ANNEX C1: Twinning Fiche

Project title: Strengthening Egyptian Drug Authority's regulatory functions

Beneficiary administration: Egyptian Drug Authority

Twinning Reference: EG 23 NDICI HE 01 25

Publication notice reference: The publication notice reference will be completed by the European Commission

EU funded project

TWINNING TOOL

(It is recommended that the complete Twinning Fiche should not exceed 10 pages, excluding annexes)

List of Abbreviations

Acronym/abbreviation	Meaning
AFD	Agence Française de Développement
AMRH	African Medicines Regulatory Harmonization Initiative
CAPA	Central Administration of Pharmaceutical Affairs
EBRD	European Bank for Reconstruction and Development
EDA	Egyptian Drug Authority
EIB	European Investment Bank
ERA	European Research Area
EU	European Union
EUD	EU Delegation in Egypt
GBT	(WHO) Global Benchmarking Tool
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLOPID-R	Global Research Collaboration for Infectious Disease Preparedness
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IPRP	International Pharmaceutical Regulators Programme
JPI AMR	EU Joint Programming Initiative on Antimicrobial Resistance
KfW	Kreditanstalt für Wiederaufbau [Reconstruction Credit Institute]
MA	Marketing Authorisation
ML	Maturity Level (in the GBT)
MSMEs	Micro, Small & Medium Size Enterprise
NODCAR	National Organization for Drug Control and Research
NORCB	National Organization for Research and Control of Biopharmaceuticals
NRA	National Regulatory Authority
PMS	Post Marketing Surveillance
QMS	Quality Management Systems
RCORE	Regional Centre of Regulatory Excellence for Vaccines
SOP	Standard Operating Procedure
SRA	Strictly Regulated Authority
UMPA	Unified Medical Procurement Authority
WHO	World Health Organisation
WLA	WHO Listed Authority

1. Basic Information

1.1 Programme: ACT-62266 – Special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023

1.2 Twinning Sector: Health and Consumer Protection

1.3 EU funded budget: EUR 1,500,000

1.4 Sustainable Development Goals (SDGs): SDG 3: Good Health and Well-being

2. Objectives

2.1 Overall Objective(s):

The **Overall Objective** is to improve the enabling regulatory environment for medicinal products including vaccines[1] in Egypt and promote Egyptian Drug Authority to become a World Health Organisation (WHO) - listed Authority (WLA)

2.2 Specific objective:

The **Specific objective** is to support the Egyptian Drug Authority (EDA) to reach WHO Global Benchmarking Tool (GBT) Maturity Level 4 for Medicinal Products, including vaccines, and to comply with WHO Good Regulatory Practices up to the level of a Stringent Regulatory Authority (SRA).

2.3 The elements targeted in strategic documents i.e. National Development Plan/Cooperation agreement/Association Agreement/Sector reform strategy and related Action Plans

In 2016, Egypt launched its first version of the Sustainable Development Strategy: Egypt's Vision 2030, as a cornerstone for a comprehensive developmental process. Egypt's Vision 2030 has provided a clear direction for the country's efforts to achieve sustainable development across its economic, social, and environmental dimensions. It has also informed the government's plans and programs, with a clear focus on inclusive and sustainable growth, as well as balanced government's development.

This strategy is also set to propel Egypt to the forefront of healthcare services and research in the Arab world and Africa. The "Knowledge, Innovation, and Scientific Research" pillar of the Economic Dimension seeks to foster a society that generates science, technology, and knowledge, employing their outputs to meet national objectives

[1] The EU definition of medicinal product includes all pharmaceuticals and biological medicines as well as vaccines and blood products.

and overcome challenges. The "Transparency and efficient government institutions" pillar works towards an efficient and effective public administration sector managing State resources with transparency, fairness and flexibility subject to accountability, maximising citizens' satisfaction and responding to their needs.

In 2023, the Egypt's 2030 Vision was updated (published in 2023)[2] with a belief that "Human-Centered Development" is key to the success of any development process. The strategic goal of "*Improve Egyptians' Quality of Life and Raise their Living Standards*", positioned at the forefront of the strategic goals of Egypt's Vision 2030, aims to provide the basic requirements of life for every Egyptian. To enable every individual to embrace a wholesome lifestyle, Egypt's Vision 2030 aims to elevate the healthcare sector, improve citizens' health status, foster preventive measures, facilitate treatment, and proactively combat the propagation of diseases and pandemics.

The Egyptian Drug Authority (EDA) was established under Law number 151 of 2019 and is a public service authority with a legal personality affiliated with the Prime Minister. It is responsible for the regulation of all pharmaceuticals, medical devices, their accessories, and IVDs in the Egyptian market[3]**.**

As stated in the Law 151 of 2019, the EDA can collaborate with national and international entities concerned with medical products and public health and those concerned with the issuance of relevant standards, within the scope of achieving EDA's objectives. The EDA can also participate in and organise domestic and international conferences as deemed necessary.

As part of its Strategic Plan for 2020-2024, the EDA has outlined several strategic objectives that the twinning project would aid in fulfilling. These include - but are not limited to - developing the legal and regulatory framework in accordance with the international standards; developing institutional performance and the effective implementation of the quality management system; ensuring the quality, safety, and efficacy of the medical products and devices; investing in human resources, leveraging capabilities and building innovative capacities.

3. Description

3.1 Background and justification:

3.1.1. General Background

Africa faces significant challenges in accessing quality, safe, and efficacious medical products and technologies. The COVID-19 pandemic has exposed the vulnerabilities of existing global supply chains and emphasised Africa's reliance on imports for essential healthcare products.

Currently, Africa imports 99% of its vaccines and over 90% of medicinal products and medical devices. In response, in May 2021, at the G20 Global Health Summit in Rome,

[2] https://mped.gov.eg/Files/Egypt_Vision_2030_EnglishDigitalUse.pdf
[3] https://edaegypt.gov.eg/

the European Union (EU) announced the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+). This initiative aims to create an enabling environment for local vaccine manufacturing in Africa, addressing barriers on both supply and demand sides. The TEI MAV+ is a key priority of the EU Global Gateway strategy and the EU Global Health strategy.

The initiative is backed by €1.2 billion from the EU budget and European development finance institutions, such as the European Investment Bank (EIB), with additional contributions from EU Member States. The Team Europe initiative will support technology transfer and develop regional manufacturing hubs in alignment with the African Union and the Africa Centres for Disease Control and Prevention (Africa CDC).

The initiative also aligns with the recently launched Partnerships for African Vaccine Manufacturing, involving several African and international counterparts. Local manufacturing presents an opportunity to stimulate growth and jobs, boost trade, diversify global value chains, engage with the private sector, and strengthen scientific and diplomatic ties with partner countries. This initiative advances universal health coverage (UHC), health systems strengthening (HSS), health security, pandemic preparedness, and human development.

The **EU-Egypt Collaboration in Health** has significantly reinforced the public healthcare system in Egypt, particularly during the COVID-19 pandemic.

In December 2020, the EU provided €89 million in budget support to the Egyptian Ministry of Health to enhance preparedness and response to the virus. Additionally, the EU initiated a specialized program to address the immediate socio-economic effects of the pandemic, focusing on vulnerable populations and women. EU-funded projects were adapted to ensure adequate access to health services for those in need.

Access to finance, a cornerstone of Team Europe's response in Egypt, was enhanced through the mobilization of €1.65 billion between April 2020 and March 2021 to support SMEs to cope with the pandemic restrictions. Additionally, ongoing EU-funded projects were redirected to support Egypt's COVID-19 response, encompassing both short-term health sector assistance and long-term support for SMEs, youth, and women. Community resilience was bolstered by adjusting or adopting programs in partnership with Agence Française de Développement (AFD), Kreditanstalt für Wiederaufbau (KfW), and the European Investment Bank (EIB). In collaboration with European Financial Institutions, ongoing projects were redirected to support Egypt's COVID-19 response, encompassing both short-term health sector assistance and long-term support for SMEs, youth, and women. The European Bank for Reconstruction and Development (EBRD) contributed to this effort by easing loan repayments for Micro, Small, and Medium Enterprises (MSMEs) and opening credit lines worth €784 million for commercial banks from April 2020 to February 2021 as part of its COVID Solidarity Package.

Egypt has actively participated in a number of European programs fostering health research and innovation. Egypt was among the first African countries to participate in the **EU Joint Programming Initiative on Antimicrobial Resistance** (“JPI AMR”), which aims to tackle the urgent global challenge of antibiotic resistance. This

collaborative effort brought together countries, research institutions, and experts to develop and implement innovative solutions to combat antimicrobial resistance. Egypt's involvement in this initiative underscores its commitment to international cooperation and highlights its role in addressing critical public health concerns. Egypt has also engaged with **the Global Research Collaboration for Infectious Disease Preparedness** ("GLOPID-R"), a network of research funding organisations aiming to facilitate a rapid and effective response to emerging infectious diseases.

Furthermore, Egypt is the only country in the region participating in the ERA4Health Partnership, which aims to strengthen the European Research Area's ("ERA") impact on health research and innovation[4]. By participating in **ERA4Health**, Egypt is able to tap into a wide range of resources and expertise, as well as access collaborative research funding opportunities. Egypt has been chosen as one of the first recipients of technology from the WHO's global mRNA vaccine hub, bolstered by the EU's recognition of Egypt's potential as an effective pharmaceutical production hub.

The Egyptian Drug Authority (EDA) is the sole regulatory authority in Egypt that is responsible for ensuring the safety, efficacy and quality of medical products that was defined by the EDA establishment law no. 151 for the year 2019 and the Executive Regulation for EDA establishment law no. 777 for the year 2020. Legal provisions and regulations for key regulatory functions define the medical products that are regulated by EDA and ensure that EDA operates independently. This legislation and other relevant information are publicly available and involve the engagement of other stakeholders including the industry and the patient community. Written Standard Operation Procedures (SOPs) are available to ensure channels of communication and decision-making are clearly established among the structures, administrations, and the departments forming the National Regulatory Authority (NRA).

3.1.2. Specific Background

The Association Council of the European Union and Egypt established new Partnership Priorities to guide their relationship until 2027, aligning with the EU Agenda for the Mediterranean, its Economic and Investment Plan, and Egypt's Sustainable Development Strategy Vision 2030. Focusing on three key areas – Sustainable Modern Economy and Social Development, Partnering in Foreign Policy, and Enhancing Stability – the partnership aims to deepen dialogue and cooperation. A sum of EUR 450 million has been allocated to Egypt for 2021-2024 under the Neighbourhood, Development and International Cooperation Instrument (NDICI), supporting green and sustainable development, human development, economic resilience through the green and digital transition, and social cohesion.

Egypt has been chosen as one of the first recipients of technology from the WHO's global mRNA vaccine hub, bolstered by the EU's recognition of Egypt's potential as an effective pharmaceutical production hub.

[4] Fostering a European Research Area for Health Research, 2021. Source: URL. ERA4Health is a collaborative effort between EU member states and associated countries, including Egypt as a non-associated third country, to address global health challenges and promote health innovation

In March 2024, The European Union (EU) and Egypt have agreed to elevate their relationship by launching a Strategic and Comprehensive Partnership for shared prosperity, stability and security, based on joint interest and mutual trust and building on the already existing positive agenda in EU-Egypt relations. Underpinning the partnership is a financial and investment package of EUR 7.4 billion for 2024-2027 period consisting of short- and longer-term support for the necessary macro-fiscal and socio-economic reform agenda composed of Macro Financial Assistance (MFA), guarantees and blending, as well as programmes and technical assistance for specific priorities.

3.1.3 Justification

The European Commission (EC) has conducted a **Health Advisory Services (HAS) mission** from 31st January to 3rd February 2022 to explore potential venues of EU support for vaccines production in Egypt, in particular COVID-19 vaccines. The mission comes in response to the request from the Egyptian government for EU support on its plans to become a regional production hub for vaccines manufacturing. The mission also relates to the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, medicines, and health technologies (MAV+) in Africa. The mission highlighted Egypt's strong position on the African continent in terms of pharmaceutical production, including biologicals and vaccines.

A potential support to strengthen the enabling environment has been identified for the development of the capacities of the Egyptian Drug Authority (EDA) in different domains. This support should include but not limited to the regulation of biologicals, extending the GBT Maturity Level of agency to ML 4 and towards becoming a WHO listed authority. This would widen the recognition of the EDA's decisions and approved products, and help the EDA in building regulatory harmonization for biologicals within Africa through the newly established African Medicine Authority (AMA).

3.2 Ongoing reforms:

EDA has established **its strategic plan for the years 2020-2024**, which stemmed from Egypt's vision 2030 and sustainable development goals (SDGs) that undergo regular reviews. An updated National Drug Policy is currently being reviewed by WHO. In this framework, EDA is applying the principles of Good Regulatory Practice (GRP) to the regulation of medical products. In addition, guidelines are in place for recognition and reliance on other NRAs. Also, EDA invested heavily in its quality management system.

The Egyptian Drug Authority (EDA) is the product of **a merger of three regulatory agencies** - the National Organization for Drug Control and Research (NODCAR), the National Organization for Research & Control of Biologicals (NORCB) and the Central Administration of Pharmaceutical Affairs (CAPA). The harmonization among previously developed Quality Management Systems (QMSs) for NODCAR, NORCB and CAPA has been a substantial challenge. However, the recent developments, modifications and improvements have led to good results. The QMS and the structure established to implement, improve and maintain it belong to the identified strengths of EDA. EDA also has sustainable Human and Financial resources to perform its regulatory activities.

The EDA enjoys stable sources of financing and competent human resource which makes EDA dynamic structure capable of performing its regulatory activities. The Authority is well equipped, with good work environment and improved laboratories of control of vaccines and biologicals. The EDA is continuing its investment in capacity building and competency of staff. A quite advanced and promising learning system has been established. One of the challenges that must be addressed is the relatively high turnover of staff, with one more possible area for improvement is the full implementation of several computerised systems for the different regulatory activities and managing the different databases.

Since its establishment, EDA has engaged with several international partners and communities and is currently a **WHO Maturity Level 3 Authority** (for vaccine production), a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), a member of the International Pharmaceutical Regulators Programme (IPRP), and an associate member of the International Coalition of Medicines Regulatory Authorities (ICMRA). Further, EDA is designated by the African Medicines Regulatory Harmonization (AMRH) initiative (AUDA NEPAD) as a Regional Centre of Regulatory Excellence (RCORE) for Vaccines Regulatory Oversight.

The Egyptian Drug Authority (EDA) has been working on **improving its regulatory framework for medicinal products**. It has established legal provisions and regulations, which are regularly updated and cover a range of functions including registration, market authorization, licensing establishments, and more. However, there is room for improvement in strategic planning, performance monitoring, and ensuring coherence and transparency in organizational policies and practices.

The Authority has also been working on **strengthening marketing authorisation procedures** for medicinal products. It has a regulatory reliance framework, but there is a need for better implementation of guidelines that govern how EDA relies on or uses information from other regulatory entities. The authority has started improving the assessment of the quality, safety, and efficacy of new categories of products like Radiopharmaceuticals, Medical gases, Plasma-derived medicinal products, and Advanced Therapy Medicinal Products (ATMPs).

Furthermore, the EDA implements **risk-based sampling of medical products** from various points in the supply chain. However, risk assessment in small sample size testing is one area that may require additional support. The EDA also acknowledges the need for access to reliable libraries and databases for identifying standard substances. Training in cell-based assays for biological product potency testing and the use of human-based reconstructed tissue models for testing is also highly sought after.

The Authority is proactive in maintaining the quality of **medicinal products post-approval**. The authority routinely issues certificates of Good Manufacturing Practices (GMP), founded on the inspections performed on manufacturing facilities. However, there is a recognised need for enhanced training of inspectors, particularly concerning new GMP guidelines for sterile products and Advanced Therapy Medicinal Products

(ATMPs). Particular collaboration in this area and/or Joint GMP inspections with a stringent regulatory authority could significantly benefit the EDA and improve these practices.

The EDA has begun publishing **public assessment** reports, but there is a need to increase the capacity of EDA's assessors in evaluating the confidentiality of information in these reports. Additionally, there is a need for more experience in joint assessments with stringent regulatory authorities to optimize practices.

On its official website, the EDA publishes notifications about sub-standard, falsified, and recalled products. To further this commitment, the EDA aims to enhance its capacity for advanced screening and detection of, and response to, substandard and falsified (SF) medical products. The incorporation of new technologies and equipment is highly encouraged. A joint-inspection focus on **Post-Marketing Surveillance** (PMS) activities with a mature regulatory system could greatly benefit the EDA in these areas.

Under the Central Administration of Pharmaceutical Care, the Egyptian Pharmaceutical Vigilance Center (EPVC) regularly issues newsletters with safety alerts and local case reports to the public, as well as newsletters to professionals and healthcare providers. However, the EDA recognizes the need to acquire skills and benefit from best practices sharing for **post-authorization safety and efficacy studies** (PASS), **vigilance inspection**, and grading of findings with its European counterparts.

The Authority maintains well-documented **procedures for clinical trial** (CT) **oversight**. An established registry of clinical trials is published by the EDA. However assistance is required for publishing data from inspections conducted by the Good Clinical Practice (GCP) inspection team, as well as clinical trial protocols in evaluation reports - making them available to the public. There is a recognised need to improve the review of clinical trial data and evaluation. Capacity building with a focus on clinical trials of ATMPs, gene therapy, and new innovative products is required. Additionally, technical support in the field of clinical trial automation is an area requiring assistance.

The Authority has incorporated numerous **automated e-services**, but there is still a need for support, especially in the full implementation of eCTD & E-Labelling system establishment for biological products. One possible area for improvement is the full implementation of computerised system for the different regulatory activities and managing the different databases.

3.3 Linked activities:

There are few active donors in the health sector with the World Bank's "Transforming Egypt's Healthcare System Project", and France's continued support to the health sector in Egypt through policy-based loans being the most prominent ones. Both the World Bank and AFD projects are mainly focused on improving the quality of primary and secondary health care services. JICA is also one of the active donors supporting the health sector.

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

The following EU legal texts are applicable to the regulation of medicinal products including vaccines:

- Directive 2001/83/EC Community Code relating to medicinal products for human use;
- Regulation (EC) no. 727/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency;
- Commission Directive 2003/94/EEC laying down principles and guidelines of Good Manufacturing Practice;
- Clinical Trial Regulation (EU) No. 536/2014;

The twinning project responds to the following domestic legislation:

- Pharmacy Professional Practice Law 127/1955
- Law No. (151) for the year 2019 Promulgating law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and the Egyptian Drug Authority (EDA) (The Official Gazette – Issue 34 Bis (A) dated Aug. 25th, 2019).
- Law No. (8) of 2021 concerning regulating blood operations and collecting plasma for manufacturing and exporting plasma derivatives.
- Law No. (214) of 2020 concerning the regulation pf Clinical Medical Research.
- Executive Regulations of the EDA:
    - Prime Minister's decree No.777 of 2020 on promulgating the Executive Regulation of the Law Establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and the Egyptian Drug Authority(EDA) Promulgated by Law No. (151) for Year 2019.
    - Prime Minister's Decree (2603) of 2021 on promulgating the Executive Regulation of Law No. 8 for year 2021.
    - Prime Minister's decree No. (927) of 2022 on promulgating the Executive Regulation of Clinical Medical Research Promulgated by Law No. (214) of 2020.

All relevant laws, executive regulations (EDA's website – Laws & Executive Regulations), ministerial decrees, EDA Chairman Decrees (EDA's website – Ministerial Decrees) and guidelines (EDA's website – Guidelines) are regularly published and updated on EDA's website since EDA's establishment.

3.5 Components and results per component

To achieve the overall objectives, the twinning partners will engage with EDA on the following aspect but not limited to

a) **Improvement of the national regulatory system** in line with good regulatory practices and international standards;
b) **Marketing authorisation** for medicinal products, including vaccines and life cycle management (renewals and variations);

c) **Import, Manufacturing and Wholesale** distributor authorisation.
d) **Regulatory inspections**, specifically Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) for medicinal products, including vaccines;
e) **Quality control testing** of medicinal products, including vaccines;
f) **Official batch release** for specific medicinal products such as vaccines;
g) **Post-marketing surveillance** and pharmacovigilance, including support for a pharmacovigilance center;
h) Oversight of clinical research/trials, including testing of vaccines**.**

On the basis of above, the twinning project will be organised in the following components:

Component 1: Improving legal framework and regulatory functions for medicinal products

Result 1.1. The current regulatory framework is assessed and key recommendations are issued.

The following indicative activities could be carried out, but not limited to:

- The regulatory framework – legislation and regulatory guidance – covering (human) medicinal products is assessed. The assessment report contains recommendations for further alignment with EU and WHO Best Practices and WHO Good Regulatory Practices (GRP). The assessment is done by the twinning partner and EDA jointly.
- Twinning partner (s) NRA(s) and/or other public administrations/mandated bodies shares with EDA best practices such as but not limited to on aspects of GRP, e.g. impartiality, management of conflicts of interests and transparency. Possible improvements are to be identified with EDA staff. Methods and training materials is to be made available for use of EDA.

Result 1.2: EDA capacity in planning, monitoring and strategy definition is strengthened.

The following indicative activities could be carried out, but not limited to:

- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies shares with EDA best practices such as but not limited to on how to develop and implement multi-annual strategic plans, establish detailed yearly roadmap (including specific activities, responsibilities, timelines, and budgetary resources) and implementation modalities.

- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies shares with EDA best practices such as but not limited to on working with ESG principles: Environmental, Sustainable Development and Good Governance and implementation modalities.

Component 2: Strengthening of marketing authorisation procedures for medicinal products

Result 2.1: Marketing authorisation function for medicinal products, including vaccines is improved

The following indicative activities could be carried out but not limited to:

- Gaps are identified on the basis of the last WHO GBT self-benchmarking and additional assessment done by the twinning partner.
- Additional regulations and guidelines related to assessment and market authorisation for locally manufactured medicinal products and vaccines are developed.

Result 2.2: Quality, Safety and Efficacy assessment is strengthened.

The following indicative activities could be carried out, but not limited to:

- SOPs for assessments of Quality, Safety and Efficacy are reviewed and improved.
- Detailed specific SOPs for assessment of Quality, Safety and Efficacy are developed for:
    - Radiopharmaceuticals;
    - Medical gases;
    - Plasma-derived medicinal products; and
    - Advanced Therapy Medicinal Products.

- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies supports QSE (Quality, Safety and Efficacy) assessors of medicinal products and vaccines in the EDA Marketing authorisation department in the implementation of the SOPs (e.g., by conducting joint assessments of generic medicinal products and reference medicinal products, both pharmaceuticals and biologicals).

- The legal and regulatory framework allowing reliance and mutual recognition of assessments and marketing authorisations made by Stringent Regulatory Authorities (SRAs) and approvals by WHO PQ is reviewed and improved.

Result 2.3: Drafting of (public) assessment reports is strengthened.

The following indicative activities could be carried out, but not limited to:

- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies shares with EDA staff best practices such as but not limited to on the topic of drafting assessment reports and informing scientists, healthcare professionals and patients about the grounds for decisions.
- Responsible EDA staff members are trained to identify the information in assessment reports that should not be published in a public assessment report.

Result 2.4: Borderline products decision making is strengthened

The following indicative activities could be carried out, but not limited to:

- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies shares best practices such as but not limited to on decision making for borderline products

Result 2.5: Pharmaceutical references and leaflet publishing, Information, advertising and promotion of medical products is enhanced.

The following indicative activities could be carried out, but not limited to:

- Best practices are shared in respect to official product information (PIL and label) versus the product dossier (summary of product information),
- Promoting the implementation of e-labelling in Egypt by training EDA staff on best practices and how to spread public awareness about the service and its utilization
- SOP is developed or improved in respect of regulation and control of marketing materials.

<u>Component 3: Improving post-approval functions of medicinal products</u>

Result 3.1: EDA's Pharmacovigilance (PV) system and implementation of the SOPs for the evaluation of safety reports, including reports of serious adverse medicines reactions and PSURs, more particularly for vaccines, is improved.

The following indicative activities could be carried out, but not limited to:

- Based on the existing PV system in EDA, existing SOPs are updated, as well as tools for their implementation,
- EDA staff is trained to implement updated SOPs, more particularly for side adverse drug reactions events linked to vaccines.
- Twinning partner(s) NRA(s) and/or other public administrations/mandated bodies share with EDA staff best practice such as but not limited to in respect of:
    - Signal detection;
    - Risk minimisation strategies including their effectiveness; and
    - Post authorisation safety studies.

Result 3.2: Good Vigilance Practices (GVP) inspection is strengthened

The following indicative activities could be carried out, but not limited to:

- Best practices in respect of Good Vigilance Practices inspection are shared with EDA staff
- EDA GVP inspectors are trained for supervision and enforcement of GVP

Result 3.3: Assessment process for manufacturing/importer authorisation and wholesale distributor authorisation function (for manufacturers, importers, wholesalers/distributors) is improved.

The following indicative activities could be carried out, but not limited to:

- EDA staff is supported by twinning partner(s) in the review of SOPs for the evaluation of applications for manufacturing, import and wholesale distribution authorisations, including EDA decisions for manufacturing, import and wholesale distribution authorisations to be made available on the EDA website.
- The legal framework allowing reliance and/or recognition of inspections and pharmaceutical authorisations from SRAs is established.

Result 3.4: Training is conducted on GDP and GMP Inspections, with a focus on vaccine manufacturing facilities, including joint missions (in the region and in the EU)

The following indicative activities could be carried out, but not limited to:

- EDA inspectors are trained (planning, conduction, reporting of results and communication of findings) to be able to conduct GDP and GMP inspections, more particularly for biological products.
- EDA inspectors are enabled to participate in joint inspections with regional or national regulatory authorities and to participate in inspections performed by WHO PQ team for vaccines.
- EDA will – together with the twinning partner(s) – assess the legislative framework and regulations and explore how to further contribute and rely on the outcome of collaborations with regional or national regulatory agencies.
- Responsible staff will be guided in developing regional or international collaborations and work sharing including the closure of (confidentiality) agreements with other regulators.

Result 3.5: Official (lot) batch release function is enhanced.

The following indicative activities could be carried out, but not limited to:

- European best practices is shared with regards to the official (lot) batch release function in EDA
- EDA staff are trained and coached on vaccine official (lot) batch release (with a possibility of EU based training).

Result 3.6: EDA laboratory testing procedures is improved.

The following indicative activities could be carried out, but not limited to:

- The twinning partner(s) and/or other public administrations/mandated bodies and EDA will assess needs for and scope of regulatory testing and develop a SOP for the identification of necessary tests.
- EDA staff capacity in quality control laboratory testing and equipment

maintenance is strengthened.

Component 4: Advancing Clinical Trial Oversight.

Result 4.1: Legal provisions on clinical trials (CT), arrangement for effective organisation and good governance of CT are established

The following indicative activities could be carried out, but not limited to:

- The twinning partner(s) – together with EDA - will review legal provisions, regulations and guidelines required to define regulatory framework of CT oversight, if needed. This includes collaboration with/strengthening the National Ethics Committee/Institutional Review Boards.
- The twinning partner(s) – together with EDA, will support the establishment of legal basis for the organisational structure and governance that allows for the smooth exchange of information within and outside the entities involved in CTs.

Result 4.2: IT structure for clinical trials /SOP for applications is reviewed.

The following indicative activities could be carried out, but not limited to:

- The twinning partner(s) – together with EDA will conduct a joint assessment of the IT systems
- Follow-up of clinical trials and recommendations will be issued.

Result 4.3: Implementation and supervision of Good Clinical Practice (GCP)

The following indicative activities could be carried out, but not limited to:

- The twinning partner(s) – together with EDA - will develop and improve SOPs for GCP.
- EDA staff members are trained in the supervision and enforcement of GCP

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

The project will be implemented in the form of a Twinning between the Beneficiary Country and 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 Adviser (RTA) to manage the implementation of project activities, Component Leaders (CL) and a pool of short-term experts 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.

The RTA will be supported by an assistant that will handle administrative arrangements for conferences, training, seminars, etc., including provision of interpreters and the ensuring of translations.

Proposals submitted by Member States 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 clearly show the administrative structure and capacity of the Member States entities. 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 Member State(s) shall include in their proposal the CVs of the designated Project Leader (PL)and the Resident Twinning Advisor (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 themandatory results in a sustainable manner.

The set of proposed activities will be further developed with the Twinning partners when drafting the initialwork plan and successive rolling work plan every 6 months, keeping in mind that the final list of activities will be decided in cooperation with the Twinning partner. The components are closely interlinked and needto be sequenced accordingly.

3.6.1 Profile and tasks of the PL:

The Project Leader is expected to be an official or assimilated agent with a sufficient rank to ensure an operational dialogue at the political level.

Basic Skill Requirements:

- University degree in public health, health economics, pharmacy, epidemiology, international health, or other relevant discipline
- Professional experience of 10years in pharmaceutical regulatory, public health or other sectors relevant to this twinning;
- Minimum 3 years of specific experience, at a senior management level, in human medicines- related regulatory functions in EU MS relevant national administrations;
- Very good spoken and written English (at least level 2 on a scale of 1 [excellent] to 5 [basic]).

Assets:

- Experience in EU-funded project management, preferably twinning;
- Specific professional experience in vaccine regulatory oversight.

Tasks to be completed:

- To supervise and coordinate the overall project preparation;
- To supervise, guide and monitor project implementation towards the timely achievement of the project results;
- To liaise with the Beneficiary Counterpart (BC) administration at the political level;
- To ensure timely availability of the expertise;
- To prepare the project progress report with the support of the RTA;
- To co-chair the project steering committees;
- To take into account the work of relevant EU bodies and agencies and establish links where appropriate.

3.6.2 Profile and tasks of the RTA:

The Resident Twinning Adviser will be based in Egypt (Cairo/Giza) to provide full-time input and advice to the project for its entire duration. She/he will be in charge of the day-to-day project implementation and coordination of project activities according to a predetermined work plan and liaise with the EDA counterpart in Egypt. (S)he should co-ordinate the project and have a certain level of understanding of all the components.

Basic skill requirements:

- University degree in health economics, public health, or other relevant discipline (such as physician, pharmacist, regulator, ..) or equivalent professional experience of 8 years in the public health sector;
- Minimum 3 years of specific experience in human medicines-related regulatory functions in EU MS relevant national administrations;
- Very good spoken and written English (at least level 2 on a scale of 1 [excellent] to 5 [basic]).

Assets:

- Experience in project management, preferably twinning;
- Experience in implementation of relevant EU legislation and EU instruments related to the project components.

Tasks:

- To coordinate and assure project implementation and implementation of all project activities;
- To prepare the initial and subsequent work plans and project progress reports, together with the PL;
- To assure the coherence and continuity of the successive inputs and the ongoing progress;
- To coordinate the activities of all team members in line with the work plan;
- To assess continuously project progress to ensure its timely implementation;
- To prepare material for regular monitoring and reporting;
- To liaise with MS and Beneficiary Country (BC) PLs and maintain

regular contact with the BC RTA;

- To provide technical advice, support and assistance to the Beneficiary institution in the areas specified in the work plan;
- To liaise with the EU Delegation Project Manager & Team Leader;
- To liaise with other relevant institutions in Egypt and with other relevant projects.

3.6.3. Profile and tasks of Component Leaders*:*

The Component Leaders will work in close cooperation with the RTA and the Beneficiary administration in order to meet the mandatory results. Their main task is to plan and coordinate activities under their respective areas of responsibility in collaboration with the partner institutions.

Basic skill requirements

- University degree in relevant discipline or equivalent professional experience of 8 years in a sector relevant to the component of the twinning for which the candidate is proposed;
- Minimum 3 years of professional experience at an operational level in relevant EU MS health administration or mandated body in a field relevant to the component for which the candidate is proposed;
- Very good spoken and written English (at least level 2 on a scale of 1 [excellent] to 5 [basic]).

Assets:

- Experience in capacity building and, ideally twinning projects

Tasks:

- To provide component coordination, guidance and monitoring in close cooperation with the BC component leader, RTA and RTA counterpart;
- Continually monitor the achievement of objectives related to their component and comparing actual progress with the specified benchmarks and time-frame;
- Support the RTA in preparing the interim, quarterly and final reports related to their component;
- To provide practical expertise and technical advice, as well as coaching to the relevant staff in the Beneficiary administration for the execution of activities relevant to their project components;
- To analyse policies and practices in the thematic area relevant to the respective component;
- To support the drafting of action plans, training plans, studies;
- To prepare and conduct training programs, to facilitate stakeholders' dialogue;
- To draft technical documents relevant to their component's results in close cooperation with the BC counterparts;
- To suggest improvements in relevant procedures and systems.

3.6.4 Profile and tasks of other short-term experts*:*

The STEs should be identified by the Project Leader/RTA and will be agreed upon with the Beneficiary Administration during the negotiation phase of the Twinning contract and following these indicative (but not exclusive) areas: good regulatory practices, pharmaceutical law. Marketing authorisation, (public) assessment reports, promotion of medical products, borderline products, vaccine lot release, good manufacturing practices, good distribution practices, pharmacovigilance, Good Vigilance Practice, clinical trials and quality control laboratory operations.

Basic Skill Requirements:

- University degree or equivalent professional experience of 8 years;
- At least 3 years of professional experience as an expert in a respective field related to the purpose of the mission foreseen in the work plan;
- Very good spoken and written English (at least level 2 on a scale of 1 [excellent] to 5 [basic]).

Assets:

- Experience in delivering capacity building activities;
- Experience in providing inputs to policy/regulatory documents, methodological guides and/or handbooks.

Tasks:

- To provide advice, expertise and/or coaching to the relevant staff of the Beneficiary administration for the execution of specified project activities;
- To plan and deliver capacity building activities (workshops, study tours, trainings);
- To suggest improvements of relevant procedures and systems including suggestions to the revision of regulatory framework;
- To provide support in drafting action plans and roadmaps;
- To report on the results of the missions;
- To liaise with RTA and BC counterparts.

4. Budget

EUR 1,500,000

5. Implementation Arrangements

5.1 Implementing Agency responsible for tendering, contracting and accounting (European Union Delegation):

The Delegation of the European Union (EUD) to the Arabic Republic of Egypt will be responsible for the tendering, contracting, and accounting. The Egyptian Drug Authority will work in close co-operation with EU Delegation all the time for the smooth implementation of the project.

Delegation of the European Union to the Arab Republic of Egypt
Address:
Nile City Towers, North Tower,
10th floor, Corniche El Nil, Ramlet Boulaq, Cairo
Telephone: +202 24619884
URL: https://www.eeas.europa.eu/delegations/egypt_en

The persons in charge of the project at the EU Delegation are:
Mrs. Alice Peslin – Team Leader Economic Cooperation and Inclusive Growth
Email: alice.peslin@eeas.europa.eu

Mrs. Iva Stamenova – Programme Manager on Agriculture and Health
Email: iva.stamenova@eeas.europa.eu

5.2 Institutional framework

The Egyptian Drug Authority is the main counterpart and beneficiary of the Twinning Project. The Authority is a comprehensive regulatory body organised into nine central administrations and employs approximately 3,000 staff members. The EDA operates directly under the Prime Minister and is headed by a President/Chairman.

The organigram of the EDA can be found in Annex 2.

5.3 Counterparts in the Beneficiary administration:

5.3.1 Contact person:

5.3.2 PL counterpart
Dr. Rasha Ziada
EDA Chairman's Assistant for Technical Development and Capacity Building Affairs
Egyptian Drug Authority
Address: 21 Abdel Aziz Al Seoud - Manial El Roda- Cairo

5.3.3 RTA counterpart
Dr. Sondos Moshtohry
Manager of the Administration for Cooperation with International Organizations,
Office of the Chairman of the Egyptian Drug Authority (EDA)
Address: 21 Abdel Aziz Al Seoud - Manial El Roda- Cairo

6. Duration of the project

Execution period of the project shall be 27 months (24 months of implementation + 3 months closure period).

7. Management and reporting[5]

[5] Sections 7.1-7.3 are to be kept without changes in all Twinning fiches.

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 the further progress.

8. Sustainability

EDA as beneficiary institution is committed to ensure the sustainability of the present twinning project. A number of strategies will be put in place, including transferring knowledge by the staff trained from this project through peer-to-peer trainings in the workplace to their workmates. The training programmes and arrangements will be discussed and agreed at the high level of EDA to create a culture of peer-to-peer learning approach. In addition, staff will be offered additional learning opportunities to acquire the knowledge and skills they need to supplement peer-to-peer trainings. Additionally most of the activities within the twinning project relate to strengthening the regulatory framework thus ensuring institutional intake and sustainability.

9. Crosscutting issues

The Commission adopted a strategic approach to pharmaceuticals in the environment as required by Article 8c of Directive 2008/105/EC as amended by Directive 2013/39/EU. The approach covers all phases of the lifecycle of pharmaceuticals, from design and production through use to disposal. This will guide the exchanges with twinning partners on these matters.

Implementing the twinning project will enhance further the regulatory environment that could further boost economic growth and availability of decent work, while advancing universal health coverage (UHC) and human development. The twinning will respect the following principles: equal participation, non-discrimination, accountability, and transparency in all phases. Strengthening pharmaceutical production is a step towards making global supply chains more resilient and will be valuable in reducing inequalities while ensuring equitable access for all, including the most vulnerable.

In general, the principles of equal opportunity will be observed to ensure equitable gender participation in the project. Equal treatment of women and men will be observed in the project staffing, implementation and management. In particular, attention to the equality principle will be given to the selection of personnel for training and capacity building activities.

10. Conditionality and sequencing

There is no conditionality in place for this twinning project.

There is no sequencing of actions, however the current twinning project will also need to coordinate and align activities with a service contract that will be commissioned by the EU Delegation to the Arab Republic of Egypt, which will support the development of National Strategy for vaccines and biologicals, covering domestic production and export. In parallel the EU Delegation intended to sign a contract for the provision of support to local manufacturing companies to reach WHO Pre-Qualification Level for medical products and vaccines produced in their facilities.

11. Indicators for performance measurement

See annex 1 – Logical Framework

12. Facilities available

The Beneficiary administration commits itself to deliver the following facilities:

- Adequately equipped office space for the RTA and the RTA's assistants for the entire duration of the secondment;
- Supply of the office room including access to computer, telephone, internet, printer, photocopier;
- Adequate conditions for the STEs/MTEs to perform their work while on mission;
- Suitable venues for the meetings and training sessions that will be held under the project.
- The Beneficiary will also guarantee the availability of staff who will be involved during the twinning project implementation;
- Full coordination and transparency are expected among all key players involved.

The EDA will ensure operational and logistical support to the RTA and the Twinning experts, as well as provide effective coordination with the other Egyptian institutions involved in the project.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical framework matrix as per Annex C1a (compulsory)
2. The Organigram of the Egyptian Drug Authority as per Annex C2

Annex C1a : Simplified Logical Framework

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	To improve the enabling regulatory environment for medicinal products including vaccines[6] in Egypt and promote Egyptian Drug Authority to become a World Health Organisation (WHO) - listed Authority (WLA)	WHO listing as WLA (Target: 2027)	WHO benchmarking reports WHO publications		Continuous high level commitment from EDA Commitment from pharmaceutical industry
Specific (Project) Objective(s)	To support the Egyptian Drug Authority (EDA) to reach WHO Global Benchmarking Tool (GBT) Maturity Level 4 for Medicinal Products, including vaccines, and to comply with WHO Good Regulatory Practices up to the level of a Stringent Regulatory Authority (SRA).	WHO endorsement of ML3 (Baseline: 2023) WHO endorsement of ML4 (Target :2027)	WHO benchmarking reports WHO publications	High staff turnover	Sufficient human and financial resources available

[6] The EU definition of medicinal product includes all pharmaceuticals and biological medicines as well as vaccines and blood products.

Mandatory results 1 (Component 1) Improving legal framework and regulatory functions for medicinal products	Result 1.1. The current regulatory framework is assessed and key recommendations are issued	Alignment with EU and WHO Best Practices and WHO Good Regulatory Practices (GRP) (Target: 2027)	Official Journal WHO publications		
	Result 1.2: EDA capacity in planning, monitoring and strategy definition is strengthened.	Recommendations issued (Target: 2026)	Project documents		
Mandatory results 2 (Component 2) Strengthening of marketing authorisation procedures for medicinal products	Result 2.1: Marketing authorisation function for medicinal products, including vaccines is improved	EDA's SOPs and/or guidelines for all types of assessments are reviewed/updated and are available (Target: 2027)	EDA database WHO benchmarking reports EDA website		
	Result 2.2: Quality, Safety and Efficacy assessment is strengthened.	35% of EDA staff trained on the updated SOPs (Target:2027)	EDA database WHO benchmarking reports EDA website		

	Result 2.3: Drafting of (public) assessment reports is strengthened.	35% of EDA staff trained on the updated SOPs (Target:2027)	EDA database WHO benchmarking reports		
	Result 2.4: Borderline products decision making is strengthened	100% EDA staff trained on borderline products (Target: 2027)	EDA database WHO benchmarking reports		
	Result 2.5: Pharmaceutical references and leaflet publishing, Information, advertising and promotion of medical products is enhanced.	Pharmaceutical references and leaflet available (Target: 2027)	EDA website Pharmaceutical references and leaflet		
Mandatory results 3 (Component 3) Improving post-approval functions of medicinal products	Result 3.1: EDA's Pharmacovigilance (PV) system and implementation of the SOPs for the evaluation of safety reports, including reports of serious adverse medicines reactions and PSURs, more particularly for vaccines, is improved.	Updated and improved Pharmacovigilance System in use (Target: 2027)	Official journal Pharmacovigilance Master File Project documents		

	Result 3.2: Good Vigilance Practices (GVP) inspection is strengthened	100% of EDA PV and GVP staff trained (Target: 2027)	Project documents		
	Result 3.3: Assessment process for manufacturing/importer authorisation and wholesale distributor authorisation function (for manufacturers, importers, wholesalers/distributors) is improved.	Legal framework established (Target: 2027)	Project documents		
	Result 3.4: Training is conducted on GDP and GMP Inspections, with a focus on vaccine manufacturing facilities, including joint missions (in the region and in the EU)	100% of GDP and GMP EDA staff trained (Target: 2027)	Project documents		
	Result 3.5: Official (lot) batch release function is enhanced.	100% of EDA staff trained on batch release functions (Target: 2027)	Project documents		
	Result 3.6: EDA laboratory testing procedures is improved.	35% of EDA staff trained on laboratory testing procedure (Target: 2027)	Project documents		

Mandatory results 4 (Component 4) Advancing Clinical Trial Oversight	Result 4.1: Legal provisions on clinical trials (CT), arrangement for effective organisation and good governance of CT are established	Regulations and guidelines for regulatory framework of CT oversight available (Target: 2027)	Official Journal EDA website		
	Result 4.2: IT structure for clinical trials /SOP for applications is reviewed.	Assessment of IT structure available (Target: 2026)	Project documents		
	Result 4.3: Implementation and supervision of Good Clinical Practice (GCP)	100% of EDA staff dealing with supervision and enforcement of GCP is trained (Target: 2027)	SOP on oversight Clinical Trials		

Annex C2 – Organigram of the Egyptian Drug Authority

Scope	Abbreviation	Tasks and Responsibilities	Number ofstaff
Pharmaceuticals	MA (marketing authorisation)	Marketing authorisation, renewal, variations, Emergencyuse Stability Pharmaceutical references, patient information	151 44 20
	VL (vigilance)	Pharmacovigilance and premarketing vigilance	79
	MC (Market control)	Import and Customs Release, Supervision of pharmacies and wholesale distributors,Promotional material Media and internet monitoringGSDP inspection	37* + 10 712 21 10 80
	LI (Licensing)	Licensing manufacturers Licensing distributorsLicensing pharmacies	574* + 22
	RI (Regulatory Inspection)	GMP inspection local and overseas" GSDP inspection Sampling medicines and starting materialsInvestigation of complaints	65 18
	LT (laboratory testing)	Total number of staff, including technical, administrative and support staff Number of technical staff, including analysts and assessorsof QC module for registration and renewal	653 282

	CT (Clinical Trial Oversight)	Evaluation, approval and follow up local clinical trials Evaluation preclinical and clinical data for registration andrenewal GCP Inspection, Providing technical support / ScientificAdvice	26

Scope	Abbreviation	Tasks and Responsibilities	Number of staff
Biologicals and Vaccines	MA (marketing authorisation)	Registration and renewal biologicals, variations andEmergence use	46
	RI (Regulatory Inspection)	GMP inspection (biologicals) GSDP Inspection Assessment Quality for marketing authorisation	19
	LT (Laboratory Testing)	Batch analysis biological products Evaluation of Quality dossier for Marketing authorisation,renewal and variations	60
	LR (Lot Release)	Batch release biologicals, complaints and post-market program Risk Benefit Analysis	19

*

Decentralised Staff Members

" GMP inspectors are divided in 34% lead inspectors, 40% senior inspectors and 26% junior inspectors.

EDA avails of the following scientific and advisory committees:

• Technical Committee for Drug Control • Specialized Scientific Evaluation Committee for Human Pharmaceuticals • Quality Module Evaluation for Human Pharmaceuticals • Variation Evaluation Committee for Human Pharmaceuticals • Bioequivilance & Bioavailability Studies Evaluation Committee for Human Pharmaceuticals • The General Committee to assess stability studies • A committee to examine clinical and preclinical medical research results for medicinal products • The Specialized Scientific Committee for Biological Products • Emergency Use Approval (EUA) Committee for Biological Products • Innovative products scientific evaluation committee	• Subcommittee on Occupational Safety and Health • Assessment of Suspected Substandard and Falsified Samples Task Force • Layout Review Committee • Licensing inspection Committee • Inspection Higher Committee • Pharmacology Committee • Pharmacy Practice Guidelines & National Drug Lists' Committee • Oncology Pharmacy Practice Committee • National Rational Antimicrobial Use Committee • Pharmacovigilance Committee