ANNEX C1bis: Twinning Light Fiche [1]

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

Publication notice reference: EUROPEAID/185059/DD/ACT/ME

EU funded project

TWINNING TOOL

[1] 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	**Instrument for Pre-Accession Assistance**
MoH	**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 Overall Objective(s):

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*[2] 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*

[2] *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.[3]

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.

[3] 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.[4] 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.[5]

[4] Montenegro Report 2024, https://enlargement.ec.europa.eu/montenegro-report-2024_en
[5] 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[6] 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.

[6] 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.

Component 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.

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.

Component 3 – 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.

Component 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

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.

Component 3 – 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, co-ordination 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)

<u>Qualifications and skills:</u>

- 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.

Component 2 - Leader 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.

Component 3 - Leader (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 (inter-ministerial 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.

Component 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**

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.

Component 3 – **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**	**Assumptions (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 professionals - Delays in national policy adoption	- Willingness of cooperation within all relevant institutions - Continued political commitment to EU integration

Specific (Project) 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	1.Existing national medical protocols improved and new medical protocols developed, for ACS and four most common malignant diseases in the country. 2.One lesson learnt seminar held to disseminate the results and the best practices acquired.	1.1 Project progress reports 1.2 Annual reports of the Beneficiary institution 1.3 Minutes from the Steering Committee Meetings 2.1 Project reports 2.2 Annual reports of the Beneficiary institution 2.3 Evaluation questionnaire/surveys of targeted staff 2.4 Minutes from the Steering Committee Meetings 3.1 Project reports 3.2 Annual reports of the Beneficiary institution	1. The dynamics of the adoption of the appropriate protocol 1.2 Political and economic instability 2. Identification of the importance of strengthening administrative capacities by certain institutions 3. Required tasks not fully fulfilled	1. Legal, institutional and strategic framework already exists 2. Willingness of cooperation within all relevant institutions 3.1Institutional and strategic

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

Mandatory results/outputs 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. **Result 1.2** – Existing national medical protocols for the treatment of breast cancer and cervical cancer are	***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 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):***	1.1.1 Evaluation reports 1.1.2 Project reports 1.1.3 Annual reports of the Beneficiary institution 1.1.4 MoH endorsement 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	1.1.1 Delays in preparation of the report and protocols due to insufficient communication between project participants and other stakeholders 1.1.2 Change of the top management 1.2.1 Delays in preparation of report and protocols due to insufficient communication between project participants and other stakeholders	1.1.1 Existence of legal and institutional framework 1.1.2 Willingness of cooperation within all relevant institutions 1.1.3 Sufficient administrative and professional capacities 1.2.1 Existence of legal and institutional framework 1.2.2 Willingness of cooperation within all

	revised and updated **Result 1.3** – New national medical protocols for treatment of acute coronary syndrome, lung cancer, and colorectal cancer are developed in compliance with EU medical standards and best practice.	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) 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	1.2.5 Protocol publication 1.3.1 Project reports 1.3.2 Evaluation reports 1.3.3 Protocol publication	1.2.2 Change of the top management 1.2.3 Delays in validation process 1.2.4 Slow consensus among clinical stakeholders 1.3.1 Political circumstances that might lead to a change in priorities of authorities 1.3.2 Change of the budget allocated for medicines and medical devices, in sense of insufficient funding for financing rights on medicines and medical devices as one of the fundamental rights arising from compulsory health insurance 1.4.1 Lack of staff 1.4.2 Slow consensus among	relevant institutions 1.2.3 Sufficient administrative capacities 1.3. Existence of legal and institutional framework

		coronary syndrome, lung cancer, and colorectal cancer) created.	1.4.1 Official decisions or minutes from the National Committee meetings 1.4.2 Protocols published on official MoH website	Committee stakeholders	1.4. Existence of legal and institutional framework
	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	***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			

	<u>Result 2/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	Assurance and Safety and integrated into the national healthcare regulatory framework, with documented legal, financial, and administrative adjustments. ***2.1 Baseline data (2025):*** Healthcare professionals at public healthcare institutions (Primary Healthcare Center of the	2.1.1 Articles in newspapers and/or website 2.1.2 Project reports 2.1.3 Evaluation reports	2.1.1 Lack of staff interested in education 2.1.2 Change of the top management of involved institutions	2.1.1 Willingness of cooperation within all relevant institutions 2.1.2 Sufficient administrative capacities

	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	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 healthcare professionals at Primary Healthcare 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.	2.2.1 Articles published on the website 2.2.2 Project reports	2.2.1 Change of the top management 2.3.1 Change of the top management	2.2.1 Existence of legal and institutional framework

	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.	**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 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 healthcare institutions (public and private), with whom HIFM has signed agreements on cooperation. ***2.3 Baseline data (2025):*** Staff employed at MoH (Directorate	2.3.1. Articles published on the website 2.3.2 Project reports 2.4.1. Articles published on the website 2.4.2 Project reports	2.4.1 Change of the top management	2.3.1 Existence of legal and institutional framework 2.3.2 Willingness of cooperation among stakeholders 2.4.1 Existence of legal and

		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):*** No study visits between HIFM and EU Member State institutions in	2.4.3 Memorandum of Understanding signed 2.5.1. Articles published on the website 2.5.2 Project reports	2.5.1 Change of the top management	institutional framework 2.4.2 Willingness of cooperation among stakeholders 2.5.1 Existence of legal and institutional framework 2.5.2 Willingness of cooperation among stakeholders

	<u>*Result 3/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.	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 to MS partner institution organised. ***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 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	3.1.1 Project report 3.1.2 Annual report of the Beneficiary institution 3.2.1 Project report 3.2.2 Annual report of the Beneficiary institution	3.1.1 Change of the top management 3.1.2 Delays in preparation of methodology due to insufficient communication between project participants and other stakeholders 3.2.1 Change of the top management 3.2.2 Delays in preparation of controlling mechanism due to insufficient communication between project participants and other stakeholders 3.3.1 Delays in institutional coordination or low prioritization of legal reforms by decision-makers. 3.3.2 Limited administrati	3.1.1 Existence of legal and institutional framework 3.1.2 Willingness of cooperation within all relevant institutions 3.2.1 Existence of legal and institutional framework 3.2.2 Willingness of cooperation within all relevant institutions

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

	Result 3.4 – Drafted proposals for enhancing the existing software solution are prepared to enable improved surveillance and detection of irregularities in prescribing practice.	consumption 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.			

Activities	Component 1 - Improving the existing national policy and quality of health care 1.1 Perform assessment of existing national policy on health care in Montenegro in the area of quality and medical protocols. 1.2 Perfor	**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, colorectal	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 1.2.1 Evaluation reports 1.2.2 Project reports	1.1.1 Change of the top management 1.1.2 Delays in perform of the analysis due to insufficient communication between project participants and other stakeholders 1.2.1 Delays in perform of the activity due to insufficient communication between	1.1.1 Existence of legal and institutional framework 1.1.2 Willingness of cooperation within all relevant institutions 1.2.1 Existence of legal and

	m 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	cancer, cervical cancer developed. **1.2 Baseline data (2025):** Protocols in the field of therapy for breast cancer and cervical cancer need to revised. **Target data (2025/26):** 1.2.1 At least one assessment on existing medical protocols performed 1.2.2 Two protocols (breast cancer and cervical cancer) 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	1.2.3 Annual reports of the Beneficiary institution 1.2.4 Articles on the website 1.3.1 Evaluation reports 1.3.2 Project reports 1.3.3 Annual reports of the Beneficiary 1.3.4 Articles on the Beneficiary official website 1.4.1 Official decisions or minutes from the National Committee meetings; 1.4.2 Protocols published on	project participants and other stakeholders 1.3.1 The dynamics of the adoption of the appropriate regulation or protocol 1.4.1 Official decisions or minutes from the National Committee meetings 1.4.2 Protocols published on official MoH website	institutional framework 1.2.2 Willingness of cooperation within all relevant institutions 1.2.3. Change of political situation in the country 1.3.1 Existence of legal and institutional framework 1.3.2 Willingness of cooperation within all relevant institutions 1.4.1 Lack of staff 1.4.2 Slow consensus among Committee stakeholders

	focused on the formal adoption process of all developed and revised clinical protocols <u>Component 2</u> - Strengthening institutional capacities of the healthcare professionals at Primary Healthcare Center of the Capital, Clinical Center of Montenegro and officials of the Health Insurance Fund	coronary syndrome, lung cancer, and colorectal cancer,) developed. ***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 five (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	official MoH website	2.1.1 Delays in perform	

	of Montenegro (HIFM) for tracking and managing the usage and control of application of different medicines**.** **Activity 2.1** Organisation 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 healthcare institutions.	**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	2.1.1 Evaluation reports 2.1.2 Project reports 2.1.3 Annual reports of the Beneficiary 2.1.4 Articles on the website 2.1.5 List of participants on workshops	of the activity due to insufficient communication between project participants and other stakeholders 2.1.2 Lack of staff interested in education	2.1.1 Willingness of cooperation within all relevant institutions 2.1.2 Motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation

	Activity 2.2 Organisation 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	medicines, consumption records, as well as managing the stocks. ***Targeted data (2025/26):*** 2.1.1. Five practical trainings, 3 days each, organised for healthcare professionals 2.1.2 At least thirty healthcare professionals at Primary Healthcare Center of the Capital and Clinical Center of Montenegro trained 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	2.2.1 Annual Reports of the Beneficiary 2.2.2 List of participants 2.2.3 Articles on the website 2.2.4 Project Report	2.2.1 Delays in perform of the activity due to insufficient communication between project participants and other stakeholders 2.2.2 Less participants than it was planned	2.2.1 Willingness of cooperation within all relevant institutions 2.2.2 Motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation

	(public and private) with whom HIFM has signed agreements on cooperation – practical examples. **Activity 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	documentation ***Targeted data (2025/26)*** – 2.2.1. At least five practical training, 3 days each, organised for HIFM staff – joint analysis of medical and supporting documentation - practical examples submitted in the member state institution. 2.2.2 At least twenty people trained for carrying out control of medical documentation, in terms of the way 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 signed agreements on cooperation.	2.3.1. Articles published on the website 2.3.2 Project reports	2.3 Change of the top management 2.4 Allocation resources	2.3.1 Existence of legal and institutional framework 2.3.2 Willingness of cooperation among stakeholders

	Activity 2.4 - Organisation 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 **Activity 2.5** – Organisation of one lesson learned seminar for all participants to	***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	2.4.1 Project Progress Report 2.4.2 Mission agenda and participants list 2.4.3 Study visit report 2.4.4 Memorandum of Understanding signed 2.5.1 Project Progress Report 2.5.2 Project website 2.5.3 HIFM official website	2.5.1 Allocation of resources 2.5.2 Less participants than it was planned	2.4.1 Willingness of cooperation within all relevant institutions 2.4.2 Motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation 2.5.1 Willingness of cooperation within all relevant institutions 2.5.2 Motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation

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

	healthcare system and their harmonisation with EU requirements in specified area. **Activity 3.2** – Development of the methodology for creating control mechanisms. **Activity 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	***Target data (2025/26):*** At least one lesson learned seminar in duration of 3 days held for 50 participants (10 people per day) to disseminate the results and best practices acquired. ***3.1 Baseline data (2025):*** There is no information on current situation in the field. ***Target data (2025/26)***: At least one joint analysis of the current situation on control mechanisms in national	3.2.2 Annual report of the Beneficiary institution 3.3.1 Final regulatory gap analysis report endorsed by the Ministry of Health and Health Insurance Fund; 3.3.2 Meeting minutes and decisions from the National Committee for Healthcare Quality Assurance and Safety; 3.3.3 Progress reports and documentation from project working groups 3.4.1 Project report 3.4.2 Annual report of the Beneficiary institution	n of legal reforms by decision-makers. 3.3.2 Limited administrative or legal capacity within institutions to process and implement proposed changes. 3.4 Delays in perform of the activity due to insufficient communication between project participants and other stakeholders 3.5.1 Allocation of resources	cooperation within all relevant institutions 3.3.1 Existence of legal and institutional framework 3.4.2 Willingness of cooperation within all relevant institutions 3.4.1 Existence of legal and institutional framework 3.4.2 Willingness of cooperation within all relevant institutions

		healthcare system performed. ***3.2 Baseline data (2025):*** Methodology for creating control mechanisms doesn't exist. ***Target data (2025/26):*** One Methodology for creating control mechanisms 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	3.5.1 Instructions/manual 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 3.4 – Joint assessment of the existing software solution in order to improve it in accordance to EU requirements in specific area **Activity 3.5 –** Proposal for improvement of the existing software solution.				

		implementation. ***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 recommendation 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.)

- 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