

# ANNEX C1bis: Twinning Light Fiche <sup>1</sup>

**Project title:** Improvement of system mechanisms for monitoring the prescription and consumption of medicines in the health system of Montenegro

Beneficiary administration: Health Insurance Fund of Montenegro and Ministry of Health

Twinning Reference: ME 22 IPA HE 01 25 TWL

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# **EU funded project TWINNING TOOL**

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<sup>&</sup>lt;sup>1</sup> For Twinning Light, the project Fiche should be detailed as it will form an annex to the Twinning Light Grant Contract together with the selected Member State proposal. The Twinning Light project Fiche, besides all the data and information mentioned under section 2.1.1, provide also concrete indications on how the work plan should be established, on the suggested schedule of activities, on the profile of short-term experts and on indicators and targets that should be used to ensure the timely achievement of the mandatory results.

## **ABBREVIATIONS**

BI	Beneficiary Institution
BC	Beneficiary Country
EU	European Union
EUIF	EU Integration Facility
HIFM	Health Insurance Fund of Montenegro
IPA	<b>Instrument for Pre-Accession Assistance</b>
МоН	Ministry of Health
MNE	Montenegro
MS	Member State
PL	Project Leader
PSC	Project Steering Committee
SDG	Sustainable Development Goal
STE	Short Term Expert

## 1. Basic Information

- 1.1 Programmes: Instrument for Pre-Accession Assistance III Annual Action Programme in favour of Montenegro for 2022 (IPAIII/2022/JAD.1003560/AAP Montenegro 2022, ACT-60881-EU Integration Facility-ME2022AAP) Direct management and Instrument for Pre-Accession Assistance III Annual Action Programme in favour of Montenegro for 2025, 2026 and 2027 (MNE2025-2027MAAP EU Integration Facility for 2025, 2026 and 2027, ACT-63249)
- 1.2 Twinning Sector: Health and Consumer protection
- 1.3 EU funded budget: *EUR* 250.000
- 1.4 Sustainable Development Goals (SDGs): Goal 3. Ensure healthy lives and promote well-being for all at all ages

#### 2. Objectives

## 2.1 <u>Overall Objective(s):</u>

To contribute to the improvement of the public healthcare system in Montenegro by introducing rational prescribing practices in line with EU standards, thereby supporting the fulfilment of Montenegro's obligations under Negotiation Chapter  $1-Free\ movement\ of\ goods$  and Chapter  $28-Consumer\ and\ health\ protection$ 

#### 2.2 Specific objective(s):

To establish a sustainable and EU-aligned system for rational prescribing of medicines in the public healthcare sector in Montenegro, by:

- 1) Improving the existing national policy on medicines and quality of health care;
- 2) Strengthening institutional capacities of healthcare professionals at Primary Healthcare Center of the Capital, the Clinical Center of Montenegro, and officials of the Health Insurance Fund of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines;
- 3) Developing proposals for appropriate control mechanisms to rationalize medicine consumption and enable continuous monitoring of pharmaceutical stocks across public healthcare institutions.
- 2.3 The elements targeted in strategic documents i.e. National Development Plan/Cooperation agreement/Association Agreement/Sector reform strategy and related Action Plans

The project goals are linked to the 2025-2028 Strategy for Improving the Quality of Health Care and Patient Safety and its 2025-2026 Action plan<sup>2</sup> prepared by the Ministry of Health, and adopted in December 2024. The Strategy is designed with the purpose of improving a key aspect of the healthcare system - the quality of health care and patient safety, which affect the daily life of Montenegro's citizens. Health is a fundamental value that not only reflects the quality of life of an individual, but is also an indicator of social justice, economic development and political stability of a country. In this context, a health policy that strives for a high level of quality and safety of health services is of vital importance for ensuring the well-being of the population. Within Operational Objective 7 of the Strategy - Harmonization of health institutions with international and EU standards in the field of

<sup>&</sup>lt;sup>2</sup> 2025-2028 Strategy for Improving the quality of health care and patient safety with its 2025-2026 Action plan https://www.gov.me/dokumenta/70392723-b4b2-4a94-baf5-11dacd7a4c99

*quality* - this Twinning project will contribute to the development of evidence-based medical protocols and institutional capacity building, specifically related to the treatment of:

- Acute Coronary Syndrome (ACS),
- Breast cancer.
- Cervical cancer.
- Colorectal carcinoma, and
- Lung cancer.

These protocols are a key requirement to reduce irrational prescribing and ensure optimal, cost-effective care, in line with best national and European practices.

## 3. Description

#### 3.1 Background and justification:

As a public institution established by the Government of Montenegro, the Health Insurance Fund of Montenegro (HIFM) is one of the key players in the healthcare system of the country. Its role is crucial in drafting and implementing numerous laws and bylaws in the areas of healthcare, health insurance, pricing and reimbursement, as well as prescription, dispensing and rational use of medicines and medical devices.

The Montenegrin public healthcare system is complex. It is built on three levels (primary, secondary and tertiary) and comprises:

- 1 Emergency Center,
- 18 Primary Healthcare Centers,
- 5 General hospitals,
- 3 Special hospitals,
- 2 Clinical Hospitals and
- Clinical Center.

Also, the Institute of Blood Transfusion of Montenegro and the Institute for Public Health are part of the Montenegrin public healthcare system.

Accession to the European Union is a key foreign policy priority of Montenegro. Through Chapter 1 -Free movement of goods and Chapter 28 - Consumer and health protection, Montenegro has obligations in the area of health policy, primarily related to the harmonization of the legislative framework for medicines and their use. One of three final measures of the Chapter 28 is that Montenegro demonstrates compliance with the legal acquis in the field of communicable diseases and provide appropriate institutional, technical and administrative capacities by the day of accession, to implement this legal acquis and fulfill reporting and coordination obligations with the EU to resolve serious cross-border threats to health. In order to fulfil the obligations arising from the negotiation process, there is a need for a more proactive approach and additional engagement. In this context, and in line with obligations that will lead to the improvement of the healthcare system, the HIFM is recognized as an institution that ensures the rights arising from the Law on Compulsory Health Insurance ("Official Gazette of Montenegro", 145/21, 048/24), especially the right to medicines and medical devices. At the same time, HIFM controls the prescription and consumption of medicines prescribed in accordance with the List of Medicines (products covered by the national health insurance system) at the expense of the Fund. Since good interdepartmental and partnership cooperation between institutions and the Government is central to the accession process itself, it is important to point out that the HIFM has a very significant role in that part and that it actively contributes to the fulfilment of all obligations aimed to improve the health system and protect the rights of patients, while ensuring compliance with European standards, guidelines and good practices. Several key legal frameworks regulate the pharmaceutical industry and the distribution of medicines in Montenegro, including: the Law on Medicines ("Official Gazette of Montenegro", No. 80/20, 084/24, 035/2025), Regulation on criteria for Establishing Maximum Prices of Medicines ("Official Gazette of Montenegro", No. 130/21, 009/22, 020/24), and Regulation on Criteria for Adding or Removing Medicines from the Basic and Additional List of Medicines ("Official Gazette of Montenegro", No. 002/23, 123/23). These laws enable the pharmaceutical industry and other healthcare and medicine distribution participants' better conditions for development, innovation and strengthening of competitiveness, and to establish transparency measures regulating the prices of medicines for human use and their inclusion in the national health insurance system.

The Ministry of Health, as a policy maker, is responsible for preparing and implementing the 2025-2028 Strategy for Improving the quality of health care and patient safety. The Strategy is designed with the purpose of improving a key aspect of the healthcare system - the quality of health care and patient safety, which affect the daily life of Montenegro's citizens.

Healthcare systems that do not ensure high quality of health care and safety are burdened with higher costs, not only because of unnecessary or ineffective treatments but also because of the impact that medical errors have on patients' health. These problems urgently require a comprehensive approach of reform that will not only improve direct health outcomes, but also reduce the economic burdens associated with health care and improve the overall satisfaction of citizens with the healthcare system. Montenegro does not have a specific law on the quality of health care, but this area is defined by the Law on Health Care ("Official Gazette of Montenegro", No. 003/16...084/24), which is not adequate and needs to be improved in order to achieve the improvement of the quality of health care in Montenegro.<sup>3</sup>

The Montenegrin healthcare system is facing different challenges. In the past few years, with the COVID 19 phenomenon, a significant increase in the irrational use of medicinal products has been observed, both in terms of misuse of approved indications as well as in terms of their excessive use. Bearing all this in mind, as well as the fact that acute coronary syndrome, breast cancer, cervical cancer, colorectal carcinoma and lung cancer demand the most expensive treatment, it is important to create national medical protocols for their treatment. Currently, Montenegro has only two of five aforementioned protocols in place – for breast cancer and cervical cancer.

The absence of standardized national medical protocols for treatment is the reason why doctors in everyday situations are free to prescribe more expensive medicines for treatment, although cheaper ones providing the same medical effects are available at the market. More favorable price of the medicine implies its wider availability on the market, which provides a higher quality of treatment to all patients in need. On the other hand, the difference between the prices of these two options opens the possibility to redirect the available amount of money on other more expensive and innovative medical treatments. Establishing national medical protocols would help healthcare professionals provide standardized care and therapy for patients, based on evidence from various healthcare facilities across the country. Unified medical protocols would offer the most effective treatment options, which would help healthcare professionals make decisions on diagnosis and therapy. National protocols are also important because they incorporate screening recommendations as well, i.e. early stage detection of illness.

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<sup>&</sup>lt;sup>3</sup> Link for Draft Strategy for Improving the quality of health care and patient safety https://www.gov.me/dokumenta/6d2ea4d1-f950-4e30-9f46-5c81f2d37dd9

By introducing tests for early detection of breast cancer, colon cancer and cervical cancer and promptly intervening with appropriate treatment methods, premature cancer deaths are being prevented and lives can be saved. In Montenegro, preventive examinations (screening) for early detection of breast, colon and cervical cancer have been implemented since 2011.

Current control system implies that control is done only partially. It means that only determinants of the medicine defined by the *List of Medicines* at the expense of the compulsory health insurance are being controlled. It also implies control of, whether the medicine with appropriate characteristics is on the *List of Medicines*, whether the prices of the medicines are in accordance with the regulations and whether the application and realization of the medicines fall within the indication area defined by the *List of Medicines*. Developing national medical protocols and their implementation into the integral information system would enable easier control and monitoring of the flow of medicines, since it would be possible to determine whether the needed medicine is applied in the manner, form, quantity and time that aligns with the health condition of the patient and the stage of their illness.

For that reason, it is necessary to revise the national policy on medicines and to define control mechanisms related to the procurement and consumption of medicines and medical devices in the public healthcare system, as the largest expenditure items in the budget that records constant growth. High consumption of medicines affects both, the financial expenditures on medicines and their increase in the overall budget for health sector. Thus, they represent a risk for financing of the healthcare system and, indirectly, for public finances.

Medical protocols are important for decision-makers as well. They help to guide decision on how to purchase certain therapeutic options, their quantities and application. They also affect standardization of all that should be done for a given disease and condition.

Given these problems, it is necessary to make specific changes in this area as soon as possible and improve the existing situation through education of healthcare professionals and policy makers – including the Ministry of Health and the Health Insurance Fund.

A more robust, evidence-based, and unified approach to prescribing is essential. This Twinning Light project proposal addresses these gaps through structured approach to a policy reform, capacity building, and control mechanisms, leveraging EU Member State expertise. In this regard, future national guidelines and protocols for the treatment of the aforementioned diseases shall be aligned with the National List of Medicines and best clinical practices, relying on the guidelines, protocols, and recommendations of relevant professional associations such as the European Society for Medical Oncology (ESMO), the National Comprehensive Cancer Network (NCCN), and the European Society of Cardiology (ESC).

## 3.2 Ongoing reforms:

Montenegro is in the intensive process of negotiation with the EU as part of its EU accession process. According to the Montenegro Report 2024 on public health, in January 2024, Montenegro signed an association agreement to join the EU4Health programme. Regarding eHealth, in July 2023 a new IT system of the Clinical Centre of Montenegro (which provides two thirds of all medical services in Montenegro) was put into operation to improve the accessibility and quality of healthcare services to patients. However, the system is not fully functional and certain aspects cause challenges for both doctors and patients.<sup>4</sup> In October 2023, the 2023-2027 Strategy for the Development of the Healthcare system of Montenegro, with the Action Plan for 2023-2024 has been adopted.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> Montenegro Report 2024, https://enlargement.ec.europa.eu/montenegro-report-2024\_en

<sup>&</sup>lt;sup>5</sup> https://wapi.gov.me/download-preview/2414cd07-7fce-41bd-9df1-11eeaba307e7?version=1.0

In December 2024, the 2025-2028 Strategy for Improving the quality of health care and patient safety, with the Action Plan for 2025-2026<sup>6</sup> has been adopted, as well.

The new Law on Medicines which is aligned with Directive 2001/83 (on the Community Code relating to medicinal products for human use), Regulation 2004/726/EC (regarding Community procedures for the authorization and supervision of medicines for human and veterinary use, and the establishment of the European Medicines Agency), Regulation 2019/6/EC (on veterinary medicines), and Regulation 2014/536/EC (on clinical trials of medicines for human use) is under preparation. Alignment with Directive 89/105/EEC on the transparency of measures regulating the pricing of medicines for human use and their introduction into national health insurance systems, through the adoption of a Regulation on amendments and supplements to the Regulation on the criteria for establishing maximum prices of medicines is planned for the third quarter of 2025.

#### 3.3 Linked activities:

Montenegro has been actively engaged in public administration reform (PAR) as part of its efforts to improve governance and align with European Union (EU) standards. These reforms are essential for enhancing the efficiency, transparency, and accountability of public administration, which are crucial for EU integration.

In order to continuously implement public administration reform in Montenegro, in December 2021, the Government of Montenegro adopted the Public Administration Reform Strategy 2022-2026 with the Action Plan for 2022-2024. This document also defines the key objective - the joint construction of a responsible, efficient, transparent and optimal public administration, focused on the needs of citizens and the economy. In this context, the need to establish a functional public administration with an effective personnel planning system based on identified needs was recognized. The accompanying Action Plan envisages an activity that includes the preparation of a Functional Analysis of the Public Administration, with recommendations for improving the health sector.

The EU is the primary supporter of Montenegro's PAR efforts. Through various instruments, such as the Instrument for Pre-accession Assistance (IPA), the EU provides financial and technical assistance to support in public administration reforms. The EU also offers guidance and establishes benchmarks that Montenegro must meet as part of its accession process. Apart from the EU, other international organizations and bilateral donors also support PAR in Montenegro. This includes the United Nations Development Programme (UNDP), the World Bank, and individual countries providing bilateral aid and technical assistance.

So far, HIFM has been involved in three projects supporting the healthcare system in Montenegro:

- TAIEX Study Visit on strengthening capacities of the Health Insurance Fund of Montenegro organized in cooperation with Health Insurance Office (Kancelář zdravotního pojištění) and Ministry of Health of the Czech Republic, 13-17 May, 2024.
- TAIEX Study visit Register of Growth and Development of Children and Youth in Montenegro organized in cooperation with Split-Dalmatia County Primary Health Center and Croatian Institute of Public Health, 26-30 May, 2024.
- TAIEX Expert Mission on implementation of the European Health Insurance Card in Montenegrin healthcare system, 19-21 March, 2025.

HIFM has submitted the application on improving and enhancing preventive measures for early detection of breast cancer, within Interreg IPA CBC Croatia - Bosnia and Herzegovina – Montenegro.

<sup>&</sup>lt;sup>6</sup> https://www.gov.me/clanak/strategija-za-poboljsanje-kvaliteta-zdravstvene-zastite-i-bezbjednost-pacijenata

- 3.4 List of applicable *Union acquis*/standards:
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
- Directive 1989/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems;
- Regulation (EC) 726/2004 of the European Parliament and of the Council of March 31, 2004 on Community procedures for the approval and supervision of medicinal products for human and veterinary use and on the establishment of the European Medicines Agency;
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

#### 3.5 Components and results per component

Component 1 – Improving the existing national policy on medicines and quality of health care

- **Result 1.1** Assessment report on existing medical practice with recommendation for policy changes in the field of quality of health care i.e. medical protocols, prepared.
- **Result 1.2** Existing national medical protocols for the treatment of breast cancer and cervical cancer are revised and updated.
- **Result 1.3** New national medical protocols for treatment of colorectal cancer, lung cancer and acute coronary syndrome are developed.
- **Result 1.4** Formal adoption of all revised and developed medical protocols by the National Committee for Healthcare Quality Assurance and Safety of the Ministry of Health, ensuring their integration into the national healthcare regulatory framework, including necessary legal, financial, and administrative adjustments to support long-term institutionalization.
- <u>Component 2</u> Strengthening institutional capacities of healthcare professionals at Primary Healthcare Center of the Capital, the Clinical Center of Montenegro, and officials of the Health Insurance Fund of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines.
- **Result 2.1** The institutional and professional capacities of healthcare personnel at the Primary Healthcare Center of the Capital and the Clinical Center of Montenegro have been strengthened in key areas, including therapy management, prescribing practices, medication dispensing, and stock control.
- **Result 2.2** Internal capacities of HIFM staff are enhanced to improve the quality of control over medical, administrative, and financial documentation particularly regarding the monitoring of prescriptions (on natural and financial indicators) in healthcare institutions, including private healthcare institutions with whom HIFM has signed agreements on cooperation.
- **Result 2.3** Enhanced internal capacity of MoH staff for policy evaluation and evidence-based decision-making.

<u>Component 3</u> – Developing proposals for appropriate control mechanisms to rationalize medicine consumption and enable continuous monitoring of pharmaceutical stocks across public healthcare institutions

- **Result 3.1** A draft methodology for developing control mechanisms for medicines use and stock monitoring is created.
- **Result 3.2** A set of proposals for establishing rational medicine consumption and stock monitoring mechanisms in public healthcare institutions is developed.
- **Result 3.3** Regulatory and procedural gaps identified and addressed to enable the full implementation of proposed healthcare quality and safety control mechanisms.
- **Result 3.4** Draft proposals for enhancing the existing software solution are prepared to enable improved surveillance and detection of irregularities in prescribing practices.

## 3.6 Expected activities:

**Component 1** – Improving the existing national policy on medicines and quality of health care

#### Activities:

- 1.1 Perform assessment of existing national policy on health care in Montenegro in the area of quality and medical protocols;
- 1.2 Perform assessment and revision of existing medical protocols for treatment of breast cancer and cervical cancer;
- 1.3 Draft national medical protocols for the treatment of acute coronary syndrome, lung cancer and colorectal cancer;
- 1.4 Conduct a targeted support action focused on the formal adoption process of all developed and revised clinical protocols.

<u>Component 2</u> – Strengthening institutional capacities of healthcare professionals at Primary Healthcare Center of the Capital, the Clinical Center of Montenegro, and officials of the Health Insurance Fund of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines

#### Activities:

- 2.1 Organization of five trainings, 3 days each, for at least 30 healthcare professionals at Primary Health Center of the Capital and Clinical Center of Montenegro in the field of admission, application of therapy, prescribing and dispensing of medicines, consumption records, as well as management of the stocks of medicines in public health institutions;
- 2.2 Organization of five practical trainings, 3 days each, for at least 20 HIFM staff concerning joint analysis of relevant medical and supporting (administrative and financial) documentation in terms of the way of conducting control of records, especially related to control of records on realization of prescribed prescriptions (on natural and financial indicators) in healthcare institutions (public and private), with whom HIFM has signed agreements on cooperation practical examples;

- 2.3 Organization of 3 targeted capacity-building workshops, 3 days each, for at least 5 MoH staff (especially from the Directorate for Pharmaceutical Policy and Directorate for Quality Control) on EU health system reforms, rational prescribing oversight, and policy evaluation;
- 2.4 Organization of one study visit for 5 participants from HIFM for 5 days to the reference MS institution from the EU country in order to exchange knowledge and practical experience on site in aforementioned areas;
- 2.5 Organization of one lesson learned seminar for all participants to disseminate the results and best practices acquired at the end of the implementation period.

<u>Component 3</u> – Developing proposals for appropriate control mechanisms to rationalize medicine consumption and enable continuous monitoring of pharmaceutical stocks across public healthcare institutions

#### Activities:

- 3.1 Joint assessment of the current situation in the field of control mechanisms in Montenegro's healthcare system and their harmonization with EU requirements in specified area;
- 3.2 Development of methodology for creating control mechanisms;
- 3.3 MoH and HIFM to jointly conduct a regulatory gap analysis to identify any legal or procedural barriers that might prevent full implementation of proposed control mechanisms;
- 3.4 Joint assessment of the existing software solution in order to improve it in accordance to EU requirements in specific area;
- 3.5 Proposal for improvement of the existing software solution.
- 3.7 Means/input from the EU Member State Partner Administration\*:
  - Capacity building
  - Exchange of knowledge, experience and conducting continuous educations trough study visits and trainings
  - Providing analysis and recommendations for improvement of internal capacities and processes
  - Visibility and communication

The project is designed to provide exchange of experience and knowledge with a MS Institution with good practice in the aforementioned project activities. The project team will consist of a Project Leader, three Component Leaders and a pool of experts for *ad hoc* assignments. All experts shall meet the formal conditions as set out in the Twinning Manual. The interested MS Partner Institution shall include in its proposal the CV's of the designated Project Leader, three Component Leaders and the proposed Short-term Experts as well as their specific tasks to which they will be assigned.

#### Profile and tasks of the PL:

The Project Leader will ensure close cooperation of all relevant stakeholders in the overall steering, coordination and management of the project. He/she supports the Twinning project team, especially the Beneficiary Country Project Leader in organizational and technical matters. Together with the BC Project Leader (PL Counterpart), he/she will also coordinate the Project Steering Committee (PSC) on behalf of the MS Partner Institution. Supported by BC Project Leader, a high-ranking Member State official or assimilated agent with a significant rank to ensure an operational dialogue at political level, throughout the entire period of implementation. He/She directs the implementation of the Twinning project and formally signs all work plan(s) and/or any updates of these implementation.

More details on the PL tasks are presented at the end of this section.

The Project Leader must comply with the following requirements:

## Qualification and skills

- University degree in the field of Medicine, Health Management, or similar areas, or equivalent professional experience of 8 years
- Minimum 3 years of specific professional experience as a high ranking official in the field of public health or healthcare management;
- Fluency in English, both written and spoken;
- Excellent computer skills;
- Excellent management and communication skills;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

#### Description of the PL tasks

#### The PL:

- Direct the implementation of the Project in cooperation with the BC Project Leader;
- Supervises and coordinates the overall thrust of the Project;
- Ensures sound and timely implementation of the envisaged activities;
- Ensures the MS experts availability and timely mobilisation in compliance with the Project work plan and needs;
- Monitors and evaluates the needs and priorities in the respective sector, project risks, progress
  against the progress budget, benchmarks, and outputs, and taking any necessary remedial
  actions if needed;
- Ensures backstopping and sound financial management of the Project in the MS;
- With the BC PL, co-chairs the Project Steering Committee (PSC) and participates in the PSC meetings;
- Prepares necessary project reports.

## 3.7.1 Profile and tasks of Component Leaders:

The Twinning team will include a team of 3 Component Leaders, who will be responsible for specific components. Each Component Leader will comply with the minimum requirements presented below:

<u>Component 1 - Leader</u> (Improving existing national policy on medicines and quality of health care)

#### **Qualifications and skills:**

- University degree in the field of Medicine, Health Management, or similar areas, or equivalent professional experience of at least 8 years;
- At least 3 years of professional experience in developing policies on medicines and quality of health care, or other areas related to the component;
- Experience in implementing at least one international or EU-funded project of a similar nature will be considered an asset;
- Strong analytical, communication and team working skills;
- Fluency in English language (both oral and written);
- Excellent computer skills;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

#### Tasks:

- Support to the project leader in coordination of all activities in the component;
- Organize, coordinate and supervise the work of the short-term experts related to the component;
- Provide technical expertise for implementing activities defined by the work plan of the corresponding component.

<u>Component 2 - Leader</u> Strengthening institutional capacities of healthcare professionals at Primary Healthcare Center of the Capital, the Clinical Center of Montenegro, and officials of the Health Insurance Fund of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines)

#### Profile:

- University degree in the field of Medicine, Health Management, or similar areas, or equivalent professional experience of at least 8 years;
- At least 3 years of professional experience years in the field of capacity building of health workers and other activities related to the component;
- Experience in implementing at least one international or EU-funded project of a similar nature will be considered an asset;
- Strong analytical, communication and team working skills;
- Excellent English language skills (both oral and written);
- Excellent computer skills;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

### Tasks:

- Support to the project leader in coordination of all activities in the component;
- Organize, coordinate and supervise the works of short-term experts related to the component;
- Provide technical expertise for implementing activities defined by the work plan of the corresponding component and delivering the required outputs.

<u>Component 3 - Leader</u> (Developing proposals for appropriate control mechanisms to rationalize medicine consumption and enable continuous monitoring of pharmaceutical stocks across public healthcare institutions)

## Profile:

- University degree in the field of Medicine, Health Management, or similar areas, or equivalent professional experience of at least 8 years;
- At least 3 years of professional experience in the field of EU requirements and best practices of the IT (software) solutions related to control mechanisms and other activities related to the component;
- Strong analytical, communication and team working skills;
- Excellent English language skills (both oral and written);
- Excellent computer skills;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

## Tasks:

• Support the project leader in coordination of all activities in the component;

- Organize, coordinate and supervise the work of the short-term experts related to the component;
- Provide technical expertise for implementing activities defined by the work plan of the corresponding component and delivering the required outputs.

## 3.7.2. Profile and tasks of other short-term experts:

The Twinning team will also comprise Short-Team Experts (hereinafter: STEs). Each STE will satisfy the requirements below.

#### IT expert

#### Qualifications and skills:

- University degree in IT or equivalent professional experience of at least 8 years;
- Minimum 3 years of professional experience in ICT with focus on Health Information Systems;
- Knowledge of regulations, protocols and best practices used in Health Information Systems;
- Strong written, verbal and interpersonal-communication in English;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

#### Other STEs

#### Qualifications and skills:

- University degree in field of medical, pharmaceutical, health system management and economic background or other depending on activity, or equivalent professional experience of at least 8 years;
- At least 3 years of professional experience working with local and central government in the field of public healthcare;
- Strong written, verbal and interpersonal-communication in English;
- Prior experience in the Western Balkans and knowledge of local language will be considered as an asset.

It is expected that the Pool of Experts (STEs and Component Leaders) will include at least, without being limited to, the experts with the following profiles:

- 1 or more STEs with practical experience in drafting medical protocols (for all medical fields aforementioned);
- 1 or more STEs with operational experience in assessment of medical records;
- 1 or more STEs with practical experience in delivering trainings and education;
- 1 or more STEs skilled in performing control of medical and supporting (financial and administrative) documentation:
- 1 or more STEs skilled in maintaining records on the usage and control of application of different medicines.

Depending on the nature of the assigned tasks, the STEs will also be required to comply with one or more of the following requirements:

- Knowledge and in-depth understanding of the EU legislation and good practice in the field of public healthcare system;
- Experience in preparation and delivery of training or other educational activities;

• Hands-on experience in the respective field of expertise

Tasks of the STEs

#### STEs will:

- Closely work with Montenegrin partners in implementing all Twinning Project activities;
- Provide specialized assistance and support to BC staff (HIFM and MoH) in the areas identified as envisaged by the Project;
- Prepare the mission according to the instructions and considering requests by Montenegrin partners;
- Draft a mission report and handle all deliverables prepared.

## 4. Budget

Maximum budget available for the Grant – EUR 250.000

## 5. Implementation Arrangements

5.1 Implementing Agency responsible for tendering, contracting and accounting

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#### 5.2 Institutional framework

The beneficiary institutions of this project are the Health Insurance Fund of Montenegro and the Ministry of Health of Montenegro.

The Health Insurance Fund of Montenegro (HIFM) is a public institution established by the Government of Montenegro. It consists of a Central Unit, 12 regional units, and 13 local branches, employing a total of 208 staff members (73 in the Central Unit and 135 across regional units and branches).

The Central Unit is organized into six sectors:

- Sector for Contracting and Normative Affairs
- Sector for Health Insurance
- Sector for Planning and Control of the Implementation of Health Care Provider Contracts
- Sector for Economic Affairs
- IT Sector
- Sector for Damage Compensation, Representation, and Property-Legal Affairs

It also includes four departments:

- Human Resources Department
- International Cooperation and Project Management Department
- Internal Audit Department
- Department of Public Procurement Affairs

Within the HIFM as the Beneficiary Institution, the staff primarily involved in the implementation of project activities will come from the Sector for Planning and Control of the Implementation of Health Care Provider Contracts.

The Ministry of Health of Montenegro (MoH) is the competent authority responsible for the development and implementation of national health policies and legislation. It ensures the organization, functionality, and development of the healthcare system, with the overarching goal of protecting and improving public health in line with European Union standards and international best practices.

The Ministry's activities are focused on ensuring the availability, accessibility, and quality of healthcare services, strengthening health system governance, and improving efficiency, equity, and resilience within the health sector.

### Main Responsibilities:

- Preparation and implementation of legal and strategic documents in the field of healthcare and public health
- Supervision and coordination of public and private healthcare institutions
- Planning and management of national health programs, including disease prevention and health promotion
- Regulation and oversight of medicinal products, medical devices, and health technologies
- Management and oversight of the compulsory health insurance system
- Monitoring healthcare service quality and proposing system improvements
- Coordination of international cooperation, particularly with EU institutions, WHO, and other international stakeholders

The Ministry is headed by the Minister of Health and is structured into several internal units, including:

- Directorate for Public Health
- Directorate for Healthcare System Development
- Directorate for Pharmaceutical Policy and Medicines
- Directorate for EU Integration and International Cooperation
- Legal, Financial, and Administrative Services

A coordination mechanism for implementing project activities will be established through the **Project Steering Committee** (**PSC**), consisting of representatives from the Contracting Authority, the Beneficiary Institutions, the Twinning Partner, and other relevant stakeholders such as the Clinical Center of Montenegro and the Primary Healthcare Center of the Capital. The PSC will monitor, supervise, and coordinate the overall progress and implementation of the project. It will also provide strategic guidance, define priorities, approve and monitor budgets, and validate project outcomes.

## 5.3 Counterparts in the Beneficiary administration:

The PL counterpart will be a public servant of the Beneficiary administration and will be actively involved in the management and coordination of the project.

#### 5.3.1 Contact person:

Milena Lakušić Independent advisor I International Cooperation and Project Management Department Health Insurance Fund of Montenegro Vaka Đurovića bb 81000 Podgorica, Montenegro

5.3.2 PL counterpart

Ružica Milutinović Đurišić
Assistant Director
Sector for Planning and Control of the Implementation of Health Care Provider Contracts
Health Insurance Fund of Montenegro
Vaka Đurovića bb
81000 Podgorica, Montenegro

## 6. **Duration of the project**

Duration of the implementation period is 8 months plus 3 months for reporting.

## 7. Sustainability

Strengthened administrative and technical capacities of the HIFM, MoH and other public health institutions involved into the project, will become a permanent asset of Beneficiary institutions. Specific knowledge on preparation of relevant documentation, gained through the provision of expertise and/or trainings and coaching will ensure strengthened capacities in the long-run.

The sustainability of project results is ensured through policy proposals that will be backed up by drafting medical guidelines, after they are consulted with both internal and external stakeholders (interministerial consultations), as required by the Beneficiary country legislation.

The EU experts shall transfer their best practices and know-how necessary to achieve mandatory results to the Beneficiary administration. Long-term cooperation between HIFM and MS partner institution will be established by signing a Memorandum of Understanding. Staff benefiting from trainings shall transfer knowledge through subsequent training to their colleagues. It is also necessary to introduce appropriate education of the general public as well about the importance of rational prescription of medicines, especially when it comes to preventing the spread of communicable diseases, but also to raise awareness that in the absence of sufficient information about the disease and in the conditions of global pandemic, irrational and excessive use of medicinal products (especially antibiotics) would lead to extremely harmful and unforeseeable consequences for public health.

The Ministry of Health will lead a nationwide public awareness campaign as part of the national patient safety agenda, with a focus on promoting the rational use of medicines and the importance of early detection. The campaign will aim to enhance public understanding, engagement, and support for ongoing healthcare system reforms.

Moreover, at the end of the implementation period a lesson learned seminar will be held to disseminate the results and the best practices acquired and to foresee future relevant activities.

## **8. Crosscutting issues** (equal opportunity, environment, climate etc...)

Implementation of the project activities does not foresee activities which may have negative impact on the environment. All parties included in the project will take care of environmental safety during the implementation of project activities. Although this proposal is not primarily aimed at improving the environment, the added value is the opportunity of decreasing medical waste by introducing rational prescribing in accordance with EU standards.

All staff will be selected for training in accordance with their function and capacities to contribute to the overall objective of the project. All activities and progress of the project will be available at the HIFM's website. Based on fundamental principles of equal opportunities and fight against discrimination, the Project activities will be implemented in a manner promoting equal participation, regardless of gender, racial or ethnic origin, religion or belief, disability, age, political or sexual orientation.

Special account of the equal opportunity principles will be taken when designing and implementing communication activities to ensure that identified target groups are reached in an equal and non-discriminatory way. Positive measures will be designed to convey messages to all segments of the general public. This Twinning Project is environmentally neutral. No negative impact on the environmental protection is envisaged.

## 9. Conditionality and sequencing

This project is not dependent on the outcomes of other actions.

#### 10. Indicators for performance measurement

#### **Component 1** - Improving the existing national policy on medicines and quality of health care

Result 1.1 – Assessment report on existing medical practice with recommendation for policy changes in the field of quality of health care i.e. medical protocols, prepared;

Result 1.2 – Existing national protocols for treatment of breast cancer and cervical cancer are revised and updated.

*Result 1.3* – New national medical protocols for treatment of colorectal cancer, lung cancer and acute coronary syndrome are created.

Result 1.4 - Formal adoption of all revised and developed medical protocols by the National Committee for Healthcare Quality Assurance and Safety of the Ministry of Health, ensuring their integration into the national healthcare regulatory framework, including necessary legal, financial, and administrative adjustments to support long-term institutionalization.

#### **Indicators:**

1.1 Baseline data (2025): Assessment report on existing medical practice concerning application of national medical protocols in the field of therapy doesn't exist.

*Targeted data* (2025/26): One integrated report on existing medical practice concerning application of medical protocols and guidelines in the treatment of acute coronary syndrome, lung cancer, breast cancer, colorectal cancer, cervical cancer developed.

1.2 Baseline data (2025): Existing national protocols in the field of therapy for breast cancer and cervical cancer need to be revised.

Target data (2025/26): Two protocols (breast cancer and cervical cancer) are revised and improved.

1.3 Baseline data (2025): There are no national medical protocols in the field of therapy for acute coronary syndrome, lung cancer and colorectal cancer.

*Target data* (2025/26): Three protocols (acute coronary syndrome, lung cancer and colorectal cancer) are created.

1.4. Baseline data (2025): There are no national medical protocols in the aforementioned field formally adopted by the National Committee for Healthcare Quality Assurance and Safety.

*Target data* (2025/26): All revised and newly developed protocols formally adopted by the National Committee for Healthcare Quality Assurance and Safety and integrated into the national healthcare regulatory framework, with documented legal, financial, and administrative adjustments.

<u>Component 2</u> — Strengthening institutional capacities of healthcare professionals at Primary Healthcare Center of the Capital, the Clinical Center of Montenegro, and officials of the Health Insurance Fund of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines

Result 2.1 – The institutional and professional capacities of healthcare personnel at the Primary Healthcare Center of the Capital and the Clinical Center of Montenegro have been strengthened in key areas, including therapy management, prescribing practices, medication dispensing, and stock control.

Result 2.2 – Internal capacities of HIFM staff are enhanced to improve the quality of control over medical, administrative, and financial documentation – particularly regarding the monitoring of prescriptions (on natural and financial indicators) in healthcare institutions, including private healthcare institutions with whom HIFM has signed agreements on cooperation.

Result 2.3 - Enhanced internal capacity of MoH staff for policy evaluation and evidence-based decision-making.

#### **Indicators:**

**2.1 Baseline data (2025):** Healthcare professionals at public healthcare institutions (Primary Healthcare Center of the Capital and Clinical Center of Montenegro) have insufficient knowledge for proper admission, application of therapy, prescribing and dispensing of medicines, consumption records, as well as managing the stocks of medicines.

**Targeted data** (2025/26): Five trainings, 3 days each, organised for at least thirty healthcare professionals at Primary Health Center of the Capital and Clinical Center of Montenegro, in order to train them for proper admission, application of therapy, prescribing and dispensing of medicines, consumption records, as well as managing the stocks of medicines..

**2.2** Baseline data (2025): Staff employed at HIFM have insufficient knowledge for proper control of medical documentation.

*Target data* (2025/26): During five practical trainings, 3 days each, at least twenty people employed at HIFM educated for carrying out control of medical documentation, in the field of conducting the control of records and application of therapy, as well as in the field of control of records and realization of prescribed prescriptions in public and private healthcare institutions, with whom HIFM has agreements on cooperation signed.

**2.3 Baseline data** (2025): Staff employed at MoH (Directorate for Pharmaceutical Policy and Directorate for Quality Control) have limited knowledge on EU health system reforms, rational prescribing oversight, and policy evaluation.

*Target data* (2025/26): During 3 targeted capacity-building workshops, 3 days each, at least 5 MoH staff from the Directorate for Pharmaceutical Policy and Directorate for Quality Control trained in order

to enhance their knowledge on EU health system reforms, rational prescribing oversight, and policy evaluation

2.4. Baseline data (2025/26): No study visits between Montenegrin beneficiary institutions and EU Member State partner institutions in the area of quality of control over medical, administrative, and financial documentation have been conducted.

*Target data* (2025/26): At least one study visit in duration of 5 days for 5 people focused on best practices in mentioned area organised to MS partner institution.

**2.5** Baseline data (2025): Healthcare professionals at public healthcare institutions and staff employed at HIFM have limited knowledge for tracking and managing the usage and control of application of different medicines.

*Target data* (2025/26): At least one lesson learned seminar in duration of 3 days held for 50 participants (at least 10 participants per day) to disseminate the results and best practices acquired.

# <u>Component 3</u> – Developing proposals for appropriate control mechanisms to rationalize medicine consumption and enable continuous monitoring of pharmaceutical stocks across public healthcare institutions

- Result 3.1 A draft methodology for developing control mechanisms for medicines use and stock monitoring is created.
- Result 3.2 A set of proposals for establishing rational medicine consumption and stock monitoring mechanisms in public healthcare institutions is developed.
- Result 3.3 Regulatory and procedural gaps identified and addressed to enable the full implementation of proposed healthcare quality and safety control mechanisms.
- Result 3.4 Draft proposals for enhancing the existing software solution are prepared to enable improved surveillance and detection of irregularities in prescribing practices.

## **Indicators:**

- 3.1 Baseline data (2025): Methodology for creating control mechanisms doesn't exist. Target data (2025/26): One Methodology for creating control mechanisms developed.
- 3.2 Baseline data (2025): Control mechanisms for rationalization of consumption of medicines do not exist.

*Target data* (2025/26): At least one proposal for rationale medicine consumption and stock monitoring mechanism developed.

3.3 Baseline data (2025): No comprehensive regulatory gap analysis conducted; existing legal and procedural obstacles not systematically mapped or addressed.

Target data (2025/26): All identified gaps (as per gap analysis report) addressed by the end of the project implementation.

3.4. Baseline data (2025): Existing software solution doesn't comprise adequate system for monitoring the doctor's prescribing model and timely detection of irregularities in prescribing practice.

*Target data* (2025/26): Analysis of the existing system provided with clear recommendations for future upgrade.

## 11. Facilities available

The beneficiary will provide the Member State experts with necessary premises, PCs connected to the internet as well as other office equipment for the implementation of the activities.

Meeting room is available on working days upon timely request.

The premises of the Health Insurance Fund of Montenegro are located at Vaka Đurovića bb, 81000 Podgorica, Montenegro.

## ANNEXES TO PROJECT FICHE

- 1. Logical framework matrix as per Annex C1b
- 3. List of relevant Laws and Regulations
- 4. Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc.)

## Annex C1b: Simplified Logical Framework

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumption s (external to project)
Overall Objective	To contribute to the improvement of the public healthcare system in Montenegro by introducing rational prescribing practices in line with EU standards, thereby supporting the fulfilment of Montenegro's obligations under Negotiation Chapter 1 – Free movement of goods and Chapter 28 – Consumer and health protection	- Positive assessment report on progress in rationale medicine prescribing practice (Chapters 1 and 28) - Inclusion of rational prescribing in EC annual country report	- EU Commission Montenegro Report on progress to accession, in particular related to Chapter 28 and Chapter 1 - Reports from the Ministry of Health and HIFM - Project final report	- Required tasks not fully fulfilled - Resistance to change among healthcare professional s - Delays in national policy adoption	Willingness of cooperation within all relevant institutions - Continued political commitment to EU integration

	To establish a sustainable and				
	EU-aligned system for				
	rational prescribing of				
	medicines in the public				
	healthcare sector				
	in Montenegro, by	477.			
	1. Improving the	1.Existing national	1.1 Project progress reports	1. The dynamics of	1. Legal, institutional
	existing national policy on	medical protocols	1.2 Annual reports of the	the adoption of the	and strategic framework
	medicines and quality of health	improved and new medical	Beneficiary institution	appropriate protocol	already exists
	care	protocols developed, for	1.3 Minutes from the Steering	1.2 Political and	
		ACS and four	Committee	economic	
		most common malignant	Meetings	instability	
Specific		diseases in the country.			
Specific (Project)			<ul><li>2.1 Project reports</li><li>2.2 Annual</li></ul>	2. Identificatio	2. Willingness
Objective(s)	2. Strengthening	2.One lesson learnt seminar	reports of the Beneficiary	n of the importance	of cooperation
	institutional capacities of	held to disseminate	institution 2.3 Evaluation	of strengthenin	within all relevant
	healthcare professionals at	the results and the best	questionnaire/sur veys of targeted	g administrati	institutions
	Primary Healthcare	practices	staff 2.4 Minutes from	ve capacities	
	Center of the	acquired.	the Steering	by certain institutions	
	Capital, the Clinical Center		Committee Meetings		
	of Montenegro, and officials of				
	the Health Insurance Fund				
	of Montenegro (HIFM) for				
	tracking and managing the				
	usage and control of		3.1 Project reports		
	application of		3.2 Annual	3. Required	0.11
	different medicines		reports of the Beneficiary	tasks not fully	3.1Institutio nal and
			institution	fulfilled	strategic

3. Developing	3. At least one	3.3 Minutes from	framework
proposals for	proposal for	the Steering	already
appropriate	possible	Committee	exists
control	control	Meetings	3.2
mechanisms to	mechanism to	3.4 Attendance	Availability
rationalize	rationalize	lists and	of data and
medicine	medicine	evaluation from	IT
consumption	consumption	seminars	infrastructur
and enable	and		e
continuous	continously		
monitoring of	monitor		
pharmaceutical	medicine		
stocks across	stocks in		
public	public		
healthcare	healthcare		
institutions.	institutions		
	developed		

Mandatory results/outp uts by components	Result 1/Component 1  Improving the existing national policy on medicines and quality of health care  Result 1.1 - Assessment report on existing medical practice with recommendation for policy changes in the field of quality health care i.e. medical protocols prepared.	1.1 Baseline data (2025: Assessment report on existing medical practice concerning application of national medical protocols in the field of therapy doesn't exist. Targeted data (2025/26): One integrated report on	1.1.1 Evaluation reports 1.1.2 Project reports 1.1.3 Annual reports of the Beneficiary institution 1.1.4 MoH endorsement	1.1.1 Delays in preparation of the report and protocols due to insufficient communicat ion between project participants and other stakeholders 1.1.2 Change of the top management	1.1.1 Existence of legal and institutional framework 1.1.2 Willingness of cooperation within all relevant institutions 1.1.3 Sufficient administrati ve and professional capacities
	Result 1.2 – Existing national medical protocols for the treatment of breast cancer and cervical cancer are	application of national medical protocols and guidelines in the treatment of acute coronary syndrome, lung cancer, breast cancer, colorectal cancer, cervical cancer developed.  1.2 Baseline data (2025):	1.2.1 Evaluation reports 1.2.2 Project reports 1.2.3 Annual reports of the Beneficiary institution 1.2.4 Expert review documents	1.2.1 Delays in preparation of report and protocols due to insufficient communicat ion between project participants and other stakeholders	1.2.1 Existence of legal and institutional framework 1.2.2 Willingness of cooperation within all

revised and	Protocols in	1.2.5 Protocol	1.2.2	relevant
updated	the field of	publication	Change of	institutions
- Paulou	therapy for	r womenmon	the top	1.2.3
	breast cancer		management	Sufficient
	and cervical		1.2.3 Delays	administrati
	cancer need to		in validation	ve capacities
	be revised.		process	, c supusius
	Target data		1.2.4 Slow	
	(2025/26):		consensus	
	Two protocols		among	
	(breast cancer		clinical	
	and cervical		stakeholders	
	cancer)			
	revised and			
	improved.		1.3.1	
			Political	
			circumstanc	
			es that might	
			lead to a	
			change in	
		1.3.1 Project	priorities of	
		reports	authorities	
		1.3.2 Evaluation	1.3.2	1.3.
		reports	Change of	Existence of
		1.3.3 Protocol	the budget	legal and
		publication	allocated for	institutional
<b>Result 1.3</b> –		•	medicines	framework
New national			and medical	
medical			devices, in	
protocols for			sense of	
treatment of			insufficient	
acute coronary			funding for	
syndrome, lung			financing	
cancer, and	1.3 Baseline		rights on	
colorectal	data (2025):		medicines	
cancer are	There are no		and medical	
developed in	national		devices as	
compliance	medical		one of the	
with EU	protocols in		fundamental	
medical	the field of		rights	
standards and	therapy for		arising from	
best practice.	acute coronary		compulsory	
	syndrome,		health	
	lung cancer		insurance	
	and, colorectal			
	cancer.		1.4.1 Lack	
	Target data		of staff	
	(2025/26):		1.4.2 Slow	
	Three		consensus	
	protocols		among	
	(acute			

r	T	Τ	Т	T	
		coronary		Committee	
		syndrome,		stakeholders	
		lung cancer,			
		and colorectal			
		cancer)			
		created.	1.4.1 Official		
			decisions or		
			minutes from the		1.4.
			National		Existence of
			Committee		legal and
			meetings		institutional
			1.4.2 Protocols		framework
			published on		
	Result 1.4 -		official MoH		
	Formal		website		
	adoption of all				
	revised and				
	developed				
	medical				
	protocols by				
	the National				
	Committee for				
	Healthcare	1.4. Baseline			
	Quality	data (2025):			
	Assurance and				
		national			
	Safety of the				
	Ministry of				
	Health,	protocols in			
	ensuring their	the			
	integration into	aforementione			
	the national	d field			
	healthcare	formally			
	regulatory	adopted by the			
	framework,	National			
	including	Committee for			
	necessary	Healthcare			
	legal, financial,	Quality			
	and	Assurance and			
	administrative	Safety.			
	adjustments to	Target data			
	support long-	(2025/26): All			
	term	revised and			
	institutionalizat	newly			
	ion	developed			
	1011	_			
		protocols			
		formally			
		adopted by the			
		National			
		Committee for			
		Healthcare			
		Quality			
	<u>I</u>	, · · · · ·	<u> </u>	<u> </u>	<u> </u>

	Assurance and			
	Safety and			
	integrated into			
<u>Result</u>	the national			
2/Component 2	healthcare			
_	regulatory			
Strengthening	framework,			
institutional	with		2.1.1 Lack	
capacities of	documented		of staff	
healthcare	legal,		interested in	
professionals at	financial, and		education	
Primary	administrative		2.1.2	
Healthcare	adjustments.		Change of	
Center of the	<b>3</b>		the top	
Capital, the			management	
Clinical Center			of involved	
of Montenegro,			institutions	
and officials of				
the Health		2.1.1 Articles in		
Insurance Fund		newspapers		
of Montenegro		and/or website		2.1.1
(HIFM) for		2.1.2 Project		Willingness
tracking and		reports		of
managing the		2.1.3 Evaluation		cooperation
usage and		reports		within all
control of		· F · · · · ·		relevant
application of				institutions
different				2.1.2
medicines				Sufficient
				administrati
<b>Result 2.1</b> –				ve capacities
The				1
institutional				
and				
professional				
capacities of				
healthcare				
personnel at the				
Primary				
Healthcare				
Center of the				
Capital and the	2.1 Baseline			
Clinical Center				
of Montenegro	Healthcare			
have been	professionals			
strengthened in	at public			
key areas,	healthcare			
including	institutions			
therapy	(Primary			
management,	Healthcare			
prescribing	Center of the			

practices, medication dispensing, and stock control.	Capital and Clinical Center of Montenegro) have insufficient knowledge for proper admission, application of therapy, prescribing and dispensing of medicines, consumption records, as well as managing stocks of medicines  Targeted data (2025/26): Five trainings, 3 days each, organised for at least thirty	2.2.1 Articles published on the website 2.2.2 Project reports	2.2.1 Change of the top management	2.2.1 Existence of legal and institutional framework
Result 2.2 – Internal capacities of HIFM staff are enhanced to improve the quality of control over medical, administrative, and financial documentation	-	3		_
<ul> <li>particularly</li> <li>regarding the</li> <li>monitoring of</li> <li>prescriptions</li> <li>(on natural and</li> </ul>	well as managing the stocks of medicines.		2.3.1 Change of the top management	

	1	T	T	T
financial	2.2 Baseline			
indicators)	in   data (2025):			
healthcare	Staff			
institutions,	employed at			
including	HIFM have			
private	insufficient			
healthcare	knowledge for			
institutions	proper control			
with who				
	as documentatio			
		2.2.1 Antiples		
signed	n Tourset destruction	2.3.1. Articles		2.2.1
agreements	_	published on the		2.3.1
cooperation.	(2025/26) –	website		Existence of
	During five	2.3.2 Project		legal and
	practical	reports		institutional
	trainings, 3			framework
	days each, at			2.3.2
	least twenty			Willingness
	people			of
	educated for			cooperation
	carrying out			among
	control of			stakeholders
	medical			
	documentatio			
	n, in the field			
	of conducting			
	the control of			
Result 2.3	- records and			
Enhanced	application of			
internal	therapy, as			
	of well as in the			
MoH staff				
policy	of records and		241	
evaluation a			2.4.1	
evidence-bas	1		Change of	
decision-	prescriptions		the top	
making.	in healthcare		management	
	institutions			
	(public and			
	private), with			
	whom HIFM			
	has signed			
	agreements on			
	cooperation.			
	Î			
	2.3 Baseline			
	data (2025):	2.4.1. Articles		
	Staff	published on the		
	employed at	website		2.4.1
	МоН	2.4.2 Project		Existence of
	(Directorate	reports		legal and
	(Directorate	Торогия		10541 4114

	for	2.4.3		institutional
	Pharmaceutica	Memorandum of		framework
	1 Policy and	Understanding		2.4.2
	Directorate for	signed		Willingness
	Quality	C		of
	Control) have		2.5.1	cooperation
	limited		Change of	among
	knowledge on		-	stakeholders
	EU health			stakenoluers
			management	
	system			
	reforms,			
	rational			
	prescribing			
	oversight, and			
	policy			
	evaluation.			
	Target data			
	(2025/26):			
	During 3			
	targeted	2.5.1. Articles		
	capacity-	published on the		2.5.1
	building	website		Existence of
	workshops, 3	2.5.2 Project		legal and
	days each, at	reports		institutional
	least 5 MoH	•		framework
	staff from the			2.5.2
	Directorate for			Willingness
	Pharmaceutica			of
	1 Policy and			cooperation
	Directorate for			among
	Quality			stakeholders
	Control			stakenoiders
	trained in			
	order to			
	enhance their			
	knowledge on			
	EU health			
	system			
	reforms,			
	rational			
	prescribing			
	oversight, and			
	policy			
	evaluation			
	2.4 Baseline			
	data (2025):			
	No study visits			
	between			
	HIFM and EU			
	Member State			
	institutions in			

		the area of			
		quality of		3.1.1	
		control over		Change of	
		medical,		the top	
		administrative		management	
		, and financial		3.1.2 Delays	
		documentatio		in	
		n have been		preparation	
		conducted		of	
		Target data		methodolog	
		(2025/26): At		y due to	
		least one study		insufficient	
		visit in		communicat	
		duration of 5		ion between	
		days for 5		project	
		people to MS		participants	
		partner	3.1.1 Project	and other	3.1.1
		institution	report	stakeholders	Existence of
	<u>Result</u>	organised.	3.1.2 Annual		legal and
	3/Component 3	C	report of the	3.2.1	institutional
	<ul><li>Developing</li></ul>	2.5 Baseline	Beneficiary	Change of	framework
	proposals for	data (2025):	institution	the top	3.1.2
	appropriate	Healthcare		management	Willingness
	control	professionals		3.2.2 Delays	of
	mechanisms to	at public		in	cooperation
	rationalize	healthcare		preparation	within all
	medicine	institutions		of	relevant
	consumption	and staff		controlling	institutions
	and enable	employed at		mechanism	
	continuous	HIFM have		due to	
	monitoring of	limited		insufficient	
	pharmaceutical	knowledge for		communicat	
	stocks across	tracking and		ion between	
	public	managing the		project	
	healthcare	usage and		participants	
	institutions	control of		and other	
		application of		stakeholders	
	<b>Result 3.1</b> – A	medicines.	3.2.1 Project		3.2.1
	draft	Target data	report	3.3.1 Delays	Existence of
	methodology	(2025/26): At	3.2.2 Annual	in	legal and
	for developing	least one	report of the	institutional	institutional
	control	lesson learned	Beneficiary	coordination	framework
	mechanisms	seminar in	institution	or low	3.2.2
	for medicines	duration of 3		prioritizatio	Willingness
	use and stock	days held for		n of legal	of
	monitoring is	50 participants		reforms by	cooperation
	created.	(at least 10		decision-	within all
		participants		makers.	relevant
		per day) to		3.3.2	institutions
		disseminate		Limited	
		the results and		administrati	
<u> </u>				I	

П					
		best practices acquired.		ve or legal capacity	
		acquired.		within	
				institutions	
				to process	
				and	
				implement	
	<b>Result 3.2</b> – A			proposed	
	set of proposals		3.3.1 Final	changes.	3.3.1
	for establishing		regulatory gap	enanges.	Existence of
	rational		analysis report	3.4 Delays	legal and
	medicine		endorsed by the	in	institutional
	consumption		Ministry of	preparation	framework
	and stock		Health and Health	of drafted	3.4.2
	monitoring		Insurance Fund;	proposals	Willingness
	mechanisms in		3.3.2 Meeting	1 1	of
	public		minutes and		cooperation
	healthcare		decisions from		within all
	institutions is		the National		relevant
	developed.		Committee for		institutions
			Healthcare		
		3.1 Baseline	Quality		
		data (2025):	Assurance and		
		Methodology	Safety;		
		for creating	3.3.3 Progress		
		control	reports and		
		mechanisms	documentation		
		doesn't exist.	from project		
		Target data	working groups		
		(2025/26):	3.4.1 Project		
	Result 3.3 -	One Methodology	3		3.4.1
	Regulatory and	for creating	report 3.4.2 Annual		Existence of
	procedural	control	report of the		legal and
	gaps identified	mechanisms	Beneficiary		institutional
	and addressed	developed.	institution		framework
	to enable the	de veloped.	3.4.3		3.3.2
	full		Instructions/manu		Willingness
	implementatio		al for changes and		of
	n of proposed		improvement of		cooperation
	healthcare		existing software		within all
	quality and		solution		relevant
	safety control				institutions
	mechanisms				
		3.2 Baseline			
		data (2025):			
		Control			
		mechanisms to			
		rationalize			
		medicine			

	consumption		
	do not exist.		
	Target data		
	(2025/26): At		
<b>Result 3.4</b> –	least one		
Drafted	proposal for		
proposals for			
enhancing the			
existing	consumption		
software	and stock		
solution are	C		
prepared to			
enable	developed.		
improved			
surveillance			
and detection			
of irregularities			
in prescribing			
practice.	3.3 Baseline		
practice.	data (2025):		
	No (2023).		
	comprehensiv		
	e regulatory		
	gap analysis		
	conducted;		
	existing legal		
	and procedural		
	obstacles not		
	systematically		
	mapped or		
	addressed.		
	Target data		
	(2025/26): All		
	identified gaps		
	(as per gap		
	analysis		
	report)		
	addressed by		
	the end of the		
	project		
	implementatio		
	n.		
	3.4 Baseline		
	data (2025):		
	· ·		
	Existing		
	software		
	solution		
	doesn't		

comprise		
adequate		
system for		
monitoring the		
doctor's		
prescribing		
model and		
timely		
detection of		
irregularities		
in prescribing		
practice.		
Target data		
(2025/26):		
Analysis of		
the existing		
system		
provided with		
clear		
recommendati		
ons for future		
upgrade.		

Activities	Component 1 - Improving the existing national policy and quality of health care  1.1 Perfor m assessment of existing national policy on health care in Montenegro in the area of quality and medical protocols.	1.1 Baseline data (2025): Assessment report on existing medical practice concerning application of national medical protocols in the field of therapy doesn't exist. Targeted data (2025/26): 1.1.1 At least one assessment of existing national policy on health care performed 1.1.2 One integrated report on existing medical practice concerning application of medical protocols and guidelines in the treatment of acute coronary syndrome, lung cancer, breast cancer,	1.1.1 Evaluation reports 1.1.2 Project reports 1.1.3 Annual reports of the Beneficiary institution 1.1.4 Articles on the website  1.2.2 Project	1.1.1 Change of the top management 1.1.2 Delays in perform of the analysis due to insufficient communicat ion between project participants and other stakeholders  1.2.1 Delays in perform of the activity due to insufficient communicat	1.1.1 Existence of legal and institutional framework 1.1.2 Willingness of cooperation within all relevant institutions
	Perfor	colorectal	reports	ion between	

1				
m assessment	cancer,	1.2.3 Annual	project	institutional
and revision of	cervical	reports of the	participants	framework
existing	cancer	Beneficiary	and other	1.2.2
medical	developed.	institution	stakeholders	Willingness
protocols for		1.2.4 Articles on		of
treatment of		the website		cooperation
breast cancer	1.2 Baseline			within all
and cervical	data (2025):			relevant
cancer	Protocols in			institutions
	the field of			1.2.3.
	therapy for			Change of
	breast cancer			political
	and cervical			situation in
	cancer need to			the country
	revised.			
	Target data		1.3.1 The	
	(2025/26):		dynamics of	
	1.2.1 At least		the adoption	
	one		of the	
	assessment on	1.3.1 Evaluation	appropriate	
	existing	reports	regulation or	1.3.1
	medical	1.3.2 Project	protocol	Existence of
1.3 Draft	protocols	reports		legal and
national	performed 1.2.2 Two	1.3.3 Annual		institutional
medical	protocols	reports of the		framework
protocols for	(breast cancer	Beneficiary		1.3.2
the treatment	and cervical	1.3.4 Articles on		Willingness
of acute	cancer)	the Beneficiary		of
coronary	revised and	official website		cooperation
syndrome, lung cancer, and	improved.			within all
colorectal	improved.			relevant
				institutions
cancer	1.3 Baseline			
	data (2025):			
	There are no		1 4 1	
	national		1.4.1 Official	
	medical		decisions or	
	protocols in		minutes	
	the field of		from the	
	therapy for		National	
	acute coronary	1.4.1.066	Committee	
	syndrome,	1.4.1 Official	meetings	1.4.1 Lack
	lung cancer, and colorectal	decisions or minutes from the	C	of staff
	cancer	National	1.4.2	1.4.2 Slow
	Target data	Committee	Protocols	consensus
	(2025/26):	meetings;	published on	among
	Three	1.4.2 Protocols	official	Committee
1.4 Conduct a	protocols	published on	МоН	stakeholders
targeted .	(acute	paonisiea on	website	
support action	(40410			

			T	T
focused on the	coronary	official MoH		
formal	syndrome,	website		
adoption	lung cancer,			
process of all	and colorectal			
developed and	cancer,)			
revised clinical	developed.			
	developed.			
protocols				
	1.4. Baseline			
	data (2025):			
	There are no			
	national			
	medical			
	protocols in			
	the			
	aforementione			
	d field			
	formally			
	adopted by the			
	National			
	Committee for			
	Healthcare			
	Quality			
	Assurance and			
	Safety.			
	Target data			
	(2025/26): All			
	five (revised			
	and newly			
	developed)			
	protocols			
	formally			
	adopted by the			
	National National			
	Committee for			
	Healthcare			
Component 2 -				
Strengthening	Quality			
institutional	Assurance and			
capacities of	Safety and			
the healthcare	integrated into			
	the national			
professionals	healthcare			
at Primary	regulatory			
Healthcare	framework,			
Center of the	with			
Capital,	documented			
Clinical Center	legal,			
of Montenegro	financial, and			
and officials	administrative			
of the Health				
Insurance Fund	adjustments		2.1.1 Delays	
			in perform	

T		T	T	T
of Montenegro			of the	
(HIFM) for			activity due	
tracking and			to	
managing the			insufficient	2.1.1
usage and			communicat	Willingness
control of		2.1.1 Evaluation	ion between	of
application of		reports	project	cooperation
different		2.1.2 Project	participants	within all
medicines.		reports	and other	relevant
Activity 2.1		2.1.3 Annual	stakeholders	institutions
Organisation		reports of the	2.1.2 Lack	2.1.2
of five		Beneficiary	of staff	Motivation
trainings, 3		2.1.4 Articles on	interested in	of the parties
days each, for		the website	education	involved and
at least 30		2.1.5 List of		good
healthcare		participants on		cooperation
professionals		workshops		among
at Primary				twinned
Health Center				institutions
of the Capital				and project
and Clinical				teams in
Center of				project
Montenegro in				implementat
the field of				ion
admission,				
application of				
therapy,				
prescribing and	2.1 Baseline			
dispensing of	data (2025):			
medicines,	Healthcare			
consumption	professionals			
records, as	at public			
well as	healthcare			
management of	institutions			
the stocks of	(Primary			
medicines in	Healthcare			
public	Center of the			
healthcare	Capital and			
institutions.	Clinical			
	Center of			
	Montenegro)			
	have			
	insufficient			
	knowledge for			
	proper			
	admission,			
	application of			
	therapy,			
	prescribing			
	and			
	dispensing of			

	medicines,		2.2.1 Delays	
	consumption		in perform	
	records, as		of the	
	well as		activity due	
	managing the		to	
	stocks.		insufficient	
	Targeted data		communicat	
	(2025/26):		ion between	
	2.1.1. Five		project	2.2.1
	practical	2.2.1 Annual	participants	Willingness
	trainings, 3	Reports of the	and other	of .
	days each,	Beneficiary	stakeholders	cooperation
	organised for	2.2.2 List of	2.2.2 Less	within all
	healthcare	participants	participants	relevant
	professionals	2.2.3 Articles on	than it was	institutions
	2.1.2 At least	the website	planned	2.2.2
	thirty	2.2.4 Project		Motivation
Activity 2.2	healthcare	Report		of the parties
Organisation	professionals			involved and
of five	at Primary			good
practical	Healthcare			cooperation
trainings, 3	Center of the			among
days each, for	Capital and			twinned
at least 20	Clinical			institutions
HIFM staff	Center of			and project
concerning	Montenegro			teams in
joint analysis	trained for			project
of relevant	proper			implementat ion
medical and	admission,			1011
supporting	application of			
(administrative	therapy,			
and financial)	prescribing			
documentation	and			
in terms of the	dispensing of			
way of	medicines,			
conducting	consumption records, as			
control of	well as			
records,	managing the			
especially	stocks of			
related to	medicines.			
control of	medicilles.			
records on	2.2 Baseline			
realization of	data (2025):			
prescribed	Staff			
prescriptions	employed at			
(on natural and	HIFM have			
financial	insufficient			
indicators) in	knowledge for			
healthcare	proper control			
institutions	of medical			
		1	1	

1				
(public and private) with	documentatio		2.3 Change	
whom HIFM	n Tours of all looks		of the top	
	Targeted data		management	
has signed	(2025/26) –			
agreements on	2.2.1. At least			
cooperation –	five practical			
practical	training, 3			
examples.	days each, organised for			
	HIFM staff –			
	joint analysis			
	of medical			2.3.1
	and			Existence of
	supporting	2.3.1. Articles		legal and
	documentatio	published on the		institutional
	n - practical	website		framework
	examples	2.3.2 Project		2.3.2
	submitted in	reports		Willingness
	the member			of
	state			cooperation
	institution.			among
	2.2.2 At least			stakeholders
	twenty people			
	trained for			
Activity 2.3 -	carrying out			
Organization	control of			
of 3 targeted	medical			
capacity-	documentatio			
building	n, in terms of			
workshops, 3	the way of			
days each, for	conducting the			
at least 5 MoH	control of			
staff	records and			
(especially	application of			
from the	therapy, as well as in the			
Directorate for	field of			
Pharmaceutical	control of			
Policy and	records and			
Directorate for	realization of			
Quality	prescribed			
Control) on EU	prescriptions		2.4	
health system	in public and		Allocation	
reforms,	private		resources	
rational	healthcare			
prescribing oversight and	institutions,			
oversight, and policy	with whom			
evaluation	HIFM has			
Cvaruation	signed			
	agreements on			
	cooperation.			

ı		1			
	disseminate the				
	results and best				
	practices	2.4 Baseline			
	acquired at the	data			
	end of the	( <b>2025</b> ):No			
	implementatio	study visits			
	n period.	between			
	1	HIFM and EU			
		Member State			
		institutions in			
		the area of			
		quality of			
		control over			
		medical,		3.1.1	
		administrative		Resource	
		, and financial		allocation	
		documentatio		3.1.2 Delays	
				in perform	
		n. Tana at Jata		of the	
		Target data		activity due	
		(2025/26):		to	
		2.4.1 At least		insufficient	
		one study visit		communicat	
		in duration of		ion between	
		5 days		project	3.1
	Component 3	organised. for		participants	Motivation Motivation
	- Developing	5 participants		and other	of the parties
	proposals for	employed at	2110 : 4	stakeholders	involved and
	appropriate	HIFM to MS	3.1.1 Project	stanciioideis	good
	control	partner	report 3.1.2 Annual		cooperation
	mechanisms to	institution			among
	rationalize	25 D 1	report of the	2.2 Dolove	twinned
	medicine	2.5 Baseline	Beneficiary	3.2 Delays	institutions
	consumption	data (2025):	institution	in perform	and project
	and enable	Healthcare		of the	teams in
	continuous	professionals		activity due	project
	monitoring of	at public		to insufficient	implementat
	pharmaceutical	healthcare		communicat	ion
	stocks across	institutions		ion between	1011
	public	and staff			
	healthcare	employed at		project	
	institutions	HIFM have		participants and other	
		limited		and other stakeholders	
	Activity 3.1 –	knowledge for		stakenoiders	3.2.1
	Joint	maintaining			Existence of
	assessment of	records on the			legal and
	the current	usage and		3.3.1 Delays	institutional
	situation in the	control of		in	framework
	field of control	application of	3.2.1 Project	institutional	3.2.2
	mechanisms in	different	report	coordination	Willingness
	Montenegro's	medicines.		or low	of
				prioritizatio	

1. a a 141	T 1. 1	2 2 2 4 1	f11	·
healthcare	Target data	3.2.2 Annual	n of legal	cooperation
system and	(2025/26): At	report of the	reforms by	within all
their	least one	Beneficiary	decision-	relevant
harmonisation	lesson learned	institution	makers.	institutions
with EU	seminar in		3.3.2	
requirements	duration of 3		Limited	
in specified	days held for		administrati	
area.	50 participants		ve or legal	
	(10 people per		capacity	3.3.1
	day) to		within	Existence of
	disseminate		institutions	legal and
	the results and		to process	institutional
	best practices		and	framework
	acquired.		implement	3.4.2
	acquirea.		proposed	
Activity 3.2 –		3.3.1 Final	changes.	Willingness of
Development		regulatory gap	J.11411.505.	_
of the		analysis report		cooperation
methodology		endorsed by the	2451	within all
for creating		Ministry of	3.4 Delays	relevant
control		Health and	in perform	institutions
mechanisms.		Health Insurance	of the	
		Fund;	activity due	
		3.3.2 Meeting	to	
		minutes and	insufficient	
		decisions from	communicat	
		the National	ion between	
		Committee for	project	
		Healthcare	participants	
		Quality	and other	
		Assurance and	stakeholders	
		Safety;		
		3.3.3 Progress		
		reports and		
Activity 3.3 -		documentation		3.4.1
MoH and	3.1 Baseline			Existence of
HIFM to		from project		
jointly conduct	data (2025): There is no	working groups		legal and
a regulatory				institutional
gap analysis to	information			framework
identify any	on current	3.4.1 Project		3.4.2
legal or	situation in	report	3.5.1	Willingness
procedural	the field.	3.4.2 Annual	Allocation	of .
barriers that	Target data	report of the	of resources	cooperation
might prevent	(2025/26): At	Beneficiary		within all
full	least one joint	institution		relevant
implementatio	analysis of the	msutuuoli		institutions
n of proposed	current			
control	situation on			
mechanisms	control			
meenamsins	mechanisms			
 	in national			
		•	•	•

	healthcare		 
	system		
	performed.		
Activity 3.4 – Joint assessment of the existing software solution in order to improve it in accordance to EU requirements in specific are	control mechanisms doesn't exist.  Target data (2025/26): One Methodology for creating control mechanisms	3.5.1 Instructions/manu al for changes and improvement of existing software solution 3.5.2 Delays in perform of the activity due to insufficient communication between project participants and other stakeholders	3.5.1 Existence of legal and institutional framework 3.5.2 Willingness of cooperation within all relevant institutions
Activity 3.5 – Proposal for improvement of the existing software solution.	existing legal and		

implementatio		
n.		
3.4 Baseline		
data (2025):		
Control		
mechanisms		
to rationalize		
medicine		
consumption		
do not exist.		
Target data		
(2025/26):		
3.4.1 At least		
one joint		
analysis of the		
existing		
software		
performed 3.4.2 At least		
one		
controlling		
mechanism		
for		
consumption		
of medicines		
rationalization		
developed.		
3.5 Baseline		
data (2025):		
Existing		
software		
solution		
doesn't		
comprise		
adequate		
system for		
monitoring the		
doctor's		
prescribing		
model and		
timely		
detection of		
irregularities		
in prescribing		
practice.		

Target data (2025/26): Analysis of the existing system provided with clear recommendati on for future		
upgrade.		

## **Annex 2. List of relevant Laws and Regulations**

#### **Relevant EU Legislation**

- Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the Community Code relating to medicinal products for human use;
- Directive 1989/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medical products for human use and their inclusion in the scope of national health insurance systems;
- Regulation (EC) 726/2004 of the European Parliament and of the Council of March 31, 2004 on Community procedures for the approval and supervision of medicinal products for human and veterinary use and on the establishment of the European Medicines Agency;
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

## **National Legislation**

- Law on Compulsory Health Insurance ("Official Gazette of Montenegro", No. 14/21, 048/24)
- Law on Health Care ("Official Gazette of Montenegro", No. 003/16...084/24)

- Law on Medicines ("Official Gazette of Montenegro", No. 80/20, 084/24, 035/2025)
- Decision on determination the basic and supplementary list of medicines ("Official Gazette of Montenegro", No. 004/24)
- Regulation on Criteria for Adding or Removing Medicines from the Basic and Additional List of Medicines ("Official Gazette of Montenegro", No. 002/23, 123/23)

#### Annex 3.

Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc.)

- $\hbox{-}\ 2023-2027\ Strategy\ for\ Development\ of\ Healthcare\ system\ of\ Montenegro\ with\ its\ 2023-2024\ Action\ plan$
- 2025-2028 Strategy for Improving the Quality of Health care and Patient Safety with its 2025-2026 Action plan