ANNEX C1: Twinning Fiche

Project title: Strengthening Rwanda Food and Drug Authority's regulatory functions related to medicinal products including vaccines

Beneficiary administration: Rwanda Food and Drugs Authority (Rwanda FDA)

Twinning Reference: RW 18 EDF HE 01 22

Publication notice reference: PROSPECT 173781

EU funded project

TWINNING TOOL

1. Basic Information

1.1 Programme

FED/2018/40-875 - Technical Cooperation Facility VI – Direct Management mode

For UK applicants: Please be aware that following the entry into force of the EU-UK Withdrawal Agreement[1] on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union and to goods originating from an eligible country, as defined under Regulation (EU) No 236/2014[2] and Annex IV of the ACP-EU Partnership Agreement[3], are to be understood as including natural or legal persons residing or established in, and to goods originating from, the United Kingdom[4]. Those persons and goods are therefore eligible under this call.

1.2 Twinning Sector

Pharmaceutical and Health Sector

1.3 EU funded budget

EUR 2 000 000

1.4 Sustainable Development Goals (SDGs)

This project is contributing to the SDG 3: Good Health and Well-being

2. Objectives

2.1 Overall Objective

Improve the enabling environment for regulation of medicinal products and vaccines in Rwanda.

2.2 Specific objective

The specific objective of this project is to support Rwanda FDA in developing a functional regulatory system and in building the capacity of its staff in selected key areas for the authority to regulate pharmaceutical products including vaccines. It will cover:

a) Improvement of the national regulatory system in line with good regulatory practices and international standards;
b) Authorisation of manufacturers of medicinal products, including vaccines;
c) Regulatory inspections, specifically Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) for medicinal products including vaccines;
d) Assessment and marketing authorisation for medicinal products including vaccines,
e) Quality control testing of medicinal products including vaccines,
f) Official batch release (Lot release) for specific products such as vaccines,

[1] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.
[2] Regulation (EU) No 236/2014 of the European Parliament and of the Council of 11 March 2014 laying down common rules and procedures for the implementation of the Union's instruments for financing external action.
[3] Annex IV to the ACP-EU Partnership Agreement, as revised by Decision 1/2014 of the ACP-EU Council of Ministers (OJ L196/40, 3.7.2014)
[4] Including the Overseas Countries and Territories having special relations with the United Kingdom, as laid down in Part Four and Annex II of the TFEU.

g) Post marketing surveillance and pharmacovigilance systems for medicinal products including vaccines,
h) Oversight of clinical trials and more particularly vaccines' clinical trials.

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

Rwanda has a well-articulated policy framework to guide its developmental aspirations. Rwanda's Vision 2050 identifies the country's overarching objectives to transform its economy and modernize the lives of Rwandans, with the aim to reach upper-middle income status by 2035 and high-income status by 2050. Vision 2050 is anchored on five pillars: i) Human Development, ii) Competitiveness and Integration, iii) Agriculture for wealth creation, iv) Urbanisation and Agglomeration and v) Accountable and Capable State Institutions. The first years of Vision 2050, up to 2024, are operationalised through Rwanda's 7-year plan: The National Strategy for Transformation (NST1), which articulates policy priorities under three key areas: social transformation, economic transformation and transformational governance.

In the framework of the new multi-annual indicative programme (MIP) for 2021-2027, the EU will consider support on investment promotion, including in the health and pharmaceutical sector. Supporting local manufacturing and access to essential health products and technologies represents an opportunity to target several development objectives and geo-political priorities shared by both the EU and the Government of Rwanda: stimulate growth and jobs, facilitate trade, diversify global value chains, engage with the private sector, mobilizing its technical expertise and financial power, and reinforce EU's scientific and diplomatic ties with Rwanda while advancing universal health coverage (UHC) and human development. The MIP will provide a framework for implementation at national level of the Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (MAV+).

In this regard strengthening of the health regulatory system will be a key component. The EU therefore intends to support the capacity of the Rwanda Food and Drug Authority (Rwanda FDA) to fully play its regulatory functions spanning the product lifecycle of medicines and vaccines, including marketing authorisation and registration, licensing and inspection of premises, market surveillance and enforcement. Team Europe will also work on human resource development strategy to train and retain the required workforce to be employed in a future pharmaceutical ecosystem. Regulatory strengthening and skills development will complement efforts made at regional level on MAV+, to develop the manufacturing of medical products in Africa. These would include support to regional production hubs (business plans, intellectual property management, technology transfer, scientific education & research, vocational training, etc.) and reinforcement of Digital Supply Chain Management Systems (DSCMS) and Supply Chain Integrity. Last, participation of Rwanda in other EU programmes such as the European & Developing Countries Clinical Trials Partnership (EDCTP) will be promoted, to enhance EU-Rwanda research cooperation in the field of health.

The Rwanda FDA Strategic Plan (SP) is aligned with the Authority's mandate and critical framework documents, including the National Health Policy (2015), the Health Sector Strategic Plan (HSSP) IV for the Ministry of Health (MoH) of Rwanda, the National Pharmacy Policy (NPP) 2016, the National Food and Nutrition Policy (2014), and Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products. Capacity building of Rwanda FDA's staff is embedded in the National Strategy for Transformation 1 (NST1) 2017–2024 under the Priority Area 3 (Enhancing demographic dividend through ensuring access to quality health for all). Capacitating Rwanda FDA contributes to access of quality health care through quality, safe and affordable medicines. The Rwanda FDA's set of regulatory laws and regulations is publicly available on its website (www.rwandafda.gov.rw). The existing authority's legal framework, including approved

laws, regulations, guidelines, standard operating procedures (SOPs), and forms for regulatory oversight, is a good starting point to build a strong regulatory system with a solid foundation.

3. Description

3.1 Background and justification

Rwanda Food and Drugs Authority (Rwanda FDA) was established by the law Nº 003/2018 of 09/02/2018 determining its mission, organisation, and functioning. The mandate of the authority is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products.

Recent announcements were made by BioNTech to establish end-to-end manufacturing capacities for mRNA-based vaccines in Africa, which will include Rwanda. Several other vaccines and medicinal products manufacturers are currently contemplating operating in Rwanda, which will require Rwanda FDA to play a more prominent role in the human medicines' oversight and regulation.

In partial response to this, the Rwanda FDA finalised its first strategic plan for 2021-2024 in June 2021 (can be found in Annex 4). It was developed through a multidisciplinary process of consultations among Rwanda FDA divisions and departments and validation with all key sector stakeholders. Three strategic priority areas are identified:

1. Strengthen the role of Rwanda FDA to ensure compliance to specified standards and requirements for regulatory processes and regulated products
2. Collaborate effectively with the public and private sectors and national and international partners
3. Enable an accountable, high-performing, innovative, and sustainable authority

To provide sufficient means for the Rwanda FDA to fulfill its mandate, a revised organisational chart has been developed and approved by the Cabinet, in its meeting of 14/12/2020, and the Prime Minister's Order N° 162/03 of 21/12/2020 determining organisational structure of Rwanda Food and Drugs Authority was also published in the official Gazette n° 41 of 21/12/2020. The new structure for Rwanda FDA aims to allow a reorganisation of the institutional arrangement for increased efficiency and performance toward effective implementation of the Authority's legal mandate. The previous organizational structure of Rwanda FDA dated 2017 included 155 staff while the new approved structure has 195 staff. The new structure is effective since December 2020.

Budgetary allocations to the Rwanda FDA are also aligned to this growing role to be held by Rwanda FDA as they have seen an increase from RWF 1.194 billion in fiscal year (FY) 2020/2021 to RWF 3.954 billion in FY 2021/2022.

The authority has therefore embarked on an agenda to strengthen its regulatory functions by building the capacity of newly hired staff responsible for key regulatory functions including the development of the national regulatory system, issuing manufacturing and wholesale/distribution authorisations, issuing marketing authorisations, conducting GMP and GDP inspections, quality control, oversight of clinical trials, pharmacovigilance, and control and post-marketing surveillance. The authority is therefore seeking assistance in the identified areas that need urgent support to enable a robust oversight of the medicines production, including vaccines, that is planned to be established in Rwanda.

The regulation of vaccines requires the Rwanda FDA to have an effective regulatory system and procedures in place to guarantee the safety, efficacy, and quality of vaccines imported or produced locally. It also requires qualified and skilled personnel in the regulation of biological medicinal

products, with exposure to the Stringent Regulatory Authorities[5] to enable Rwanda FDA to achieve its mandate of protecting public health.

The Rwanda FDA was benchmarked in 2018 using the WHO Global Benchmarking Tool (GBT) to check its level of compliance with maturity level three indicators (ML3). Rwanda FDA maturity level is currently ML1, but it has undergone a self-assessment in September 2021 and aims to be assessed externally by WHO during 2022. ML3 is a prerequisite level for Rwanda FDA, set by the WHO to allow manufacturers in Rwanda to apply for vaccines prequalification. In the long term, the Rwandan government is looking for the authority to become one of the first regulatory authorities on the continent reaching ML4 and considered as a WHO Listed Authority[6].

The regulation and control of human medicines including vaccines by Rwanda FDA necessitates continuous improvement reflecting the current state of science and technology, with an improved understanding of quality and safety issues. This falls under the scope of the present twinning project, which should trigger and lead to institutional changes by maintaining an acute awareness of scientific developments in the pharmaceutical field (including vaccines) via partnerships with more established regulatory bodies.

3.2 Ongoing reforms

In recent years, Rwanda has taken a number of steps to improve its health sector, including enhancing the efficiency of healthcare, implementing infrastructure projects and applying effective policies aimed at improving the healthcare system in the country.

To support the vaccine manufacturing agenda in the country, Rwanda intends to establish a biotechnology research and training hub in partnership with several stakeholders. This initiative aims at developing required skills for the bioproduction industry. Rwanda FDA will get involved in working with and in supporting this training and research hub together with other stakeholders.

Regulation and inspection of food and pharmaceutical products is covered by the law No 47/2012 of 14/01/2013. Amongst other, the law governs aspects linked to exercising activities linked to pharmaceutical products, manufacturing of items regulated under the law, inspection of pharmaceutical products, etc. Revision of the law and alignment with WHO Good Regulatory Practices is however needed.

Rwanda FDA takes part in the health sector mechanisms foreseen for policy dialogues including sector working groups and joint health sector reviews with development partners undertaken twice a year. Currently, the health sector in collaboration with its stakeholders is reviewing its health policy of 2015 to accommodate all health needs and changes occurred in this period.

The implementation progress of projects targeting Rwanda FDA, including the twinning, will continuously be presented and discussed during the Ministry of Health weekly coordination meeting, in which all institutions in the Health Sector including Rwanda FDA present the progress of projects involving local or international partners, among other items.

3.3 Linked activities

Rwanda FDA has benefited from support from a limited number of partners so far, but the landscape is expanding.

[5] List of Stringent Regulatory Authorities (who.int)
[6] WHO-Listed Authority (WLA)

USAID supports the Rwanda FDA through three mechanisms namely: 1) USAID Global Health Supply Chain Program Procurement and Supply Management (GHSC-PSM) managed by Chemonics International which supports Rwanda FDA in strengthening regulatory functions through staff training and the development of guidelines, policies and tools. 2) The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, managed by Management Sciences for Health (MSH) supports RFDA in the development of strategic plans and regulatory documents, the training and licensing of WHO pharmacovigilance center resources, and procurement of IT equipment; and 3) Promoting the Quality of Medicines Plus (PQM+) managed by United States Pharmacopeia (USP) that supports RFDA post marketing activities, laboratory capacity building, and registration processes. USAID is also supporting the automation of Rwanda FDA regulatory operations and processes with the installation of an enhanced integrated regulatory management information systems.

World Health Organization (WHO) is supporting the Rwanda FDA in the process of achieving Maturity Level 3. WHO has already assisted the Authority in conducting a self-assisted benchmarking in September 2021, and based on the findings, helped FDA write up an Institutional Development Plan (IDP) to address the identified gaps. WHO is currently supporting Rwanda FDA implement the required policy actions and strategic interventions for capacity on regulatory approval, WHO prequalification, capacity building on registration dossiers assessment, development/validation of regulatory documents including public health emergency related and clinical trials regulation, all of which should be finalized by the end of February 2022. WHO will then conduct the formal benchmarking evaluation toward the certification of Rwanda FDA regulation Maturity level 3.

More partners are, however, confirming future support to the Rwanda FDA. These include:

EU: As complementary measures to the twinning operation envisioned in the fiche, the EU Delegation in Rwanda has provided funding for acquisition of an isolator and corresponding equipment for the Rwanda FDA Quality Control Laboratory, as a first step to support efforts in favor of regulatory oversight of local manufacturing of human medicines and vaccines. The EU will also be providing funding to Enabel to further support Rwanda FDA (see below).

Enabel: (a) Intervening on strengthening quality control mechanisms. Enabel has strengthened the LIMS (Laboratory Information Management System) and supported digitalisation of quality control laboratory processes. (b) Enabel is also considering providing further regulatory support to Rwanda FDA, equipment needed in the Quality Control Laboratory to strengthen quality testing, and support for reinforced pharmacovigilance including digitalisation of the reporting system for side events (all the above EU funded). To this end, Enabel is currently putting together a project proposal to support Rwanda FDA to strengthen its regulatory frameworks including vaccine regulatory frameworks (e.g. aligning Rwanda FDA legal instruments to the international standards) that would complement the Twinning operation's scope. The project will include short and long-term components, through capacity building, coaching and monitorship. It will have a component on expertise development through support to the master's in Biotechnology training at University of Rwanda. Enabel through Belgium's study fund, is planning to provide technical expertise through Quamed for legal framework and regulatory support as well as for licensing and GMP.

Germany: Facilitating study tours for Rwanda FDA staff to visit a BioNTech factory in Marburg and the Paul-Ehrlich-Institut in early 2022 (led by GIZ/KeNUP Foundation).

Netherlands: Strengthening Rwanda FDA capacity for GMP inspections and certification in regulation of vaccine manufacturing. Possible extension to support to quality control laboratory (coaching offered by experts in vaccine manufacturing) and registration (market authorisation) could be envisioned.

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

The following EU legal texts are relevant to medicinal products and vaccine production issues:

- Directive 2001/83/EC of 06/11/2001 on the Community code relating to medicinal products for human use.
- Regulation (EC) No 726/2004 of 31/03/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.
- Clinical trial Directive 2001/20/EC and Clinical Trials Regulation (Regulation (EU) No 536/2014) from 31 January 2022
- The twinning project could also benefit from the experience of the European Health Emergency Preparedness and Response Authority (HERA), which, among other activities, identifies and ensures the availability of critical production sites for medical countermeasures, engages in intelligence gathering and surveillance in relation to health threats and relevant medical countermeasures, and promotes research and innovation. Commission Decision C(2021)6712 on establishing the Health Emergency Preparedness and Response Authority could therefore be relevant in this context.

The twinning project responds to the following domestic legislations:

- Law Nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority determining its mission, organization and functioning.
- Law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

All these laws and all regulations used by Rwanda FDA are available at Rwanda FDA website (https://rwandafda.gov.rw/web/) or Ministry of Health website (https://www.moh.gov.rw/publications) under “publication” section.

3.5 Components and results per component

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**

Result 1.1: The current legal framework is assessed and key recommendations for improvement implemented

- A report is drafted about the legal framework – legislation and regulatory guidance – covering human medicinal products, based on potential inputs from other partners. The report contains recommendations to align with EU and WHO Best Practices and WHO Good Regulatory Practices (GRP). The assessment is done by twinning partner and Ministry of Health/Rwanda FDA jointly.
- Key recommendations will be drafted for inclusion by parliament and government into national legislation. The twinning partner will assist legislators when drafting explanation and guidance.
- Ministry of Health/Rwanda FDA staff is trained on the application of GRP and training materials remain available for later use.

Result 1.2: Rwanda FDA capacity in planning, monitoring and strategy definition is strengthened

- Rwanda FDA management is instructed on how to design, based on its multi-annual strategic plan, a detailed yearly roadmap (including specific activities, responsibilities, timelines and resources) and implement it.
- Rwanda FDA management and responsible staff are trained on drafting a staffing plan and implement a training plan.

Result 1.3: Improvement of marketing authorisation function, including registration of products in emergency situations, timelines for processing of marketing authorisation applications and related tracking system

- Based on the outcome of the last WHO GBT self-benchmarking performed and potential additional assessment by the twinning partner, gaps are identified and additional regulations and guidelines related to assessment and market authorisation for medicinal products and vaccines are developed
- Available staff for assessment of QSE (Quality, Safety and Efficacy) of medicinal products and vaccines in the marketing authorisation department is trained.
- Establishment of the legal framework allowing reliance and/or recognition of assessments and marketing authorisations made by SRAs (Stringent Regulatory Authorities) and approvals by WHO PQ

Result 1.4: Improvement of manufacturing/importer authorisation and wholesale distributor authorisation function.

- Rwanda FDA staff is supported in the review of SOPs for the evaluation of applications for manufacturing, import and wholesale authorisations and in making these decisions available on the Rwanda FDA website on a regular basis.
- Establishment of the legal framework allowing reliance and/or recognition of inspections and pharmaceutical authorisations from SRAs.

Result 1.5: Training conducted on GDP and GMP inspections, (including vaccine manufacturing facilities), including joint missions (in the region or/and in the EU)

- Rwanda FDA inspectors are trained (planning, conduction, reporting of results and communication of findings) to be able to conduct GDP and GMP inspections, including biological products
- Rwanda FDA inspectors are enabled to participate to joint inspections under EAC joint activities and AMA (when established) and to participate to inspections performed by WHO PQ team for vaccines.

Result 1.6: Legal provisions on clinical trials (CT) of human medicinal products, arrangement for effective organisation and good governance of CT of human medicinal products, are established

- The twinning partner – together with MoH and Rwanda FDA, will review legal provisions, regulations and guidelines required to define regulatory framework of CT oversight for human medicinal products, if needed. This includes collaboration with/strengthening of the Rwanda National Ethics Committee (RNEC).
- The twinning partner – together with MoH and Rwanda FDA, will establish a legal basis for the organisational structure and governance that allows for the smooth exchange of information within and outside the entities involved in CTs of human medicinal products (e.g. Rwanda FDA, RNEC, or clinical research organisation).

Result 1.7: Regional collaboration on all regulatory functions improved

- Rwanda FDA and MoH will – together with the twinning partner – assess the legislative framework and regulations and explore how to further contribute and rely on the outcome of collaborations in EAC or with AMA, when operational.
- Responsible staff will be guided in developing regional or international collaborations and work sharing including the closure of (confidentiality) agreements with other regulators.

Component 2: Strengthening of market surveillance and control function - vigilance & laboratory testing functions

Result 2.1: Improving the legal framework requiring Marketing Authorization Holders (MAH) to set up a pharmacovigilance system (PV) for their medical products, report serious events and send periodical safety update reports (PSURs) periodically.

- Ministry of Health officials and Rwanda FDA staff are supported in drafting legal framework requiring pharmacovigilance systems to be put in place by MAH.

Result 2.2: Improving Rwanda FDA's 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.

- Based on the existing PV system in Rwanda FDA, update existing SOPs as well as tools for their implementation, and staff is trained to implement updated SOPs, including adverse drug reactions linked to vaccines.

Result 2.3: Improving the Rwanda FDA laboratory testing procedures.

- The twinning partner and Rwanda FDA will assess needs for and scope of regulatory testing and develop a SOP for the identification of necessary tests.
- Rwanda FDA staff capacity in quality control laboratory testing and equipment maintenance is also strengthened

Component 3: Support the establishment of the official batch release function for vaccines

Result 3.1: A framework for the establishment of the official batch release function in Rwanda FDA is developed

- Based on existing regulations, SOP for official batch release of vaccines is developed (protocol review & independent testing, if need be) as well as tools to implement it.
- Available staff are trained and coached on vaccine official batch release (with a possibility of EU based training).

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 implementation of project activities, Component Leaders (CL) and 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 co-operation between the partners aiming to achieve the mandatory results in sustainable manner.

The set of proposed activities will be further developed with the Twinning partners when drafting the initial work 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 inter-linked and need to 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 political level.

Basic Skill Requirements:

- University degree in public administration, public health, health economics or other relevant discipline or equivalent professional experience of 8 years in public administration, public health or other sectors relevant for 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 vaccines 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 Rwanda (Kigali) 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 RTA counterpart in Rwanda. (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, public administration 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 on-going progress;
- To coordinate the activities of all team members in line with the work plan;
- To assess continuously project progress to assure 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 Rwanda 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' dialog;
- To draft technical documents relevant to their component's results in close cooperation with the BC counterparts;
- To suggest improvements of relevant procedures and systems.

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

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

Basic Skill Requirements:

- University degree or equivalent professional experience of 8 years;
- At least 3 years of professional experience 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 2 000 000

5. Implementation Arrangements

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

The Delegation of the European Union (EU) to the Republic of Rwanda will be responsible for the above (tendering, contracting, and accounting). Rwanda FDA will work in close co-operation with EU Delegation all the time for the smooth implementation of the project.

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5.2 Institutional framework

The Rwanda Food and Drug Authority is the central counterpart and beneficiary of the Twinning Project. However, the project will also extend assistance to other institutions, as specified in this fiche. Other Rwandan stakeholders for strengthening Rwanda Food and Drug Authority's regulatory functions related to medicinal products and vaccine production include the Ministry of Health and the Rwanda National Ethics Committee.

5.2.1. Rwanda FDA administration, organizational structure, and relationship between departments

The law No 003/2018 of 09/02/2018 establishing Rwanda FDA grants legal personality, administrative and financial autonomy to the Authority. Moreover, Rwanda FDA falls within the category of non-commercial public institutions.

Rwanda FDA operates under the Ministry of Health. It is supervised by a Board of Directors and headed by a Director General. Members of the Board of Directors and the Director General are appointed by the Government of Rwanda. At present, the Authority has 194 employees, and its operations are organised into two technical departments, and one support department. Rwanda FDA also has a standalone Quality Control Laboratory Division. The organigram of Rwanda FDA can be found in Annex 2.

The two technical Departments and their main roles are the following:

Department of Drugs and Food Assessment and Registration consists of four (4) Divisions; for Human Medicine & Devices; Veterinary Medicine & Devices; Processed Foods; and Cosmetics & Household Chemicals; respectively. Currently, the Department has 46 staff.

The Department's role is to assess dossiers submitted to Authority and issue registration/ marketing authorization (MA) to products that comply to the Rwanda FDA requirements. The objective of this regulatory function is to provide a system which ensures that only products which have been duly assessed and registered by the Authority are allowed to be manufactured, imported, distributed, sold or supplied to end users.

The sister **Department of Inspection and Safety Monitoring** (see below) comes in to ensure that products registered and complying with the Rwanda FDA requirements are the ones available on the Rwandan market.

The process of assessment of application dossiers for MA includes the review of data on quality, safety and efficacy submitted by the applicant. The same standards are applied to imported and locally manufactured products. Nevertheless, the evaluation of complex data used to support market authorization of new or novel products may require specialized resources and experience that are partially available in the Rwanda FDA. Therefore, from time to time, Rwanda FDA may elect to prepare its own assessment report, rely on evaluation reports prepared by other National Authorities, rely on decisions made by another NRA, or use a combination of these approaches.

The **Department of Inspection and Safety Monitoring** consists of three (3) Divisions; for Inspection and Compliance; Import & Export Control; and Pharmacovigilance & Safety Monitoring; respectively. Currently, this Department has 74 staff.

This department oversees the inspection and licensing of all foods and drugs handling premises and monitoring of illegal operators of foods and drugs outlet, substandard and counterfeit regulated products through regular supervision and post-marketing surveillance. It ensures stakeholders service providers and the public receive the right information on the regulated products. It also ensures the verification, monitoring and certification of food and medicinal product promotion materials to ensure that misleading, biased and inaccurate information about regulated products is not disseminated. This department is responsible for post market surveillance and pharmacovigilance, and also regulates the conduct of clinical trials in the Country.

The **Quality Control Laboratory** (QCL) as a standalone division has 4 units including the Medicines and Cosmetics Testing Unit, Food Testing Unit, Pesticides & Poisons Substances and Chemical Unit, and Medical Devices and Instrumentation Unit. The division is mandated to perform laboratory testing for regulated products, from which samples are obtained from pre-market, post-shipment and post-market surveillance in order to ensure products compliance with the set standards, and to enable the two technical departments to make evidence-based regulatory decisions. The division currently has 29 employees.

The **Chief Finance Office** as a support department has 3 units namely Planning Unit, Finance Unit and Human Resource & Administration Unit. This office has 30 Staff. This department supports the smooth functioning of the two technical department and QCL by availing and managing the required human and financial resources and oversee planning of the entire Authority to ensure complementarity and coordination.

A new Vaccine unit is to be established at Rwanda FDA around the same period as the start of the twinning operation. Because of the inherent variability of vaccines originating from the biological nature of manufacturing raw materials and required quality testing methods, Government of Rwanda deems it important that Rwanda FDA has a unit overseeing the regulation of vaccine manufacturing in Rwanda. The proposed unit will have the following essential control sections;

- **Registration, Inspection and Licensing Section** under which there will be Experts for Vaccines Registration, and for Vaccines Manufacturing Facility Licensing;
- **Quality Control and Lot Release Systems Section** under which there will be Good Manufacturing Practices (GMP) and Chemistry, Manufacturing and Controls (CMC) Experts, Laboratory Scientists and Laboratory Technicians.
- The Unit will also have Legal and Regulatory Experts, and a Head.

This unit is proposed to have 18 staff. Details are compiled in Annex 3, which also displays the breakdown of staff and qualifications level in each division.

Although concerned vaccines are authorized for emergency use by WHO, and fully licensed, Rwanda FDA believes that it is strategic to bring in a reduced number of registration and licensing personnel for forward looking reasons. At this stage, they will be able to team up with the rest of the personnel in other areas, since the intention is to build the capacity of all vaccine unit staff in all the areas of the entire process rather than segmented trainings focusing on each respective area.

5.3 Counterparts in the Beneficiary administration

Rwanda FDA has designated a PL (Project Leader) with responsibility for the overall coordination of the project activities and a counterpart to the RTA (Resident Twinning Adviser) who is Head of Department at Rwanda FDA. He will be assisted by the Director of Planning to allow swift implementation and monitoring of the twinning project. The designated team has knowledge of the Institution and sufficient expertise to cover all areas included in the project description.

5.3.1 Contact person

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5.3.2 PL counterpart

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5.3.3 RTA counterpart

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6. Duration of the project

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

7. Management and reporting[7]

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

Rwanda FDA as beneficiary institution is fully willing and 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 Rwanda FDA 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.

The sustainability of the project results is dependent on sufficient number of personnel from the Beneficiary administration to be assigned to work in the implementation of and benefit from the

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

project. This implies commitment by Rwanda FDA, Ministry of Health and Ministry of Finance to avail sufficient budget and human resources to the authority, to fulfil its regulatory mandate linked to the regulation of human medicines.

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

The overall objective of this project is to support Rwanda FDA in building its capacity to regulate locally manufactured pharmaceutical products including vaccines for the local, continental, and international markets. This will help respond to vaccine inequity issues and help contribute to the SDG Goal 3 of Good Health and well-being.

In general, the principles of equal opportunity will be observed to ensure equitable gender participation in the project. Furthermore, the principle of implementation of this partnership project will minimise paper use during project implementation (paperless work).

Equal opportunity in the project will be assured in accordance with EU standards and equal opportunity policies. 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 preconditions or prior activities for this Twinning project. Nevertheless, it is important that Rwandan authorities remain committed to achieve the envisaged results and objectives, throughout the duration of the project. The Rwanda FDA will ensure operational and logistical support to the RTA and the Twinning experts, as well as provide effective coordination with the other Rwandan institutions involved in the project.

11. Indicators for performance measurement

See annex 1 – Logical Framework

12. Facilities available

The Beneficiary 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 is expected among all key players involved.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical framework matrix as per Annex C1a (compulsory)
2. Organigram of Rwanda FDA
3. Details on proposed vaccine unit and staff qualifications within Rwanda FDA
4. Rwanda Food and Drugs Authority Strategic Plan 2021–2024

5. Summary of WHO Self-benchmarking of Rwanda FDA (September 2021)

Annex C1a : Simplified Logical Framework

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	Enabling environment for regulation of medicinal products and vaccines in Rwanda	• Improved indicators in WHO Global Benchmarking for regulatory activities in the scope of the Twinning fiche	• WHO benchmarking report • Official Gazette • Rwanda FDA reports and website • Project reports		• Continuous political support to improve environment towards vaccine manufacturing • Continuous investment of other stakeholders and other donors

Specific (Project) Objective(s)	Support Rwanda FDA in developing a functional regulatory system and in building the capacity of its staff in selected key areas for the authority to regulate pharmaceutical products including vaccines and local manufacturing.	• Number of Rwanda FDA staff trained in relevant areas • Number of new/updated regulatory texts officially published • Number of SOPs and tools adopted • Number of assessments /inspections done	• Project reports • Rwanda FDAinspection and assessment reports available on Rwanda FDA website • Official Gazette		• Sufficient human and financial resources allocated to pair the Twinning Administration staff. • Good coordination among partners supporting Rwanda FDA • Required expertise mobilized through EU regulatory agencies

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.1: Current legal framework assessed and key recommendations for improvement implemented	• Number of updated/new regulations submitted for formal approval • Number of Rwanda FDA and MoH staff trained in Good Regulatory Practices (Baseline 2021=0; Target 2024=9)	• New or updated regulations officially approved and available on Rwanda FDA website • Governmental reports • Official Gazette • Training reports • MoH reports	• Lack of commitment of the relevant institutions to the project; • Lack of coordination and cooperation amongst institutions, including Rwanda FDA and MoH • Delays in official approvals of the new regulations proposed • Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.2: Rwanda FDA capacity in planning, monitoring and strategy definition is strengthened	• Key instructions on how to organise planning, monitoring and strategy design (in particular covering human medicines) are provided • A strategic plan is defined, including, specific activities, responsibilities, timelines and resources and monitoring • Number of relevant Rwanda FDA staff trained in planning, monitoring and strategy definition (Baseline 2021=0; Target 2024=4) • Number of Rwanda FDA management supported/trained to draft staffing and training plan (Baseline 2021=0; Target 2024=4) • Staffing and training plan developed	• Annual roadmaps available • Minutes of meetings where regular monitoring is done • Rwanda FDA reports • Training reports • Staffing and training plans • Training reports • WHO Global Benchmarking	• Lack of commitment of the relevant institutions to the project; • Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.3: Marketing authorisation function, including registration of products in emergency situations, timelines for processing of marketing authorisation applications and related tracking system improved	• Based on updated/new regulations for MA function , updated/new SOPs and tools developed • Number of staff trained in the assessment of data for Quality, Safety and Efficacy in marketing authorisation department (Baseline 2021= 10 (basic trainings in human dossier assessment for market authorization; Target 2024=15) • Legal framework for recognition of inspections made by Stringent Regulatory Authorities adopted	• Project reports • Rwanda FDA reports • SOPs • Training reports including pre and post-tests to assess progression	• Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.4. Manufacturing/importer authorisation and wholesale distributor authorisation function improved	• SOPs and tools updated and developed • Number of staff trained in the new SOP/tools for licensing establishments (Baseline 2021=10; Target 2024=20) • Legal framework for recognition of inspections made by Stringent Regulatory Authorities adopted	• Project reports • Rwanda FDA reports • Official Gazette • SOPs • Training reports • Rwanda FDA website	• Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.5: Training conducted on GDP and GMP Inspections, including vaccine manufacturing plants, including joint missions (in the region or/and in the EU)	• Number of Rwanda FDA inspectors trained (planning, conduction, reporting of results and communication of findings) to conduct GDP and GMP inspections, including biological products (Baseline 2021=0; Target 2024=10) • Number of missions/trainings to conduct GDP and GMP inspections (Baseline 2021=0; Target 2024=12)	• Project reports • Rwanda FDA reports • Training reports including pre- and post tests to assess progression	• Covid restrictions may hinder in-person trainings and missions • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.6: Legal provisions on clinical trials (CT) of human medicinal products, arrangement for effective organisation and good governance of CT of human medicinal products are established	• Legal provisions, regulations and guidelines required to define regulatory framework for CT oversight established • Legal basis for the organisational structure and governance that allows for the smooth exchange of information within and outside the entity responsible for CT established	• Project reports • Official Gazette • Reports from Rwanda FDA and other stakeholders	• Lack of coordination and cooperation amongst institutions, including Rwanda FDA and National Ethic Committee	• Sufficient human and financial resources allocated
Component 1: **Improving legal framework and regulatory functions linked to medicinal products**	Result 1.7: Regional collaboration on all regulatory functions improved	• Assessment and implementation of recommendations of legislative framework and regulations provided	• Project reports • Rwanda FDA reports • Training reports	• Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 2: Strengthening of market surveillance and control function - vigilance & laboratory testing functions	2.1: Legal framework requiring Marketing Authorization Holders (MAH) to set up a Pharmacovigilance System for their medical products and report serious events expedited and Periodical Safety Update reports periodically improved	• Legal framework for pharmacovigilance systems for MAH and Rwanda FDA drafted with Ministry of Health	• Official Gazette • Project report • WHO benchmarking report on PV function	• Lack of commitment of the relevant stakeholders; • Lack of coordination and cooperation amongst institutions, including Rwanda FDA and MoH	• Sufficient human and financial resources allocated

Component 2: Strengthening of market surveillance and control function - vigilance & laboratory testing functions	Result 2.2: Rwanda FDA's Pharmacovigilance System and implementation of the SOPs evaluation of safety reports including reports of serious adverse medicines reactions and periodic safety update reports (PSURs) is improved	• SOPs for evaluation of safety reports updated, including adverse drug reactions linked to vaccines. • Number of staff trained on analysis of periodic safety update reports (PSURs), including adverse drug reactions linked to vaccines. (Baseline 2021=5, Target 2024=5 – recipient of more advanced trainings) • Number of staff trained to implement SOPs (Baseline 2021=4, Target 2024=4 recipient of more advanced trainings)	• Training reports • Project reports • Rwanda FDA reports • WHO benchmarking report on PV function	• Pharmacovigilance system not fully operational • Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated

Component 2: Strengthening of market surveillance and control function - vigilance & laboratory testing functions	Result 2.3: Rwanda FDA laboratory staff able to conduct regulatory testing	• SOP on detection of falsified and substandard medicines and Active Pharmaceutical Ingredients (APIs) available and implemented. • Rwanda FDA staff trained in quality control laboratory testing and equipment maintenance	• Project reports • Rwanda FDA reports	• Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated
Component 3: Support the establishment of the official batch release function for vaccines	Result 3.1: Function vaccine official batch release established	• SOP for official batch release of vaccines is developed • Number of staff trained on how to conduct vaccine lot release based on proposed SOP (Baseline 2021=0; Target 2024=8)	• Project reports • Rwanda FDA reports • Training reports • WHO benchmarking report on NRA Lot Release function	• Covid restrictions may hinder in-person trainings • Trained staff leave Rwanda FDA	• Sufficient human and financial resources allocated