ANNEX C1: Twinning Fiche

Project title: Support the establishment of the state control authority for medicines and medical devices

Administration and beneficiaries: Ministry of Health of Ukraine

Reference to Twinning: UA 24 UF HE 01 25

Publication reference: EuropeAid/183923/DD/ACT/UA

The project is funded by the EU

TWINNING TOOL

List of Abbreviations

AA	Association Agreement
API	Active pharmaceutical ingredient
BCPL	Beneficiary Country Project Leader
CMU	Cabinet of Ministers of Ukraine
DCFTA	Deep and Comprehensive Free Trade Area
EU	European Union
EUDAMED	European Database on Medical Devices
GCP	Good Clinical Practice
GDP	Good Distribution Practices
GFA	Gesellschaft für Agrarprojekte in Übersee
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
GVP	Good Pharmacovigilance Practice
GLP	Good Laboratory Practice
GxP	May be used instead of GDP, GMP, GCP and GVP, GLP
NSDC	National Security and Defense Council of Ukraine
MOH	Ministry of Health of Ukraine
MRP	Mutual Recognition Procedure
MSPL	Member State Project Leader
PL	Project Leader
PSC	Project Steering Committee
SAFEMed	Safe, Affordable, and Effective Medicines for Ukrainians
SCA	State Control Authority
SEC	State Expert Center of the Ministry of Health of Ukraine
SMDC	State Service of Ukraine on Medicines and Drugs Control
RTA	Resident Twinning Advisor
SDGs	Sustainable Development Goals
SoHO	Substances of human origin
SOP	Standard Operating Procedure
STE	Short Term Expert
UDI	Unique Device Identifier
USAID	US Government through the US Agency for International Development
WHO	World Health Organisation

1. Basic information

1.1. Programme: C(2024)4604 on the financing of the Ukraine Facility pillar III for 2024, Technical Cooperation Facility for Ukraine 2024, direct management (OPSYS reference: UAFacility/2024/ACT-62766)

The legal basis of this procedure is Regulation (EU) 2024/792 of the European Parliament and of the Council of 29 February 2024 establishing the Ukraine Facility: https://eur-lex.europa.eu/eli/reg/2024/792/oj/eng, rules on nationality and origin are defined in Article 11 of the Ukraine Facility Regulation.

1.2. Twinning Sector: HE – Health and consumer protection

1.3. EU funded budget: EUR 1 500 000

1.4. Sustainable Development Goals (SDGs): 3 – Good health and wellbeing. Ensure healthy lives and promote well-being for all at all ages; 8 – Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all; 16 – Peace, justice and strong institutions.

2. Objectives:

2.1. Overall Objective(s):

The overall objective of this Twinning project is to support strengthen Ukraine's health sector and protect patients' interests by ensuring access to quality, safe, effective, and innovative medicines, medical devices, and cosmetic products.

2.2. Specific objective:

The specific objective of this Twinning project is to build the State Control Authority (SCA) as a regulatory body capable of functioning within the network of the EU competent authorities. This is to be achieved by establishing and strengthening the administrative capacity of the State Agency for Medical Devices as an independent body with a special status that implements the state policy on the development, registration, quality control, safety and efficacy of medicinal products, medical devices and medical devices for in vitro diagnostics; cosmetics; trafficking and countering illicit trafficking in narcotic drugs, psychotropic substances and precursors; SoHO, including blood and blood component donation; and the functioning of the blood system, the organisational structure, working methods and financing of which will comply with EU best practices.

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 Association Agreement between Ukraine, of the one part, and the European Union, the European Atomic Energy Community and their Member States, of the other part (hereinafter the "AA"), became effective in September 2017. By this AA, Ukraine

committed to approximate its healthcare legislation to the EU legislation, and therefore to implement this part of the EU *acquis*.

Ukraine's integration into the EU envisages harmonisation of the key elements of its legal systems and the establishment of the Deep and Comprehensive Free Trade Area (hereinafter the "DCFTA"). From the standpoint of medicines circulation, this means that the regulatory systems of the EU, EU Member States and Ukraine must be harmonised on the basis of the best European practices. To this end, the legislation of Ukraine and the EU on medicines, medical devices, in vitro diagnostic medical devices and cosmetic products should use the same terminology and implement consistent market regulation rules.

Given that Ukraine is not currently an EU member state, EU regulations do not automatically apply in Ukraine. Therefore, the national legislation should be adapted to the EU legislation in accordance with the AA, and the national regulatory system of Ukraine should be fully harmonised with the relevant EU regulatory systems, and the national regulatory authority – the SCA – should become part of the EU regulatory network when Ukraine will become an EU Member State. All this is necessary to fulfil the free trade area requirements and to be able to cooperate as an equal partner.

One of Ukraine's steps towards reforming its health system in the field of pharmaceuticals and harmonising its national legislation on medicines for human use with the EU *acquis* is the adoption of the new Law of Ukraine on Medicines No. 2469-IX, which, among other significant updates regarding marketing authorisation, clinical trials, import, labelling, promotion and distribution of medicines, also introduced fundamental changes to the regulatory system in this area. This Law, which became effective on August 18, 2022 (but has not yet entered into force), envisages the establishment of a state control authority for medicines circulation based on the model of similar EU agencies.

In its Report of November 08, 2023, the European Commission noted that although this Law partially harmonised the legislation on medicines for human use with the EU *acquis*, Ukraine is not yet fully compliant with EU standards for the quality, safety and efficacy of medicines for human use. Therefore, this Twinning project is vital for the consistent delivery of further efforts to implement EU standards.

Given that Ukraine, as an EU candidate state, has started the accession negotiations, the MOH, as the main central executive body in the healthcare sector, should take a more active role in harmonising the main elements of the legal systems and implementing the EU *acquis*. This Twinning project will contribute to Ukraine's ongoing large-scale efforts to meet its pre-accession commitments.

By supporting the reform of the regulatory system in the field of medicines, medical devices, in vitro diagnostic medical devices, cosmetic products, and clinical trials, the project will also contribute to the implementation of the healthcare development strategy in Ukraine, outlined in the decision of the National Security and Defense Council of Ukraine (hereinafter the "NSDC"), of July 30, 2021, which envisages the harmonisation of the Ukrainian legislation on the circulation of medicines and medical devices with EU legislation. This support will cover the following activities, in particular:

- reforming the system of state authorities in the field of medicines circulation; establishing a European-standard state competent authority; and establishing

proper communication of the newly established authority with the relevant EU entities;

- streamlining the approaches to licensing and inspection of activities related to the circulation of medicines, mandatory application of the relevant good practices (GxP) at all key stages of the medicines circulation;
- bringing the state marketing authorisation procedure and liability of marketing authorisation holders for medicines in line with the European directives;
- mandatory introduction of approaches to pharmacovigilance, promotion and advertising of medicines adapted to the EU requirements;
- fine-tuning of requirements for the operation of pharmacies as healthcare facilities;
- phased introduction of 2D coding/labelling with the application of a two-dimensional barcode to the packaging of medicines;
- introducing mechanisms for technical regulation of the circulation of medical devices that will be compliant with the European regulations.

Bringing Ukraine's regulatory system in line with the EU standards and practices will have a positive impact on boosting EU enlargement progress and will prepare Ukraine to fulfil the EU accession obligations.

3. Description

3.1. Background and justification:

Currently, medicines for human use are regulated by three institutions, namely: the Ministry of Health of Ukraine, the State Expert Center of the Ministry of Health of Ukraine (hereinafter the "SEC"), and the State Service of Ukraine on Medicines and Drugs Control (hereinafter the "SMDC").

The Ministry of Health, as the main central executive authority that formulates and implements the state policy in the field of healthcare, through its structural unit – the Pharmaceutical Department – conducts state marketing authorisation (renewal of a marketing authorisation) for medicines, approves variations to marketing authorisation dossiers for medicines, decides on temporary or complete prohibition of medicines through termination of the marketing authorisations, makes decisions on conducting and terminating clinical trials of medicines, and performs other functions envisaged by the Law of Ukraine on Medicines N 123/96-VR in its previous edition.

In order to accomplish these tasks of the MOH, the SEC was established in 2010 and is governed by its Charter and orders of the MOH. The SEC provides the Ministry of Health with recommendations and conclusions on marketing authorisation (renewal of a marketing authorisation) for medicines and variations to marketing authorisation documents, provides methodological support for the development of medicines, including pre-clinical studies and clinical trials, conducts audits of pharmacovigilance systems of applicants, provides recommendations regarding the complete or temporary prohibition of medicines, and exercises other powers required by the Ministry of Health to fulfil its powers under the Law of Ukraine on Medicines in the N 123/96-VR in its previous edition.

The SEC also conducts an expert evaluation of clinical trial materials, based on the results of which it provides recommendations to the Ministry of Health on the possibility of

conducting a clinical trial, conducts a clinical audit of a clinical trial to ensure compliance with good clinical practice, provides methodological assistance to ethics committees operating at healthcare facilities, analyses information received from the sponsor regarding the life cycle of a clinical trial, assesses substantial modifications and takes appropriate measures to protect subject health.

The SMDC is the central executive body within the regulatory system of Ukraine that implements the state policy on quality control and safety of medicines, including medical immunobiological products and medical devices; and circulation and counteraction to illegal trafficking of narcotic drugs, psychotropic substances and precursors; donation of blood and blood components; and functioning of the blood system. The SMDC certifies laboratories for quality control of medicinal products; certifies pharmacists and pharmacist assistants; issues licenses for production, import (except for APIs), wholesale and retail trade of medicines; creates and manages the license register for the listed types of licensing operations; and monitors the compliance with requirements for quality and safety of medicines at all stages of circulation, including good practices (manufacturing, distribution, storage, pharmacy); monitors the compliance with licensing conditions; controls the importation of medicines into the customs territory of Ukraine; and acts as an authorised body in the field of blood and blood components donation and blood system functioning. In addition to the above functions related to medicines, the SMDC is responsible for state regulation and control over the circulation of narcotic drugs, psychotropic substances and precursors as well as combating their illegal trafficking.

The circulation of medicines for human use, including the conduct of clinical trials is regulated by the special Law of Ukraine – the Law on Medicines, and a number of bylaws. As the new Law on Medicines partially transposing the EU *acquis* is expected to come into force, all bylaws need to be amended to a certain extent. Currently, the Ministry of Health, the SEC and the SMDC need to draft about 80 new regulations and procedures to strengthen pharmacovigilance; improve the conduct of clinical trials introduce GMP for certification of pharmaceutical production; revise licensing procedures for production, import, wholesale and retail trade of medicines, pharmaceutical development, bioequivalence of generic medicines, and post-authorisation efficacy studies; adapt industry standards in the form of guidelines to the EU industry standards (Good Pharmacy Practice (GPP), Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), Good Pharmacovigilance Practice (GVP), and control procurement of medicines during medicine sale/dispensing, etc.

Establishment of the SCA implies that the new body will take over all functions of the SMDC and the SEC (except for health technology assessment), and some functions of the Ministry of Health. The SCA structure, in particular, is to include units that will perform tasks aimed at inspecting clinical trials, preparing scientific conclusions on clinical trials in the form of a decision to authorise a clinical trial or refuse to authorise a clinical trial, analysing information related to the investigational medicinal product obtained during clinical trials, and other tasks arising from Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

At the same time, the Ministry of Health will formulate the state policy in the field of medicinal products, including clinical trials (adoption of regulations), and the SCA will implement such state policy (application of adopted regulations).

Regarding the current regulation of the ***medical devices market***, the Ministry of Economy of Ukraine designates the conformity assessment bodies (designated bodies) that assess the conformity of products before placing them on the market.

The Ministry of Health is assessing candidates for designation and, following this assessment, submits proposals to the Ministry of Economy of Ukraine to designate or reject the designation of conformity assessment bodies.

The SMDC is responsible for market surveillance of medical devices. The key legislative acts regulating this area are the technical regulations on medical devices approved by the Decree of the Cabinet of Ministers of Ukraine (hereinafter the "CMU") dated October 2, 2013, N 753 on Medical Devices, Decree N 754 on In Vitro Diagnostic Medical Devices, and Decree N 755 on Active Implantable Medical Devices. To harmonise the Ukrainian legislation with the EU *acquis* in this area, the Law of Ukraine on Medical Devices and Medical Devices for In Vitro Diagnostics and new technical regulations that will be in line with the current EU regulations are currently being drafted. However, in order to fully implement all necessary mechanisms for technical regulation in this area, it is necessary to implement a number of EU bylaws, gain access to European Database on Medical Devices (EUDAMED), introduce a national nomenclature for Unique Device Identifier (UDI) product coding, etc.

The reform of the regulatory system governing the circulation and conformity assessment of medical devices envisages that the Ministry of Economy of Ukraine will remain the main technical regulator, while the Ministry of Health will remain the central executive body that will be formulating the state policy in this area, and the functions of a special technical regulator will be transferred to the SCA. The SCA will also perform the function of market surveillance for medical devices. Conformity assessment of medical devices will be conducted by designated conformity assessment bodies.

The current regulation of ***cosmetic products*** in Ukraine is also undergoing active transformation and gradual harmonisation with the EU legislation. In 2021, a new technical regulation on cosmetic products was adopted (approved by CMU Decree N 65 of January 20, 2021), based on EU Regulation N 1223/2009 dated November 30, 2009. However, it has not yet been brought into force, as the transition period is continuing.

Before such technical regulation was enacted, the entry into the Ukrainian cosmetics market had to be based on a sanitary epidemiological certificate. However, the Law of Ukraine on Public Sanitary and Epidemiological Welfare was repealed on October 01, 2023, which led to a legislative vacuum in this area.

The Law of Ukraine on General Safety of Non-Food Products and the Law of Ukraine on Consumer Protection are the core regulatory acts in this area. These legal acts need to be harmonised with the EU *acquis*.

Currently, market surveillance of cosmetic products is conducted by the State Service of Ukraine on Food Safety and Consumer Protection (hereinafter "the State Consumer Protection Service"). Starting from August 03, 2024 (with the entry into force of the new Technical Regulation), this function will be exercised by the SMDC. However, it is planned that the market surveillance functions for cosmetics will be handed over to the SCA. Currently, the Ministry of Health is the special technical regulator in this area, as

well as the owner of the electronic notification system for the persons responsible for placing products on the market. It is planned that technical regulation of cosmetic products will also be transferred to the SCA.

Current regulation of activity of ***cord blood banks, other human tissues and cells***. Currently, in Ukraine, the regulation of the economic activity of banks of umbilical cord blood, other tissues and cells of the human body is regulated by the Ministry of Health. In the future, in the process of implementing the Twinning project, it is planned to consider the possibility of transferring these functions, as well as regarding the regulation of SoHO to the competence of the newly created SCA.

This way, the adoption and implementation of the EU *acquis* in the field of medicines, medical devices, in vitro diagnostics medical devices, and cosmetic products is a prerequisite for Ukraine to fulfill its accession obligations under the Association Agreement.

Currently, Ukraine has already taken initial steps towards the adoption of the legislation on medicines for human use that partially transposes Directive (EC) 2001/83/EC, drafted the Law of Ukraine on Medical Devices and In Vitro Diagnostics Medical Devices that is in line with Regulations (EU) 2017/745 and 2017/746 of April 05, 2017, and adopted a new technical regulation on cosmetic products that is in line with EU Regulation (EC) N 1223/2009 of November 30, 2009.

However, with the adoption of the new laws, it is necessary to review the existing by-laws and adopt new by-laws so that they are fully harmonised with the relevant directives and regulations. In this context, the value of this Twinning project will be expert assistance for implementation of a very complex legislative review expected to take place in 2024-2025. It is expected that focused knowledge transfer and support by qualified practitioners from the EU Member States who possess relevant practical experience and are fully competent at best practices in their countries will be highly beneficial and helpful for drafting regulatory amendments and new acts, implementation of the EU best regulatory practices in the field of medicines, medical devices and cosmetic products.

Along with the harmonisation of the legal framework, it is also necessary to establish a state control authority that would be operating in accordance with the highest ethical, professional and quality standards, and whose staff members will be able to rationally apply best practices recognised both in the EU and worldwide and would be constantly building on their knowledge and competencies both strategically and operationally. In this context, the project is seen as a unique and desired opportunity to gain a better understanding of the EU's best practices in this area through networking and sharing specific experiences with professionals from a similar EU institution.

This Twinning project will play a key role in building strong institutional capacity of the future SCA by providing a targeted set of activities consisting of expert missions, individual training, workshops, study visits and internships, which should provide knowledge transfer regarding the latest relevant EU recommendations and feedback on good practices (as well as lessons learned).

3.2. Ongoing reforms:

Adoption of the new Law of Ukraine on Medicines is an important step towards harmonising the national legislation with the EU *acquis* and is in line with the strategic plan of Ukraine. The Law envisages reforming the system of state authorities responsible for the circulation of medicines. It provides for the establishment of the SCA as a European-standard competent authority as well as the establishment of proper communication between the newly created body and the relevant competent EU authorities and agencies.

The Law also streamlines the approaches to licensing and inspection of activities related to the circulation of medicines and establishes mandatory application of the relevant good practices (GxP) at all key stages of the medicines circulation. The Law lays the foundation for bringing the marketing authorisation procedure and the liability of marketing authorisation holders in line with the applicable European directives and regulations.

The Law also stipulates that Ukraine needs to introduce approaches to pharmacovigilance, inspection of clinical trials, promotion and advertising of medicines, functioning of pharmacies as healthcare facilities, and phased introduction of 2D coding/labeling with two-dimensional barcodes on the packaging of medicines, that would be adapted to the EU requirements.

However, one of the key reforms being implemented in Ukraine under the new Law on Medicines is the establishment of a single state control authority (SCA) that will be implementing the state policy on production, market access, quality control, safety and efficacy of medicines, and the conduct of clinical trials.

The Law stipulates that the SCA will combine the functions currently performed by the SMDC and the SEC, and certain functions of the Ministry of Health.

The main functions of the SCA will include:

- state control over compliance with the legislation on quality, safety and efficacy of medicines at all stages of circulation (development, manufacturing, import, export, storage, transportation, distribution, disposal and destruction);
- state control over the licensees' compliance with the licensing terms and conditions and good practices (GxP);
- expert evaluation of clinical trial materials, based on the results of which authorisations for clinical trials are granted and modifications to clinical trial materials are made;
- inspecting clinical trials for the compliance with good clinical practice;
- decisions on state authorisation of medicines;
- providing scientific advice on state authorisation of medicines, etc.

The ***medical devices*** sector is also undergoing reforms, including development of the draft Law of Ukraine on Medical Devices and In Vitro Diagnostic Medical Devices and new technical regulations that should comply with Regulations (EU) 2017/745 and 2017/746. The key provisions of the reform are related to the approval of regulatory acts on the following:

- national nomenclature of medical devices that must be compliant with the international nomenclature, for manufacturers and other individuals or legal entities; designated authorities and certificates of conformity;
- a system for assigning unique product identifiers for validation, collection, processing and publication of information ("UDI issuing entity");
- authorisation of distributors of medical devices on the market;
- a database of medical device efficacy trials, which should be interoperable with the database of clinical trials of medicines in terms of efficacy trials of companion diagnostic devices;
- development of a portal for reporting adverse events, etc.

Technical regulation of ***cosmetic products*** in Ukraine is also in the process of active harmonisation with the EU legislation and requires revision of the national legislation and its adaptation to the EU law.

Hence, Ukraine is actively reforming the spheres of medicines, medical devices and cosmetic products, coupled with the revision of existing legislation/adoption of new regulations. In the context of Ukraine's European integration intentions and the opening of negotiating chapters, it is important to fully and properly harmonise the national legislation with the EU *acquis* in the course of such reforms. As the main central executive body that is responsible for formulating and implementing the state health policy, the Ministry of Health is authorised and responsible for such harmonisation. The implementation of this Twinning project will contribute to the achievement of the objectives in the designated areas. Following the adaptation to EU law and the revision/adoption of all required bylaws, the European Commission will assess the level of alignment with the EU *acquis* and reflect the findings in its report.

3.3. Linked activities:

As the main body within the system of central executive authorities responsible for formulating and implementing the state health policy, the Ministry of Health closely cooperates with international partners, and health reform is a part of Ukraine's international commitments.

The Ministry of Health is a recipient of several international technical assistance projects. These include:

1. ***Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed)*** funded by the US Government through the US Agency for International Development;
2. ***WHO*** support for the implementation of regulatory guidelines (GMP, GDP) under the Biennial Collaborative Agreement (BCA) 2024-2025 – Ukraine
3. ***Memorandum of Cooperation between GFA Consulting Group GmbH*** and specialised institution "Ukrainian Transplant Coordination Center" on blood safety system under the EU-funded technical assistance project "Support to Ukraine for Developing a Modern Public Health System".

3.4. List of applicable Union acquis/standards/norms:

List of applicable Union acquis/standards/norms is provided in Annex 2.

3.5. Components and results per component

Component 1 – Alignment of Ukraine's regulatory framework with the EU acquis

Within this Component, the Ministry of Health needs support to update and revise the existing legislation, and draft new regulations required to implement the EU norms and standards on medicines, medical devices, and cosmetic products. The list will be finalised by the Ministry of Health and the Twinning project team in accordance with the needs of the beneficiary at that time.

In the context of the Component 1, the following results will be achieved:

1. Developed a list of measures and an action plan for the alignment of the Ukrainian legislation with the EU *acquis*.
2. Draft legal acts prepared in accordance with the list of measures and the action plan, fully adapted to the EU legislation.

Component 2 – Definition of SCA structure and operational parameters

Within this Component, the Twinning project team will provide recommendations on the structure, funding, procedure and operating methods of the SCA, as well as on the draft internal regulations that will govern the SCA's work.

In the context of the Component 2, the following results will be achieved:

1. Recommendations provided on the structure, funding system, procedure and operating methods of the SCA in accordance with the best EU regulatory practices.
2. Recommendations provided on the implementation of internal policies of the SCA, including those on conflict of interest and internal management procedures.
3. Recommendations provided on the system of remuneration of the SCA's employees and the bonus system based on key performance indicators.
4. A strategy developed for communication (information exchange) between the SCA and the civil society, industry, other national regulatory authorities and international organisations.
5. Recommendations provided to enhance the efficiency of laboratories.

Component 3 – Support in capacity building of the SCA with advanced methodologies in line with the best EU regulatory practices

The EU regulatory framework for medicines, medical devices, and cosmetic products will be new to the staff members of the newly established SCA. In order to maximise the benefits of this Twinning project, it is necessary to support the development and implementation of the quality management system (QMS), i.e. to implement the best European practice for the leveraging data, regulatory science, innovation and competitiveness, and a mechanism for assessing the satisfaction of internal and external customers and other interested parties to improve the system continuously, for the establishment of the requirements for keeping documentation, as well as for monitoring the process of regulatory documents preparation.

The first part of the support will be of a general nature to design the operational standards for all staff members of the SCA and for the future benchmarking of QMS, including risk management principles. The second part of the support will be specialised trainings and expert exchange. The trainings will primarily be addressed to the employees of the existing agencies (Ministry of Health of Ukraine, the State Expert Center of the Ministry of Health of Ukraine (hereinafter the "SEC"), and the State Service of Ukraine on Medicines and Drugs Control (hereinafter the "SMDC") who eventually will be employed by the SCA.

In the context of the Component 3, the following results will be achieved:

1. the SCA's staff trained on the role of the SCA as a competent agency for conducting preclinical and clinical trials of medicines.
2. the SCA's staff trained on the role of the SCA as a competent agency for marketing authorisation of medicines.
3. the SCA's staff trained on the role of the SCA as the competent agency for pharmacovigilance.
4. the SCA's staff trained on the role of the SCA as a competent agency for inspections in the field of production and circulation of medicines, including pharmacovigilance inspections, good clinical practice inspections, good laboratory practice inspections;
5. the SCA's staff trained on the role of the SCA as a competent agency for licensing imports of medicines.
6. the SCA's staff trained on the role of the SCA as a competent agency for compliance inspections (GMP/GDP).
7. the SCA's staff trained on laboratory quality control of blood and blood components.
8. the SCA's staff trained on the role of the SCA as a competent agency for market surveillance of medical devices and cosmetic products.
9. the SCA's staff trained on quality control of medicines in circulation. Hemovigilance process.
10. the SCA's staff trained on licensing and control of narcotic drugs, including plants, psychotropic substances and precursors.
11. the SCA's staff trained on procurement and testing of donor blood and donor blood components.
12. the SCA's staff trained on the production of medicines in a pharmacy setting (extemporaneous production of medicines).
13. the SCA's staff trained on compliance with safety and quality standards for all the steps from donation and collection from a donor body, over testing, processing, storage and distribution, to eventual application in the patients' body;
14. All the employees of the SCA have basic knowledge of the EU regulatory practice (both general awareness and job-specific knowledge) and are able to cooperate with experts from national regulatory authorities of the EU Member States at the required level of knowledge.

3.6. Means/input from the EU Member State Partner Administration(s)*:

The project will be implemented in the form of a Twinning Contract between the Beneficiary Country and the EU Member State(s). The implementation of the project requires one Project Leader (PL) with responsibility for the overall coordination of project activities and one Resident Twinning Advisers (RTA) to manage implementation of project activities, Component Leaders (CL) and a pool of short-term experts (STE) within the limits of the budget. It is essential that the team has sufficiently broad expertise to cover all areas included in the project description.

Proposals submitted by Member State(s) shall be concise and focused on the strategy and methodology and an indicative timetable underpinning this, the administrative model suggested, the quality of the expertise to be mobilised and show clearly 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 expected results/outputs.

The interested Member State(s) shall include in their proposal the CVs of the designated Project Leader (PL) and the Resident Twinning Adviser (RTA), as well as the CVs of the potentially designated Component Leaders (CLs).

The Twinning project will be implemented by close cooperation between the partners aiming to achieve the Expected results in a sustainable manner.

The set of proposed activities and indicators will be further developed with the Twinning partners when drafting the initial work plan and successive rolling work plan every three months, keeping in mind that the final list of activities will be decided in cooperation with the Twinning partners.

Due to security reasons the project is expected to be implemented in a 'hybrid' mode (combining online and offline events and means of collaboration). In line with the flexibility arrangements for the implementation of Twinning projects in Ukraine, RTA and short-term experts may be allowed to work from their home country(ies) using the videoconferencing facilities. The decision on the format of implementation of the twinning project is to be taken by the implementing partners according to security situation in the country and security policies, rules and procedures of the implementing partners. The exact arrangement shall be agreed in the work plan, with the overall assumption that the remote work contributes to the successful implementation of the project. If the security situation changes after the conclusion of the contract, the project format may be changed to a standard offline implementation arrangement.

3.6.1. Profile and tasks of the PL:

Successful implementation of a Twinning project requires the involvement of two Project Leaders appointed in the Member State on the one hand (Member State Project Leader) (MS PL) and a Project Leader of the beneficiary on the other hand (Beneficiary Country Project Leader) (BC PL).

The Twinning partner MS PL will act as a partner of the BC PL, and they will together closely cooperate to provide the overall management and coordination of the project.

The MS PL should be an official or equivalent agent with an appropriate level/experience to ensure operational dialogue at political level throughout the implementation period. He/she manages the implementation of the Twinning project and officially signs off on all work plans and/or any updates to this implementation.

The Twinning partner EU MS PL must have a good understanding of operation of EU national competent authorities in the field of medicines, medical devices and cosmetic products. He/she must also have good project management skills and experience to address any issues that may arise during the project, such as the need for possible adjustments to adapt the Twinning Partner's approaches to the needs of the SCA, and to ensure that the project goals, objectives and deliverables are met and to facilitate their implementation.

The MS PL is expected to devote at least 4 days per month to the project in his/her home administration. In addition, he/she will coordinate, on behalf of the Member States, the Project Steering Committee (PSC), which will meet online or in person at least once every two months.

The MS PL must meet the following requirements (qualifications and skills):

- confirmed contractual relationship with a public administration or competent authority (see Twinning manual 4.1.4.2);
- university degree in one of the fields: pharmacy, healthcare, law; or at least 8 years of equivalent professional experience;
- at least 3 years of professional experience in the field of pharmacy, in healthcare institutions or in healthcare administration;
- Previous experience in project management or as a team leader will be considered an asset;
- Previous experience in international cooperation will be considered an asset;
- Previous experience in change management will be considered an asset
- experience in implementing at least one Twinning projects will be considered an asset;
- fluency in English, both written and oral;
- excellent management and communication skills.

The main tasks of the MS PL are:

- project management together with the BC PL;
- overall coordination and control of the Twinning project;
- assuring the quality and timely implementation of the planned activities, and achievement of the mandatory results;
- coordinate MS experts' work and availability;
- communicate with the EUD;
- monitoring and evaluation of project risks, project progress against the project budget, benchmarks and results;
- Ensure the backstopping functions and financial management jointly with the BC PL, co-chairing the Project Steering Committee (PSC) and participating in its meetings;
- participate in the preparation of the initial and subsequent work plans, as well as in the preparation of interim and final reports.

3.6.2 Profile and tasks of the RTA:

The Resident Twinning Adviser (RTA) will be appointed by the administration(s) of the partner country or their competent authority. He/she will be seconded to Ukraine for a period of 18 months, during which he/she will be responsible for the direct implementation of the project under the general supervision of the MS PL. The RTA will work in the office space provided by the Ministry of Health (18 months). The RTA will be responsible for coordinating all activities planned under the Twinning.

The RTA must meet the following requirements (qualifications and skills):

- proven contractual relationship with a public administration or mandated body (see Twinning Manual 4.1.4.2) responsible for health;
- university degree in one of the following fields: pharmacy, healthcare, or dentistry; or at least 8 years of equivalent professional experience;
- at least 3 years of professional experience in the field of authorisation or licensing of medicines/medical devices or pharmacovigilance or clinical trials.
- experience in implementing at least one international or EU-funded project of a similar nature; such experience in Twinning projects will be considered an asset;
- fluency in English, both written and oral;
- excellent communication, coordination and reporting skills.

The main tasks of the RTA are as follows:

- participate in drafting the work plan and deliverables of the Twinning project;
- oversee the daily implementation of the Twinning project in the beneficiary country;
- provide technical advice and support to the MOH in the context of the pre-defined work plan;
- coordinate and monitor the project implementation, assessing risks that may arise and providing proposals for necessary corrective action;
- liaise with the MOH on a daily basis and facilitate effective interaction and communication between the Twinning partners;
- manage a team of short-term experts, providing them with guidance, and supervising their performance and results;
- organise presentation events (kick-off and closing events);
- organise and participate in the Project Steering Committee (PSC) meetings;
- report to the Project Steering Committee (PSC) on the progress achieved;
- fulfil all necessary administrative functions.

3.6.3 Profile and tasks of Component Leaders:

The Twinning project team includes 3 Component Leaders.

It will be considered an advantage if the EU Member State proposes Component Leader(s) who can manage more than one component.

The Component Leader is responsible for coordinating the activities within the component under the supervision of the RTA.

The main tasks of the Component Leaders are:

- interacting with the BC to provide effective support within the project and achieve specific deliverables of the component;
- provide technical advice and support to the MOH in the context of the pre-defined work plan;
- planning the activities required to achieve the deliverables under the component;
- supervising short-term experts together with the RTA.

Each Component Leader must meet the following requirements (qualifications and skills):

- proven contractual relation to a public administration or mandated body;
- university degree in one of the following fields: pharmacy, healthcare, dentistry or similar disciplines relevant to the project; or 8 years of equivalent professional experience;
- at least 3 years of professional experience specific to the component;
- experience in implementing at least one international or EU-funded project of a similar nature; such experience in Twinning projects will be considered an asset;
- Previous experience in consulting, training and mentoring in related areas will be considered an asset;
- fluency in English, both written and oral;
- proactivity, analytical skills, and a good team player.

The main tasks of the Component Leaders are:

- interacting with the BC to provide effective support within the project and achieve specific deliverables of the component;
- provide technical advice and support to the MOH in the context of the pre-defined work plan;
- planning the activities required to achieve the deliverables under the component;
- supervising short-term experts together with the RTA.

3.6.4 Profile and tasks of other short-term experts (STEs):

The Twinning team will have a group of short-term experts (STEs) to provide specialised know-how for the individual tasks of the project. It is estimated that the project will require at least 13 short-term experts of various profiles, specifically:

1. preclinical and clinical trials of medicines.
2. marketing authorisation of medicines.
3. pharmacovigilance;
4. inspections of production and circulation of medicines, including pharmacovigilance inspections, good clinical practice inspections and good laboratory practice inspections;
5. licensing of imports of medicines;
6. compliance inspections (GMP/GDP);
7. laboratory quality control of blood and blood components;
8. market surveillance of medical devices and cosmetic products;
9. quality control of medicines in circulation. Hemovigilance process;
10. licensing and control over the circulation of narcotic drugs, including plants, psychotropic substances and precursors;

11. procurement and testing of donor blood and donor blood components;
12. compliance with safety and quality standards for all the steps from donation and collection from a donor body, over testing, processing, storage and distribution, to eventual application in the patients' body;
13. production of medicines in pharmacies (extemporaneous production of medicines;

Each STE must meet the following requirements:

- university degree in one of the following fields: pharmacy, medicine, dentistry, life sciences, law or similar disciplines specific to the project; or 8 years of equivalent professional experience;
- at least 3 years of professional experience working at a regulatory/controlling body in the field of medicines or medical devices;
- previous experience in consulting, training and mentoring in the relevant field of expertise;
- fluency in English, both written and oral;
- experience in drafting legislation (regulations, guidelines, instructions) will be considered an asset;
- in-depth knowledge and understanding of the EU legislation, good practices in the field of medicines or medical devices; SoHO including donation of blood and blood components will be considered an asset;
- hands-on experience in the relevant field of knowledge will be considered an asset.

The main tasks of short-term experts (STEs) are:

- cooperate with the Ukrainian partners on the implementation of all project activities;
- provide expert assistance and support to the MOH, the SEC and the SMDC in the areas and under the conditions specified in this Twinning Fiche;
- provide technical advice and support to the MOH in the context of the pre-defined work plan;
- prepare additional materials if required for the activities necessary for the project implementation and achievement of its goals;
- fulfil the assignments of the RTA and respond to the requests and needs of the Ukrainian partners;
- prepare the necessary reports, including the final project performance report.

4. Budget

The maximum budget available is EUR 1 500 000.

5. Implementation Arrangements

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

The person in charge at the EU Delegation to Ukraine:

Ms Mira Didukh
Project Manager
Delegation of the European Union to Ukraine
101, Volodymyrska Street, Kyiv, Ukraine, 01033

The Delegation of the European Union to Ukraine together with the Twinning Programme Administration Office (PAO) will control the quality of all twinning documentation, check that the good financial management of the Twinning project is in compliance with EC rules, receive and examine all twinning project reports, support all twinning stakeholders, including beneficiary administration and Member States.

The person in charge at the PAO in Ukraine:

Twinning Programme Administration Office (PAO)
National Agency of Ukraine on Civil Service
15, Prorizna Street, Kyiv, Ukraine, 01033
Monitoring will be performed by the EU Delegation to Ukraine.

5.2 Institutional framework

The project's beneficiary administration is the Ministry of Health. However, the MOH, the SEC and the SMDC are part of the current regulatory system. Their interaction and the existing institutional structure of the MOH are presented in the Annex.
The project implementation will lead to changes in the institutional framework, in particular:

- transition of the functions related to the state marketing authorisation/renewal of marketing authorisation for medicines, decision-making on the conduct/refusal to conduct clinical trials, technical regulation of medical devices and cosmetic products, from the MOH (Pharmaceutical Department) to the SCA;
- transition of the SMDC's functions to the SCA;
- transition of the SEC's functions to the SCA (except for health technology assessment).

5.3 Counterparts in the Beneficiary administration:

5.3.1 Contact person:

Taran Maryna
Chief Specialist of the Department of International Cooperation and European Integration of the Ministry of Health of Ukraine
7 Hrushevskoho Street, Kyiv
Ministry of Health of Ukraine

5.3.2 PL counterpart

Maryna Slobodnichenko
Deputy Minister of Health for European Integration
7 Hrushevskoho Street, Kyiv
Ministry of Health of Ukraine

5.3.3 RTA counterpart

Oleksandr Hritsenko
Deputy Head of Pharmaceutical Department, Ministry of Health of Ukraine
7 Hrushevskoho Street, Kyiv
Ministry of Health of Ukraine

6. Duration of the project

The project's implementation period is 18 months

7. Management and reporting

7.1 Language

The official language of the project is the one used as contract language under the instrument (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

A project steering committee (PSC) shall oversee the implementation of the project. The main duties of the PSC 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 discuss 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 further progress.

8. Sustainability

This Twinning project will support the MOH in building an institutionally capable SCA, focusing in particular on harmonising the industry's regulatory framework, as well as further consolidating the operational capacity of the SCA's staff to implement the new regulations.

The Twinning project has been launched at a time when the legislation regulating medicines, medical devices, and cosmetic products is undergoing a thorough review for the purpose of implementing the EU *acquis*. Supporting the MOH in developing a new legislative framework aligned with the EU *acquis* will lead to sustainable achievements, as the implementation acts, guidelines, procedures, etc. produced during the project - once adopted, will become part of Ukraine's legislative framework that will govern the sectors of medicines, medical devices, and cosmetic products for many years.

It is also expected that building the SCA as an institutionally capable regulatory body responsible for the regulation of medicines, medical devices, and cosmetic products in Ukraine will yield sustainable results. The management decisions, internal regulations,

SoPs, job descriptions, etc., developed and implemented within structure of the SCA through this Twinning project will remain embedded in it.

The sustainability of the staff training results is linked to building, improving and strengthening the institutional capacity of the SCA. Staff training will reduce staff turnover and serve as an incentive for employees to continue their employment with the SCA. Also, following the entry into force of the new Law of Ukraine on Medicines, it will be possible to hire staff for the SCA in accordance with the new job classification that will be developed within the Twinning project. The sustainability and commitment of the SCA's human resources is a positive factor for the sustainability of the Twinning achievements, as it relates to the increased administrative capacity that is likely to remain implanted in the institution as a permanent asset.

In addition, taking into account the recruitment plans of the SCA, Twinning experts providing training will be requested to develop and include in their reports brief support materials that senior staff can later use to train newly recruited staff during their induction period, even if this occurs after the Twinning project is completed.
Also, the SCA will implement the efforts made by Twinning experts in planning and developing communication solutions for it, which means that the SCA will independently implement the communication action plan developed by the project.

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

The project implementation will be based on the principles of gender equality and non-discrimination. The project activities will be carried out in a way that encourages equal participation, regardless of gender, racial or ethnic origin, religion or belief, disability, age, political or sexual orientation.

Particular focus will be placed on equality in the design and conduct of staff training, site visits, and communication strategy to ensure that the identified target groups are reached in an equal and non-discriminatory manner.

No negative environmental impact is expected in the course of the Twinning project.

10. Conditionality and sequencing

The recent adoption of the Law of Ukraine on Medicines, as well as of the new technical regulation on cosmetic products, and the upcoming adoption of the new Law of Ukraine on Medical Devices and in Vitro Diagnostic Medical Devices are prerequisites for the implementation of the Twinning project. That is why this project should focus on the harmonisation of legislation with the EU *acquis*, as well as on support to the establishing and capacity-building of the new SCA, as this will contribute to a better application of the new legislative provisions.

11. Indicators for performance measurement

Please refer to Annex C1a –Logical Framework Matrix.

Mandatory result 1: Draft regulatory framework on medicines, medical devices and cosmetic products is aligned with the EU *acquis*.

Indicators:

1. Action plan developed.
2. Regulatory documents drafted.

Mandatory result 2: SCA structure and operational parameters defined.

Indicators:

1. Recommendations, methodologies, draft internal policies, SOPs for the SCA's functions developed.
2. Staffing chart and structure, strategies and recommendations developed that will contribute to a better operational efficiency of laboratories developed.

Mandatory result 3: SCA's capacity strengthened with advanced methodologies in line with the best EU regulatory practices.

Indicators:

1. Employees are trained.
2. EMA Benchmarking completed.

12. Facilities available

The MOH will provide the following facilities to accommodate the RTA and his/her assistants:
An office with approximately 20 m² of space, equipped with desks and shelves for documents, telephone, Wi-Fi and computers. This office will be at the full disposal of the RTA and his/her team. The office is located in a building managed by the MOH.

The building will have a permanent security service (during and outside of normal business hours) and will be secured by an alarm system outside of normal business hours. This office can be used for meetings and negotiations.

The MOH will also provide a conference room, which will be available to the Resident Advisor and the Twinning team for meetings. This room can be used for training sessions, workshops, etc. This room will have video projectors and other equipment necessary for recording and playback of audio and video, as well as translation. The building also has a shelter that can be used in case of missile attacks.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical Framework matrix as per Annex C1a (compulsory)
2. List of applicable Union *acquis*/standards/norms
3. Current institutional structure
4. Organisational structure of the State Expert Center of the Ministry of Health of Ukraine
5. Organisational structure of the State Service of Ukraine on Medicines and Drugs Control

ANNEX C1 a: Simplified Logical Framework

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	Strengthen Ukraine's health sector and protect patients' interests by ensuring access to quality, safe, effective, and innovative medicines, medical devices, and cosmetic products.	Improved safety of medicines, medical devices, and cosmetic products for consumers.	Report of the European Commission, EMA Benchmarking. WHO Benchmarking, official websites of the Government of Ukraine, adoption of draft legal acts.	Impossibility to establish the SCA due to the associated political and economic factors.	Sufficient political support from the authorities Sufficient budget financing allocated
Specific (Project) Objective(s)	To build the SCA as a regulatory body capable of functioning within the network of the EU competent authorities.	SCA established. Further alignment with the EU *acquis*.	Expert evaluations, reviews, analytical reports, SOPs, well trained staff who can participate in the EU regulatory network. Report on the comparison of the SCA and an EU agency involved in the same procedures (EMA Benchmarking).	Martial law in Ukraine. Impossibility to establish the SCA due to associated political and economic factors.	Sufficient political support from the authorities Sufficient budget financing allocated
Mandatory results/outputs by components	***1. Draft regulatory framework on medicines, medical devices and cosmetic products is aligned with the EU acquis*** 1. Develop a list of measures and an action plan for the alignment of the Ukrainian legislation with the EU *acquis.* 2. Prepare draft regulations that are fully aligned with the EU legislation.	Action plan developed. Regulatory documents drafted.	Expert evaluations, surveys, analytical reports, draft regulations submitted for public discussion or official updates on the adoption of regulations in accordance with the national procedure.	Security situation disrupts project implementation	Hybrid work mode established to continue work
	2. SCA structure and operational parameters defined. 1. Provide recommendations on the structure, funding system, procedure and operating methods of	Recommendations, methodologies, draft internal policies, SOPs for the SCA's functions developed.	Expert evaluations, reviews, and draft documents (staffing charts, internal regulations, SOPs, etc.). Report on the comparison of the SCA and an EU agency	Martial law in Ukraine. Impossibility to establish the SCA due to the political and economic factors associated with the war.	Sufficient political support from the authorities Sufficient budget

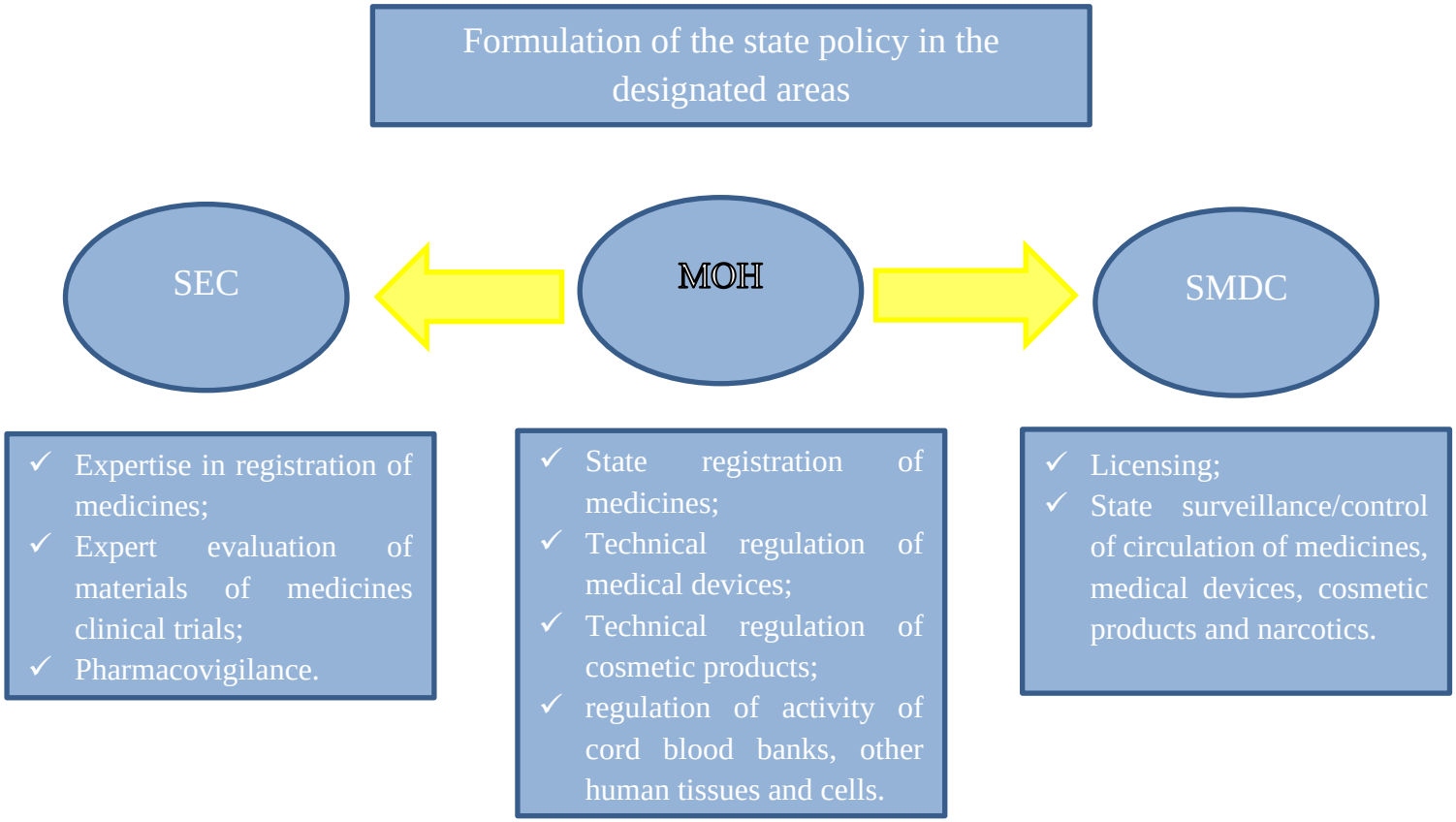
	the SCA in accordance with the best EU regulatory practices. 2. Provide recommendations on the implementation of internal policies of the SCA, including those on conflict of interest and internal management procedures. 3. Provide recommendations on the system of remuneration for the SCA's employees and the bonus system based on key performance indicators. 4. Develop a strategy for communication (information exchange) between the SCA and the civil society, industry, other national regulatory authorities and international organisations. 5. Provide recommendations to enhance the efficiency of laboratories. 6. Support for establishment of the SCA and a system of laboratories.	Staffing chart and structure, strategies and recommendations developed that will contribute to a better operational efficiency of laboratories.	involved in the same procedures (EMA Benchmarking).		financing allocated Hybrid work mode established to continue work
	3. SCA's capacity strengthened with advanced methodologies in line with the best EU regulatory practices for: 1. conducting preclinical and clinical trials of medicines; 2. authorisation of medicines; 3. pharmacovigilance; 4. inspections of production and circulation of medicines, including pharmacovigilance inspections, good clinical practice inspections and good laboratory practice inspections; 5. licensing of imports of medicines; 6. compliance inspections (GMP/GDP);	Employees are trained. EMA Benchmarking completed.	Training records, expert evaluations, reviews, analytical reports, and draft documents (internal regulations, SOPs, etc.).	Training cannot be conducted abroad due to the legislation-imposed travel restrictions. Training cannot be conducted in Ukraine due to security threats. The trained personnel are not employed as SCA not yet established.	Trainings organised on-line. People to participate in the trainings are currently employed by the Ministry of Health of Ukraine, the State Expert Center of the Ministry of Health of Ukraine and the State Service of Ukraine on

	7. laboratory quality control of blood and blood components; 8. market surveillance of medical devices and cosmetic products; 9. quality control of medicines in circulation; Hemovigilance process; 10. licensing and control over the circulation of narcotic drugs, including plants, psychotropic substances and precursors; 11. procurement and testing of donor blood and donor blood components; 12. production of medicines in pharmacies (extemporaneous production of medicines; 13. compliance with safety and quality standards for all the steps from donation and collection from a donor body, over testing, processing, storage and distribution, to eventual application in the patients' body; ***14.*** basic knowledge of the EU's regulatory practice (for all staff members of the SCA).				Medicines and Drugs Control will be transferred to the SCA.

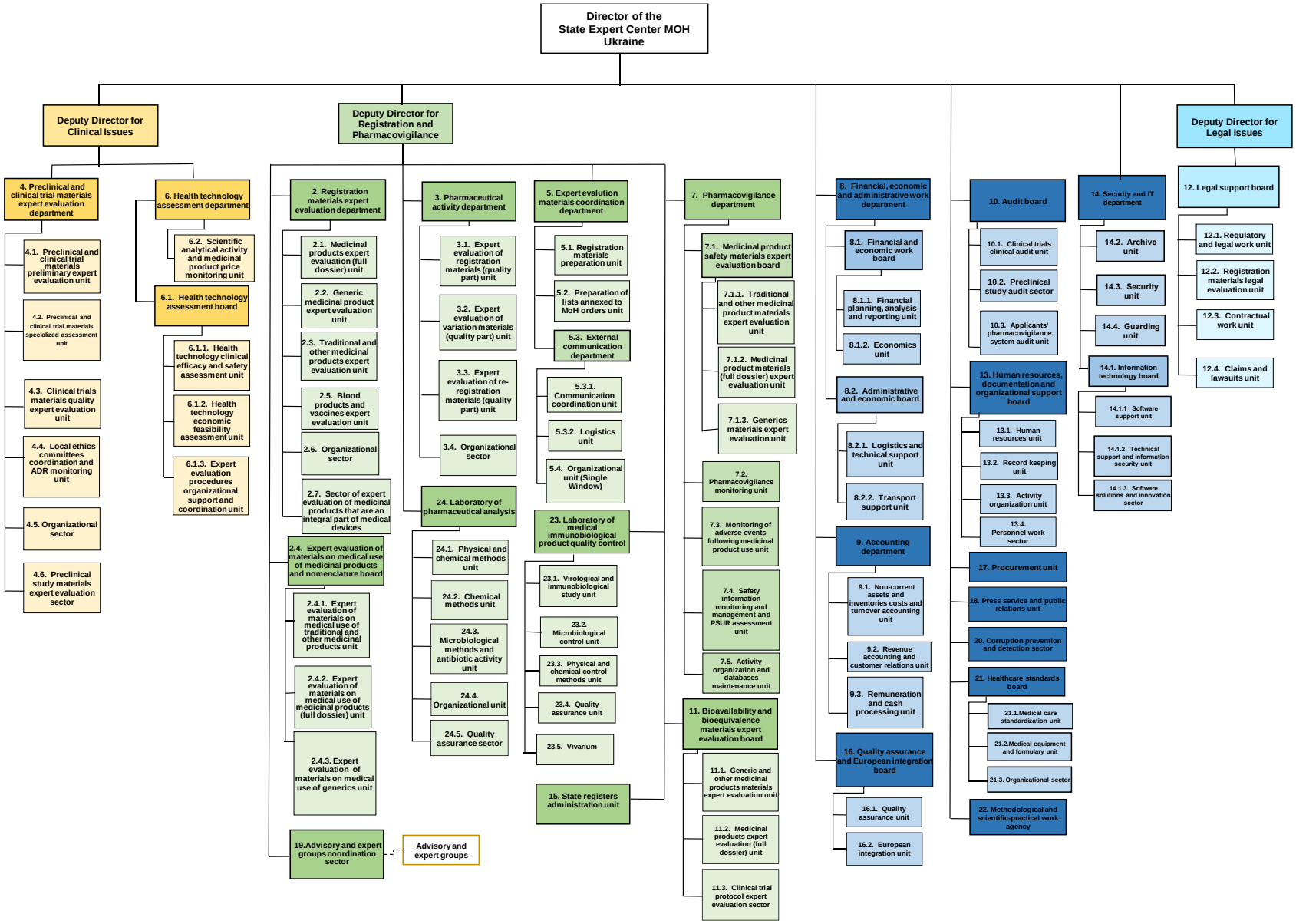
ANNEX 2: The EU *acquis* in respect of medicinal products, medical devices and cosmetic products

Directive 2001/83/EC as amended	Codification of medicinal products directives
Regulation (EC) No 726/2004	Regulation establishing the centralised procedure and the European Medicines Agency
Regulation (EU) No 2017/745	Medical Devices Directive
Regulation (EU) No 2017/746	In vitro diagnostics medical devices Directive
Regulation (EC) No 1223/2009	Cosmetic products Directive
Directive 96/45/EC	Methods of analysis necessary for checking the composition of cosmetic products
Directive 2003/94/EC	GMP Directive (medicinal products)
Directive 2001/20/EC	Good clinical practice in the conduct of clinical trials on medicinal products for human use
Regulation (EU) No 536/2014	Clinical trials on medicinal products for human use
Directive 2011/62/EU	Medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products
Regulation (EC) No 141/2000 and 847/2000	Orphan medicinal product regulation
Regulation (EU) No 2020/1043	Clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)
Regulation (EC) No 540/95	Reporting suspected unexpected adverse reactions which are not serious
Implementing Regulation (EU) No 520/2012	Pharmacovigilance activities
Guideline on good pharmacovigilance practices	Pharmacovigilance practices
Implementing Regulation (EU) No 2017/556	Detailed arrangements for the good clinical practice inspection procedures
Guideline on Good Distribution Practice	Commission Guidance document
Regulation (EC) No 1901/2006 and 1902/2007	Regulation medicines for children
Directive 89/105/EEC	Transparency Directive (pricing and reimbursement of medicinal products)
Regulation (EC) No 1394/2007	Advanced Therapy Medicinal Products regulation
Directive 2002/98/EC	Standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
Directive 2004/23/EC	Standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

ANNEX 3 Current institutional structure



ANNEX 4 Organisational structure of the State Expert Center of the Ministry of Health of Ukraine (SEC)



ANNEX 5 Organisational structure of the State Service of Ukraine on Medicines and Drugs Control (SMDC)