry of Health is entitled to conduct joint procurement procedures; this has happened in the past, usually for expensive drugs. Outpatient medicines and medical devices are procured at the pharmacy level (no tendering is required for the outpatient sector).

Serbia

In Serbia, a national compulsory HIF finances the provision of health care at all levels, contracts the provision of services by health care facilities and controls the implementation of assumed obligations when concluding such a contract. The contribution rate to the HIF amounts to 10.3%, in equal shares of 5.15% for both employer and employee. Health care allocations in 2015 were 9.4% of gross domestic product, according to participants' answers to the pre-workshop survey. Total health care expenditure amounted to €444 per capita. From this amount, the costs of the HIF were €242 per capita which, with an additional €16, makes total public expenditure on health €258 per capita. A total of 42% of health care spending is private, which in 2015 amounted to €186 per capita (out-of-pocket expenditure for different types of health service).

Medicines are reimbursed in accordance with the Ordinance on the List of Medicines Prescribed and Dispensed at the Expense of the Compulsory Health Insurance[15] and Ordinance on the Conditions, Criteria, Method and Procedure for Placing a Medicine on the List of Medicines, Amendments to the List of Medicines, or the Removal of Medicines from the List of Medicines.[16] Medical devices and procedures are reimbursed/costed in accordance with the Ordinance on Contracting Health Care from Compulsory Health Insurance with Health Care Service Providers (adopted each year). Key criteria for reimbursement are the therapeutic benefit of a medicine and/or relative therapeutic benefit (added value compared to existing alternatives). Applying for placement of a medicine on the positive list requires consideration of pharmacotherapeutic and pharmacoeconomic justification of the medicine and financial resources provided for by the HIF's financial plan.

Reference prices for medicines on the HIF positive list are defined by the prices in reference countries Croatia, Italy and Slovenia. If the medicine is not on the list in any of these three countries, six additional countries – Bulgaria, Hungary, Latvia, Lithuania, Romania and Slovakia – are used for comparison, or the price is set at the same or lower than the price of a similar medicine already on the HIF positive list.

The Central Commission for Medicines makes the final proposal for the positive list on application for reimbursement by the marketing authorization holder; this is adopted by the HIF steering committee. Other committees involved are expert committees in various fields including the National Expert Commission and the Commission for the Assessment of the Analysis of the Pharmacoeconomic Justification Placement of a Medicine on the List of Medicines, its Amendments and the Removal of a Medicine from the List of Medicines.

The HIF conducts centralized public procurement for medicines from the positive list in accordance with the needs of the health care facilities from the network plan. It also conducts centralized public procurement for medical devices and consumables for medical equipment as specified by regulation.[17] All other devices/equipment, disposable medical devices, disposable parts and/or individual parts of medical equipment are procured directly by health care facilities in public procurement procedures.

Slovenia

Slovenia also has a social insurance-based health system, with one compulsory health insurance company – the Health Insurance Institute of Slovenia – which is the country's HIF. Contributions to the HIF depend on the salary or other income earned by the insured person (solidarity). The largest proportion of payments to the HIF come from employer and employee contributions.

Publicly funded medicines go through standard pricing and reimbursement processes, which are separate. The competent authority for the pricing process is the Agency for Medicinal Products and Medical Devices (JAZMP). The list price is determined through external price referencing based on prices in Austria, France and Germany. A company can apply for a higher price than the external reference price only in special circumstances by undergoing an assessment of comparative effectiveness, budget impact and unmet need.

Reimbursement decisions, including price negotiations, are the responsibility of the HIF. A company

[15] Official Gazette of the Republic of Serbia No. 43/19, 55/19, 56/19, 73/19 and 87/19.

[16] Official Gazette of the Republic of Serbia No. 41/14, 125/14, 48/15 and 14/18.

[17] Regulation on the planning and type of goods and services implemented by centralized public procurement, Official Gazette of the Republic of Serbia No. 34/19 and 64/19.

prepares a file and submits it to the HIF once marketing authorization is granted and the maximum allowable price determined (through external price referencing conducted by JAZMP).

The HIF requests an opinion about reimbursement from the National Committee for Reimbursement of Medicines Reimbursement. This functions as a consultative body, assessing medicines and providing an opinion on type and size of clinical benefit, the importance of the medicinal product in the health care system in relation to priorities, pharmacoeconomic aspects including cost–effectiveness and budget impact analysis and ethical considerations. In reimbursement procedures, priorities are set in law and should be taken into account. These include paediatric population, communicable diseases, malignancies and muscular and musculoskeletal disorders. The Committee's opinion is published online and is publicly available. In the case of a positive or conditional positive opinion, the HIF may enter into negotiations with the pharmaceutical company about the price, commercial arrangements and other conditions of sales (such as potential managed entry agreements).

Hospitals can also use "nonreimbursed" medicines from their budget: each hospital conducts a separate public tender for medicines and other products.

Kosovo[18]

The health authority of Kosovo[19] is the responsible policy-maker overseeing two levels of regulation and financing. Secondary and tertiary health care are financed by the health authority's grants, coordinated by the University Clinical Hospital Service. Primary health care is financed by an area entity grant through municipalities. The private sector plays an important role, but only a small proportion of the population are individually insured by private insurance companies. A compulsory HIF institution is currently not in place. The executive bodies of the health authority are responsible for public health, for regulation of medicines and medical devices (including authorization, import, quality control and pharmacovigilance) and for inspection of health activities and the health sector, which has a total of 650 public and private hospitals and a number of retail pharmacies that are all private.

A new drug management cycle has recently been implemented, based on methodology from WHO within a defined policy and legal framework. The first step is approval by the health authority of an essential medicines list (the last version was approved in September 2019 with the help of WHO). The second step is financing through the budgets of the University Clinical Hospital Service and municipalities. The products on the essential medicines list are free for hospitalized patients as part of hospital services. Municipalities and hospitals create plans and request funding. The first pricing regulation is from 2019, with the final phase of calculations expected to be introduced in April 2020.

Procurement for all hospitals is centralized, undertaken by the University Clinical Hospital Service. Procurement of medicines (essential medicines list products) is done centrally by the health authority. Some procurement is also done directly by health institutions.

[18] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

[19] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Status of HTA in the Balkan region

Participants were asked to share details about their countries' and areas' experience of HTA via the survey and during group workshop discussions. Only Serbia and Croatia reported that HTA had been implemented. In Serbia the legislative grounds for HTA have been laid out and implementation of the new law on health care is ongoing. This includes laying the ground for details of how HTA will be addressed. In Croatia use of HTA is still not mandatory (covered by a legal framework). An HTA agency was considered in 2017 *(14)*, but in present there is an HTA department/unit at the Ministry of Health level. Slovenia has no established HTA system, but there are decision pathways where HTA elements are used at various levels and in several procedures. Bosnia and Herzegovina is in the process of implementing legislative processes that can be used to support the use of HTA in decision pathways. In Albania, North Macedonia and Montenegro as well as Kosovo,[20] participants stated that the need to implement HTA has been acknowledged at a political level by the ministry of health/health authorities.

Details on the status of HTA in all countries and areas, and on its use in Serbia, Croatia and Slovenia – the countries most experienced with HTA – are provided below. The developmental status of HTA implementation is summarized in Table 3.

Table 3. Developmental status of HTA implementation

Country	HTA framework	HTA agency/unit	Transparency of decisions	Network membership
Albania	Not yet, but positive political will	Not yet	Need for increased transparency recognized	Not yet at an institutional level
Bosnia and Herzegovina	HTA acknowledged in decentralized legislation	No plans for a central agency or unit	Need for increased transparency recognized	–
Federation of Bosnia and Herzegovina	New law on evidence passed and existing rulebook on procedures similar to HTA	Not yet	Need for increased transparency recognized	Not yet at an institutional level
Republic of Srpska	New law on evidence proposed for 2020	Not yet: the Public Health Institute is planning to set up a unit to manage HTA (but who will be responsible for the analysis is not yet determined)	Need for increased transparency recognized	Not yet at an institutional level

[20] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Table 3. Contd.

Country	HTA framework	HTA agency/unit	Transparency of decisions	Network membership
Croatia	Yes, but HTA not mandatory for any decision	Yes: since 2009 an agency; since 2019 a unit in the Ministry of Health	Need for increased transparency recognized	EUnetHTA, with three partners: the Ministry of Health, HIF and Croatian Institute of Public Health; International Network of Agencies for HTA, represented by the Ministry of Health; European Commission HTA Network, represented by the Ministry of Health; International Society for Pharmacoeconomics and Outcomes Research HTA, represented by Ministry of Health employees
Montenegro	Not yet, but positive political will	Not yet	Need for increased transparency recognized	No information
North Macedonia	Not yet, but positive political will	Not yet, but elements of HTA in a draft methodology for selection of medicines for the positive list	Need for increased transparency recognized	Not yet at an institutional level
Serbia	Yes, legal framework and plan for HTA under implementation	Institute for Public Health "Dr Milan Jovanovic Batut" appointed as responsible for managing HTA	Need for increased transparency recognized	EUnetHTA affiliated member: Ministry of Health
Slovenia	Not yet, but elements of HTA in an existing framework	Elements of HTA used by JAZMP and	Need for increased transparency recognized	EUnetHTA with three partners: the Ministry of Health, National Institute of Public Health, JAZMP
Area	**HTA framework**	**HTA agency/unit**	**Transparency of decisions**	**Network membership**
Kosovo[21]	Not yet, but plans for implementing HTA initiated: health authorities and University Clinical Hospital Service to have central roles in commissions	Not yet: a plan is in place for a unit within an existing institution rather than an agency	Need for increased transparency recognized	No information

Note: EUnetHTA = European Network for HTA.

Albania

An HTA framework or an HTA agency or unit has not yet been implemented. There is a political will to implement a plan. Increased transparency is considered to be of high importance, but how this can best be achieved is not yet determined.

[21] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Bosnia and Herzegovina

An HTA framework or an HTA agency or unit has not yet been implemented. HTA is acknowledged in decentralized legislative processes. Increased transparency of the decisions is considered to be of high importance. Further details on the individual administrative entities are set out below.

Federation of Bosnia and Herzegovina

The Federal Ministry of Health has passed a new law on evidence and a rulebook with procedures similar to HTA.[22] This provides a legal basis for HTA and monitoring of personnel, medical equipment and consumption of medicines in health care. Each canton in the Federation will probably implement its own HTA framework. Increased transparency of the decisions is considered to be of high importance, but how this can best be achieved is not yet determined.

Republic of Srpska

The Ministry of Health plans to propose a new law on health care in 2020. This provides a legal basis for the field of HTA and for establishment of an HTA management system. The Public Health Institute may take a coordinating role and is planning to set up an HTA unit, but not an agency. After the new law is passed, by-laws will be drafted to define the roles of all actors in the HTA process precisely. Increased transparency of the decisions is considered to be of high importance.

Croatia

Formal activities in the area of HTA in Croatia began in 2009, at the Department for Development, Research and HTA. Until recently, HTA activities were undertaken by the Agency for Quality and Accreditation in Health Care and Social Welfare, but as of 1 January 2019, the HTA provider is the Ministry of Health, Directorate for Health Tourism and Quality of Health Services, Department of HTA. HTA production is funded by public funds, which cover personnel costs only (mainly employees' general salaries). Croatia is an EU member, and the Ministry of Health is an affiliated member of the European Network for HTA (EUnetHTA). Capacity-building through EUnetHTA partnership was also an important part of the former HTA agency, and Croatia has contributed to several EUnetHTA deliverables.

There are some elements of an HTA framework, in Croatia. The Act on Quality of Health Care and Social Welfare mentions HTA but does not define all aspects of this process; nor does it define sustainable links to reimbursement, investment or disinvestment decision processes. An ordinance on HTA is still being drafted. Topics can be proposed by decision-makers, including the Ministry of Health, HIF and hospital management, and a plan is being formulated to enable manufacturers to be commissioners of HTA. Requests for assessments are made on a case-by-case basis, depending whether the commissioners believe that HTA could help in the decision-making process.

The intention is to involve stakeholders within every assessment – primarily, manufacturers and patient organizations. Also, in many cases, professional societies are contacted to provide useful information

[22] Pursuant to Article 56, paragraph (3) of the Law on Records in Health Sector (Official Gazette of the Federation of Bosnia and Herzegovina No. 37/12); Rulebook on the method and time for delivery and reporting forms (Official Gazette of the Federation of Bosnia and Herzegovina No. 61/18); Rulebook on how to introduce new health technologies in health care institutions and private practice, as well as the approval process of Health Technologies (Official Gazette of the Federation of Bosnia and Herzegovina No. 84/14).

and insight into the topic of interest. The Department of HTA provides both single and multiple technology assessments, depending on the topic selected.

According to the national guidelines, a full HTA report should be conducted in line with the EUnetHTA's HTA Core Model® *(30)*. Since economic evaluations are not mandatory in Croatia, as defined by the law, and owing to a lack of staff and experts in certain areas, however, the majority of assessments done at the national level contain only the first four domains of the HTA Core Model® (description of the health problem and its treatment, description of health technology and its comparators, clinical efficacy and safety), along with recommendations for a decision. Although contact is made with manufacturers, and they do provide some information, no formal submission files from industry are used in the HTA process. The current capacity for HTA production is modest – estimated at six reports in 2020 – primarily due to a very low number of employees.

The decision-makers informed by HTA are the Ministry of Health and HIF, who decide in particular on capital investments in health care and adoption of new health programmes. The HIF may use HTAs to decide whether to place new medicines, medical devices and other technologies on positive lists, or to make decisions on full or partial coverage of costs or decisions related to deletion of existing technologies from the lists of medicines/medical devices. HTAs with recommendations, produced by the Department for HTA, may also be taken into consideration and critically appraised by the HIF committees for medicines, orthopaedic aid and general medical technical assistance before they provide their recommendations to the HIF administrative board. The board then makes the final decision on putting the medicine/medical device on the relevant list, and on its reimbursement status.

Responsibility for implementing HTA-based decisions lies with the Ministry of Health and the HIF. The Ministry may use various strategies when it comes to implementing HTA-based decisions, depending on the programme for which the decision was reached. No monitoring of the implementation of HTA-based decisions takes place.

Beyond the use of HTA for decision-making within the Ministry of Health and HIF, HTA is not related to or integrated into other national systems or frameworks. There are several examples of good practice through which HTA has made it possible to expedite the listing process. All HTA reports produced by the HTA unit are publicly available on a webpage.

Montenegro

An HTA framework or an HTA agency or unit has not yet been implemented. There is political will for gradual implementation of a plan to have an HTA unit, not an agency. Transparency of the decisions is considered to be of high importance, but it has not yet been determined how to reinforce it.

North Macedonia

An HTA framework or an HTA agency or unit has not yet been implemented. There is positive political will to implement HTA, and there are elements of HTA in a draft methodology for selection of medicines for the positive list. Transparency of the decisions is considered to be of high importance, but it has not yet been determined how to reinforce it.

Serbia

Serbia has worked systematically on capacity-building in the field of HTA for more than a decade (since the Serbia Health Project of 2003). The recently adopted 2019 law on health care[23] introduces HTA and sets out its main principles that apply to all health technologies. It also provides broad recommendations on the content of HTA (based on comparative analysis of benefits, risks and costs of new health technologies compared to existing alternatives). The law does not regulate how HTA will be implemented in detail, but several articles indicate obligations to apply HTA. The process and the content of HTA will be further outlined in a new rulebook expected to be finalized before October 2020.

The Ministry of Health has been an affiliated member of EUnetHTA since February 2019. Strengthening HTA capacity and cooperation with EUnetHTA are regarded as important facilitators.

Currently, HTAs in Serbia are initiated based on commissions from the Ministry of Health or the HIF. The topics are identified by regulators, who are also the decision-makers. In accordance with the new law, decisions informed by HTA are reimbursement for medicines and procurement for medical devices. The Ministry of Health and HIF are also responsible for implementing HTA-based decisions. Under the new law, HTA will be used for new medicines in the reimbursement decision process. Assessments of new medicines are within the remit of the HIF, which will review dossiers submitted by the industry (the applicant).

Pharmacotherapeutic assessment is done by the National Expert Commission (experts in fields of medicine, pharmacy or dentistry) based on individual and personal experience, assessments taken from European guidelines or assessments of the medicine's license holder. Pharmacoeconomic assessment is performed by the Pharmacoeconomics Commission and is based on the price of a drug, direct costs, comparison with costs of generic drugs for the same indication (if applicable) and budget impact analysis. The price and reimbursement status of a drug in other EU countries are taken into account. In the assessment process, the Pharmacoeconomics Commission refers to experiences and decisions from other countries – in particular, to the recommendations of professional institutions such as the National Institute for Health and Care Excellence and the Scottish Medicines Consortium of the United Kingdom and the French Haute Autorité de Santé. No criteria are established to use while performing relative effectiveness assessment.

For medical devices and procedures, HTA will be used in decisions regarding new health technologies introduced for use in health care facilities, or at certain levels of health care, for the first time. The Institute for Public Health "Dr Milan Jovanovic Batut" is responsible for HTA concerning medical devices and procedures. According to the law, the health care facility, private practice, manufacturer or marketing authorization holder of a medical device will submit an application to the Ministry of Health to issue a license to use the new health technology. The Institute will assess medical devices and procedures and give an opinion in collaboration with national experts, competent health institutions, relevant higher education institutions, scientific research institutions, public agencies and other bodies, or organizations and international institutions. The Minister will issue a license for use, based on the opinion. Information contained in the license will include conditions for the application of the new technology, the level of the estimated risk of harmful consequences to the life and health of patients and the level of health care to which the new technology is applied. The new health technology can be applied in the health care system at the level for which the license is issued.

In accordance with the law, the cost of an opinion on HTA will be covered by the applicant. Relevant questions regarding HTA will be defined in the new rulebook, including cost-sharing, stakeholder involvement, type and domains of HTA, the process and the content of appraisal and decision-making.

[23] Official Gazette of the Republic of Serbia No. 25/19.

File templates will be revised to introduce the HTA dossier by the applicant. There is no record at this time of capacity in terms of the number of assessments.

Activities defined in the action plan for the new law on health care are implemented under the Second Serbia Health Project. The Ministry of Health and the World Bank are monitoring implementation of defined measures. A situation analysis and proposal for activities to include HTA in the decision-making process (which was adopted by the Ministry of Health in November 2019) identified key bottlenecks and weaknesses in decision-making, which need to be addressed through the actions specified in the action plan for 2019–2021. Following implementation, the Policy and Legal Advice Centre will produce an analysis report.

Slovenia

Slovenia has no official HTA body, but the need to establish a national HTA system has been taken up in the national health plan *(15)*. Currently, elements of HTA are implemented in terms of assessment used for several levels and procedures. This includes the pricing and reimbursement procedures for medicines and procedures connected to reimbursement of other products and programmes (other than medicines). Slovenia is a member of the EU and has been involved in HTA capacity-building and collaboration through EUnetHTA, of which JAZMP and the National Institute of Public Health are affiliated entities.

For the medicines pricing procedure, the medicinal company submits an application to JAZMP, including evidence for the assessment of relative therapeutic value, pharmacoepidemiologic data and economic data. JAZMP reviews the data, gathers information from its sources, activates a consultative committee and forms an opinion. The decision can be supported by an independent opinion from the ethical practice board, a tertiary clinical department or statements from specialists. JAZMP determines an exceptionally highest price for medicinal products (the price not to be exceeded on the Slovenian market). At the moment, JAZMP is involved in EUnetHTA assessment activities, where the scientific aspect – such as assessment of clinical efficacy and effectiveness – is done.

For the reimbursement procedure of medicinal products, products are identified/proposed by industry, the Ministry of Health, health care providers or the HIF. Either industry or a health care provider produces the evidence to be reviewed. The HIF reviews the evidence and may obtain an additional expert opinion; it also provides the final decision on reimbursement and the highest price (which cannot exceed the maximum price determined by JAZMP).

The Ministry of Health's Health Council evaluates new health programmes (not medicinal products). In this case, effectiveness, professional eligibility, economic efficiency, population perspective and organizational efficiency are aspects of the evaluations.

Kosovo[24]

Plans to implement HTA have been initiated at the health authority level and by the University Clinical Hospital Service. It is anticipated that HTA production and working group commissions will be decided and appointed by the health authority and/or University Clinical Hospital Service. Transparency of the decisions is considered to be of high importance.

[24] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Facilitators (opportunities) and barriers (challenges) for HTA in the Balkan region

During the breakout session on the second day of the workshop, participants were randomly assigned to four groups and asked to discuss implementation or improvement of HTA using a SWOT analysis approach, presenting options for future action as part of the group discussion. The survey sent out ahead of the workshop also asked participants to comment on facilitators and barriers. The combined main points of the SWOT analysis are outlined in Box 1. A summary of the group discussions and the survey is presented below.

Box 1. Combined main points of the SWOT analysis during group discussions

Strengths	Weaknesses
• Political support (of the ministry of health/health authorities) to implement HTA (all countries and areas – via endorsement of resolution WHA67.23) • Similar health systems based on solidarity principles and compulsory HIFs (except Kosovo[25]) • Rising awareness of HTA as a means to support UHC • Support of the World Bank and WHO • Some legal basis in place (all countries and areas, but variable) • Adopted public health strategy in place (some countries and areas) • National medicine policy under development (some countries and areas) • Health information systems in place or under development (some countries and areas) • Interests of relevant institutions (HIFs, public health institutes and universities) for inclusion in assessments, including of health economics • Recognized potential benefit (at a political level) for HTA in the process of placing a medicine on the list of reimbursed medicines	• Human resources (number of staff) • Lack of expertise and experience (lack of qualified staff) • Lack of institutionalized HTA (most countries and areas) • Lack of recognition of benefits of HTA • Reimbursement rarely declined – current system perceived to function well (Slovenia) • Lack of established legal framework with clear directions for HTA (most countries and areas, except Serbia) • Poor quality of existing data (epidemiological, costing, hospital usage and local data) • Lack of regulated communication between institutions and authorities • Weak transparency of the decisions and limited willingness to be more transparent • Dysfunctional relations between decision-making bodies and payers (HIFs) • Weak multidisciplinary approach • Lack of general awareness of HTA

[25] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Box 1. Contd.

Opportunities	Threats
• International/European contacts: cooperation with International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Health Technology Assessment international (HTAi) and EUnetHTA • European regulation of HTA • Regional cooperation among Balkan countries and areas (similar health systems) • Investing in health information systems as a source of data • Opportunities to cooperate at a regional technical level • Development of specific registers • Pressure for transparency in decision-making • Interest of the media in reforms • Very expensive upcoming technologies will increase demand for HTA • Comparable pricing structures • Making systems more sustainable • Increasing access to health care services • Enabling access to expensive, orphan and innovative drugs • Making HTA an integral part of the decision-making process • Raising awareness among national stakeholders and improving collaboration and transparency – greater focus on stakeholder education • Revealing success stories • Language similarities	• Political fluctuations – other topics are more important in the short run • Lack of financial support/funds • Lack of good examples of success • Negative pressure from experts who ask what HTA has to offer • Conflict of interest between different interest groups • Corruption • Sluggishness in adapting rapidly to new requirements for regulatory change • Pressurized ad hoc prioritization • General assumption that new and expensive is always better • Pressure of very expensive upcoming technologies (could also be an opportunity) • Negative pressure from patients' associations and health professionals • Short deadlines to complete the application documentation/assessments

Main facilitators

Political support and models for HTA

Several participants stated that their countries and areas are ready for HTA thanks to substantial political support. They mentioned that national HTA agencies or models for HTA implementation should comply with resolution WHA67.23 on health intervention and technology assessment in support of UHC. Actively using resolution WHA67.23 was considered a major opportunity for implementing HTA as it

urges countries and areas to engage in and collaborate with national, regional and global networks of HTA stakeholders. Training programmes and networks for capacity-building should also learn from existing networks. Table 4 sets out the different statements participants made abouts the best or most realistic way to organize HTA in their contexts.

Table 4. Workshop participants suggestions for the best or most realistic organization of HTA in their country or area

Country	Best way to organize HTA
Albania	An HTA agency should be a government institution dependent on the Ministry of Health. It should have access to multidisciplinary technical experts and a governing board. The HTA agency might apply to a national health care system using an interactive model. Different decision-makers should be able to access costs and benefits relevant to their settings. Decisions about its work procedures should be taken by its governing board, which should have members representing different stakeholders.
Croatia and Slovenia	Due to the small sizes of the countries and centralized decision-making processes, one national institution for HTA or an HTA unit within an existing institution responsible for HTA (autonomous in recommendations in order to avoid conflicts of interest) would be the best option. This institution could include other relevant partners in a multi-institutional network approach.
Bosnia and Herzegovina	Owing to highly decentralized decision processes, there is no role for a national HTA agency. HTA units in each canton of the Federation of Bosnia and Herzegovina coordinate at the federal level, and one in the Republic of Srpska is more realistic. Participants from the Republic of Srpska stated that their Institute of Public Health has been appointed to set up HTA. This will be an HTA unit rather than an HTA agency.
Montenegro	The most realistic opportunities for HTA involve establishment of a national committee for HTA in the Ministry of Health, involving experts from universities, other relevant experts, doctors and staff of the Institute of Public Health and Ministry of Health.
North Macedonia	Establishing an HTA body is an issue that still needs to be discussed to decide whether it should be a separate legally mandated entity (an agency) or could exist in different organizations or different institutions (a unit). HTA support needs at a national level include a consensus-building process and establishment of a regional network/platform for collaboration (see details in the following text).
Serbia	The new law on health care creates an opportunity to have more than one HTA body and the possibility that HTA can be performed by applicants (industry). Rules for this are under development.
Area	**Best way to organize HTA**
Kosovo[26]	The health authorities have made attempts to have an HTA unit (not a separate legal entity), but until now this has not been functionalized.

Appropriate frameworks and national strategies

Having a legal framework in place, as established in Croatia and Serbia and recently set up in Bosnia and Herzegovina, was considered important but not a factor sufficient to ensure establishment of a functional HTA system or framework. It was stressed that some countries and areas have a public health strategy in place, that national medicine policies are under development, and that health information systems are in place or in development. Altogether, these were considered important facilitators related to the framework.

[26] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

North Macedonia stressed that support (technical and expert) of a consensus-building process at the highest level is needed, involving key stakeholders (Ministry of Health, HIF, Agency for Medicines and Medical Devices, medical community) to define the scope, roles, responsibilities, legal framework and obstacles. This process could lead to technical support in regulation adaptation – primarily related to decision-making, but also to integration of HTA into contracting/negotiations, developing a financing plan of the process and so on. Expert support for appraisal of the methodology used in the economic evaluations within the decision-making process – especially for the innovative medicines – was considered vital for the national strategy.

Demonstration of gains through examples

Demonstrating gains through examples was stressed by several participants as a major facilitator. It was suggested that this should be an aspect addressed in an additional workshop, with presentations of relevant cases and more time for discussions, both in country- and area-specific groups and in cross-country and areas groups.

Opportunities to collaborate and share information

The presence of participants from all the western Balkan countries and areas in the workshop was considered positive. Cooperation across the Balkan region was felt to be of importance, specifically related to using and/or developing joint HTA reports, participating in joint training and education, and sharing of experience. Such cooperation should involve both countries that are members of the EU and countries and areas that are not (yet) members.

North Macedonia suggested establishment of a WHO-supported regional formal professional closed network/platform of the key institutions in each country and area (similar to the WHO Pharmaceutical Pricing and Reimbursement Information network) to facilitate exchange of information on coverage, positive lists, costing, expenditure, sharing appraisal reports and economic evaluation methodologies. Its purpose would be to overcome the gap between needs and resources for expertise, to avoid duplication of evaluations, and to facilitate and monitor the institutionalization process in each member country and area. It could also support joint regional projects on specific technologies of regional interest.

Several participants thought that HTA production should follow the basic structure of the EUnetHTA's HTA Core Model®, which would allow sharing of analysis (evidence). It was also stressed that ongoing legislative processes influencing HTA at the EU level *(21)* may influence HTA (in a positive way, depending on their outcome) in the whole region. A point mentioned during the discussion was that although HTA needs to be implemented based on local needs, the technical methodology should be the same, and HTA products should be shared to avoid unnecessary duplication of work. A systematic approach to topic prioritization would be required. Moreover, a lean and efficient system should be developed due to limited resources. Bilateral joint assessments with countries that are leading the way in HTA assessment – like France and Germany – could be developed further in competency-building exchange programmes.

Similarities in spoken languages, or at least the ability to understand languages in the region across country and area borders are also relevant in this context. Participants from Croatia stated that their experience of EUnetHTA has revealed that joint work and cooperation at the European level is extremely beneficial. Some institutions in Slovenia have skills of assessment of clinical efficacy and effectiveness and have also participated in EUnetHTA; these should further develop their skills and expertise. Several

participants reported established interactions with European and international organizations and institutions as opportunities for capacity-building within HTA. These includes EUnetHTA, WHO, ISPOR, HTAi, the World Bank and EU Funds. Further, having access to horizon scanning[27] data relevant to the region (European upper-middle-income countries (slow adaptors)) was mentioned as valuable.

Involvement of experts and building capacity

Implementing HTA depends on the involvement of experts in the fields of medicine – including all relevant professions – health economics, project management, statisticians, information specialist and others. Developing HTA capacity is crucial for the proper and effective implementation of HTA processes. It must include the scientific, regulatory and social dimensions of the issue and include stakeholders and decision-makers. This means education and training at both the local and international levels. With the exception of two examples from Serbia and Slovenia regarding the current capacity in each country at an institutional and educational level, opportunities related to institutions were not reported in the survey. However, the Balkan region has a relatively high education level, and countries and areas in the region have important educational and governmental institutions in place. The group discussions revealed that institutions such as HIFs, public health institutes, health care institutes, medicines agencies, universities and other educational institutes do contribute and are interested to contribute with expertise for assessments. In all countries and areas, individual experts are active in international societies with capacity-building opportunities, and the capacity of individual experts should used.

In answers to the survey and the discussion, it was argued that building capacity on the technical side – including appropriate frameworks to allow universities, hospitals and stakeholders to engage – is important, but might not create any value unless a more holistic approach to framework levels is included. The importance of developing a sustainability plan or a roadmap for HTA to assess the capacity of existing human resources and the needs for new skills, to define tasks clearly and to propose financing sources was noted.

Increased transparency of the decisions

An important opportunity for HTA is increased transparency. In this way, HTA could be considered a means to reduce corruption and build trust (in the health care system). Another favourable aspect mentioned is that HTA is not only a strategic point for planning at the national level but might also be used to ensure the supply of essential health technologies and adequate pricing of health technologies at the regional level.

Barriers and challenges

Lack of resources and political instability

Investing in HTA is considered a long-term investment, with substantial uncertainty related to short-term political gains. Political gain (popularity) from increased public (budget) spending in the short run to allow long-term gains that are not easy to measure or demonstrate is highly uncertain. Therefore,

[27] Horizon scanning is defined by the HTA Glossary as "the systematic identification of health technologies that are new, emerging, or becoming obsolete and that have the potential to effect health, health services and/or society. Related terms include early awareness systems" *(31)*.

according to several participants, the most important barrier to implementing HTA is related to resource availability, combined with political instability. In the discussion, participants mentioned that this applies to all countries and areas, even Slovenia, which has the highest gross domestic product in the region. In addition, current pricing and reimbursement processes for medicines in Slovenia are considered (by policy-makers) to work quite well, and the added benefit of investing in HTA is thought to be uncertain.

Lack of skilled personnel and multidisciplinary approaches

A lack of skilled personnel was reported as a major barrier for all countries and areas. Capacity needs include skills in:

- conducting HTA
- horizon scanning
- interpreting HTA
- negotiating and applying the appropriate type of managed entry agreement
- interpreting HTA for early dialogue with licence holders
- implementing HTA-related legislation
- outcome assessment for decision-makers.

Participants discussed whether this lack of skilled personnel (of human resources) is related to a lack of skills in the technical or academic sense only, or to a lack of number of humans as such (in small countries) or a lack of political will or ability to prioritize resources for public employees. These are all factors that need to be assessed.

Lack of appropriate frameworks

To be effective, an HTA body must have a defined remit and involve stakeholders in its processes, as well as having a link to decision-makers. With the exception of Serbia, participants described that clear legal frameworks for decisions are still lacking, although increased political will to implement such frameworks exists. Convincing examples showing where such frameworks have created gains in relevant settings would be beneficial.

The broad range of technologies and HTA as a threat to supply

A broad range of relevant technologies relates to the breadth of the budget that decision-makers are seeking to optimize. Participants from Albania felt that if HTA is being conducted at the level of a health plan or at the national level it should include all health technologies, including current standard or commonly used interventions, using clearly defined explicit criteria. Otherwise, clinical practices and policies will be distorted, with investment and practice gravitating towards those interventions that are free of evaluation, for which hurdles for introduction are lower. Other participants argued that HTA could start with a predefined set of technologies and then gradually be introduced to a larger set of

technologies or decision pathways. A barrier would then be related to agreeing on clear criteria for when to use HTA.

During the discussion, participants argued that convincing examples of what works for small countries with strong economic constraints are lacking. It was also noted that the perfect should not get in the way of the possible. One option is to start small and gain experience, and then broaden the scope of HTA. Furthermore, it was argued that some of these challenges could be overcome by greater collaboration and expressing similar demands to industry.

The situation of technology supply and availability of certain technologies at acceptable prices was mentioned. Several participants feared that putting too great a demand on industry to deliver evidence (like asking for submission files) or even to pay for assessments might endanger the supply of essential medicines and technologies. With similar demands from comparable European countries facing the same challenges, this threat may be reduced.

Confidentiality and available information

For new medicines in particular, information related to performance and pricing may be considered confidential. Another framework-related barrier is the lack of electronic systems and databases for monitoring drug (and technology) utilization at all levels of the health care system. The North Macedonian Agency of Medicines and Medical Devices is working on developing an electronic system to monitor drug utilization at all levels. The Lithuanian Medicines Agency model is under consideration because of its Twinning Light project with the North Macedonian Agency on "harmonization of the legislation for medicinal products with EU legislation". Similar twin projects might be valuable for other countries as well.

Strong conflicts of interest

During the SWOT analysis discussion, several participants mentioned strong conflicts of interest and corruption as threats to UHC and HTA. The independence of the assessor and transparency of the process were common stated fundamental aspects that should be reflected in implementation processes.

Recommendations

The workshop revealed substantial interest in continuing information exchange. Impressions of political will were also positive. The recommendations set out below are based on those provided by presenting HTA experts, group and plenary discussions at the workshop. Details of a roadmap for future action (Fig. 2) need to be developed based on the local context, but major gains related to collaboration are possible.

Fig. 2. Steps for implementing a roadmap for HTA implementation

Source: adapted from a slide presented by R Khaveci during the workshop on health intervention and technology assessment in support of UHC held in Ljubljana, Slovenia, in February 2020.

Recommendations for future collaboration in the Balkan region

The main recommendations for future collaboration within the region can be summarized as follows.

- Even stronger political support should be sought from ministries of health and health authorities for collaboration.
- Reflecting on convincing examples of good practice from European countries with similar challenges and of similar sizes to countries and areas in the Balkan region, and sharing relevant examples of how more rigid HTA frameworks can create gains should be explored.
- Synchronized multilevel approaches, including the adoption of public health plans with support from the World Bank, WHO and the EU as adopted by Serbia and other comparable countries, represent model examples to be shared in greater depth.
- Support for capacity-building and a network for HTA and decision-making processes should be encouraged, both across the Balkan region and with other European countries with similar challenges and of similar sizes.
- The WHO Regional Office for Europe can play a role by advocating and organizing the official platform for countries and areas in the region.
- Engaging in European and international networks – including ISPOR, EUnetHTA, the International Horizon Scanning Initiative and EuroScan International Network – to facilitate training of relevant staff should be continued.
- Involving the World Bank should be explored.

Recommendations for future action at the country and area level

Implementation and improvement strategies need to be agreed on locally. Some general recommendations to overcome the barriers presented and discussed during the workshop are provided below.

- The idea of HTA and institutionalization should be promoted to decision-makers, ensuring links with the most important decision- and policy-makers.
- Support for a local roadmap for action should be encouraged.
- Raising awareness and gaining trust among the public and health experts should be pursued. This should involve identifying and building relations with key stakeholders (including experts, academia, industry and patients).
- Discussions should be started to review the options and needs of policy-makers and key stakeholders. For this, WHO guidance and predefined tools such as SWOT analysis, analysis of opportunities and threats from political, economic, social and technological forces, risk assessment and needs assessment can be used.
- Options and remits for HTA frameworks, as well as capacity- and network-building, human resources and communication strategies should be presented. When outlining options, both those considered optimal and those considered suboptimal should be included. Time should be allowed for policy-makers and key stakeholders to understand the concepts and form opinions.
- National public health and medicines plans should be developed.
- Multi-institutional and multisectoral collaboration to avoid overlapping of activities should be ensured. Mechanisms for updating clinical guidelines and protocols should be set up.
- The national legal framework should be reviewed and an appropriate regulatory framework on HTA, compatible with EU practices, should be endorsed.
- Institutions involved in potential HTA activities should be mapped.
- The remit of the HTA body should be defined and the conditions created for systematic application of HTA as a tool for support in decision-making.
- An integrated transparent health information system should be established.
- Drug and technology utilization monitoring electronic systems should be developed or improved.
- Education, training and expertise in the field of HTA should be ensured through educational institutions.
- HTA models at the clinical level regarding health care quality should be developed, including providing success stories.

Conclusions

The developmental status of HTA in the Balkan region varies. Facilitators of HTA identified via the workshop include political will, collaboration in networks, structured health systems, relevant examples of gain and institutional frameworks. Barriers include political instability, small economies and restricted human resources. Recommendations for future action include strengthening collaborative initiatives, involving stakeholders, mapping needs and options and developing roadmaps towards sustainable HTA frameworks in support of UHC.

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Annexes

Annex 1. Workshop agenda

Time	Topic	Facilitators
Day 1		
09:00 – 09:30	Welcome and introduction of attendees Introduction and workshop objectives	Ministry of Health of Slovenia WHO Representative in Slovenia
09:30 – 10:15	Introduction: link to UHC, benefits package and pricing, reimbursement and procurement Q&A	WHO
10:15 – 13:00	Experience of HTA in the Balkan region: journey to HTA Q&A	Attendees
14:00 – 15:30	WHO guidelines on institutionalizing HTA Mandate Legal framework Financing Q&A	WHO headquarters
Day 2		
09:00 – 10:15	Establishing and running an agency Staffing Stakeholder engagement Communication	WHO and experts
10:15 – 11:30	HTA processes Submission approaches Assessment/appraisal/decision-making Secretariat roles Committee roles and training Q&A	WHO and experts

Time	Topic		Facilitators
12:00 – 13:00	HTA network and support Where to find useful HTA information/webpages/public reports EU Developing and evaluating communication strategies to support informed decisions and practice based on evidence (DECIDE) consortium Pan American Health Organization Regional Network of HTA for the Americas (RedETSA) HTAi International Network of Agencies for HTA ISPOR Q&A		Experts and WHO
14:00 – 15:00	Technical collaboration examples Beneluxa Initiative EUnetHTA		Experts
15:30 – 16:30	Overcoming challenges: next steps		Working groups
16:30 – 18:00	Reports from working groups and discussion of next steps, including training needs		All
Day 3			
09:00 – 13:00	Option 1: Medical devices and WHO Model List of Essential In Vitro Diagnostics (to include prioritization and horizon scanning and case examples)	Option 2: Medicines (to include prioritization and horizon scanning and case examples)	Option 1: Medical Devices and In Vitro Diagnostics programmes, WHO headquarters Option 2: ISPOR

Annex 2. Preparatory survey

1. Health system overview	
Health system financing structure	How is health care financed in your country or area? (For example, via insurance, taxes etc.)
Pricing and reimbursement	How are medicines, medical devices and procedures reimbursed/costed? Are any priority criteria in place for reimbursement/public financing? At what level are reimbursement decisions made, and by whom? (For example, national decisions by the ministry of health, regional decisions, hospital-based decisions etc.)
Procurement	At what level are medicines and/or medical devices procured? (For example, national, regional, area, hospital-based, etc.)
2. Development status of HTA	
Do you have decision processes involving HTA in your country or area? **If yes:** please answer the questions below **If no:** continue with **section 3**	
HTA initiation	Who are the commissioners of HTA (the ones asking for HTA)? Who suggests topics? How are topics identified, selected and prioritized for HTA? Which technologies are (most often) subjects for HTA? Is there a legal basis for the HTA process (is HTA required by law for public reimbursement)?
HTA production	Who is the HTA provider? (For example, universities, national HTA office, regional HTA office, hospital-based HTA, etc. Please provide names of HTA organizations if applicable.) Who pays for the HTA production? What is covered (general salary or per HTA)? What stakeholders are involved in HTA production? What kind of HTA products are delivered? (For example, single technology assessments or multiple technology assessments.) What domains of HTA are included in the reports? (For example, relative effectiveness, cost and cost–effectiveness, organizational, others.) Are the HTAs based on submission files from industry? What is the current capacity for HTA production (approximate number of products per year)?
Decision-making	Who are the decision-makers? (If applicable, describe stakeholder involvement.) What kind of decisions are informed by HTA? (For example, reimbursement, procurement, other (please specify).) How is the HTA appraisal and decision process carried out?
Implementation	Who is responsible for implementing HTA-based decisions? How is the implementation done? Is there any monitoring of the implementation?

2. Development status of HTA (condt.)	
Integration	How does HTA interact with other systems in your country or area? How does HTA contribute with regard to access to health commodities?
Transparency	How is information about the HTA assessment made public?
3. Opportunities for HTA and prognosis for HTA development	
System level	How do you see HTA being institutionalized in your country or area? How do you see governance of HTA developing in your country or area? (For example, the need for national and/or regional institutions, technology scope for HTA, HTA products, decision framework(s), collaborative agreements (national, regional, European, international).)
Capacity level	What do you see as major opportunities in developing HTA capacity in your countries and areas? (For example, political will; government, private and educational institutions; interactions with EU-based organizations and institutions; interactions with relevant international organizations and institutions.) What type of skills/capabilities do institutions involved in HTA need to build to meet the objectives of implementing HTA in the decision-making process? (For example, at the level of topic identification and selection, assessment (effectiveness and/or health economics), decision-making, implementation, other.) Is your country or area's institution currently involved in any HTA-related knowledge sharing/joint exercises with EU Member States or institutions in EU countries?
4. Challenges in implementing HTA	
System level	What do you consider the major barriers in implementing HTA in decision-making in your country or area? (If possible, specify for medicines, medical devices, other technologies.) Do you have any suggestions of how to overcome these challenges?
Capacity level	What do you consider the most critical challenges for capacity-building and efficient use of existing capacity? Do you have any suggestions of how to overcome these challenges?

Annex 3. Publications and hyperlinks shared during the workshop

Title	Link	Type of source
HTA activities at WHO	https://www.who.int/health-technology-assessment/en/	WHO webpages
Guidance for institutionalizing HTA mechanisms for reimbursement (draft version 2020)	Updated version shared with participants (not yet published)	WHO guidance
WHO Model List of Essential In Vitro Diagnostics	https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/	WHO resource
Essential Medicines and Health Products Information Portal	https://www.who.int/medicines/publications/essentialmedicines/en/	WHO resource
Global Atlas of medical devices	https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/	WHO resource
International Network of Agencies for HTA	http://www.inahta.org/	Network
HTAi	www.htai.org	Scientific society
HTAi regional meeting in Ukraine	https://htai.org/workshops-2/htai-regional-meeting-series/ukraine/	Network
ISPOR	www.ispor.org	Scientific society
ISPOR HTA Central – the HTA resource centre for informing health care decisions	https://www.htacentral.org/	Resources/tools
EUnetHTA	www.eunethta.eu	Network
EUnetHTA methodology guidelines	https://www.eunethta.eu/methodology-guidelines/	Resources/tools
EUnetHTA POP-database	https://www.eunethta.eu/pop-database/	Resources/tools
EUnetHTA HTA Core Model®	https://www.eunethta.eu/hta-core-model/	Resources/tools
EuroScan International Network	https://www.euroscan.org	Horizon scanning
International Horizon Scanning Initiative	https://ihsi-health.org/	Horizon scanning
Beneluxa Initiative	https://beneluxa.org	Network
University of York Centre for Reviews and Dissemination (CRD)	https://www.crd.york.ac.uk/CRDWeb/Homepage.asp	Network information resource
Cochrane Library	https://www.cochranelibrary.com/	Network information resource
Cochrane handbook for systematic reviews for interventions	https://training.cochrane.org/handbook	Network guideline
CRD's guidance for undertaking reviews in health care	https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf	Guidelines
EU Patient-Centric Clinical Trial Platforms	http://www.eu-pearl.eu/	EU project
Swedish Agency for HTA and Assessment of Social Services method	https://www.sbu.se/en/method/	HTA agency resources/tools
Canadian Agency for Drugs and Technologies in Health	https://www.cadth.ca/	HTA agency

Title	Link	Type of source
National Institute for Health and Care Excellence	https://www.nice.org.uk/	HTA agency
System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway	www.nyemetoder.no	National HTA system homepage
HTA glossary	http://www.htaglossary.net	Resources/tools
Regional Database of HTA Reports of the Americas	www.redetsa.org	Database
EU legislative proposal on HTA	https://ec.europa.eu/health/technology_assessment/eu_cooperation_en	Legislative proposal

Annex 4. Desktop review

To identify recent literature addressing HTA in the Balkan region, a nonexhaustive desktop review was performed.

Methods

The literature search was restricted to PubMed combining words for HTA and names of countries and areas in the Balkan region and eastern Europe (HTA OR "health technology assessment") AND (Albania OR Balkan OR Bosnia OR Croatia OR Macedonia OR Montenegro OR Serbia OR Slovenia OR eastern Europe OR Kosovo[28])). The search was performed on 17 February 2020 and was restricted to the last 10 years for reviews and five years for all other kinds of publication. Based on titles and abstracts, the full text of all relevant publications was inspected. Publications not specifically mentioning the Balkan region or countries participating in the workshop were excluded. Meeting abstracts were excluded.

Results

The search for reviews retrieved a total of 33 references classified as reviews from the last 10 years. No relevant systematic reviews or any other publications classified as reviews were found addressing HTA facilitators or barriers to HTA in the Balkan region.

The general search retrieved a total of 166 references for the last five years. The full text of a total of 17 of these was retrieved, based on title and abstract. In addition, a publication by Dankó and Petrova from 2014 was included, based on prior knowledge. Details of the publications included in the review are set out in Table A4.1. Summaries of selected publications are outlined below the table.

Table A4.1. Literature reviewed

Title	Country or area
Papers addressing individual countries and areas of the Balkan region	
Atanasijevic D, Zah V. Health technology assessment in Serbia. Int J Technol Assess Health Care. 2017;33(3):384–9.	Serbia
Culig J, Antolic S, Szkultecka-Dębek M. Drug policy in Croatia. Value Health Reg Issues. 2017;13:27–30.	Croatia
Beletsi A, Koutrafouri V, Karampli E, Pavi E. Comparing use of health technology assessment in pharmaceutical policy among earlier and more recent adopters in the European Union. Value Health Reg Issues. 2018;16:81–91.	EU- not Balkan region only shortly commented on in the text below
Detiček A, Janzic A, Locatelli I, Kos M. Decision-making criteria for medicine reimbursement in Slovenia: an expert panel discussion. BMC Health Serv Res. 2018;18(1):496.	Slovenia
Guzvic V, Catic T, Kostic M. Health technology assessment in central-eastern and south Europe countries: Bosnia and Herzegovina. Int J Technol Assess Health Care. 2017;33(3):390–5.	Bosnia and Herzegovina

[28] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

Title	Country or area
Huić M, Tandara Hacek R, Svajger I. Health technology assessment in central, eastern, and south European countries: Croatia. Int J Technol Assess Health Care. 2017;33(3):376–83.	Croatia
Mahmić-Kaknjo M, Marušić A. Analysis of evidence supporting the Federation of Bosnia and Herzegovina reimbursement medicines lists: role of the WHO Essential Medicines List, Cochrane systematic reviews and technology assessment reports. Eur J Clin Pharmacol. 2015;71(7):825–33.	Bosnia and Herzegovina (not directly addressing HTA)
Milevska Kostova N, Chichevalieva S, Ponce NA, van Ginneken E, Winkelmann J. The former Yugoslav Republic of Macedonia: health system review. Health Syst Transit. 2017;19(3):1–160.	North Macedonia
Prevolnik Rupel V. Current implementation of health technology assessment in healthcare system in Slovenia. Int J Technol Assess Health Care. 2017;33(3):360–4.	Slovenia
Other papers	
Dankó D, Petrova G. Health technology assessment in the Balkans: opportunities for a balanced drug assessment system. Biotechnol Biotechnol Equip. 2014;28(6):1181–9.	Balkan region (known to the authors in advance)
de Labry Lima AO, García-Mochón L, Martínez AC, Ruiz EM, Balbino JE. Mapping capacity to conduct health technology assessment in central, eastern, and south-eastern Europe. Croat Med J. 2016;57(1):66–70.	Central, eastern and south-eastern Europe
García-Mochón L, Espín Balbino J, de Labry Lima AO, Martínez AC, Martin Ruiz E, Pérez Velasco R. HTA and decision-making processes in central, eastern, and south-eastern Europe: results from a survey. Health Policy. 2019;123(2):182–90.	Central, eastern and south-eastern Europe
Godman B, Novakovic T, Tesic D, Oortwijn W, Martin AP, Parker M et al. Addressing challenges for sustainable health care in central and eastern Europe. Expert Rev Pharmacoecon Outcomes Res. 2016;16(6):685–7.	Central and eastern European countries
Kaló Z, Gheorghe A, Huić M, Csanádi M, Kristensen FB. HTA implementation roadmap in central and eastern European countries. Health Econ. 2016;25(Suppl 1):179–92.	Central and eastern European countries
Kawalec P, Tesar T, Vostalova L, Draganic P, Manova M, Savova A et al. Pharmaceutical regulation in central and eastern European countries: a current review. Front Pharmacol. 2017;8:892.	Central and eastern European countries
Kolasa K, Kaló Z, Zah V. The use of non-economic criteria in pricing and reimbursement decisions in central and eastern Europe: issues, trends, and recommendations. Expert Rev Pharmacoecon Outcomes Res. 2016;16(4):483–8.	Central and eastern European countries
Malinowski KP, Kawalec P, Trąbka W, Czech M, Petrova G, Manova M et al. Reimbursement legislations and decision-making for orphan drugs in central and eastern European countries. Front Pharmacol. 2019;10:487.	Central and eastern European countries
Vella Bonanno P, Bucsics A, Simoens S, Martin AP, Oortwijn W, Gulbinovič J et al. Proposal for a regulation on health technology assessment in Europe – opinions of policy-makers, payers and academics from the field of HTA. Expert Rev Pharmacoecon Outcomes Res. 2019;19(3):251–61.	EU- not Balkan region only shortly commented on in the text below

Albania

Based on the limited search strategy, no publications specifically addressing HTA in Albania were identified.

Bosnia and Herzegovina

In a paper from 2015 by Mahmić-Kaknjo and Marušić, the basic medicines list of the Federation of Bosnia and Herzegovina is compared with the WHO essential medicines lists, and with evidence supporting additional inclusions and exclusions (Cochrane systematic reviews and HTA reports) not on the WHO list. The authors argue that the results of the study may provide support to decision-makers for useful (HTA) methodology, and that establishment of an independent, government-financed body – which could help provide scientific criteria for a transparent decision-making system for reimbursement – is inevitable. In a supplement to their publication, they provide a detailed description of the medicines reimbursement system in the Federation of Bosnia and Herzegovina.

A paper by Guzvic et al. from 2017 describes recent trends in HTA within Bosnia and Herzegovina. In addition to providing an overview of the developmental status of HTA, the authors also summarize the country's health care systems, reimbursement and legislation frameworks to enhance more unified access to medicines. They report on decentralized decision frameworks and health care systems with differences in health policy and access to health care, and 12 decentralized HIFs (not including that of the Brcko District).

Guzvic et al. note that in the Federation of Bosnia and Herzegovina – one of two autonomous republics in the country with a federal ministry and 10 canton ministries of health – HTA was recognized by legislation in 2010. According to the legislation, the Federal Ministry of Health should appoint an HTA committee with a four-year mandate to provide opinions on new technologies to the Ministry. In 2017 this committee was not yet established, and HTA was not yet introduced at full capacity. Activities related to evidence-based medicine and HTA in the Federation were restricted to professional associations.

The authors report that in the Republic of Srpska – the second autonomous republic of Bosnia and Herzegovina with one ministry of health – pharmacoeconomic analysis has been introduced recently for highly expensive drugs. This analysis is optional for reimbursement, but some kind of budget impact analysis is required. ISPOR is reported to have a chapter in Bosnia and Herzegovina. The country is not a member of the EU, and the paper also discusses some consequences of this with regard to legislation. The authors conclude that challenges remain regarding assessment standards, development of more transparent approaches, a lack of experts and issues related to the political environment.

Croatia

Implementation of HTA in Croatia is described in a paper by Huić et al. from 2017, and the country's drug policy is described in another paper by Culig et al. from the same year. Both provide a short description of Croatia's health care system and decision-making frameworks. The authors note that the public is covered by a basic HIF. Huić et al. report that centralized HTA activities were commenced in 2009 with the establishment of an HTA department within the Agency for Quality and Accreditation in Health Care and Social Welfare (the national HTA agency). In 2012 the Ministry of Health implemented a new health care strategy. In 2016, a formal ordinance on HTA passed a public consultation process, but in 2017 it was not yet implemented.

Main decision-makers able to request an HTA are described by Huić et al. as the Ministry of Health, the HIF and hospital management teams, but HTA was not mandatory in 2017. HTA was reported to be part of the strategy, but it was not covered by a legal framework. Huić et al. also report on the HTA agency's history of national and international network collaboration, stakeholder involvement and report production. The HTA agency has delivered guidelines, created a database of national HTAs, proposed further HTAs and provided education on HTA methods. Furthermore, in 2017 the HTA agency became a partner of EUnetHTA and contributed to EUnetHTA assessments. The authors describe international collaboration within EUnetHTA and ISPOR as major facilitating factors. Main barriers are described as the lack of a legal framework and limited human resources. Huić et al. point out that stronger political support and appropriate funding are needed to implement HTA fully in Croatia.

The Culig et al. paper was a response to ISPOR's review of drug policy in various countries, and it describes the establishment of the HTA agency. The authors report that budget impact analysis is mandatory, and that cost–effectiveness analysis is beneficial. They also note that there are two reimbursement lists: the basic (100% coverage) and the supplementary (from 10% to 90% coverage). The basic list covers hospital drugs, and there is also a special drug list for expensive (mainly hospital) drugs. According to Culig et al., submission files from reimbursement applicants are received by the HIF after European Medicines Agency approval. The HIF funds a multidisciplinary expert committee responsible for making proposals to the Ministry of Health. HTA can be requested but is not mandatory. Drug reimbursement decisions are made via ordinances of the Ministry of Health. Directives on prescribing are included in the drug list. Pricing is based on reference prices, and negotiated prices/agreements are confidential.

Montenegro

No publications specifically addressing HTA in Montenegro were identified.

North Macedonia

A health system review by Milevska Kostova et al. from 2017 provides an analysis of recent developments in the organization, governance and financing of health care provision reforms and performance. HTA is not mentioned, but the section on transparency and accountability notes: "Transparency and accountability have been an important challenge facing all economic sectors including the health sector. Due to a lack of publicly available data usable for analysis, the culture of evidence-based policy-making has only recently begun to gain understanding and acceptance." The national health strategy for 2020 is described as a step towards greater transparency in the same section.

Serbia

A paper by Atanasijevic and Zah from 2017 presents an overview of HTA in Serbia. The authors describe demographic and epidemiological data, the basics of the health care system, the organization of health care institutions and financing. As with the situation in other European countries, the major burden of illness in Serbia is noncommunicable diseases. In 2012 a reform to create greater efficiency in primary care was initiated, and an Australian diagnosis-related group-based system was implemented for acute inpatient hospital care. The Ministry of Health also recognized a need to establish a transparent decision-making process and prioritized HTA as a component of two "Serbia Health" projects. In 2017 a new health care law described the role of the national compulsory HIF in HTA. The authors state that the World Bank was crucial in driving these reforms and funding the projects. They note that the

regulation of HTA by law is mainly about affordability. Evidence of quality, safety and efficiency is often accepted as provided by the applicant. Although not (yet) an EU country, drug marketing authorization done by the Serbian Agency for Drugs and Medical Devices is harmonized with EU regulations. Pricing and reimbursement decisions are national. The decision process for reimbursement is initiated by applications for reimbursement sent to the HIF – expert committees assess the quality of documentation, and pharmacoeconomic evaluations are performed by the HIF and specialized committees. Appraisal of the application, taking into account expert committee and pharmacoeconomic data, is performed by a central drug committee. Final approval, based on the committee's recommendations, is given by the Ministry of Health, Ministry of Finance.

Atanasijevic and Zah note that the Ministry of Health also has an HTA committee. Its scope in 2017 mostly related to planning and capital investments rather than technology assessment. The scope of the central drug committee is closer to the concept of HTA, as it uses "very rapid assessments". In 2017 there were no prioritization criteria or criteria for co-payment levels, and no patient involvement in decisions. The authors stress that some medicines are underused owing to lack of coverage, and that lack of criteria is a major problem compromising the decision process. They state that knowledge of the role and benefits of HTA was suboptimal among Serbian decision-makers.

Slovenia

Prevolnik Rupel analyses the current state of HTA implementation in Slovenia in a paper from 2017, which also provides insight into the country's health system. The author notes that Slovenia has one compulsory HIF that provides full coverage for defined health services, while all other services involve cost-sharing of between 5% and 95%. In 2017 no unified criteria for introduction and reimbursement of health technologies were in place. Medicines are assessed by the Slovenian HIF, which follows the rules of inclusion in the medicines list. Medical devices are also considered by the HIF but follow the rule of the lowest price. Other technologies are introduced through the Ministry of Health's Health Council, following procedures for handling projects. In 2017 there was no systematic use of HTA, and HTA was not defined by legislation. According to the author, some principles of HTA are found in the decision-making processes for medicines. Challenges to creation of a sustainable HTA process include defining smart approaches for coordination of fragmented activities, capacity-building, defined priority-setting, inclusion of stakeholders and transparency in decision-making.

A paper outlining an expert panel discussion of decision-making criteria for medicine from 2018 by Detiček et al. gives details about reimbursement. It notes that the seven decision-making criteria for Slovenia were formed with medicine health benefits and economics as the most important. The experts suggested re-evaluating decisions with the inclusion of real-world data, and noted that social aspects of the disease and medicine impact on the community had largely been ignored in 2018. Although HTA is discussed in the paper, the authors provide no conclusions on methods or suggestions for implementation of the criteria.

Kosovo[29]

No publications specifically addressing HTA in Kosovo[30] were identified.

[29] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

[30] All references to Kosovo in this report should be understood to be in the context of United Nations Security Council Resolution 1244 (1999).

More general papers: relevant models and roadmaps

The opportunity for a balanced drug assessment system in the Balkans was reviewed and analysed by Dankó and Petrova in 2014. The paper states that the Balkan region is not a precisely defined area, but commonly includes countries and areas in southern central Europe that share several historical, cultural, political and economic characteristics. These include Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Montenegro, North Macedonia, Romania, Serbia and Slovenia. These are described as middle-income countries with large differences in economic development. Common characteristics of the region are small national economies that are highly exposed to economic cycles in the Eurozone and dependent on imports of processed products, and that have high unemployment and workforce emigration rates. The health systems generally have mandatory national health insurance managed by publicly owned HIFs, as well as publicly owned health care institutions.

In the average Balkan country and area, medicines are reported to be reimbursed either through prescription (outpatient) budgets or from hospital budgets. Tenders for expensive drugs are used in some countries and areas. Medicines need their prices to be registered or authorized, typically by the ministry of health or health authorities. The authors identify a lack of explicit HTA frameworks and guidelines for pricing and listing processes. Decision-making is commonly done by expert committees, but key elements of cost–effectiveness analysis are lacking. Furthermore, local epidemiological data are missing. Some of the larger countries in the region (Bulgaria, Croatia, Greece and Serbia) have a limited number of trained HTA experts, and HTA expertise in other countries is reported to be low. Relevant health economic education is available at several universities in the region, and HTA experts or health economists work as consultants for the governments.

The paper describes three models of HTA:

- economical (pharmacoeconomic assessment of submission files);
- qualitative comparative assessment of submission files (building on expert judgement commonly found in regulatory agencies);
- balanced (multicriteria analysis, integrating economical evaluation with the qualitative assessment).

The authors argue for a balanced model with transparent processes, understandable considerations and participants held responsible for their decisions. Strong pharmaceutical budget constraints and limited HTA resources are described as external factors influencing the choice of a balanced model. Appropriate methodology and a well designed process are given as factors in support of effective and transparent models. For the balanced model, the authors considered both "light" and "heavy" models of balanced HTA. The light or pragmatic model includes a simplified HTA process involving simplified economic evaluation with an assessment of value for patients and society. The authors conclude that light models with secondary assessments should be used wherever possible. They also recommend that HTA systems in the Balkan region should initially focus on new innovative medicines seeking reimbursement.

A paper from 2016 by Kaló et al. compares HTA implementation in central and eastern European countries to HTA practice in western European countries. The authors specifically argue that HTA roadmaps are not fully transferable without taking into account country-specific characteristics such as country size, gross domestic product per capita, social values, public health priorities and fragmentation of health care financing.

More general papers: process mapping, practice and capacity

A paper by García-Mochón et.al from 2019 reports results from a survey on HTA and decision-making processes in central, eastern and south-eastern European countries. Potential respondents were identified through a literature review of 118 contacts from 24 countries. The results were based on responses from 13 countries, including Balkan region countries Bulgaria, Croatia, Greece, Serbia and Slovenia. The authors report that all participants offered very similar responses. In general, pricing and reimbursement decision structures were well defined but heterogeneous. Most assessment topics arose as a result of requests from technology manufacturers. Among respondents reporting assessments, 11 reported assessing medicines, seven assessing medical devices and three assessing procedures. In most cases, submission files from industry were assessed.

The authors point out that although economic evaluation is formally required in Slovenia, in practice only budget impact is employed. Furthermore, while Croatia has HTA guidelines including economic evaluation, only budget impact is required. Half the respondents reported having HTA guidelines, but these were mainly instructions to manufacturers – only Croatia and Poland reported a full HTA process guideline. Half the countries reported having legislation requiring mandatory HTA. In general, criteria for appraisal included benefits, harms and costs. Other aspects were less common. Overall, the criteria for reimbursement of medicines were clearer than those for other technologies. The HTA systems differed in the degree of stakeholder involvement. Less than half the respondents reported having an open process, and one country (Poland) reported that their process was only partially open. The reported timelines needed to conduct an HTA ranged from 90 to 365 days. Contract schemes for patient access were reported by a third of respondents. Less than half the countries reported using HTA for disinvestment decisions, and only two (Croatia and Hungary) reported having a strategy for technology implementation. One third of respondents reported that monitoring mechanisms were in place. The authors conclude that there is wide heterogeneity in HTA, related to the degree of development of HTA structures, methods and processes.

A paper from 2016 by de Labry Lima presented a survey providing insight into HTA capacity in central European countries. Answers from were received 41 respondents from the 257 subjects contacted, including responses from Slovenia. The authors report that the most important factor limiting HTA implementation is lack of funding, followed by a lack of skilled training. Other factors mentioned were lack of access to a network (national or international) and lack of political support.

Godman et al. address challenges for sustainable health care in central and eastern Europe in a paper summarizing abstracts from the fifth international meeting on this topic held in Belgrade, Serbia, in 2015. The authors conclude that differences between countries in terms of access to and reimbursement of new medicines and their assessment are appreciable. They also note that HTA is a way forward to enhance transparency in decision-making and access. Furthermore, they emphasize that patient-level data can improve decision-making and that cooperation between relevant stakeholder groups is required.

A systematic review by Beletsi et al. from 2018 compares HTA use in pharmaceutical policy among early adopters in the EU (England, United Kingdom; France; Germany; and Sweden) and more recent adopters (Bulgaria, Hungary, Poland and Romania). The Balkan countries participating in the workshop were not among the cases included. The authors state that the early adopters of HTA more often emphasize improving quality of care, equity and efficient use of resources as objectives for HTA-informed policy-making. Later adopters more often emphasize the budget impact of new therapies.

More general papers: EU proposal on regulation of HTA

A paper providing expert opinions on the EU regulation on HTA by Vella Bonanno et al. from 2019 was included for inspection of the full text. This paper notes that in January 2018 the European Commission published a proposed regulation on HTA, providing the basis for permanent and sustainable cooperation (on HTA) at the EU level beyond 2020. It covers four main pillars of HTA activities:

- joint clinical assessments;
- joint scientific consultations, whereby developers can seek advice from HTA authorities;
- early identification of promising emerging health technologies;
- continuing voluntary cooperation in areas not covered by joint clinical assessments.

The proposed regulation has been subject to a number of changes as part of the co-decision procedure between institutions of the EU and Member States. Its final character and adoption status are developing and as yet unknown. According to the proposal, individual EU countries will continue to be responsible for assessing non-clinical (for example, economic, social and ethical) aspects of health technologies, and for making decisions on pricing and reimbursement. If implemented, the regulation will have consequences for national legislation on HTA and implementation of HTA in EU countries. It will also strongly affect those non-EU countries affected by the Eurozone and will open up new possibilities for cooperation.

Discussion

This desktop review aimed to provide an overview of the developmental status of HTA in the Balkan region as described in recent literature. The review was not exhaustive. Several additional information sources exist to facilitate fuller mapping of HTA development and relevant models for HTA frameworks, and broader scope for inclusion could be used. Nevertheless, the review confirmed the information shared during the meeting. Comparing the literature and the information collected during the workshop indicates progress, in that barriers are less related to capacity concerning technical skills, tools and access to the network. The needs to identify sustainable relevant models and to convince policy-makers of gains seem to have become more important in the period between the dates of the included articles and the workshop.

Conclusions

In general, the authors of the retrieved literature identify a lack of explicit HTA frameworks in the Balkan region. The region is described as sharing common characteristics, such as having small national economies highly exposed to economic cycles in the Eurozone and dependent on imports of processed products. The health systems are noted to have mandatory national health insurance managed by publicly owned HIFs, as well as publicly owned health care institutions. In the average Balkan country and area, medicines are reported to be reimbursed either through prescription (outpatient) budgets or from hospital budgets. Tenders appeared in some countries for expensive drugs. Medicines need their prices to be registered or authorized, typically by the ministry of health. Some models and suggestions of roadmaps for HTA for the region and/or central and eastern European countries and areas are presented.

The WHO Regional Office for Europe

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