



TWINNING FICHE

Project title: Harmonisation of the legislation for medicinal products with EU legislation and building capacities for its implementation

Beneficiary administration: Agency for medicines and medical devices of the Beneficiary Country

Twinning Reference: MK 15 IPA HE 01 18 TWL

Publication notice reference: EuropeAid/161636/DD/ACT/MK

EU funded project

TWINNING INSTRUMENT

1 Basic Information

1.1 Programme: European Union Integration facility 2015 - Commission Implementing Decision of 09.12.2015, C(2015)9126 final, Dec.no. IPA/2015/037-906 / EU Integration Facility; Direct management

For British applicants: Please be aware that eligibility criteria must be complied with for the entire duration of the grant. If the United Kingdom withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, you will cease to receive EU funding (while continuing, where possible, to participate) or be required to leave the project on the basis of Article 12.2 of the General Conditions to the grant agreement.

1.2 Twinning Sector: Health protection

1.3 EU funded budget: 250,000 EUR

1.4 Beneficiary Country: the Beneficiary country¹ as per Financing Agreement

2 Objectives

2.1 Overall Objective(s):

The main objective of this programme is supporting the Agency for medicines and medical devices - MALMED in accordance with the international standards and good pharmaceutical practices, as well as adoption, implementation and enforcement of the national pharmaceutical legislation in accordance to the EU *acquis*.

2.2 Specific objective:

The specific objective of this project is:

1. Harmonisation of the national pharmaceutical legislation with EU *acquis*,
2. Strengthening the capacities of the MALMED

Contribution to National Development Plan/Cooperation agreement/Association Agreement/Action Plan

Link with the EC Progress Report 2018

In its country report, released on 17 April 2018, the European Commission noted that: "National legislation on medicines for human and veterinary use is partly aligned with the *acquis*. Maximum sale prices criteria for medicines are set by the Health Insurance Fund but the medicines covered by the national health insurance are available to the patients only in the first days of the month. Supplementary measures for proper quality and traceability controls of medicines for human and veterinary use subject to parallel trade need to be introduced" (chapter 28 – *Consumer and health protection*)

¹ As per Financing Agreement concerning the IPA II 2015 Annual Action Programme

Link with the MALMED annual strategy paper for development

MALMED adopts annual strategy for promoting national health values, good pharmaceutical practices, safety, efficacy and quality of the medicinal products. MALMED also strive towards improvement of the national legislation on medicines and medicine devices and towards capacity building of MALMED staff.

National strategy of pharmaceuticals

Ministry of health adopted the National strategy of medicines with an aim to ensure safety, efficacy and quality of the medicines present on the market. The National strategy is to contribute to the accomplishment of the basic human right for quality, effective and safe medicines and medical treatments, as well as to promote and enhance public health.

Link with the Stabilisation Association Agreement (SAA) with the EU is the framework for relation with EU

Further approximation of the country's legislation to that of the Community.

Link with Regulation (EU) No 231/2014 of the European Parliament and of the Council of 11 march 2014 establishing an Instrument for Pre-accession Assistance (IPA II)

One of the specific objectives of the financial assistance under IPA II pursues is to strengthen the ability of the beneficiaries to fulfil the obligations stemming from Union membership by supporting progressive alignment with the Union *acquis*, implementation and enforcement of harmonised legislation. Furthermore, the IPA II Regulation states that financial assistance shall, among other, mainly address the following policy areas: reforms in preparation for EU membership and related institution and capacity-building and education, promotion of gender equality, and human resources development.

This project will contribute to achieving progress in building up and strengthening good governance and the administrative, institutional and absorption capacities at the level of a regulating authority in the field of medicines and medical devices, including adequate human resources, needed to adopt and enforce the *acquis* –related legislation.

Link with National programme for adoption of *acquis* (NPAA) Chapter 28

5. MEDICINES FOR HUMAN AND VETERINARY USE

5.1 Medicines for human use

In 2017, a Methodology for changing the methodology for the manner of drug prices formation ("Official Gazette of RM No. 148/17) was adopted. In March 2018, a new Rulebook was adopted on the content of the request / notification and the manner of reporting or approval of the changes in the marketing authorization or the already submitted documentation of a medicinal product that has a marketing authorization ("Official Gazette of the Republic of Macedonia No. 42/18)", which harmonized the EU measures 32008R1234 and 32012R0712.

SHORT TERM PRIORITIES 2019

5. HUMAN MEDICINES AND VETERINARY USE

5.1 medicines for human use

- Law on medicines for human use

EPP Drug Act (2015.1300.7278) (deadline December 31, 2019)

- Law on Medical Devices

EPP: (2015.1300.7279) (deadline December 31, 2019)

3 Description

3.1 Background and justification:

MALMED, is relatively new independent authority established in September 2014 as continuation of the work and obligations of the Bureau of medicines that was a body within the Ministry of Health since 2001.

Based on the Law of medicines and medical devices, , MALMED became only representative authority in the country for enforcement and, control of medicines and medical devices. In June 2015, MALMED with all departments and supportive administration (35 employees) moved to new premises. :

MALMED organisational scheme is as follows:

- Pharmaceutical department which includes units for marketing authorisation of medicines, OTC medicines, herbal medicinal products and border-line products, as well as clinical trials, pharmacovigilance and medical device unit,
- Department for information of medicines and medical devices, and
- Inspection department,
- and Departments for IT technology, legal advices, finance and public calls.

MALMED has a good cooperation with the European medicines Agency (EMA), as well as with EDQM

Ongoing reforms

The Ministry of Health launched the amendments to the law on medicines and medical devices, currently in Parliamentary procedure. Amendments mainly refer to the procedures for parallel imports of medicines.

For further improvement of the process of marketing authorisation of medicines and medical devices, MALMED has prepared new electronic integrated Data Management System (DMS). It defines the procedure of marketing authorisation and variations of medicines. In future there are planned other activities to be incorporated in this system. The pilot project should start by first half of 2018. MALMED has already started with education for the DMS for the marketing authorisation holders and MALMED staff. Twinning project will contribute for improvement and development of the current DMS.

In late 2017 MALMED started two projects, which are currently ongoing, regarding improvement of pharmacovigilance awareness among health care professionals and pharmacists. The project involves MALMED's expert for pharmacovigilance and health care professionals and it is implemented in the whole territory of the country. The first benefits from this enhanced education are seen as the number of adverse reaction reports increased. The second project is dedicated to combating counterfeit and falsified medicines, and preparing national strategy on this issue. MALMED intention was to mobilise all institutions involved in the process and to improve collaboration, understanding, practice, and expertise about this specific issue. This project involves many institutions: MALMED, Ministry of Health, Customs administration, Pharmaceutical faculty, Ministry of internal affairs, State market inspectorate, State Office for Industrial Property, etc.

3.3 Linked activities:

Instrument for Pre-accession Assistance (IPA) 2010

The European Commission's [Instrument for Pre-accession Assistance \(IPA\) programme](#)²⁷ supports the participation of enlargement countries in the work of selected EU agencies. The activities of the European Medicines Agency (EMA) under the IPA programme aim to build working relationships with the beneficiary national competent authorities, to prepare for their future collaboration in the [European medicines regulatory network](#).

To achieve this aim, the programme offers assistance to the beneficiaries' national competent authorities in aligning their **standards and practices** with those established in the EU and contributes to the creation of **communication and information exchange systems** that enable their effective participation in the networks of the EU regulatory system. Programme activities include:

- inviting beneficiary countries to participate in EMA meetings and training courses as observers;

- organising ad hoc conferences and training sessions to exchange views, introduce the EU legal framework and identify areas for action.

This programme allows the candidate and potential candidate countries as the Beneficiary Country-BC, to prepare themselves for participation in the activities of the EMEA and to develop the member states' confidence in the systems in place. Furthermore, this should enable the EMEA, the member states and the beneficiary countries to work as equal, mutually respected partners. In the context of medicinal products, the project is designed to establish with the beneficiary countries an internationally open dialogue and working mechanisms. This would facilitate the adoption of common technical requirements in order to identify areas where additional action might be needed to ensure the smooth transposition of their legislation into the EU *Acquis Communautaire* and participation in EMEA committees. Indeed, a solid understanding of the EMEA's work is necessary to explain the roles/links between the EMEA, the Member States and the European Commission. This will facilitate the transposition of EU technical regulations and European technical acts into the national legislation of the participating Candidate and Potential Candidate Countries. Furthermore, this project will provide support for aligning their standards and practices with those established in the European Union with regard to the implementation of the Community law. This means transposing the regulations supporting the legislation into the EU *acquis communautaire* and establishing working procedures to make the laws and regulations operational.

TAIEX (Technical Assistance and Information Exchange instrument of the European Commission)

“Workshop on Good Manufacturing Practice and Good Distribution Practise Inspections”, December 2013;

Study visit in AEMPS (Madrid) on “Good Manufacture Practise”, June 2014;

"Transposition of EU Legislation on Medical Devices", January 2017

Collaboration with the TAIEX mission provided professional knowledge and practical experience between EU and BC institution- MALMED.

The policy and legislative developments deriving from the twinning project will be subject of extensive consultations with the concerned stakeholders in the area of medicines and medical products, as well as the stakeholders dealing with surveillance of quality of medicines. Furthermore, in accordance with the Public Administration Reform Strategy 2018-2022, the professionalization and the competences of the staff in MALMED and in the other involved stakeholders are expected to increase.

The training programme on medicinal products for human use should contain activities to ensure preparedness for the implementation of the falsified medicines Directive (which amends Directive 2001/83/EC) and the introduction of the safety features on each pack of prescription medicines.

3.4 List of applicable Union acquis/standards:

- Directive 2001/83/EC and 2004/27/EC (procedures for marketing authorization for drugs)
- Directive 2001/20/EC and 2005/28/EC (implementation of GCP in the conduct of clinical trials)
- Directive 2003/94/EC (implementation of the principles of GMP)
- Directive 2004/24/EC (as regards traditional herbal drugs)
- Directive 2141/96/EC (procedures for transfer of marketing authorization for drugs)
- Directive 2001/83/EC and 2004/10/EC (GLP principles)
- [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

3.5 Results per component

Component 1:

Mandatory Result 1: improvement and harmonisation of the legal framework on medicines and medical devices

In the context of Mandatory Result 1 the following indicative sub-results will be achieved:

1. 1. Current legislation for medicines and medical devices (Law of medicines and medical devices) revised and weaknesses and shortcomings in the following segments defined:

- chapter I and II (General provisions)
- chapter III (medicines)
- chapter IV (medical devices)
- chapter V and VI (inspection and sanctions)

1.2. Current procedures framework (by-laws and other internal procedures) related to medicines and medical devices revised and weaknesses and omissions defined.

The measurable indicators in relation with Mandatory Result 1 are represented by reports that will be the base for future harmonisation of the Law of medicines and medical devices, planned to start by end of 2019, as follows:

- Assessment Report of the current legislation with recommendations for improvement will be developed and sent to the Ministry of health and MALMED.
- Assessment Report and number of proposed amendments and/or updates of existing bylaws, Guidelines, SOPs and Manuals, according to the EU legislation and practices.

Component 2:

Mandatory result 2: Recommendations for the development of the MALMED administrative capacity for implementation of regulation according EU practices (Functionality in practice for the harmonisation of the legislation) drafted

In the context of Mandatory Result 2 the following indicative sub-results will be achieved:

2.1. Revision of the current organisational structure as well as, functions and responsibilities of the relevant units of MALMED, compare to the organisational structure of the MS (Assessment report).

2.2 Training needs analysis conducted by departments regarding EU practices in the field of medicines, inspection and medical devices.

2.3 At least 30 employees trained through workshops organised in MALMED, lectures and study visit in MS.

The measurable indicators in relation with Mandatory result 2 are:

- Based on the Assessment report, comparative analysis prepared (as mention in 2.1), an improved organisational model developed, covering the system and taking into consideration best EU practices
- National training plan of MALMED established
- At least 30 staff members trained within workshops, study visit and expert missions

Component 3:

Mandatory result 3: Recommendation for establishment of drug utilisation system

In the context of Mandatory Result 3 the following indicative sub-results will be achieved:

- 3.1 Analysis of the current situation and obligations regarding drug utilisation carried out
- 3.2 Recommendations for Methodology for drug utilisation drafted
- 3.3 Recommendations for Drug utilisation data base drafted
- 3.4 Training of at least 5 employees regarding drug utilisation

The measurable indicators in relation with mandatory result 3 are:

- Draft version of guideline for drug utilisation issued
- Drug utilisation data base set up
- At least 5 employees trained for drug utilisation

3.6 Expected Activities

Component 1:

Mandatory result 1: improvement and harmonisation of the legal framework on medicines and medical devices

1.1. Expert mission with MS expert and working groups from relevant staff from each department and local experts, which will be established to follow the revision of the current law by chapters. Recommendations will be proposed.

1.2. Expert mission with MS expert and working groups from relevant staff from each department that will be established, to follow the revision of the current procedures framework (by-laws and other internal procedures) related to medicines and medical devices and to define weaknesses and omissions.

Component 2:

Administrative capacity development of the MALMED's staff for implementation of regulation according EU practices (Functionality in practice for the harmonisation of the legislation).

2.1 Expert mission from MS and relevant working group from MALMED to conduct and develop comparative analysis of the organisational structure, functions and responsibilities of the relevant units in MALMED, taking into consideration best EU practices in MS and a report with recommendations for improvement. Presentation of the structural model of the partner agency from MS, by expert/s.

2.2. To carry out strategic training needs analysis (TNA) based on the report under 2.1 and covering the whole system. Based on the TNA, to elaborate a National Training Plan (with concrete priorities, target groups, ions, timing, financial and human resources) with the relevant staff from MALMED.

2.3. To organise 3 workshops related to best practices from MS of:

- marketing authorisation of medicines,
- marketing authorisation of medical devices,
- good practices for inspection and licensing

2.4. To organise 3 joint inspections with experts from MS and MALMED inspectors regarding GMP, GDP, GPv and GCP in the beneficiary country.

2.5 To carry out direct transfer of know-how, preferably throughout 3 study visit to Member State with relevant employees (max 7 from departments of medicines, medical device and inspection) of MALMED for maximum 5 days, focused on best practices according Union *acquis* on medicines and medical devices (precise area of interest will be determined upon agreement with the selected MS).

2.6 Three (3) expert missions related to legislation analysis and recommendations, and practical enforcement of the regulations on medicines and medical devices. Topics will be defined upon agreement.

Component 3:

Mandatory result 3: Recommendation for establishment of drug utilisation system

3.1. Expert mission. Expert MS and working group from MALMED are to analyse the current situation and compare to drug utilisation practise in the member states.

3.2. To organise and carry out 1 study visit (max 5 participants for 5 days) focussed on functioning and methodology of data base of drug utilisation system as well as supporting IT system, in a member state.

3.3 To make a draft proposal for Guidelines for drug utilisation and pilot version of a database.

3.7 Means/ Input from the Member State Partner Administration:

The project will be implemented in the form of a Twinning Light contract envisaged to provide exchange of experience and know-how with a MS Institution with good practice in the stated project activities. The Twinning Partner shall provide an adequate team of experts – one MS Project Leader, responsible for overall coordination of project activities and a pool of Short Term Experts (STEs) with suitable knowledge to carry out the activities described.

Proposals submitted by Member State 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. Proposals shall be detailed enough to respond 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.

The interested MS Partner Institution shall include in its proposal the CV's of the designated Project Leader and the proposed Short-term Experts as well as their specific tasks to which they will be assigned to. MS Partner Institution is encourage to assign Component Leaders for each describe component accordingly

The MS Partner Administration should demonstrate experience in delivery of services in the relevant project fields mentioned above. This experience should be described in the proposal. Experience in providing assistance in similar EU projects would be considered as an advantage.

3.7.1 Profile and tasks of the Project Leader

The MS Project Leader will manage the project team of selected member state(s) and co-ordinate the implementation of activities.

Profile Project Leader - Requirements:

- Proven contractual relation to a public administration or mandated body
- At least University degree² preferably in the field of pharmacy or medicine and general professional experience of 2 years
- At least 2 years of specific professional experience in the field of medicine/pharmaceuticals;
- Previous experience in project management will be considered as an asset;
- Fluent in English.

Tasks of the Project Leader

- Supervise and coordinate the overall work plan of the project;
- Ensure the achievement of the projected outputs;
- Co-manage the implementation of the project with the Beneficiary Country Project Leader;
- Co-ordinate MS experts' work and availability;
- Communicate with the beneficiary and EUD;
- Ensure the backstopping functions and financial management;
- Co-chair the Project Steering Committee Meetings;
- Draw up reports in accordance with the Twinning Manual;
- Where necessary, provide technical assistance and advice under the project.

3.7.2 Profile and tasks of the Short-Term Experts (STEs)

Other specialist staff will be made available by the Twinning Light Partner to support the implementation of activities. The proposed pool of short-term experts is expected to cover all relevant areas targeted under this project in order to achieve the mandatory results.

Profile of the short-term experts –

STE 1

- have at least University degree³ preferably in the area relevant for the implementation of the project or equivalent professional experience of 5 years;
- At least 3 years of working experience in medicine/pharmaceutical sector
- Proven contractual relation to a public administration or mandated body
- Fluency in English;
- Computer literacy.

² For reference on equivalent qualification see: EPSO website-Annex 1 (http://europa.eu.int/epso/on-line-applications/pdf/guide-1242-171104_en.doc)

³ For reference on equivalent qualification see: EPSO website-Annex 1 (http://europa.eu.int/epso/on-line-applications/pdf/guide-1242-171104_en.doc)

Asset:

- Experience in preparation of legal framework and methodological tools in the field of medicines;
- Experience in conducting trainings in the field of medicines;
- Knowledge of international standards in this field;

Tasks of the short-term experts

- Preparation of reports an analysis exchange of experiences and best practices examples;
- Participation in the round tables- presentation of the experience, best practices and study cases in the field of medicines;
- Provision of findings, recommendations and reports as foreseen under the project in close cooperation and coordination with the relevant Institution.
- Developing programme for training of trainers and conducting trainings with the relevant representatives
-

Profile of the short-term experts –

STE 2

- have at least University degree⁴ preferably in the area relevant for the implementation of the project or equivalent professional experience of 5 years;
- At least 3 years of working experience in the field of medical devices;
- Proven contractual relation to a public administration or mandated body
- Fluency in English;
- Computer literacy.

Asset:

- Experience in preparation of legal framework and methodological tools in the field of medical devices;
- Experience in conducting trainings in the field of medical devices;
- Knowledge of international standards in this field;

Tasks of the short-term experts

- Preparation of reports an analysis exchange of experiences and best practices examples;
- Participation in the round tables- presentation of the experience, best practices and study cases in the field of medical devices
- Provision of findings, recommendations and reports as foreseen under the project in close cooperation and coordination with the relevant Institutions.
- Developing programme for training of trainers and conducting trainings with the relevant representatives

Profile of the short-term experts –

STE 3

⁴ For reference on equivalent qualification see: EPSO website-Annex 1 (http://europa.eu.int/epso/on-line-applications/pdf/guide-1242-171104_en.doc)

- have at least University degree⁵ preferably in the area relevant for the implementation of the project or equivalent professional experience of 5 years;
- At least 3 years of working experience in the field of inspection and licensing of medicines and medical devices;
- Proven contractual relation to a public administration or mandated body
- Fluency in English;
- Computer literacy.

Asset:

- Experience in preparation of legal framework and methodological tools in the field of inspection and licensing of medicines and medical devices;
- Experience in conducting trainings in the field of inspection and licensing;
- Knowledge of international standards in this field;

Tasks of the short-term experts

- Preparation of reports an analysis exchange of experiences and best practices examples;
- Participation in the round tables- presentation of the experience, best practices and study cases in the field of inspection and licensing of medicines and medical devices
- Provision of findings, recommendations and reports as foreseen under the project in close cooperation and coordination with the relevant Institutions.
- Developing programme for training of trainers and conducting trainings with the relevant representatives

**Profile of the short-term experts –
STE 4**

- have at least University degree⁶ preferably in the area relevant for the implementation of the project or equivalent professional experience of 5 years;
- At least 3 years of working experience in the field of drug utilisation
- Proven contractual relation to a public administration or mandated body
- Fluency in English;
- Computer literacy.

Asset:

- Experience in preparation of legal framework and methodological tools in the field of drug utilisation;
- Experience in conducting trainings in the field of drug utilisation;
- Knowledge of international standards in this field;

Tasks of the short-term experts

- Preparation of reports an analysis exchange of experiences and best practices examples;

⁵ For reference on equivalent qualification see: EPSO website-Annex 1 (http://europa.eu.int/epso/on-line-applications/pdf/guide-1242-171104_en.doc)

⁶ For reference on equivalent qualification see: EPSO website-Annex 1 (http://europa.eu.int/epso/on-line-applications/pdf/guide-1242-171104_en.doc)

- Participation in the round tables- presentation of the experience, best practices and study cases in the field of drug utilisation
- Provision of findings, recommendations and reports as foreseen under the project in close cooperation and coordination with the relevant Institutions.
- Developing programme for training of trainers and conducting trainings with the relevant representatives

4 Budget

The project will be implemented through a Twinning Contract estimated at maximum 250,000 EUR

Twinning Contract	Total (EUR)	IPA contribution	
		EUR	%
	250,000	250,000	100

In addition to the IPA budget as a rule, the BC institution should cover the non-eligible costs as per Twinning manual (Annex 7, art4; Article 14.9 of General Conditions)

5 Implementation Arrangements

5.1 Implementing MALMED 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 payments.

The contact person on behalf of the EU Delegation is:

Ruzica Andronikova
 Programme Manager/adviser
 Delegation of European Union
 Sv. Kiril I Metodij 52b, 1000 Skopje
 Tel: +389 2 3248 522
 Fax: +389 2 3248 501
 E-mail: ruzica.andronikova@eeas.europa.eu

5.2 Institutional framework

The MALMED is the main beneficiary of this project. In addition, the Ministry of health, in accordance with the legal regulation (the Law of medicines and medical devices), is endorsing authority of the Law of medicines and medical devices and will be included as partner institution with representative. MALMED is key institution for implementation of the legal provisions.

Co-ordination mechanisms between institutions and departments

The MALMED will be directly responsible for co-ordination and management of the project and will support the Twinning Light project team in organizational and technical matters. Activities will be conducted in close cooperation with the Ministry of health and the DEU.

In line with the relevant provisions of the Twinning Manual (Revision 2017) A Project Steering Committee (PSC) will be established at the beginning of the project to monitor the implementation of the project comprising of senior representatives the Beneficiary Country Project Leader, the Member State Project Leader, other representatives from MS and Beneficiary County and the representatives from the Contracting Authority- EU the final and exact composition of the PSC will be agreed with the Contracting Authority at the start-up of the project. Any observer to the PSC should be approved by the Contracting Authority.

MS and BC Twinning Light Partners will arrange regular and ad-hoc coordination and information exchange meetings with other stakeholders as necessary.

5.3 Main counterpart in the BC

5.3.1 Beneficiary Country:

Assist prof. Qahil Ibraimi

Director of MALMED

Bul.Sv Kiril i Metodij No.54

Skopje

Phone:+389 2 5112394

e-mail: qahil@malmed.gov.mk

5.3.2 BC Project Leader will be:

Head of unit for pharmacoecconomy evaluation **Mrs Merjem Hadjihamza**

Head of unit for medicines **Mrs Marija Trajchuleski (deputy project leader)**

BC Contact person will be:

Biljana Dimitrova

biljana.dimitrova@malmed.gov.mk

Elona Chilku

elona.chilku@malmed.gov.mk

6.Duration of the project

The implementation of the project will be 8 months. The execution period of the contract shall enter into force upon the date of notification by the Contracting Authority of the contract signed by all parties, whereas it shall end 3 months after the implementation period of the Action.

7 Sustainability

The beneficiary administration is fully committed to ensuring long term impact of the Twinning Light project. The MS Twinning partners shall transfer the know-how necessary to achieve the mandatory results to the Beneficiary administration. During the project, the twinning partners should develop documents/handouts, guidelines that will be easily accessible for later use by the beneficiary administration. Staff benefiting from trainings/study visit shall transfer knowledge through subsequent training to their colleagues. Moreover, the proposed Evaluation/Lessons Learnt Seminar at the end of the implementation which capitalises and presents the concrete results with practical implications for further follow up will add to the sustainability of results. The mandatory results are fully in line with and contribute to the general Public Administration Reform Strategy (2017-2022), which envisages a set of steps, which should lead to more effective, efficient and improved management of institutions, human resources and processes, resulting with more efficient creation of policies, improved functionality and organisation, merit-based human resources management, more efficient and cost effective public services, as well as bigger responsibility, reporting and transparency of institutions, public servants and managing structures.

8 Crosscutting issues

8.1 Civil society

In compliance with the provisions of the IPA Implementing Regulation, the civil society will be involved through the mainstreaming mechanism developed. Representatives from the civil society shall be invited to participate in the workshops.

8.2 Equal Opportunity

The project will be implemented according to the regulations of the national legislation providing equal opportunities for men and women. Twinning partners will be expected to comply with EU Equal Opportunity policies.

8.3 Environmental considerations

Any ecological friendly initiative which can be taken will have to be implemented.

8.4 Communication and publicity

All requirements to ensure the visibility of EU financing will be fulfilled in accordance with R. (EC). N. 718/2007⁷.

9 Conditionality and sequencing

9.2 Conditionality

Appointment of the relevant staff by the beneficiaries to participate in training activities is a condition to be reflected during project implementation.

7

See Article 62 and 63 of R. (EC). N. 718/2007

9.3 Sequencing

10. Indicators for performance measurement (to be developed)

Keys milestones will be:

1. Approval of the Twinning project fiche;
2. Successful completion of a Twinning selection process;
3. Signature of the Twinning contract, including the Twinning Work Plan;
4. Commencement of the twinning partnership (inter alia, the arrival in the country of the Resident Twinning Advisers);
5. End of the implementation period;
6. Submission of the final report.

11. Facilities available

The project will be located in the premises of the MALMED. MALMED will ensure appropriate support and basic equipment for the work of the experts. This includes administrative support, office space, computers, telephone and fax and other necessary facilities. This contribution should also include logistical support for various training activities, including selection of trainees (in consultation with the MS/Mandatory body experts), as well as providing the MS/Mandatory body experts with the documents and information necessary for project implementation. For project interventions in regional offices, the latter shall provide the MS experts with all the necessary support throughout the period of their intervention.

ANNEXES TO ACTION DOCUMENT

1. Logical framework matrix in standard format (compulsory) PLEASE REFLECT THE ABOVE COMMENTS UNDER Results/ Activities in the log frame matrix too.
2. List of relevant Laws and Regulations (optional)
3. Organogram of the BC institution

ANNEX 1

LOGFRAME PLANNING MATRIX	Harmonisation of the legislation for medicinal products with EU legislation and building capacities for its implementation		
		Total budget: € 250 000	IPA budget: € 250 000

Overall objective	Objectively verifiable indicators	Sources of Verification
The main objective of this programme is supporting the Agency for medicines and medical devices - MALMED in accordance with the international standards and good pharmaceutical practices, as well as adoption, implementation and enforcement of the national pharmaceutical legislation in accordance to the EU <i>acquis</i> .	Efficient functioning of the key institution responsible for this area	EC Reports EC Peer review reports

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
The specific objective of this project is: 1. Harmonisation of the national pharmaceutical legislation with EU <i>acquis</i> , 2. Strengthening the capacities of the MALMED	-Improvement of the current legislative of medicines and medical devices - Functionality in practice of the harmonization of the legislation, (recommendations for improvement of by laws and guidelines) -Improved operational capacity of the staff for implementation	- EC reports; - Annual Report of the MALMED of medicines and	- Staff committed to respond to the tasks assigned and assisting the twinning partners during their assignment;

	-Strengthening the independent status of the MALMED of medicines and medical devices and improvement in providing professional and administrative services in the field of medicines and medical devices	medical devices	
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p><u>Component 1:</u> Mandatory Result 1: improvement and harmonisation of the legal framework for medicines and medical devices In the context of Mandatory Result 1 the following indicative sub-results will be achieved:</p> <p>1. 1. Revision of the current legislation for medicines and medical devices (Law of medicines and medical devices) and defining weaknesses and omissions in all segments:</p> <ul style="list-style-type: none"> • chapter I and II (General provisions) • chapter III (medicines) • chapter IV(medical devices) • chapter V and VI (inspection and sanctions) <p>1.2. Revision of the current procedures framework (by-laws and other internal</p>	<p>-Assessment Report of the current legislation with recommendations for improvement will be developed and distributed for consideration to Ministry of health and MALMED.</p> <p>-Assessment Report and number of proposed amendments and/or updates of existing bylaws, Guidelines, SOPs and Manuals, according to the EU legislation and practices.</p> <p>-Reports will be the base for future harmonisation of the Law of medicines and medical devices, planned to start by end of 2019.</p> <p>Based on the Assessment report, comparative analysis prepared (as mention in 2.1), an improved organisational model</p>	<p>- Lists of participants in trainings and working groups, evaluation forms, etc,</p> <p>- Report for screening and allocation of critical points of the current law</p> <p>- Report for recommendation of amendments of the current law of medicines and medical device</p> <p>-Report for recommendation of amendments</p>	<p>- Respective authority have sufficient capacities and are willing to cooperate on the issues linked with implementation;</p> <p>- Highly motivated and trained staff remains in the key institution Agency of medicines and medical devices;</p>

<p>indicative sub-results will be achieved:</p> <p>2.1. Revision of the current organisational structure as well as, functions and responsibilities of the relevant units of MALMED, compare to the organisational structure of the MS (Assessment report).</p> <p>2.2 Training needs analysis conducted by departments regarding EU practices in the field of medicines, inspection and medical devices.</p> <p>2.3 At least 30 employees trained through workshops organised in MALMED, lectures and study visit in MS.</p> <p>Component 3: Mandatory result 3: Recommendation for establishment of drug utilization system In the context of Mandatory Result 3 the following indicative sub-results will be achieved:</p> <p>In the context of Mandatory Result 3 the following indicative sub-results will be achieved:</p>	<ul style="list-style-type: none"> -Draft version of Guideline for drug utilization -Establishment of drug utilization data base - At least 5 staff trained for drug utilization 		
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<p>3.1 Analyse of the current situation and obligations regarding drug utilization</p> <p>3.2 Recommendation for Methodology for drug utilization</p> <p>3.3 Recommendation for drug utilization data base</p> <p>3.4 Training of employees regarding drug utilization</p>			
Activities	Means	Specification of costs	Assumptions
<p>Component 1:</p> <p>Mandatory result 1: improvement and harmonisation of the legal framework for medicines and medical devices</p> <p>1.1. Expert mission with MS expert and working groups from relevant staff from each department and local experts, that will be established to follow the revision of the current law by chapters. Recommendations will be proposed. .</p> <p>1.2. Expert mission with MS expert and working groups from relevant staff from each department that will be</p>	<p>MS twinning partner input:</p> <ul style="list-style-type: none"> - MS Project Leader, - pool of short-term experts. <p>BC partner input:</p> <ul style="list-style-type: none"> - BC Project Leader, - BC contact person, - Key institutions staff. 	<p>EURO 250.000</p>	<ul style="list-style-type: none"> - Appropriate expertise is available (in view of limited experience with IPA); - Beneficiary institutions can make (qualified) staff available to participate actively and contribute in all Project activities.

<p>established, to follow the revision of the current procedures framework (by-laws and other internal procedures) related to medicines and medical devices and to define weaknesses and omissions.</p> <p>Component 2: Administrative capacity development of the MALMED's staff for implementation of regulation according EU practices (Functionality in practice for the harmonization of the legislation).</p> <p>2.1 Expert mission from MS and relevant working group from MALMED to conduct and develop comparative analysis of the organisational structure, functions and responsibilities of the relevant units in MALMED, taking into consideration best EU practices in MS and a report with recommendations for improvement. Presentation of the structural model of the partner agency/ies from MS, by expert/s</p> <p>2.2. To carry out strategic training needs analysis (TNA) based on the report under 2.1 and covering</p>			
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<p>the whole system. Based on the TNA, to elaborate a National Training Plan (with concrete priorities, target groups, ions, timing, financial and human resources) with the relevant staff from MALMED.</p> <p>2.3. To organise 3 workshops related to best practices from MS of:</p> <ul style="list-style-type: none"> - marketing authorisation of medicines, - marketing authorisation of medical devices, - good practices for inspection and licensing <p>2.4. To organise 3 joint inspections with experts from MS and MALMED inspectors regarding GMP, GDP, GPv and GCP in the beneficiary country.</p> <p>2.5 To carry out a 3 study visit to Member State with relevant employees (max 7 from departments of medicines, medical device and inspection) of MALMED for maximum 5 days, related to medicines and medical devices (precise area of interest will be determined upon agreement with the selected MS), focussed on the best practices according EU <i>acquis</i>.</p> <p>2.6 Three (3) expert missions related to legislative and practise of medicines and medical devices. Topics will be defined upon agreement.</p>			
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<p>Component 3: Mandatory result 3: Recommendation for establishment of drug utilisation system 3.1. Expert mission. Expert MS and working group from MALMED To analyse current situation and compare to drug utilization practise in MS 3.2. To organise and carry out 1 study visit (max 5 participants for 5 days) focussed on functioning and methodology of data base of drug utilization system as well as supporting IT system, in the MS 3.3 To make a draft proposal for Guideline for drug utilization and pilot version for data base</p>			
<p>Preconditions:</p> <ol style="list-style-type: none"> 1) Appointment of counterpart in the beneficiary before launching the tender procedure; 2) Allocation of working space and facilities by the beneficiary for technical assistance before launching the tender procedure; 3) Organisation, selection and appointment of members of working groups, steering and coordination committees, seminars by the beneficiary for the proper functioning of the project; 4) Appointment of the relevant staff by the beneficiaries to participate in training activities. 			

ANNEX 2 – List of relevant Laws and regulations

- Law of medicines and medical device (Official Gazette no.106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228 / 15, 7/16, 53/16);

2. ANNEX 3 Organogram of the BC institution

