ANNEX C1bis: Twinning Light Fiche

Project title: Strengthening the administrative capacity of the Institute for Medicines and Medical Devices of Montenegro regarding the requirements of the EU accession process

Beneficiary administration: Institute for Medicines and Medical Devices of Montenegro

Twinning Reference: MN 21 IPA HE 01 24 TWL

Publication notice reference: EUROPEAID/180627/DD/ACT/ME

EU funded project

TWINNING TOOL

ABBREVIATIONS	
AAP	Annual Action Plan
AO	Administrative Office
BC	Beneficiary Country
CInMED	Institute for Medicines and Medical Devices
CFCU	Central Financing and Contracting Unit
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
GDP	Good Distribution Practices
GVP	Good Vigilance Practices
LP	Lead Partner
MS	Member State
PL	Project Leader
PSC	Project Steering Committee
RTA	Resident Twinning Advisor
SAA	Stabilisation and Association Agreement
TNA	Training Needs Analysis
ToC	Table of Concordance
STE	Short-Term Experts
PL	Project Leader

1. Basic Information

1.1: Programme: Instrument for Pre-Accession Assistance III - Annual Action Programme in favour of Montenegro for 2022 (IPA/2022/JAD.1003560/AAP Montenegro 2022, ACT-60881-EU Integration Facility-ME2022AAP) – Direct management

1.2 Twinning Sector: *Health and consumer protection.*

1.3 EU funded budget: *EUR 250.000*

1.4 Sustainable Development Goals (SDGs): This project will address SDG 3 "*Good Health and Well-Being"*

2. Objectives

2.1 Overall Objective(s):

Provision of quality, safe and effective medicines and medical devices of appropriate performances on the Montenegrin market and supporting the development of the pharmaceutical market.

2.2 Specific objective:

Strengthening the administrative capacity and internal competences of the Institute for Medicines and Medical Devices of Montenegro with a focus on meeting the requirements of the EU accession process and harmonization of Montenegro's legal framework to align closely with the EU acquis

2.3

The Development Strategy of the Institute for the period 2022 – 2026, named: „Institute for Medicines and Medical Devices of Montenegro ready to become part of the European family“ determines strategic priorities and guidelines for the development of the Institute as a public authority of Montenegro for a five-year period, taking into account regulatory environment within Montenegro, western Balkan region and the European Union. Main goal of this strategy is to actively contribute to the creation of conditions for the development of pharmaceutical sector, as well as to the protection of public health through the regulation of medicines and medical devices in accordance with the EU acquis.

Based on challenges the Institute faces, this strategy defines key strategic areas and goals and analyses Institute’s strengths and weaknesses, threats and opportunities, as well as an action plan to meet strategic goals. Therefore, the strategic planning of the Institute's development is based on setting organizational, professional and technical bases for continuous improvement of working operation and business results, through regulatory harmonization, digitalization and process optimization, as well as through establishing partnership relations based on common values.

3. Description

3.1 Background and justification:

The pharmaceuticals sector in Montenegro is currently regulated by the Law on Medicines, approved by the Parliament in 2020. The Law, inter alia, defines the scope of action of the Institute and designates it as the Montenegrin authority in charge of pharmaceuticals. This law regulates the conditions for the manufacturing, marketing and testing of medicinal products for human use, measures for providing quality, safety and efficacy of medicinal products, competence of bodies in the field of medicinal products, as well as other relevant issues for performing these activities. The provisions of this Law applies on medicinal products intended for placing on the market, which are manufactured industrially or by a manufacturing process involving an industrial process.

Montenegro’s legal framework stipulating technical requirements and conformity assessment procedures for manufacturing, importing and placing on the market and/or putting into use medical devices is regulated by the Law on Medical Devices, which was adopted in 2019.

This project is regarded as a unique and much sought opportunity to gain a better understanding of state-of-the-art EU practices in the domain by liaising and sharing concrete experiences with professionals from an analogous institution. The Twinning will play a key role in strengthening the Institute administrative capacity by delivering a well-targeted mix of capacity building activities – consisting of tailored training, on-the-job assistance, workshops and joint activities that will mainly consist of the transfer of knowledge on the latest EU operational procedures including implementation of EU GMDP guidelines and the Compilation of Union Procedures, and feedback on examples of good practices (as well as on mistakes to be avoided). Strengthening of the Institute's administrative capacity will be of great importance for the fulfilment of another closing benchmark in Chapter 1 related to the obligation of Montenegro to demonstrate that it has the adequate administrative capacity to properly implement and enforce legislation transposing the EU pharmaceutical acquis and medical devices acquis, by the time of accession. The operational and practical approach will build upon previously gained theoretical knowledge and hands-on expertise acquired by the Institute staff and will be beneficial in terms of increased ability to independently perform daily duties. Similarly, the Twinning support is expected to help familiarization with newly- entrusted inspection tasks as well as to provide advice in designing effective working tools and in developing the technical and soft skills necessary to perform effective checks.

Targeted knowledge transfer and on-the-job support by qualified Member States practitioners, who possess relevant hands-on expertise and are fully conversant with good work practices in their own country, are expected to be very beneficial and help in drafting a comprehensive, clear and fully aligned set of rules and guidelines.

Area of medicines and medical devices is first closing benchmark for Negotiation Chapter 1 – Freedom of movement of goods. It is necessary to enhance and consolidate the institutional and operational capacities of the Institute for Medicines and Medical Devices of Montenegro to perform its statutory duties and contribute to the health care system improvement and patient protection, by ensuring compliance with the EU standards, guidelines and good practices.

The Project will contribute to the ongoing, massive effort undertaken by Montenegro to fulfil pre-accession obligations arising from Chapter 1 of the acquis. Free movement of goods encompasses the elimination of all technical barriers to the trade between the EU Member States. Due to the width and complexity of the related process of alignment with the Union acquis, the Twinning′s remit will be to support CInMED in its role of a sectoral Regulatory Body dealing with free movement of goods, thus contributing to the implementation of the activities envisaged by the Programme of Accession of Montenegro to the EU for the period 2022-2024.

3.2 Ongoing reforms:

Based on the Law on Medicines and the Law on Medical Devices, it is necessary to **revise the existing bylaws in the field of medicines** in order to achieve full compliance with the relevant EU regulations, and to adopt bylaws in the field of medical devices, bearing in mind that in this area there were no corresponding acts for implementation of the law.

The organizational structure was also changed in order to improve efficacy and evaluate applications for issuance of marketing authorisations from the Institute's jurisdiction, within the legally prescribed deadlines. Currently the Institute is organized in **6 expert centers** and one center for support (legal, economics and IT): Centre for medicines authorization, Centre

for medicines quality, safety and efficacy assessment, Centre for marketing and safe use of medicines, Centre for inspection supervision and market control, Centre for medical devices and Centre for development, science and innovations.

Currently the Institute employs 70 people. Administrative capacities are structured as follows:

- ✓ Number of employees on ***expert positions***: 48
- ✓ Number of employees in other fields – ***support***: 22
- ✓ Number of ***PhDs***: 6
- ✓ Number of ***Masters of Science***: 7
- ✓ Number of employees ***specialized*** in medicine or pharmacy: 14
- ✓ Number of ***doctoral students***: 10

Almost half of the mentioned employees were employed in the last two years with no previous experience in the regulatory affairs in the area of medicines and medical devices, and although they had an initial training in their respective fields, they need to be further educated especially for the expert scientific assessment of the documentation on medicines quality, safety and efficacy. In this moment, the Institute relies on external expert from other EU and regional regulatory bodies and universities.

3.3 Linked activities:

1. IPA Programme with the European Medicines Agency (EMA); IPA Assistance Programme – Participation in meetings and trainings as observers; Beneficiary: Institute for Medicines and Medical Devices of Montenegro; (between 2011-2017);
2. IPA 2014 Technical Assistance for Alignment and Implementation of the EU Internal Market acquis; EuropeAid/137978/IH/SER/ME; Institute for Medicines and Medical Devices of Montenegro was not a direct beneficiary of the funds; Activities related to support for preparation of secondary legislation in the field of medical devices. The project started on 26 November 2018 with an implementation period of two years – 26 November 2020;
3. Support to the **Agency for Medicines and Medical Devices of Montenegro (CALIMS);** EuropeAid/168188/IH/ACT/ME; Twinning project MN 16 IPA HE 01 20; Beneficiary: Institute for Medicines and Medical Devices of Montenegro, 340.000 euro; Twinning project with Agency for medicines and medical devices of Croatia (HALMED) with the aim to enhance and consolidate the institutional and operational capacities of CInMED. The project started on 29 January 2021 and lasted for 21 months, until 19 July 2022;
4. Collaborative grant scheme for innovative project ideas, Budget line: IPA II – Multi-annual Programme for Montenegro on Employment, Education and Social Policies (2015-2017); Monitoring the prescription of diclofenac with the aim of optimisation of its safe use, Reference: EuropaAid/1624567/ID/ACT/ME; Beneficiary: Institute for Medicines and Medical Devices of Montenegro, 75.000 euro; Monitoring the prescription of Diclofenac with the aim of optimisation of its safe use. The project started on 16 March 2020 and lasted for two years, until 16 November 2022;
5. Supply of equipment to specialized institutions of Montenegro for EU Internal Market Acquis implementation; EuropeAid/140478/IH/SUP/ME (Contract No. CFCU/MNE/144); Beneficiary: Institute for Medicines and Medical Devices of Montenegro, 293.071 euro; Laboratory equipment supplied: Modular Multipurpose

Powder Diffraction System and Benchtop Energy Dispersive X-Ray Fluorescence (EDXRF) Spectrometer for Elemental Analysis. Quantitative acceptance was signed on the day of delivery: 7th of December 2020 and after the initial checks Qualitative acceptance was signed on the 18th of December of the same year. After the delivery of the equipment, through following months, installation, IQ/OQ qualifications (Installation Qualification - IQ / Operational Qualification - OQ), as well as initial trainings for proper use and maintenance of the equipment were successfully carried out;

6. Data sharing and Investigative Platform against Organised Thefts of Medicines – MEDI-THEFT; European Commission DG HOME (ISF -Police), Co-partner, 40.000 euro; Strategic analysis and cross-border cooperation between public and private stakeholders through the development of an intelligence-based platform; The project started on 1 November 2021 and finalized on 31 October 2023;
7. TAIEX Expert Mission on marketing authorization of veterinary medical products on 07/03/2023 - 10/03/2023 Podgorica;
8. TAIEX Expert Mission on Challenges of Bioequivalence Assessment in applications for Generic Medicinal Products and Other types of application on 15-17/10/2019, Podgorica;
9. Instrument for Pre-accession Assistance (IPA) advanced virtual EMA training April 2021;
10. TAIEX Expert Mission on Conducting Inspections in Pharmacovigilance organized in co-operation with the Agency for Medicines and Medical Devices of Montenegro;
11. TAIEX Study Visit on Conducting Pharmacovigilance. Inspection organized in co-operation with Agency for Medicinal Products and Medical Devices of Croatia (HALMED) 25 February - 1 March 2019.

3.4 List of applicable *Union acquis*/standards:

- 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,
- 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 (EC) 1394/2007 of the European Parliament and the Council of 13 November 2007 on advanced therapy medicinal products and amends Directive 2001/83/EC and Regulation (EC) 726/2004,
- Regulation (EC) No 1901/2006 of the European Parliament and Council of 12 December 2006 on medicinal products for pediatric use and amendments to Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004,
- Regulation (EC) 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products,

- Regulation (EC) 1234/2008 of November 24, 2008 regarding the evaluation of variations of the marketing authorisation for medicinal products for human and veterinary use,
- Directive 2003/94/EC of October 8, 2003 on principles and guidelines of Good Manufacturing Practice for medicinal products for human use and investigational medicinal products for human use
- Regulation (EU) No 1252/2014 of 28 May 2014 on principles and guidelines of Good manufacturing practice for active substances,
- Guidelines of November 5, 2013 on Good Practice in the Distribution of Medicines for Human Use,
- Guidelines of March 19, 2015 on Good Practice in the Distribution of Active Substances for Medicinal Products for Human Use,
- Regulation (EU) 1235/2010 of the European Parliament and the Council of December 15, 2010, which in the part of pharmacovigilance for medicinal products for human use amends Regulation (EC) 726/2004 and Regulation (EC) 1394/2007,
- Good practice guidelines in pharmacovigilance (GVP) (EudraLex-Volume 9-Pharmacovigilance guidelines),
- Compilation of Union Procedures on Inspections and Exchange of Information,
- 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,
- Directive 89/105/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 (EU) 2017/745 of the European Parliament and Council of April 5, 2017 on medical devices, which amends Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and revokes Council Directives 90/385/EEC and 93/42/EEC.
- Regulation (EU) 2017/746 of the European Parliament and the Council of April 5, 2017 on in vitro diagnostic medical devices and repeals Directive 98/79/EC and Commission Decision 2010/227/EU.

3.5 Components and results per component

Component 1: Strengthening administrative capacity and internal competences of the CInMED

Result 1 - Strengthened administrative capacity and internal competences of the CInMED in the field of Medicines

Sub - result 1.1: Strengthened the internal capabilities of CInMED for conducting independent administrative and substantive assessments of documentation and improvement of the national medicines database. This includes different types of applications for issuing marketing authorizations for human medicines, specifically focusing on quality, safety, and efficacy documentation.

Sub - result 1.2: Strengthened CInMED's internal expert competencies for assessing variations, ensuring that medicines on the market are consistently accompanied by the most updated information.
Sub - result 1.3: Strengthened CInMED's internal expert competencies for dealing with medicines shortages

Result 2 - Strengthened administrative capacity and internal competences of the CInMED in the field of Medical Devices

Sub - result 2.1: Increased internal competencies in medical device vigilance and market surveillance, encompassing the management of quality defects and the protocol for withdrawing medicinal products from the market.

Result 3 - Strengthened administrative capacity and internal competences of the CInMED in the field of GxP inspections

Sub - result 3.1: Increased CInMED's internal competencies in conducting GxP inspections, ensuring compliance with EU guidelines on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)

Sub - result 3.2: Increased CInMED's internal capabilities to monitor rapid alerts and evaluate quality defects in medicines.

Result 4 - Strengthened internal competences of CInMED for public relations and international cooperation

Sub - result 4.1: Increased CInMED's internal competencies for public relations and international cooperation through training sessions, exchange of experience and joint participation in EC and EMA working groups.

Component 2: Recommendations for further harmonization of legal framework in Montenegro to achieve alignment with EU acquis

Result 5 - Set of recommendations for alignment with EU acquis and further harmonization of legal framework in Montenegro

Sub - result 5.1:
Set of recommendations to align the Law on medicines with the most recent EU acquis.

Sub - result 5.2:
Set of recommendations to align the Law on medical devices with the most recent EU acquis.

3.6 Expected activities:

Component 1 - Result 1 -: Strengthened administrative capacity and internal competences of the CInMED in the field of Medicines

Sub - result 1.1
Activities:
A.1.1.1: Joint review of assessments of medicines quality documentation, using practical examples from applications submitted in the Member State.
A.1.1.2: Conducted joint review of assessments of safety and efficacy documentation for different legal basis applications, utilizing practical examples from applications submitted in the Member State.
A.1.1.3: Conducted joint review of assessments of administrative and regional documentation for different application types, addressing major challenges. This activity should be conducted through a three - day study visit, involving five participants from CInMED in the Member State.
A.1.1.4: Organized training sessions on the national registry of medicines, mode and type of data on medicines imported into the national medicines database. This activity should be conducted during a two - day study visit involving three participants from CInMED in the Member State.

Sub - result 1.2
Activity:
A.1.2.1 Joint review of the assessments of variations documentation, using practical examples from variations submitted in the Member State. This activity should be conducted through a three - day study visit involving five participants from CInMED in the Member State.

Sub - result 1.3
Activity:
A.1.3.1: Organized workshop on medicines shortages actions in European Union

Result 2 - Component 1: Strengthened administrative capacity and internal competences of the CInMED in the field of Medical Devices

Sub - result 2.1
Activities
A.2.1.1: Training sessions on European medical devices vigilance system and market surveillance, encompassing the management of quality defects and the protocol for withdrawing medicinal products from the market.

Result 3 - Component 1: Strengthened administrative capacity and internal competences of the CInMED in the field of GxP inspections

Sub - result 3.1
Activities:
A.3.1.1 Perform joint and/or mock up GMP - (practical training – joint/mock up inspection) in the Member State or some other country, depending on inspection plans
A.3.1.2 Perform joint and/or mock up GDP - (practical training, joint/mock up inspection) in Montenegro or Member State, depending on inspection plans

Plan and location of joint inspections depend on the annual plan of inspections in the Member State and CInMED. Inspectors from CInMED would join inspection team from the MS in their already planned and scheduled inspections, as observers and vice versa. Also mock up inspection could be planed.

Sub - result 3.2
Activity:
A.3.2.1 Training sessions on monitoring rapid alerts and evaluate quality defects of medicines using practical examples from the Member State.

Result 4 - Component 1: Strengthened internal competences of CInMED for public relations and international cooperation

Sub - result 4.1
Activity:
A.4.1.1. Training sessions for public relations and international cooperation – practical examples and exercises to help achieve good communication and collaboration with future EU regulatory partners.
A.4.1.2. Training sessions for social media visibility enhancement, digital marketing skills and crisis management PR

Result 5 - Component 2: Recommendations for alignment with EU acquis and further harmonization of legal framework in Montenegro

Sub - result 5.1:
Activity:
A.5.1.1 Perform joint analysis of legal framework in Montenegro and suggest priority steps and recommendations for achieving full alignment with EU acquis concerning Law on medicines

Sub - result 5.2:
Activity:
A.5.2.1 Perform joint analysis of legal framework in Montenegro and suggest priority steps and recommendations for achieving full alignment with EU acquis concerning Law on medical devices

3.7 Means/input from the EU Member State Partner Administration:

Profile and tasks of the PL: (Project leader can simultaneously be one of the component leaders)

A high-ranking Member State official or assimilated agent with a sufficient rank to ensure an operational dialogue at political level, throughout the entire period of implementation. He 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:

- Proven contractual relation to a public administration or mandated body

Qualification and skills

- University degree in the field of Pharmacy, Medicine, Dentistry, Law or equivalent professional experience of at least 8 years;
- At least three years of professional experience in the field of pharmaceuticals, public health protection or health care administration;
- Fluency in the English language, both written and spoken;
- Experience in implementing at least one international or EU-funded project of a similar nature will be considered an asset;
- Excellent management and communication skills;
- Computer literacy.

Description of the PL tasks

The PL:

- Directs 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 project 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.

3.7.1 Profile and tasks of Component Leaders*:*

The Twinning Team will include a team of 2 Component Leaders. Each Component Leader will comply with the minimum requirements presented below:

Component Leader 1 (Strengthening administrative capacity and internal competences of the CInMED)

Qualifications and skills

- University degree in the field of Pharmacy, Medicine, Dentistry or similar discipline relevant to the Project or equivalent professional experience of 8 years;
- At least 3 years of specific experience 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 initiative, analytical and team working skills;
- Fluency in English language (both oral and written)

Component Leader 2 (Recommendations for further harmonization of legal framework in Montenegro to achieve alignment with EU acquis)

Qualifications and skills

- University degree in the field of Law, Pharmacy, Medicine, Dentistry or similar discipline relevant to the Project or equivalent professional experience of 8 years;
- At least 3 years of specific experience related to the component;
- Experience in implementing at least one international or EU-funded project of a similar nature will be considered as asset;
- Strong initiative, analytical and team working skills;
- Fluency in English language (both oral and written);

Each Component Leader will be responsible for coordinating the assigned component.

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

The Twinning team will comprise a pool of Short-Term Experts (hereinafter: STEs). Each STE will satisfy the requirements listed below.

Qualifications and skills

- University Degree in the field of Pharmacy, Human Medicine, Veterinary Medicine, Dentistry, Biosciences, Law or other depending on the activity or equivalent professional experience of at least 5 years[1].
- At least three years of professional experience working in a regulatory and/or supervisory body in the field of medicines and medical devices;
- Fluency in the English language, both written and spoken;
- Excellent communication skills;
- Computer literacy.

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 STE(s) with practical experience in the administrative assessment of applications for Marketing Authorizations for Human medicines;
- 1 or more STE(s) with practical experience in the substantive (QSE) assessment of applications for Marketing Authorizations for Human medicines;
- 1 or more STE(s) with practical experience in the administrative and substantive assessment of variations

[1] Additionally, for some activities under this Twinning Light, the STEs should hold a university degree in specific areas as for some of the activities (i.e. GMP and GDP inspections) minimum qualifications are set out in the relevant EU legislation - *Compilation of Community Procedures on Inspections and Exchange of Information updated to include new EU formats and procedures.* In line with this document, inspectors should have the same level of qualification as the "Qualified Person" as defined in Art. 48 of Directive 2001/83/EC, in Art. 52 of Directive 2001/82/EC and this means a university course of study with the listed basic subjects.

- 1 STE with practical experience in dealing with medicine shortages
- 1 STE with operational experience in Medical Devices assessment and Medical Devices surveillance activities;
- 1 or more STE(s) skilled in performing GMP inspections;
- 1 or more STE(s) skilled in performing GDP inspections ;
- 1 or more STE (s) with Experience in drafting legislation, guidelines and instructions in the field of medicines and/or medical devices to ensure approximation with the EU legislation and other international acts / guidelines in the sector;
- 1 or more STE (s) with experience in Public Relations and International communication

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

- Knowledge and in-depth understanding of the EU legislation and good practices in the field of medicines and/or medical devices, with emphasis on their specific area of expertise;
- Experience in preparation and delivery of training or other educational activities;
- Hands-on experience in the respective field of expertise;
- Experience in design and delivery of communication events and campaigns in the domain of medicinal products / pharmaceuticals and experience to interact with media professionals.

Tasks of the STEs

STEs will:

- Closely work with Montenegrin partners in implementing all Twinning Project activities;
- Provide specialized assistance and support to CInMED staff in the areas identified, and in the modalities envisaged, by this Twinning Fiche;
- Prepare the mission according to instructions, familiarizing themselves with relevant documentation, and drafting supporting materials, if the mission requires (e.g. if delivering training);
- Diligently perform the mission, according to the instructions and considering the requests by Montenegrin partners;
- At the end of the mission, draft a brief mission report and handle all deliverables prepared.

4. Budget

Twinning light project budget: Max 250.000 €

5. Implementation Arrangements

5.1 Implementing Agency responsible for tendering, contracting and accounting:

The Delegation of European Union will act as a Contracting Authority for the project, which will be responsible for all aspects for the project's tendering, contracting and accounting.

The contact person on behalf of the EU Delegation is:

Felix Schaus

Attacheé – Project Manager

Vuka Karadžica 12

81000 Podgorica

Tel.: +382 (0) 20 444 600

Web: www.delmne.ec.europa.eu

Email: DELEGATION-MONTENEGRO-*TWINNING@eeas.europa.eu*

5.2 Institutional framework

The beneficiary institution of this project is the Institute for Medicines and Medical Devices of Montenegro (CInMED)

The Institute is organized in 6 expert centers and one center for support (legal, economics and IT). Centers that will benefit from this project are:

— *Centre for medicines authorization,*

— *Centre for medicines quality, safety and efficacy assessment,*

— *Centre for marketing and safe use of medicines,*

— *Centre for inspection supervision and market control,*

— *Centre for medical devices.*

The first two centers are conducting the same process of issuing marketing authorizations and they cooperate closely. Other centers are independent in their jurisdictions. Centre for development, science and innovations will be in charge for organizational and technical part of project conducting.

Results of the project will not lead to a major change of the institutional framework as described, but they might lead to some changes such as more precise job descriptions or division of jurisdiction between centers.

5.3 Counterparts in the Beneficiary administration:

Mira Kontić

Deputy Managing Director

email address: mira.kontic@cinmed.me

Anđela Drašković

Regulatory Associate in the department of medicines and for scientific and research activities

email address: andjela.draskovic@cinmed.me

5.3.1 Contact person

Anđela Drašković

Regulatory Associate in the department of medicines and for scientific and research activities

Bulevar Ivana Crnojevića 64a, Podgorica, Montenegro

email address: andjela.draskovic@cinmed.me

Specify the name, official position and postal address

5.3.2 PL counterpart

Mira Kontić

Deputy Managing Director

Bulevar Ivana Crnojevića 64a, Podgorica, Montenegro

6. Duration of the project

8 months

7. Sustainability

This Twinning Light Project will provide support to CInMED to increase its institutional and expert capacity in the field of Medicines and Medical devices in a more specific and detailed way, making it a continuation of all the previous EU funded projects.

CInMED has recruited 20 new employees in the past two years and this project represents a great opportunity for further consolidation of the new employees and the senior staff. CInMED puts a lot into education and competences of its employees, particularly the new ones, therefore we expect that this project will help further professional development and motivation in the growing CInMED team.

Twinning Experts delivering training will be asked to develop and include in their mission reports concise support materials, which senior staff can further use to train newly recruited employees during their introduction period, even after the delivery of the relevant capacity building activity, or after the Twinning Light Project's conclusion. It is expected that this will maximise the sustainability of results, extending it to CInMED newly recruited staff that could not directly benefit from the Twinning experience.

Another specific objective with the focus on the alignment of sectoral legal framework will help draft legislation documents and new laws. Providing support to CInMED in producing

legislation aligned with the newly adopted legislation in EU, will lead to sustainable achievements, as all the acts prepared – implementing acts, guidelines and instructions – once approved, will be part of the Montenegrin body of law for the years ahead.

Knowledge and experience of CInMED experts gained through the activities in the Twining light project will help increase work efficacy and therefore better financial results for CInMED in the future.

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

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

Not applicable

10. Indicators for performance measurement

Beneficiary of this project will be Institute of Medicines and Medical devices of Montenegro (CInMED), employees that work in different Centres and fields of the Institute.

Component 1: Strengthening administrative capacity and internal competences of the CInMED in the field of Medicines

Result 1: Strengthened administrative capacity and internal competences of the CInMED in the field of Medicines

Sub - result 1.1: Strengthened the internal capabilities of CInMED for conducting independent administrative and substantive assessments and improvement of the national medicines database. This includes different types of applications for issuing marketing authorizations for human medicines, specifically focusing on quality, safety, and efficacy documentation.

Sub - result 1.2: Strengthened CInMED's internal expert competencies for assessing variations, ensuring that medicines on the market are consistently accompanied by the most updated information.
Sub - result 1.3: Strengthened CInMED's internal expert competencies for dealing with medicines shortages

Indicators

1.1.1 Number of practical examples, from the Member State, of medicine quality documentation assessment reviewed during a workshop

1.1.2 Number of practical examples from the Member State of the safety and efficacy documentation for different legal basis applications assessment, reviewed during a workshop

1.1.3 Number of people trained in the assessment of the administrative and regional documentation of different types of applications, through practical examples, during one study visit in the MS

1.1.4 Number of people trained about national registry of medicines and mode and type of data imported into the national medicines database, during one study visit in the MS

1.2.1. Number of people trained for the assessments of the variations documentation from the member state, during one study visit in the MS

1.3.1 Number of people attending workshop on medicines shortages

Target:

1.1.1 Two practical examples from the Member State of the quality documentation assessment reviewed during a workshop

1.1.2 Two practical examples of the safety and efficacy documentation for different legal basis applications from the Member State reviewed during a workshop

1.1.3 Five people trained in the assessment of the administrative and regional documentation of different types of applications, through practical examples, during one study visit in the MS.

1.1.4 Three people trained about national registry of medicines and mode and type of data imported into the national medicines database, during one study visit in the MS.

1.2.1 Five people trained for the assessments of the variations documentation from the member state, during one study visit in the MS

1.3.1. Five people attending workshop on medicines shortages

Result 2: Strengthened administrative capacity and internal competences of the CInMED in the field of Medical Devices

Sub - result 2.1: Increased internal competencies in medical device vigilance and market surveillance, encompassing the management of quality defects and the protocol for withdrawing medicinal products from the market.

Indicators:

2.1.1 Number of people trained for carrying out medical devices market surveillance, vigilance, technical evaluation of medical devices, quality defects and withdrawal from the market

2.1.2 Number of joint and/or mock up surveillances conducted on the territory of Montenegro or territory of the Member State

Target:

2.1.1 Four people trained for carrying out medical devices market surveillance, vigilance, technical evaluation of medical devices, quality defects and withdrawal from the market;

2.1.2 One joint and/or mock up surveillance conducted on the territory of Montenegro or territory of the Member State;

Result 3: Strengthened administrative capacity and internal competences of the CInMED in the field of GxP inspections

Sub - result 3.1: Increased CInMED's internal competencies in conducting GxP inspections, ensuring compliance with EU guidelines on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

Sub - result 3.2: Increased CInMED's internal capabilities to monitor rapid alerts and evaluate quality defects in medicines.

Indicators:
3.1.1. Number of joint and/or mock up GMP inspection conducted on the territory of the Member State or some other country, depending on the inspection plans
3.1.2 Number of joint and/or mock up GDP inspection conducted on the territory of Montenegro or on the territory of the Member State, depending on the inspection plans
3.2.1 Number of people trained for rapid alerts and quality defects

Target:
3.1.1 One joint and/or mock up GMP inspection conducted on the territory of the Member State or some other country, depending on the inspection plans
3.1.2 One joint and/or mock up GDP inspection conducted on the territory of Montenegro or on the territory of the Member State, depending on the inspection plans
3.2.1 Ten people trained for rapid alerts and quality defects

Result 4 - Strengthened internal competences of CInMED for public relations and international cooperation
Sub - result 4.1: Increased internal competences of CInMED for public relations and international cooperation through training sessions, exchange of experience and joint participation in EC and EMA working groups

Indicators:
4.1.1. Number of people trained for public relations and international cooperation activities through training sessions, exchange of experience and joint participation in EC and EMA working groups
4.1.2 Number of people trained social media visibility, digital marketing and crisis management PR

Target
4.1.1: Three people trained for public relations and international cooperation activities, through training sessions, exchange of experience and joint participation in EC and EMA working groups

4.1.2. Two people trained for social media visibility, digital marketing and crisis management PR

Component 2: Recommendations for further harmonization of legal framework in Montenegro to achieve alignment with EU acquis

Result 5 – Set of recommendations for alignment with EU acquis and further harmonization of legal framework in Montenegro

Sub - result 5.1: Set of recommendations for alignment of Law on medicines with the most recent EU acquis

Sub - result 5.2:
Set of recommendations for alignment of Law on medical devices with the most recent EU acquis

Indicator
5.1.1 Gap report and draft of proposed recommendations for amendments to the Law on medicines that need further harmonization with the most recent EU legislation
5.2.1 Gap report and draft of proposed recommendations for amendments to the Law on medical devices that need further harmonization with the most recent EU legislation

Target:
5.1.1. One gap report and draft of proposed recommendations for amendments to the Law on medicines that need further harmonization with the most recent EU legislation

5.2.1 One gap report and draft of proposed recommendations for amendments to the Law on medical devices that need further harmonization with the most recent EU legislation

11. Facilities available

The Beneficiary will provide the Member State experts with the necessary working premises for the implementation of the activities. The premises of the Institute for Medicines and Medical Devices of Montenegro are located at Bulevar Ivana Crnojevića 64a, Podgorica, Montenegro. Meeting room is available on working days upon timely request. In the CInMED building all security-related issues have been addressed (the building has a security service during and outside working hours and it is also secured by an alarm system outside working hours.) CInMED has a fully equipped conference room with a capacity for 80 people, which is used, for training, seminars and conferences. This conference room is equipped with the video projector and an interpretation booth.

ANNEXES TO PROJECT FICHE

Annex 1. Logical framework matrix

Annex 2. List of relevant Laws and Regulations

Annex 1: Simplified Logical Framework matrix

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	*Provision of quality, safe and effective medicines and medical devices of appropriate performances on the Montenegrin market and supporting the development of the pharmaceutical market.*	Increased efficacy of CInMED in the process of assessment of applications for marketing authorisation of medicines	EC Progress Report CInMED yearly activity reports	Institute for Medicines and Medical Devices staff - maintaining sufficient number of assessors, trained GMDP inspectors and other employees with appropriate competences	Cooperation with other institutions in the healthcare system of Montenegro Political and economic instability in Montenegro

Specific (Project) Objective(s)	Strengthening the administrative capacity and internal competences of the Institute for Medicines and Medical Devices of Montenegro with a focus on meeting the requirements of the EU accession process and harmonization of Montenegro's legal framework to align closely with the EU acquis	Strengthened capacity of Institute of Medicines and Medical Devices Set of recommendations for harmonization of legal framework in Montenegro in order to achieve increased alignment with EU acquis	CInMED yearly activity reports Twinning Light Project Reports Official Gazette of Montenegro EC Progress Report	Resource allocation - the effective allocation of human and technological resources Conditions for employees in public sector are worsened and Institute is not able to maintain its staff due to better conditions offered by the pharmaceutical industry Political and economic instability and lack of political support for adoption and enforcement of legislation Loss of critical competencies or key people in the project	CInMED staff turnover remains within levels that do not threaten the delivery and the sustainability of capacity strengthening Full commitment and motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation
Mandatory results/outputs by components	Component 1 Result 1 - Strengthened administrative capacity and internal competences of the CInMED in the field of Medicines Sub - result 1.1: Strengthened the internal capabilities of CInMED for conducting independent administrative and substantive assessments of documentation and improvement of the national medicines database. This includes different types of applications for issuing marketing authorizations for human medicines, specifically focusing on quality, safety and efficacy documentation. Sub - result 1.2: Strengthened CInMED's internal expert competencies for assessing variations, ensuring that medicines on the market are consistently accompanied by the most updated information.	Result 1 Sub - result 1.1.: Indicators: 1.1.1 Number of practical examples, from the Member State, of medicine quality documentation assessment reviewed during a workshop (Baseline:0; Target:2) 1.1.2 Number of practical examples, from the Member State, of the safety and efficacy documentation for different legal basis applications assessment reviewed during a workshop (Baseline:0; Target:2) 1.1.3 Number of people trained in the assessment of the administrative and	Final Twinning light Report CInMED yearly activity reports Documentation produced under the project (Assessment reports, joint inspection reports, Set of recommendations for harmonization of legal framework List of participants on trainings	Resource allocation - the effective allocation of human and technological resources Loss of critical competencies or key people in the project Less participants than it is planned	Full commitment and motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation Good communication and cooperation between Project Leader and Short term experts

	Sub - result 1.3: Strengthened CInMED's internal expert competencies for dealing with medicines shortages Result 2 - Strengthened administrative capacity and internal competences of the CInMED in the field of Medical Devices Sub - result 2.1: Increased internal competencies in medical device vigilance and market surveillance, encompassing the management of quality defects and the protocol for withdrawing medicinal products from the market. Result 3 - Strengthened administrative capacity and internal competences of the CInMED in the field of GxP inspections Sub - result 3.1: Increased CInMED's internal competencies in conducting GxP inspections, ensuring compliance with EU guidelines on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Sub - result 3.2: Increased CInMED's internal capabilities to monitor rapid alerts and evaluate quality defects in medicines. Result 4 - Strengthened internal competences of CInMED for public relations and international cooperation Sub - result 4.1: Increased CInMED's internal competencies for public relations and international cooperation through training sessions, exchange of experience and joint participation in EC and EMA working groups. Component 2: Recommendations for further harmonization of legal framework in Montenegro to achieve alignment with EU acquis Result 5 - Set of recommendations for alignment with EU acquis and further harmonization of legal framework in Montenegro Sub - result 5.1: Set of recommendations to align the Law on medicines with the most recent EU acquis.	regional documentation of different types of applications, through practical examples, during one study visit in the MS (Baseline:0; Target: 5) 1.1.4 Number of people trained about national registry of medicines and mode and type of data imported into the national medicines database, during one study visit in the MS (Baseline:0; Target:3) Sub - result 1.2: 1.2.1 Number of people trained for the assessments of the variations documentation from the Member State, during one study visit in the MS (Baseline:0; Target: 5) Sub - result 1.3: 1.3.1 Number of people attending workshop on medicines shortages (Baseline:0; Target: 5) Result 2 Sub - result 2.1: Indicators: 2.1.1 Number of people trained for carrying out medical devices market surveillance, vigilance, technical evaluation of medical devices, quality defects and withdrawal from the market (Baseline:0; Target: 4) 2.1.2 Number of joint and/or mock up surveillances conducted on the territory of Montenegro or territory of the Member State (Baseline:0; Target:1) Result 3 Sub - result 3.1 Indicators: 3.1.1. Number of joint and/or mock up GMP inspection conducted on			

	Sub - result 5.2: Set of recommendations to align the Law on medical devices with the most recent EU acquis.	the territory of the Member State or some other country, depending on inspection plans (Baseline:0; Target:1) 3.1.2 Number of joint and/or mock up GDP inspection conducted on the territory of Montenegro or on the territory of the Member State; (Baseline:0; Target:1) Sub - result 3.2: Indicators: 3.2.1 Number of people trained for rapid alerts and quality defects (Baseline:0; Target:10) Result 4 Sub - result 4.1: Indicators: 4.1.1: Number of people trained for public relations and international cooperation through training sessions, exchange of experience and joint participation in EC and EMA working groups (Baseline:0; Target:3) 4.1.2. Number of people trained for social media visibility, digital marketing and crisis management PR (Baseline: 0; Target:2) Result 5 Sub - result 5.1: 5.1.1. Gap report and draft of proposed recommendations for amendments to the Law on medicines that need further harmonization with the most recent EU legislation (Baseline: 0; Target:1) Sub - result 5.2: 5.2.1 Gap report and draft of proposed recommendations for amendments to the Law on medical devices that need further harmonization with the most recent EU legislation (Baseline: 0; Target:1)			

Activities	A.1.1.1: Joint review of assessments of medicines quality documentation using practical examples from applications submitted in the Member State. A.1.1.2: Conducted joint review of assessments of safety and efficacy documentation for different legal basis applications, utilizing practical examples from applications submitted in the Member State . A.1.1.3: Conducted joint review of assessments of administrative and regional documentation for different application types, addressing major challenges. This activity should be conducted through a three - day study visit, involving five participants from CInMED in the Member State. A.1.1.4: Organized training sessions on the national registry of medicines, mode and type of data on medicines imported into the national medicines database. This activity should be conducted during a two- day study visit involving three participants from CInMED in the Member State. A.1.2.1 Joint review of assessments of variations documentation using practical examples from variations submitted in the Member State. This activity should be conducted through a three - day study visit involving five participants from CInMED in the Member State. A.1.3.1: Organized workshop on medicines shortages actions in European Union A.2.1.1: Training sessions on European medical devices vigilance system and market surveillance, encompassing the management of quality defects and the protocol for withdrawing medicinal products from the market. A.3.1.1 Perform joint and/or mock up GMP - (practical training – joint/mock up inspection) in the Member State or some other country, depending on inspection plans		Final Twinning light Report Documentation produced under the project (Assessment reports, joint inspection reports, Set of recommendations for harmonization of legal framework) List of participants on trainings	Achieving results consistent with project plans Less participants than planned	Full commitment and motivation of the parties involved and good cooperation among twinned institutions and project teams in project implementation. Good communication and cooperation between Project Leader and Short term experts

	A.3.1.2 Perform joint and/or mock up GDP - (practical training, joint/mock up inspection) in Montenegro or Member state, depending on inspection plans A.3.2.1 Training sessions on monitoring rapid alerts and evaluate quality defects of medicines using practical examples from the Member State. A.4.1.1. Training sessions for public relations and international cooperation – practical examples and exercises to help achieve good communication and collaboration with future EU regulatory partners. A.4.1.2. Training sessions for social media visibility enhancement, digital marketing skills and crisis management PR A.5.1.1 Perform joint analysis of legal framework in Montenegro and suggest priority steps and recommendations for achieving full alignment with EU acquis concerning Law on medicines A.5.2.1 Perform joint analysis of legal framework in Montenegro and suggest priority steps and recommendations for achieving full alignment with EU acquis concerning Law on medical devices				

Annex 2. List of relevant Laws and Regulations

Relevant EU Legislation (not directly applicable in Montenegro)

- 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,
- 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 (EC) 1394/2007 of the European Parliament and the Council of 13 November 2007 on advanced therapy medicinal products and amends Directive 2001/83/EC and Regulation (EC) 726/2004,
- Regulation (EC) No 1901/2006 of the European Parliament and Council of 12 December 2006 on medicinal products for pediatric use and amendments to Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004,
- Regulation (EC) 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products,
- Regulation (EC) 1234/2008 of November 24, 2008 regarding the evaluation of variations of the marketing authorisation for medicinal products for human and veterinary use,
- Directive 2003/94/EC of October 8, 2003 on principles and guidelines of Good Manufacturing Practice for medicinal products for human use and investigational medicinal products for human use
- Regulation (EU) No 1252/2014 of 28 May 2014 on principles and guidelines of Good manufacturing practice for active substances,
- Guidelines of November 5, 2013 on Good Practice in the Distribution of Medicines for Human Use,
- Guidelines of March 19, 2015 on Good Practice in the Distribution of Active Substances for Medicinal Products for Human Use,
- Regulation (EU) 1235/2010 of the European Parliament and the Council of December 15, 2010, which in the part of pharmacovigilance for medicinal products for human use amends Regulation (EC) 726/2004 and Regulation (EC) 1394/2007,
- Good practice guidelines in pharmacovigilance (GVP) (EudraLex-Volume 9-Pharmacovigilance guidelines),
- Compilation of Union Procedures on Inspections and Exchange of Information,
- 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,
- Directive 89/105/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 (EU) 2017/745 of the European Parliament and Council of April 5, 2017 on medical devices, which amends Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and revokes Council Directives 90/385/EEC and 93/42/EEC.
- Regulation (EU) 2017/746 of the European Parliament and the Council of April 5, 2017 on in vitro diagnostic medical devices and repeals Directive 98/79/EC and Commission Decision 2010/227/EU.

National Legislation

> Law on medicines (Official Gazette of Montenegro, No. No. 80/20)
> Law on medical devices (Official Gazette of Montenegro No. 024/19)

Rulebooks

> Rulebook on more detailed conditions for issuance of marketing authorisation for a medicine (Official Gazette of Montenegro No 21/16 and 55/19)
> Rulebook on detailed content of pharmaceutical testing of medicines (Official Gazette of Montenegro No 38/09)
> Rulebook on content and manner of conducting pharmaceutical testing of medicines with the Aim of Quality Control (Official Gazette of Montenegro No 4/10)
> Rulebook on detailed content of pharmacological-toxicological study of medicines (Official Gazette of Montenegro No 68/09)
> Rulebook on the form, content, manner and period of reporting on sale of medicines (Official Gazette of Montenegro No 2/13)
> Rulebook on more detailed conditions and documentation required for approval and conduct of clinical trials of medicines for human use (Official Gazette of Montenegro No. 2/14)
> Rulebook on manner and conditions of advertising of medicines (Official Gazette of Montenegro No. 2/14)
> Rulebook on the manner of collecting of data and reporting and monitoring adverse reactions to medicines for use in human medicine (Official Gazette of Montenegro No 46/14)
> Rulebook on more detailed conditions and manner of entering a medicine into the Register of Traditional Herbal Medicines (Official Gazette of Montenegro No 04/15)
> Rulebook on more detailed conditions and manner of entering a medicine into the Register of Homeopathic Medicines (Official Gazette of Montenegro" No 06/15)
> Rulebook on more detailed conditions and manner of determining fulfilment of conditions for performing wholesale of medicines (Official Gazette of Montenegro No 45/21).
> Rulebook on more detailed conditions and manner of determining fulfilment of conditions for performing manufacturing of medicines (Official Gazette of Montenegro No 72/15)
> Rulebook on the contents and manner of labelling the outer and immediate packaging of a medicine and content of the package leaflet (Official Gazette of Montenegro No 21/16 and 67/18)