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| Twinning Fiche  **Project title:** Support to the Agency for Medicines and Medical Devices of Montenegro (CALIMS)  **Beneficiary administration:** Agency for Medicines and Medical Devices of Montenegro (CALIMS)  **Twinning Reference:** MN 16 IPA HE 01 19  **Publication notice reference: EuropeAid/168188/IH/ACT/ME** |

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| **EU funded project**  ***TWINNING INSTRUMENT*** |

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| ABBREVIATIONS | |
| AAP | Annual Action Plan |
| ADR | Adverse Drug Reaction |
| AO | Administrative Office |
| AR | Adverse Reaction |
| BC | Beneficiary Country |
| CALIMS | Agency for Medicines and Medical Devices |
| CFCU | Central Financing and Contracting Unit |
| CT | Clinical Trial |
| DP | Decentralized Procedure |
| EMA | European Medicines Agency |
| GCP | Good Clinical Practices |
| GMP | Good Manufacturing Practices |
| GDP | Good Distribution Practices |
| GVP | Good Vigilance Practices |
| ICH | International Conference on Harmonisation |
| LP | Lead Partner |
| MA | Marketing Authorisation |
| MD | Medical Device |
| MoE | Ministry of Economy |
| MRP | Mutual Recognition Procedure |
| MS | Member State |
| PIC/S | Pharmaceutical Inspection Co-operation Scheme |
| PL | Project Leader |
| PSC | Project Steering Committee |
| PV | Pharmacovigilance |
| RTA | Resident Twinning Advisor |
| SAA | Stabilisation and Association Agreement |
| SFMG | Strategy of Montenegro for the Implementation of the Union *acquis* in the Field of Free Movement of Goods 2014-2018 |
| TNA | Training Needs Analysis |
| ToC | Table of Concordance |
| WHO | World Health Organization |
| ISO | International Organization for Standardization |

**1. Basic Information**

1.1 Programme: Country Action Programme for Montenegro for 2016 (Financing Decision: IPA/2016/037896/02/ME) under indirect management with ex ante control.

*For UK applicants: Please be aware that following the entry into force of the EU-UK Withdrawal Agreement\* on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union and to goods originating from an eligible country, as defined under Regulation (EU) No 236/2014\*\*, are to be understood as including natural or legal persons residing or established in, and to goods originating from, the United Kingdom. Those persons and goods are therefore eligible under this call.*

*\* Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.*

*\*\* Regulation (EU) No 236/2014 of the European Parliament and of the Council of 11 March 2014 laying down common rules and procedures for the implementation of the Union's instruments for financing external action.*

*\*\*\* Annex IV to the ACP-EU Partnership Agreement, as revised by Decision 1/2014 of the ACP-EU Council of Ministers (OJ L196/40, 3.7.2014).*

*\*\*\*\* including the Overseas Countries and Territories having special relations with the United Kingdom, as laid down in Part Four and Annex II of the TFEU].*

1.2 Twinning Sector: Health and consumer protection

1.3 EU funded budget: EUR 400,000

**2. Objectives**

***2.1 Overall Objective(s):***

To assist Montenegro in the process of accession to the EU by contributing to legislation alignment and enforcement in the field of free movement of goods (Chapter 1), with special focus on finalising the transposition of the Union *acquis* and supporting the application of the EU and international good practices (ICH, PIC/S …) in the field of pharmaceuticals and medical devices.

***2.2 Specific Objective:***

To enhance and consolidate the institutional and operational capacities of the Agency for Medicines and Medical Devices of Montenegro (CALIMS[[1]](#footnote-1)) to perform its statutory duties and contribute to the health care system improvement and patients’ protection, by ensuring compliance with the EU standards, guidelines and good practices relevant to Chapter 1 of the Union *acquis* – ‘Free Movement of Goods’ concerning registration, marketing and consumption of medicines and medical devices.

***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 Stabilisation and Association Agreement (SAA)[[2]](#footnote-2) states that the aims of the association between the European Communities and their Member States, and the Republic of Montenegro include, inter alia, “to support the efforts of Montenegro to develop its economic and international cooperation, including the approximation of its legislation to that of the Community” (Article 1(d) of the SAA) and “to promote harmonious economic relations and gradually develop a free trade area between the Community and Montenegro” (Article 1 (d) and (f) of the SAA).

In observance of these stipulations, 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.

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* – requiring that more than 1000 legal acts of various nature be harmonised in total – Programme of Accession of Montenegro to the EU for the period 2015-2018 divided Chapter 1 into 4 subchapters, namely: 1. General Principles; 2. Horizontal Measures – that in turn includes Standardisation, Metrology, Accreditation, Market Surveillance, 3. Vertical Measures – i.e. technical regulations for different types of products, and 4. Procedural Measures.

As stated in the Specific Objective, the Twinning’s remit will be to support CALIMS 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 2015-2018 – more specifically by subchapter 3 – Vertical measures, as well as by the Strategy of Montenegro for the Implementation of the Union *acquis* in the Field of Free Movement of Goods 2014-2018 (SFMG) and its Action Plan.

Firstly, the Project aims to assist CALIMS in the process of harmonisation of the secondary legislation on pharmaceuticals with:

* the new Law on Medicines, which is expected to be adopted in the first quarter of 2020;
* the new Law on Medical Devices, which entered into force on 30th April 2019.

This is fully in line with the SFMG requirements for further alignment “*with the relevant acquis and provision of the basis for adoption of all necessary secondary legislation*”[[3]](#footnote-3) to ensure consistency with the amended Law on Medicines.

Secondly, the Twinning support will be granted to support approximation of primary and secondary legislation on medical devices, which presently is not in line with the Union *acquis.*[[4]](#footnote-4)

Besides, Twinning institutional capacity building activities will be tailored to fit the actual needs of CALIMS in order to enhance its strategic and operational capacity. In this sense, the Twinning action will be fully in line with the activities planned under the SFMG with a view to achieving full integration into the EU market implying “*not only transposition of the EU legal acts into the national legislation*” but also “*effective implementation of national legislation in the market”* and *“pre-approval and post-approval inspection surveillance*”.

From an operational point of view, the Twinning will be financed under the Country Action Programme for Montenegro for 2016 (CAP 2016) in the field of Competitiveness and Innovation which covers Chapter 1 (amongst others) and which is coordinated by the Ministry of Economy of Montenegro.

Finally, it should be noted that by supporting the development of an improved legal and operational environment in the domain of medicines and medical devices the Project will contribute to the implementation of the Strategy for Health Care Development in Montenegro, issued by the Ministry of Health – whose time horizon extends to 2020. The support will address at least 4 of the 5 “*key processes to be regulated (KPR)*” identified by the Strategy in the section on *National Medicines Policy*, namely KPR1: Establishing institutional framework (laws and other regulations); KPR2: Registration of medicines and medicinal products; KPR3: Quality control and researching medicines and medicinal products; and KPR4: Control of production and internal and external trade.

**3. Description**

***3.1 Background and justification***

The pharmaceuticals sector in Montenegro is currently regulated by the **Law on Medicines**[[5]](#footnote-5), approved by the Parliament in 2011. The Law, inter alia, defines the scope of action of CALIMS and designates it as the Montenegrin authority in charge of pharmaceuticals by stipulating that “*[t]he activities regarding the evaluation of quality, safety and efficacy of a medicine, and other professional activities in the field of medicines shall be performed by the Agency for Medicines and Medical Devices established by the Government*” (Law on Medicines, Article 7).

The activities falling within the competence and responsibility of CALIMS and as well as the rules regulating CALIMS’ structure and functioning are set out in Articles 8 to 15 of the Law on Medicines. Notably, Article 8 (17) mentions CALIMS responsibilities in meeting the obligations of accession, indicating that it is a national regulatory body that proposes “the harmonisation of regulations in the field of medicines with the EU legislation and with the regulations and guidelines of international institutions”.

In line with the legal and institutional framework in Montenegro, CALIMS performs a wide range of activities meant to ensure the safety, quality and efficiency of medicines in the pre- and post-marketing phases. Such activities include, inter alia, the assessment of Marketing Authorisations for both human and veterinary medicines, provision of expert opinions in classification of medicines including ‘borderline’ products, the approval of clinical trials and surveillance tasks meant to monitor their conduct, pharmacovigilance activities in the post-marketing phase, as well as licensing of medicines manufacturers and wholesalers registered in Montenegro in compliance with Good Manufacturing Practices and Good Distribution Practices.[[6]](#footnote-6)

Montenegro’s legal framework stipulating technical requirements and conformity assessment procedures for manufacturing, importing and placing on the market and/or putting in use medical devices was regulated by the Law on Medical Devices which was adopted in 2004 and subsequently amended in 2009 and 2011. The new Law on Medical Devices which is harmonised with the revised EU legislative framework (notably, new regulations on medical devices[[7]](#footnote-7)) entered into force on 30th April 2019.

As stated in the Programme of Accession of Montenegro to the EU and the SFMG, the adoption and subsequent enforcement of “*Vertical”* primary and secondary legislation in the field of medicines and medical devices is a precondition for meeting the accession obligations under Chapter 1: *Free Movement of Goods*. The first closing benchmark for Chapter 1 foresees the obligation of Montenegro to adopt and put in force legislation transposing Directive 2001/83/EC on the community code relating to medicinal products for human use and legislation transposing Directive 2001/82/EC relating to medicinal products for veterinary use, including establishing the authorisation process for medicinal products in both fields. Following the adoption of the new Law on Medicines, it will be necessary to revise the existing and adopt new secondary legislation in order to complete the harmonisation with the provisions of the relevant Directives.[[8]](#footnote-8)

In this context, the added value of the Twinning will be the provision of expert assistance to CALIMS in performing a very challenging legislative revision exercise expected in 2020-2021. 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 CALIMS in drafting a comprehensive, clear and fully aligned set of rules and guidelines. This is of great importance for meeting the first closing benchmark as the assessment of its fulfilment will be possible only after all the relevant secondary legislation is adopted i.e. after the national legislation is aligned with the EU *acquis* relating to medicinal products for human and veterinary use.

Legislative revision in the light of the pre-accession obligations will require CALIMS to perform new tasks, such as pharmacovigilance controls, and the above mentioned Medical Device reactive inspections following adverse events.

CALIMS’ commitment to work according to the highest ethical, professional and quality standards is attested by the recent achievement of ISO 9001:2015 certification and ISO/IEC 27001:2013 certification[[9]](#footnote-9), as well as by the joint efforts of its employees to soundly apply the EU and internationally acknowledged good practices. At the same time, it is widely perceived that it is necessary to further improve corporate knowledge and competencies, both at strategic and operational levels.

In this context, the 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 MS institution. The Twinning will play a key role in strengthening CALIMS’ administrative capacity by delivering a well-targeted mix of capacity building activities – consisting of tailored training, on-the-job assistance, workshops, study visits and one internship – that will mainly consist of the transfer of knowledge on the latest EU work guidelines, and feedback on examples of good practices (as well as on mistakes to be avoided). Strengthening of CALIMS’ 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 New, Global, and Old Approach product *acquis*, by the time of accession.

The operational approach will build upon previously gained theoretical knowledge and hands-on expertise acquired by CALIMS staff in the past 10 years and will be beneficial in terms of increased ability to perform daily duties. Similarly, the Twinning support is expected to help CALIMS’ familiarisation 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.

***3.2 Ongoing reforms***

As the adoption of the new Law on Medicines is a crucial step in the legislative alignment, its adoption will be followed by the revision of the existing/adoption of the new secondary legislation in order to complete harmonisation with the provisions of the relevant Directives. After the new Law on Medicines is adopted, CALIMS will be authorised and fully responsible for harmonising the secondary legislation with the new legal provisions. This will include a full review of the existing implementing acts as well as drafting of new ones and finally establishing a fully aligned legal framework on medicines for the years ahead. After all necessary secondary legislation is adopted, the European Commission will evaluate the harmonisation with the *acquis* in the area of human and veterinary medicines (fulfilment of the first closing benchmark for Chapter 1).

***3.3 Linked activities***

Since its establishment, CALIMS benefitted from several projects for training/capacity building in the field of medicines, medical devices and harmonisation with the Union *acquis.*

1. **Project for education of employees of Agency for Medicines and Medical Devices of Montenegro** (CALIMS) by the Agency for Medicines and Medical Devices of Croatia (HALMED) in the area of **quality of medicines**. Training activities focused on knowledge transfer concerning the evaluation of documentation on the quality of human medicines submitted within the applications for marketing authorisations. The project was implemented with the support from WHO in May 2009.
2. **Project for training and capacity building of CALIMS staff** by the Agency for Medicines and Medical Devices of Serbia (ALIMS). The purpose of the project was to strengthen CALIMS’ employees’ competence and expertise in respect of the evaluation of quality, safety and efficacy of medicines, clinical trials, pharmacovigilance and medical devices. The project was financed by the World Bank, and was implemented between May 2011 and July 2012.
3. **Project for training CALIMS staff** by the Agency for Medicines and Medical Devices of Croatia (HALMED) in the domain of bioequivalence studies evaluation (assessment of generic applications). The project was financed by WHO and was implemented between March and May 2012.
4. CALIMS was among the beneficiaries in the ***IPA Project 2011 Development of Quality Infrastructure and Metrology (DQIM) – Montenegro*** (*EuropeAid/132571/C/SER/ME*). The purpose of the project was to facilitate trade and free movement of goods in compliance with the Union *acquis* related to Chapter 1 - Free movement of goods (including medicines and medical devices). The project provided technical assistance for the alignment of secondary legislation – rulebooks related to the Law on Medicines. The project was implemented between March 2013 and June 2015.
5. In 2010-14 and 2017, CALIMS participated in the ***IPA Programme with the European Medicines Agency (EMA)*** together with the representatives from other Candidate Countries. CALIMS employees were attending regular meetings of EMA working groups and committees, which significantly contributed to the development of CALIMS’ administrative capacity.
6. Presently, CALIMS is one of the beneficiaries of ***IPA 2014 Technical Assistance for Alignment and Implementation of the EU Internal Market acquis (EuropeAid/137978/IH/SER/ME).*** The overall objective of the project is to facilitate trade and internal market development in compliance with the Union *acquis* in the field of Chapter 1: Free movement of goods and Chapter 28: Consumer and health protection. CALIMS received support for preparation of complete documentary package for the Working Group for Ch. 28 related to the final approval of the new Law on Medicines and ToCs. The project started on 26 November 2018 with an implementation period of two years

***3.4 List of applicable Union acquis/standards/norms***

***See Annex 2***

***3.5 Components and results per component***

**Result 1 - Component 1 – CALIMS Institutional Capacity and Visibility strengthened**

**Sub-result 1.1:** Enhanced background knowledge on good practices in the implementation of the Union *acquis* and international guidance in the field of medicines and medical devices leads to improved strategic planning capacity at institutional level, based on tailored support and exchanges of experience delivered by the Twinning partners to CALIMS’ staff

**Sub-result 1.2:** Secondary legislation in the field of Medicines and in the field of Medical Devices (MD) aligned with the Union *acquis* following the approval of the relevant Laws.

**Sub-result 1.3:** CALIMS’ capacity to effectively communicate with the stakeholders and to promote institutional visibility increased

**Result 2 - Component 2 – Post-Marketing Pharmacovigilance System and Medical Devices Surveillance System in Montenegro enhanced**

**Sub-result 2.1:** Enhanced administrative capacity of CALIMS’ staff to fulfil its legal tasks and responsibilities in relation to the PV and MD surveillance in the post-marketing phase, by managing and maintaining a comprehensive and effective supervision system of safety of authorised medicines and medical devices that encourages ADR and medical devices AR reporting and allows prompt detection of any change in their risk-benefit balance.

**Sub-result 2.2:** Administrative capacity of CALIMS’ staff to perform PV inspections enhanced

**Result 3 - Component 3 –Authorisation and Inspection Systems for Medicines and Clinical Trials in Montenegro improved**

**Sub-result 3.1:** Strengthened capacity of CALIMS’ staff to professionally and effectively assess Marketing Applications for Human and Veterinary Medicines, in compliance with the EMA Marketing Authorisation Guidance Documents.

**Sub-result 3.2:** Enhanced CALIMS capacity to perform inspections of medicines manufacturers and wholesalers, in full compliance with the EU GMP and GDP guidelines

**Sub-result 3.3:** Enhanced administrative capacity of CALIMS staff to perform risk-benefit assessment process for clinical trial approvals with professionalism and impartiality and to ensure full compliance with the applicable legislation and internationally recognised Good Clinical Practice (GCP) Guidelines.

**Sub-result 3.4:** Enhanced administrative capacity of CALIMS’ staff to adequately monitor ongoing clinical trials in compliance with the GCP Guidelines.

***3.6 Means/ Input from the MS Partner Administration:***

Proposals submitted by the Member States shall be concise and focussed on the strategy and methodology and an indicative timetable underpinning this, the administrative model suggested, the quality of the expertise to be mobilised and clearly show the administrative structure and capacity of the Member State entity/ies. The proposals shall be detailed enough to correspond adequately to the Twinning Fiche, but are not expected to contain a fully elaborated project. They shall contain enough detail about the strategy and methodology and indicate the sequencing and mention key activities during the implementation of the project to ensure the achievement of overall and specific objectives and mandatory results/outputs.

Activities will be designed taking on board the indicators of achievement attached to each Guaranteed Result. Any support action aimed to contribute to the production of rulebooks, guidelines, strategic planning documents and action plans - and of operational procedures, depending on the case – will be carried out considering the administrative culture and the regulatory background of the Beneficiary country, as well as the mission, objectives and working practices in the Beneficiary Institution.

Capacity building actions envisaged under each Component will be designed and delivered as a collaborative and open knowledge exchange that facilitates capitalisation of the MS experiences by the Beneficiary Institution, and takes into account both Montenegro’s and CALIMS’ peculiarities in terms of size and, with regard to CALIMS, of organisational structure. Thus, it is expected that training and on-the-job training will adopt an operational approach complementing theoretical information with relevant case studies, tested practices and field experiences, allowing time for joint discussions, guided practical applications and, where appropriate, targeted advice and recommendations.

The Twinning Partners shall ensure that the EU funded Twinning project has high and consistent level of visibility. A minimum of two visibility events will be organised during the implementation, namely a kick-off meeting on project commencement and a final event at the end of the implementation period.

The compliance with the provisions of the document ‘Communication and Visibility in EU-financed external actions” (available at [*https://ec.europa.eu/europeaid/sites/devco/files/communication-visibility-requirements-2018\_en.pdf*](https://ec.europa.eu/europeaid/sites/devco/files/communication-visibility-requirements-2018_en.pdf)) will be ensured.

**3.6.1 Profile and tasks of the Project Leader:**

The Project Leader will be appointed by the MS Lead Partner institution. In the interest of the smooth implementation of the Project, he/she will be a high-ranking civil servant, or hold an equivalent position that enables him/her to maintain a sound operational dialogue and backing at political level, throughout the entire period of implementation of the Project. 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*

* Proven contractual relation to a public administration or mandated body (see Twinning Manual 4.1.4.2);
* 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;
* Undertakes all the activities necessary for the good organisation and delivery of activities to be implemented in the MS – such as study visits;
* 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.

**3.6.2 Profile and tasks of the RTA:**

One Resident Twinning Advisor (RTA) will be made available by the MS administration(s) or by their mandated body. His/her secondment will last for 18 months, during which he/she will be responsible for the direct implementation of the project under the overall supervision of the MS Project Leader.

During this period, the RTA will work at CALIMS premises on a full-time basis, providing day-to-day assistance to the beneficiary institution.

The RTA will coordinate the inputs required for the successful implementation of all the project activities: he/she will directly advise and assist CALIMS staff, play a key role in facilitating relations and communication between the twinning partners, manage the team of Short Term Experts and give them adequate briefing, monitor the quality of inputs provided and outputs produced. The RTA tasks are presented in greater detail at the end of this section.

The RTA must comply with the following minimum requirements:

*Qualification and skills*

* Proven contractual relation to a public administration or mandated body (see Twinning Manual 4.1.4.2);
* University Degree in the field of Pharmacy, Medicine, Dentistry or equivalent professional experience of at least 8 years;
* At least 3 years of specific professional experience in the field of medicines / medical devices marketing authorisation and/or pharmacovigilance and/or clinical trials approval or inspection;
* Experience in implementing at least one international or EU-funded project of a similar nature will be considered an asset;
* Fluency in the English language, both written and spoken;
* Excellent communication, coordination and reporting skills;
* Computer literacy.

**Description of the RTA tasks**

The RTA:

* Oversees the day-to-day implementation of the Twinning project in the BC;
* Provides technical advice and assistance to CALIMS, in its role of the Beneficiary Institution, according to the overall Twinning project;
* Coordinates and monitors project implementation, assessing risks that may arise and proposing corrective actions, as appropriate;
* Interacts daily with the Beneficiary Institution and facilitates communication with the MS Twinning Partners;
* Coordinates and briefs the Component Leaders as well as other short-term experts, supervising the quality of their work and outputs;
* Organises the Twinning visibility events (kick-off and final events);
* Organises, and participates in, the PSC meetings;
* Reports to the PSC on the progress achieved by the Project;
* Executes administrative issues (e.g. reporting);
* If required, networks with other institutions relevant to this Project in Montenegro and in the MS.

**3.6.3 Profile and tasks of Component Leaders:**

The Twinning Team will include a team of 3 Component Leaders. Each Component Leader will comply with the minimum requirements presented below:

Component Leader 1 (CALIMS Institutional Capacity and Visibility strengthened)

*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 (Post-Marketing Pharmacovigilance System and Medical Devices Surveillance System in Montenegro enhanced)

*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 as asset;
* Strong initiative, analytical and team working skills;Fluency in English language (both oral and written);

Component Leader 3 (Authorisation and Inspection Systems for Medicines and Clinical Trials in Montenegro improved)

*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);

Each Component Leader will be responsible for coordinating the assigned component, under the RTA supervision. They will, inter alia:

* Interact with the Beneficiary performing a detailed assessment of the needs for support within the Component under their respective responsibility;
* Plan the activities to be delivered;
* Work as Short-Term Experts within the Component under their respective responsibility;
* Brief and supervise the work of other short-term experts, in collaboration with the RTA.

Due to budgetary restrictions it would be considered an advantage if the MS proposes Component Leader(s) who could cover more than one component.

**3.6.4 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 8 years[[10]](#footnote-10).
* 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.

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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 STE with operational experience in performing PV activities and inspections, in compliance with the EU rules and good practices, and in applying relevant tools and techniques;
* 1 STE with operational experience in Medical Devices surveillance activities;
* 1 STE with hands-on experience in approval and supervision of CTs;
* 1 or more STE(s) with practical experience in the assessment of applications for Marketing Authorisations for Human and/or Veterinary medicines;
* 1 or more STE(s) skilled in performing GMP and GDP inspections;
* 1 or more STE(s) with practical experience in the classification of medicinal products;
* 1 STE with hands-on experience in planning, design and implementation of communication actions in the field of Medicines and Medical Devices.

Other profiles may be identified based on TNA and other identified needs. Depending on the nature of the assigned tasks, the STEs will be also required to comply with one or more of the following requirements:

* Experience in drafting secondary 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;
* 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

Under the RTA coordination, the STEs will:

* Closely work with Montenegrin partners in implementing all Twinning Project activities;
* Provide specialised assistance and support to CALIMS staff in the areas identified, and in the modalities envisaged, by this Twinning Fiche;
* Prepare the mission according to instructions from the RTA, familiarising themselves with relevant documentation, and drafting supporting materials, if the mission requires (e.g. if delivering training);
* Diligently perform the mission, according to the RTA 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**

**Maximum budget available for the grant:**

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| --- | --- | --- | --- |
|  | **Total Budget** | **IPA funding** | **National Contribution** |
| Twinning Contract | EUR 400,000 | EUR 340,000 | EUR 60,000 |

**5. Implementation Arrangements**

***5.1 Implementing Agency responsible for tendering, contracting and accounting (AO/CFCE/PAO/European Union Delegation/Office):***

In its capacity of IPA Implementing Agency, the Directorate for Finance and Contracting of the EU Assistance Funds (CFCU) is solely and fully accountable for the sound implementation of all IPA-funded contracts in full compliance with contractual provisions and according to procedures governing the indirect management of the EU support. At the same time, as the BC Administrative Office (AO), the CFCU facilitates Twinning contracts implementation in Montenegro, provides all necessary assistance to Twinning Partners both from the BC and from the MS, assists the RTA after his/her arrival in the country providing him/her with the RTA Welcome Pack and all necessary Twinning-related information.

The Project Implementation Unit of the Ministry of Economy and CALIMS will provide appropriate technical support and collaborate with the CFCU throughout project implementation, making sure that the Twinning activities are correctly, efficiently and effectively implemented.

The progress of the Project is monitored by the EU Delegation, NIPAC and the CFCU, through the following activities:

* Organisation of the PSC meetings. The PSC will meet on a quarterly basis and jointly examine activities undertaken and progress achieved, discuss any risks affecting the project’s implementation and propose appropriate countermeasures, and analyse plans for future activities. The PSC will be composed of the 2 Twinning Project Leaders, the PAA and his/her Montenegrin counterpart as well as the representatives of the MoE, the CFCU, the EU Delegation and NIPAC. Other members can be appointed as appropriate.
* Submission of Quarterly Progress Reports and a Final Report that measure progress achieved and provide feedback on problems encountered / delays that occurred (or that may be encountered/occur) during implementation, if any.

*Contact data:*

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***5.2 Institutional framework***

The Agency for Medicines and Medical Devices of Montenegro (*Agencija za ljekove i medicinska sredstva Crne Gore*) – CALIMS – is the sole Beneficiary Institution of this Twinning Project.

CALIMS is managed by a Director, and governed by a Management Board appointed by the Government of Montenegro, that determines its business policy and elects the Director. A Supervisory Board, also appointed by the Government of Montenegro, monitors CALIMS’ activities. At present, CALIMS has 39 employees and its operational structure is organised in 3 Sectors:

1. Sector for Medicines and Medical Devices – where all specialist Departments are located;
2. Sector for General and Financial Affairs; and
3. Sector for Information Technology and Quality.

The **Sector for Medicines and Medical Devices** consists of 8 Departments and performs all professional tasks in line with the CALIMS competences defined by the Law on Medicines and the Law on Medical Devices. Currently, the Sector has 27 employees. 5 Departments will be involved in the activities to be delivered under Twinning Components B and C, as presented below.

The **Pharmacovigilance Department**. This Department carries out the following tasks: establishing and managing a system of collection, recording, assessment and response to the ADR data; performing the risk assessment of data collected through the PV system, making it available to health care professionals and, if necessary, to the general public; setting up and maintaining systematic and clear records of all relevant information about the effects of adverse drug reactions. The Department also organises continuous education of health care professionals in the field of pharmacovigilance and cooperates with the Uppsala Monitoring Centre (UMC) – the WHO authorised centre for ADRs, as well as with other agencies and institutions – to exchange the latest information relating to the safe use of medicines. It also proposes the harmonisation of national legislation with the EU legislation relating to the PV. The PV Department currently has 2 employees.

The **Medical Devices Department.** TheMD Department’s tasks are related to the competences defined in the Law on Medical Devices, namely: keeping the register of medical devices, and the register of manufacturers and legal entities engaged in the MD wholesale and retail trade; receiving and processing applications for the MD registration (entry in the Register) and for the issuance of licenses to import MDs that are not included in the Register; issuing expert opinions on the MD classification; performing the activities related to the system of MD vigilance and processing requests for MD clinical trials. It also proposes the harmonisation of the national legislation in the field of medical devices with the EU legislation and with the guidelines issued by international institutions. The Department currently has 3 employees.

The two above-mentioned Departments will be the Beneficiaries of Twinning Component B.

The **Department for Issuing Marketing Authorisations for Medicines for Human and Veterinary Use** currently has 13 employees. It is responsible for administrative and expert assessment of quality, safety and efficacy of applications for issuing (or variation or renewal) of MAs for medicines for human and veterinary use. The Department also makes proposals to harmonise national legislation in the field of medicines with EU legislation, ICH Guidelines and other international professional standards / guidelines.

The **Department for Import/Export Authorisations, Certificates and Opinions** receives and processes applications for: licenses for the import of medicines that do not have a marketing authorisation, licenses for the manufacturing of medicines and GMP certificates, licenses for wholesale of medicines and GDP certificates; it also issues expert opinions on the classification of products in the Medicines Registry, making decisions on classification of the border-line products, whenever required. The Department currently has 3 employees; however, the staff of the Marketing Authorisation Department also contribute to the activities of this Department.

The **Department for Clinical Trials of Medicines for Human and Veterinary Use** is in charge of the receipt and processing of applications for approval of clinical trials for human and veterinary medicines. The Department also receives notifications about the conduct of clinical trials for medicines that have marketing authorisation, and exercises a surveillance / quality control function, by performing controls of clinical trials and issuing GCP certificates. Additionally, the Department participates in the activities related to the issuance of marketing authorisations of medicines i.e. evaluation of data on efficacy and safety of medicines (pre-clinical and clinical data submitted within the MA applications). Finally, it formulates proposals to harmonise national legislation in the field of clinical trials with the EU legislation and the guidelines of international institutions. The Department currently has 3 employees.

The Department for Clinical Trials of Medicines for Human and Veterinary Use, the Department for Import/Export Authorisations, Certificates and Opinions as well as the Department for Issuing Marketing Authorisations for Medicines for Human and Veterinary Use will be supported by the Twinning Project under Component C.

On the other hand, it is expected that the Component A of this Twinning Project will benefit CALIMS by addressing issues of general scope – such as CALIMS’ strategic planning and institutional communication – or by performing the activities that allow fine tuning of the capacity building activities performed under the other two Components.

Overall project coordination will be ensured by CALIMS’ management that will supervise the implementation of the Twinning Project on a continuous basis, and promote and facilitate the proactive collaboration of staff from relevant departments.

The **Ministry of Economy (MoE)** coordinates and supervises the implementation of the SFMG, to which the Twinning project aims to contribute. Thus, it is expected that the MoE will play a supervisory role, periodically monitoring the implementation of the Twinning activities and the achievement of the envisaged targets.

***5.3 Counterparts in the Beneficiary administration:***

***5.3.1 Contact person:***

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***5.3.2 PL Counterpart:***

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***5.3.3 RTA Counterpart***

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**6. Duration of the project**

Duration of the execution period: 21 months.

**7. Management and reporting**

**7.1 Language**

The official language of the contract is English. All formal communications regarding the Project, including interim and final reports, shall be produced in the language of the contract.

**7.2 Project Steering Committee (PSC)**

The PSC shall oversee the implementation of the Project. The main duties of the PSC will include verification of the progress and achievements via-à-vis the mandatory results/outputs chain (from mandatory results/outputs per component to impact), ensuring good coordination among the actors, finalising the interim reports and discussing the updated work plan. Other details concerning the establishment and functioning of the PSC are described in the Twinning Manual.

**7.3 Reporting**

All reports shall have a narrative section and a financial section. They shall include as a minimum the information detailed in section 5.5.2 (interim reports) and 5.5.3 (final report) of the Twinning Manual. Reports need to go beyond activities and inputs. Two types of reports are foreseen in the framework of Twining: interim quarterly reports and final report. An interim quarterly report shall be presented for discussion at each meeting of the PSC. The narrative part shall primarily take stock of the progress and achievements via-à-vis the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

**8. Sustainability**

This Twinning Project will provide support to CALIMS to increase its institutional capacity and visibility, placing the focus – *inter alia* - on the alignment of sectoral legal framework as well as on the further consolidation of the CALIMS employees’ operational capacity to enforce the new rules.

The Twinning Project is deliberately launched at the time when the legal framework on medicines and medical devices in Montenegro is undergoing a thorough revision. Providing support to CALIMS in producing secondary legislation aligned with the newly adopted legislation and, ultimately, with the Union *acquis* 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.

The sustainability of results concerning CALIMS’ strategic planning capacity is expected to be twofold: the validity of deliverables will be ensured by their same time horizon, while the administrative capacity built by the Twinning during the assisted planning exercise will remain embedded in the institution.

The sustainability of capacity building efforts is closely intertwined with institutional history, and principally with trends characterising human resources and their rate of replacement. In this sense, it is highlighted that over the past 3 years CALIMS recorded a low turnover (yearly average: 2 employees). This is also due to corporate retention measures – such as facilitation of employees’ educational activities and support to formal education and teaching (financing of PhD studies and other forms of education, supporting the inclusion of the CALIMS staff in the teaching activities at the University of Montenegro) – which have so far been effective. Also, after the adoption of the new Law on Medicines it will also be possible to employ additional staff in CALIMS in line with the new job classification that will be prepared.

The stability and commitment of CALIMS human resources provides a fertile ground to the sustainability of the Twinning achievements as they concern increased administrative capacity that is likely to remain firmly implanted in the institution as a permanent asset.

Furthermore, taking into account CALIMS recruitment plans, Twinning Experts delivering training will be asked to develop and include in their mission reports concise support materials that senior staff can use to train newly recruited employees during their induction period, even when this happens after the delivery of the relevant capacity building activity, or after the Twinning Project’s conclusion. It is expected that this will maximise the sustainability of results, extending it to CALIMS’ newly recruited staff that could not directly benefit from the Twinning experience.

Finally, efforts undertaken by the Twinning experts in planning and designing pilot communication actions will be continued by CALIMS which will autonomously undertake the implementation of the Communication Action Plan drafted by the Project.

**9. Crosscutting issues**

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.

As concerns participation in the capacity building actions delivered at CALIMS, equal participation will be ensured by participation of all employees having a professional interest in the respective activities – in compliance with the CALIMS Employees Code of Conduct (Article 9) and corporate Integrity Plan.

Special account of the equal opportunity principles will be taken when designing and implementing communication activities (under Components A and B), 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.

**10. Conditionality and sequencing**

The recently adopted Law on Medical Devices as well as the upcoming adoption of the new Law on Medicines in Montenegro are a precondition for the Twinning Project implementation. This is in consideration of its focus on legal alignment with the Union *acquis* as well as of the capacity building activities that are partly centred on strengthening institutional competencies to soundly apply the new provisions.

**11. Indicators for performance measurement**

**Please refer to Annex 1 – Logical framework matrix.**

**12. Facilities available**

CALIMS will make available the following facilities for hosting the RTA and his/her assistants:

An office of approximately20m2, furnished with work desks and shelves for storing documentation. It has a telephone, Wi-Fi connection and PCs. There are no CALIMS employees in this office (it will be at the full disposal of the RTA and his/her team). This office can be locked and as it is located in the CALIMS 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). This office can be used as a meeting room and, additionally, CALIMS has a meeting room within the Director’s office that will be made available to the RTA for organising meetings.

CALIMS has within its building a 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.

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**ANNEXES TO PROJECT FICHE**

**Annex 1. Logical framework matrix**

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

1. Crnogorska Agencija za ljekove i medicinska sredstva – CALIMS [↑](#footnote-ref-1)
2. signed on 15th October 2007 and in force since 1st May 2010. [↑](#footnote-ref-2)
3. See SFMG, Section 4.2.9 Pharmaceuticals. [↑](#footnote-ref-3)
4. For further details, please see SFMG, Section 4.1.15 Medical Devices. [↑](#footnote-ref-4)
5. New Law on Medicines was drafted and sent to the European Commission for their opinion on the alignment of this proposed law with the *acquis*, in 2018. In line with the comments received during 2018 and 2019, the remaining issues have been resolved during September 2019 and the version of the text of the proposed law prepared in line with the comments from the European Commission has been was submitted for further adoption procedure within the Government and the Parliament of Montenegro. The new Law is expected to be adopted by the end of the first quarter of 2020. [↑](#footnote-ref-5)
6. Please note that further information on CALIMS tasks is provided in section 4 *Institutional framework*. [↑](#footnote-ref-6)
7. <http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en> [↑](#footnote-ref-7)
8. There are currently 17 pieces of secondary legislative acts (rulebooks, guidelines) in force adopted pursuant to the current Law on medicines (from 2011). After adoption of the new law, it will be necessary to amend some of these existing acts in accordance with the new law, and it will also be necessary to adopt some completely new ones that we have not had before. [↑](#footnote-ref-8)
9. CALIMS is also accredited under MEST EN ISO/IEC 17020:2013 standard by the Accreditation Body of Montenegro. [↑](#footnote-ref-9)
10. Additionally, for some activities under this Twinning, 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*](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf)*.* 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. [↑](#footnote-ref-10)