Support Facility to Partnership Priorities EU-Algeria

Twinning project fiche

Support for capacity development of the National Agency of Pharmaceutical Products– ANPP

Beneficiary administration

National Agency of Pharmaceutical Products– ANPP

Ministry of Pharmaceutical Industry

Twinning reference
DZ 18 ENI HE 01 22

This project is financed by the European Union

TWINNING INSTRUMENT

Table of contents

1. Basic information 5
   1.1. Programme 5
   1.2. Twinning sector 6
   1.3. Budget funded by the European Union 6
   1.4. Sustainable Development Goals 6
2. Objectives 6
   2.1. Overall objective 6
   2.2. Specific objective 6
   2.3. Targeted elements in the strategic documents 6
      2.3.1. Strategic framework 6
      2.3.2. Institutional anchoring and contribution to the implementation of the government's action plan 7
3. Description 8
   3.1. Background and justification 8
   3.2. The development of the ANPP and the extension of its scope of prerogatives 9
   3.3. Ongoing reforms 11
   3.4. Linked activities 11
   As part of the Support Programme for the implementation of the Association Agreement 11
"European solidarity response to Covid-19 in Algeria" programme 12
   3.5. List of applicable union acquis/standards/norms 12
   3.6. Results 12
      Result 1 : ANPP has a modern and efficient organization capable to carry out all its missions 12
      Result 2 : ANPP optimizes its processes related to the registration of pharmaceutical products 13
      Result 3 : ANPP optimizes the processes related to the approval of medical devices 13
      Result 4 : ANPP inspections in pharmaceutical establishments are optimized 13
      Result 5 : laboratory capacities are strengthened in terms of quality management and research 13
   3.7. Means/input from the EU member state (s) administration (s) 14
      3.7.1. Profile and tasks of the PL 14
      3.7.2. Profile and tasks of the RTA 15
      Profile and tasks of results/outputs 16
      3.7.3. Profile and tasks of other short term experts 16
      3.7.4. Translation and interpretation 16
4. Budget 16

5. Implementation arrangements 16
5.1. Implementing body responsible for contracting and financial management 16
5.2. Institutional framework 17
5.3. Counterparts in the beneficiary administration 17
5.3.1. Contact Person 17
5.3.2. PL counterpart 17
5.3.3. RTA counterpart 17
5.3.4. Results/outputs responsibls 18
6. Duration of the project 18
7. Management and reporting 18
7.1. Language 18
7.2. Project Steering Committee 18
7.3. Reporting 18
8. Sustainability 18
9. Cross-cutting issues (equal opportunities, environment, climate, etc.) 19
10. Conditionality and sequencing 20
11. Performance indicators 20
Available facilities 21
AnnexII : Simplified logical framework 24
Annex III : ANPP Estimated schedule 31

LIST OF ACRONYMS

ANPP :	National Agency of Pharmaceutical Products
PL :	Project Leader
RTA :	Resident Twinning Advisor
CTD :	Common Technical Document
MS :	Member States (EU)
BC :	Beneficiary country
PP :	Pharmaceutical Products
TAIEX :	Technical assistance and information exchange
EU :	European Union

1. Basic information

1.1. Programme

This project will be funded within the framework of the programme entitled: Support Facility to Partnership Priorities, EU- Algeria (2018/041-143) – direct management.

Support Facility to Partnership Priorities EU- Algeria [1] : the Support Facility was set up in December 2019 to support the implementation of the priorities of the EU-Algeria partnership.

The common priorities of the EU-Algeria partnership are part of the renewed European Neighbourhood Policy (2015) which takes into account the specificities of each partner country. They were approved in March 2017 and cover 5 areas of common interest;

ii) governance and fundamental rights;
iii) socio-economic development and commerce;
iv) security and strategic dialogue;
v) human dimension, migration and mobility.

The Support Facility is largely reflected in the financing of institutional cooperation projects in the form of twinning projects with the administrations of EU Member States.

The operational monitoring of the action is entrusted to the Delegation of the European Union in Algeria in coordination with the Coordinator of the Support Facility.

***For UK applicants**: please note that following the entry into force of the EU-UK Withdrawal Agreement on 1 February 2020 and in particular Articles 127(6), 137 and 138, references to natural or legal persons residing or established in a Member State of the European Union and to goods originating in an eligible country, within the meaning of Regulation (EU) No 236/2014 and Annex IV of the ACP Partnership -EU Agreement, shall be understood to include natural or legal persons resident or established in the United Kingdom and goods originating in the United Kingdom. These people and goods are therefore eligible under this call.*

[1]Hereinafter referred to as "Support Facility "

1.2. Twinning sector

Health and consumer protection (HE).

1.3. Budget funded by the European Union

€ 1 150 000

1.4. Sustainable Development Goals

The objectives of this twinning project are:

Objective 3 : Access to Health
Objective 3 covers all major health priorities and calls for improving reproductive, maternal and child health; to end communicable diseases; reduce non-communicable diseases and other health risks; and to ensure universal access to safe, effective, quality and affordable medicines and vaccines, as well as health coverage.

Objective 9 : Build resilient infrastructure, promote sustainable industrialization that benefits everyone and enhance innovation
Infrastructure, industrialization and innovation are the three engines of economic growth. When inclusion, resilience and sustainability are also considered in the implementation of these drivers, the economic growth can foster sustainable development.

Objective 12 : Responsible consumption and production
Sustainable consumption and production patterns enable efficient use of resources and can reduce the effects of economic activities on the environment. To this end, the objective is to decouple economic growth from resource development, and to ensure that chemicals and hazardous wastes are managed in a way that minimizes their impact on people and the environment.

2. Objectives

2.1. Overall objective

The general objective of the twinning is to support the implementation of the pharmaceutical policy set up by the Ministry of Pharmaceutical Industry, and which aims in particular to improve health safety by strengthening the existing system in order to guarantee quality, the safety and efficacy of pharmaceuticals and medical devices as well as their performance in order to protect public health.

2.2. Specific objective

The specific objective is to strengthen the capacities of the National Agency of Pharmaceutical Products to ensure its new missions of evaluation, audit, inspection and quality control as well as missions of safety of pharmaceutical products and the performance of medical devices.

2.3. Targeted elements in the strategic documents

2.3.1. Strategic framework

The Support Facility to Partnership Priorities programme accompanies the Algeria-EU joint commitments with targeted institutional support activities. The main objective of the Support Facility is to:

- Strengthen the capacities and expertise of Algerian administrations and institutions
- Consolidate and deepen the rapprochement between the Algerian administration and the citizens.

This twinning project falls within the framework of these two objectives of the Support Facility and, more specifically, within the framework of the common priority of partnership n°i: **socio-economic development and trade.**

2.3.2. Institutional anchoring and contribution to the implementation of the government's action plan

Article 66.24 of the Algerian Constitution — All citizens have the right to the protection of their health.

Health has always been one of the priorities of the Algerian Government in the framework of successive action plans. This twinning is fully part of a dynamic of reforms led by the Algerian State translated into:

- The Constitution enshrines the right to health;
- The Government Action Plan (MAP) dated February 2020;
- The Economic Recovery Plan for the period 2020-2024 whose implementation of the sectoral strategy is entrusted to the Ministry of Pharmaceutical Industry, created in 2020.

The policy of this sector is based on three essential pillars:

- Regulation and pharmaceutical activities;
- Production/export/clinical research;
- Strategic Watch.

Law No. 18-11 of 18 Chaoual 1439 corresponding to 2 July 2018 relating to health, amended and supplemented by Ordinance No. 20-02 of 30 August 2020, which stipulates, in particular, in its following articles:

Art. 3. - The health objectives consist in ensuring the protection of the health of citizens through equal access to care, the guarantee of the continuity of the public health service and health security. Health activities are based on the principles of prioritization and complementarity of prevention, care and rehabilitation activities of the various structures and health facilities.

Art. 4. - The national health policy is based, in particular in its implementation, on intersectorality, through the contribution, organization and orientation of the various actors involved in the field of health.

Art. 205. — The State ensures the availability of pharmaceutical products and medical devices and guarantees access to products, in particular essential products, at any time and in any parts of the national territory. It also ensures compliance with the requirements of efficiency, safety and quality in the manufacture, import, export, distribution and delivery of pharmaceutical products and medical devices. It also oversees the rational use of medicinal product and their promotion.

Art. 206. — The State supports, through incentive measures, national production and encourages pharmaceutical research and development, in particular by promoting investment in this field.

The pharmaceutical industry's sectoral strategy aims to ensure that the necessary resources are in place to meet national needs in terms of pharmaceuticals and medical devices, but also to focus on exports.

A series of regulatory and administrative measures have been put in place to encourage and promote local production, in particular those relating to the opening of new production units, the registration of new pharmaceutical products, as well as the introduction of a new pricing policy including new economic and/or pharmaco-economic parameters such as the integration rate for inputs and services from domestic production.
The aim of this regulatory reform is also to stimulate manufacturing pharmaceutical establishments, particularly multinationals, to locate the production of high-value-added medicines with an export-oriented vision, such as innovative bio-drugs for diabetes and cancer.

As such, **the research component** in the sector is expected to play an important role in the **interactivity between universities and the pharmaceutical industry in the spirit, in particular, of the development of biotechnology for an innovative drug industry**, and high value-added

This dimension marks Algeria's desire to prioritise innovative and quality national production.

Under the supervision of the Ministry of the Pharmaceutical Industry, the ANPP, an operational and scientific institution, succeeds the National Pharmaceuticals Control Laboratory (LNCPP).
It is therefore responsible for guaranteeing and ensuring compliance with regulations on pharmaceuticals and medical devices in accordance with international guidelines. This is a real challenge for this newly created agency (April 2020) following thorough reforms undertaken in the health sector.

3. Description

3.1. Background and justification

Algeria, like many countries in the world, is experiencing an increase in non-communicable diseases such as cardiovascular diseases, diabetes and cancer.
In recent years, studies and surveys regularly point out that the main cause of death in Algeria is cardiovascular disease and that cancer has experienced a significant increase, raising the concern of actors and health officials. The treatments used in the aforementioned fields, especially in oncology, are constantly evolving in terms of consumption, as well as in the discovery of new innovative therapies...

To this end, the pharmaceutical industry of pharmaceutical products and medical devices in Algeria is expected to occupy a prominent place in the field of public health; currently regulated by Health Law No. 18-11 of 2 July 2018, amended and supplemented, published in Official Journal No. 46 of 29 July 2018, in particular its Title V. This law relates, inter alia, to the creation of the National Agency of Pharmaceutical Products as an establishment responsible for the registration, approval and control of pharmaceutical products and medical devices for use in human medicine (Title V, 4th chapter).

Initially placed under the supervision of the Ministry of Health, ANPP is transferred under the supervision of the Ministry of the Pharmaceutical Industry in 2020, under Ordinance No. 20-02 of 30 August 2020 amending and supplementing the health law of 2018 This change was initiated as part of the new approach to the revival of the pharmaceutical industry aimed at developing and encouraging local production, as well as the regulation of the national market.

ANPP is responsible, in particular, and in accordance with Executive Decree No. 20-391 of 19 December 2020 amending and supplementing Executive Decree No. 19-190 of 3 July 2019 fixing the missions, organization and operation of the National Agency of Pharmaceutical Products, published in Official Journal No. 78 of 27 December 2020:

- for the registration, approval and quality control of pharmaceutical products and medical devices before they are placed on the market;
- for the contribution to the definition of the rules of good pharmaceutical practices and carry out audits and on-site inspections;
- for asking the competent authorities to take the necessary measures to protect the health of the citizen when a pharmaceutical product or a medical device presents or is suspected of presenting a danger to public health;
- for undertaking any study, research, training or information action in the fields of its competence and to contribute to the promotion of scientific research in the field of pharmaceutical products and medical devices and to constitute the databases therein afferent;
- for implementing international cooperation actions.

3.2. The development of the ANPP and the extension of its scope of prerogatives

The establishment and the revision of the regulatory framework, in particular, the missions of ANPP in the registration, approval, evaluation, inspection, audit and quality control before marketing the pharmaceutical products and medical devices, confirms the exponential development of the ANPP in terms of missions and human plus material resources.

In terms of human resources, ANPP has more than 300 employees (of which more than 60% are women). ANPP includes two annexes in Oran and Constantine, a number that will evolve.

Today ANPP faces major challenges in its structure as an agency aiming to:

- preserve public health
- contribute to the development of the pharmaceutical industry.

To this end, several areas require support, including:

- The organizational strengthening through, in particular, the managerial, technical and scientific component;
- The modernization of the communication of ANPP to better exchange with the pharmaceutical operators on one hand, and the public on the other hand;
- The improvement of the coordination between the various departments of the Agency and streamlining the dissemination of information internally;
- The modernization of the registration process of pharmaceutical products and approval of medical devices to which online access has been established;
- The upgrading to standards concerning good pharmaceutical practices and on-site audits and inspections;
- The regular updating of recognized standards (WHO, EU and USA);
- The development of research areas in relation to ANPP missions.

Like its counterparts in Europe and abroad, ANPP works according to the guidelines and procedures established by the International Council for Harmonization (an international association governed by Swiss law) and adopts the same processes leading to the decision of registration (DE) and that of approval.

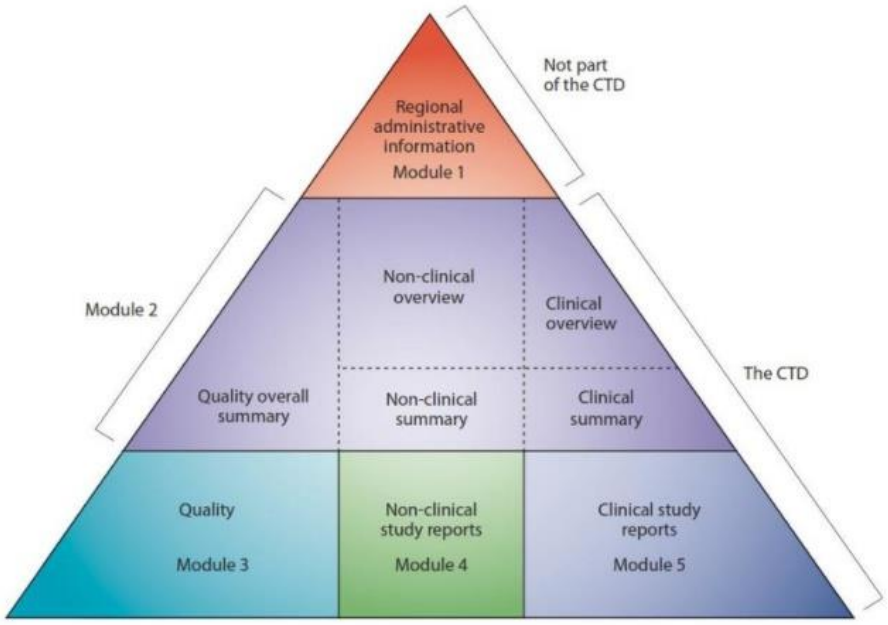
It adopts the **Common Technical Document** which is a file format used for the submission of marketing authorization applications for a pharmaceutical product (DE).

The main advantage of the CTD is that it is common to most health authorities around the world for the submission of a marketing authorization file (MA). The CTD was developed by the European Medicines Agency, its American equivalent (Food and Drug Administration) and Japanese (Ministry of Health, Labour and Welfare). It is maintained by the International Conference of Harmonization (ICH) which harmonizes drug regulation.

The registration dossier is a set of documents that may include all the required information concerning medicinal products, which are required by the regulatory authorities for the granting of marketing authorization. The main information included in the dossier is administrative information, data on the quality, safety and efficacy of the pharmaceutical product, which can be submitted in a CTD (Common Technical Document) in paper or electronic format.

The CTD format consists of 5 modules:

- Module 1: contains the administrative information and that relating to the prescription. This module 1 is not part of the harmonized CTD as it is specific to each country.
- Module 2: common to each region, aims to summarize the chemical, pharmaceutical and biological data, the non-clinical and clinical data of Modules 3, 4 and 5
- Module 3: common to each region, is the Quality part of the dossier which separates information on the active substance (3.2.S) and the associated finished product (3.2.P) into two different sections. These two sections are organized very closely.
- Module 4: common to each region, contains non-clinical information, that is to say the information collected during the use of the medicinal product in animals, in the form of study reports on pharmacology , pharmacokinetics and toxicity.
- Module 5: common to each region, contains clinical information, that is to say the information collected during the use of the drug in humans. It will mainly include clinical studies reports (concerning biopharmaceutical, pharmacokinetic, pharmacodynamic studies and clinical studies of efficacy and safety) as well as post-marketing pharmacovigilance data.



Triangle of the Common Technical Document (CTD)

The ANPP inspection, which has 20 inspectors, ensures that enforceable regulatory provisions regarding good pharmaceutical practices are implemented by pharmaceutical establishments (manufacturing, operation, wholesale distribution, import and export) as well as the quality and safety of pharmaceutical products, including raw materials and medical devices.

It deals with reports relating to quality defects in pharmaceutical products and medical devices and with pharmacovigilance and materiovigilance reports that may lead to an inspection.

3.3. Ongoing reforms

The creation of a Ministry of the Pharmaceutical Industry, the establishment and development of the ANPP are important milestones in the implementation of reforms of the pharmaceutical industry sector.

The Ministry of the Pharmaceutical Industry is responsible for implementing the national policy of the pharmaceutical industry, particularly in its aspects related to patient safety, the preservation of public health and the development of industries in the pharmaceutical sector along the lines following:

- Axis 1: Guarantee the continuous availability of pharmaceutical products, in particular essential drugs.
- Axis 2: Implement tools and regulatory systems guaranteeing quality, efficiency and safety. The commissions of the registration of medicinal product and medical device approval, the inter-sectoral economic committee of medicinal product and the committee of clinical expert are placed with the ANPP.
- Axis 3: Establish the national pharmaceutical industry as a wealth-creating sector through the implementation of a new price-fixing procedure, prioritizing the registration of generic medicines and similar biotherapeutic products and better management of raw material import programmes.
- Axis 4: Guarantee the economic accessibility to pharmaceutical products for all citizens by accelerating the approval procedure for pharmaceutical establishments, encouraging subcontracting, the developing of the export component through the orientation of several investment projects in local manufacturing with a correlated export projection.

3.4. Linked activities

As part of the Support Programme for the implementation of the Association Agreement

Support to the National Toxicology Center: within the framework of P3A, the Center benefited from three training actions for the establishment of:

- Methods for the analysis and assessment of residues and contaminants in food of animal origin ;
- Analytical methods for the detection and quantification of chemical residues and contaminants in foodstuffs of animal origin ;

Support to the National Competition Council to carry out "a sectoral study on the competitiveness of the market of pharmaceutical products for human use in Algeria" during 2018.

TAIEX (Technical Assistance and Information Exchange) requests: the health sector has benefited from several actions under the TAIEX instrument implemented as part of the Support to the Association Agreement Programme

- Seminar on vector control; April 2011
- Seminar on smoking cessation assistance; February 2013
- Seminar on telemedicine, digital medical solidarity and access to care: Algerian achievements and experience in the EU; April 2016

Health Sector Support Program (2011 – 2016)

The Ministry of Health, Population and Hospital Reform benefited from a EU programme implemented with 15 million Euros budget. The PASS programme objectives were the

consolidation of reforms and strengthening the human resources capacity of the institution, national public health institutes and hospitals of all statuses.

The programme has three main components:

- Improving the management of the epidemiological transition,
- Implementing tools and instruments for steering the sector and financing,
- Strengthening sector's skills and capacity building.

"European solidarity response to Covid-19 in Algeria" programme

This 43 million € programme EU programme implemented by the United Nations Development Programme in Algeria and the Algerian health authorities aimed to stop the spread of the corona virus by providing public health structures with medical equipment, early detection materials, and to acquire protective equipment for the benefit of nursing staff.

KFW-UNDP Support Project

Fight against Covid 19 which aims to provide ANPP with equipment to international standards in order to strengthen its capacity to carry out the quality controls of medical products necessary to fight the epidemic throughout the manufacturing process and before the implementation of the lot market for these products.

3.5. List of applicable union acquis/standards/norms

The European Commission's Directorate-General for Health and Food Safety (**DG SANTE**) carries out the overall EU policy and monitors the application of legislation in these areas. The CHAFEA Executive Agency implements the Health programme.

In order to promote the emergence of common policies in more specific sectors, EU has also set up other specialized bodies. One example is the **European Monitoring Center for Drugs and Drug Addiction** (EMCDDA), created in 1993 and located in Lisbon (Portugal), which produces comparative statistics on the consumption and circulation of drugs in the EU.

This list also includes the **European Medicines Agency** (EMA), which issues marketing authorisations for medicines, valid in the Member States of the European Union.

The EU programme for health, **EU4Health** for the financial year 2021-2027 established by Regulation (EU) 2021/522 provides funding to eligible entities, health organizations and NGOs from EU or non-EU countries associated with the programme. This programme is implemented through annual work programmes. The latest, which came into force in March 2021, focuses on 4 areas: disease prevention, crisis preparedness, health systems and digital technology, with a cross-cutting focus on cancer. It replaces the expired 2014-2020 programme.

3.6. Results

Result 1 : ANPP has a modern and efficient organization capable to carry out all its missions

By strengthening the organization of the ANPP both in terms of management and alignment of support services (administration, management, communication) on the requirements of its businesses, output 1 contributes to achieve the specific objective. This strengthening will result in an improvement in the general skills and the updating of the scientific knowledge and skills of ANPP staff. Similarly, the consolidation of the organization, operation and working methods will enable to establish an administrative organization with modern management tools (procedures, performance standards, forward planning of employment and skills). The acceleration of the digitization and dematerialization process is also part of the desire for greater control of the ANPP's business processes, guaranteeing the quality and efficiency of the services rendered both in terms

of registration and certification and inspection.

Result 2 : ANPP optimizes its processes related to the registration of pharmaceutical products

The registration of pharmaceutical products is at the heart of the ANPP's activity and, as such, represents one of its essential missions. This mission allows to ensure the efficiency and safety of the pharmaceutical products placed on the market, but must also be carried out within a reasonable time allowing their widest availability and responding to the innovative capacities of the sector. By consolidating its methodological and scientific approaches to the evaluation of pharmaceutical products, ANPP is committed to ensure compliance with internationally recognized standards. Similarly, the generalization of online filing of registration applications will facilitate their introduction, just as computerization will speed up their processing and strengthen their monitoring, enabling to speed up the registration process. The training of staff in the evaluation of files submitted for registration is also part of this desire for efficient processing in compliance with internationally recognized standards. By training evaluator trainers and developing assessment guidelines, ANPP is committed to a process not only of sustainability of the acquired knowledge at the end of the twinning project but also of developing its registration process of pharmaceutical products in response to the future developments of guidelines and procedures established by the ICH.

Result 3 : ANPP optimizes the processes related to the approval of medical devices

The approval of medical devices is also one of the main missions of ANPP. By strengthening the implementation of methods and good practices for the evaluation and approval of medical devices, ANPP ensures, on one hand, their compliance with the regulations in force and that they meet internationally recognized standards on the other hand. Similarly, in order to facilitate patients' access to medical devices and thus improve their quality of life, ANPP wishes to reduce approval delays and will generalize the online filing of approval applications as well as the computerization of their processing and monitoring. By training its staff in the methods of evaluating medical device approval files but, in addition, by training assessor trainers, ANPP will ensure the sustainability of the acquis at the end of the twinning project and will be able to integrate future evolutions of the guidelines and procedures established by the ICH. Similarly, by training all of its evaluators to ISO 13485 standard, ANPP will lay the foundations for the establishment of a system of the certification of medical devices and qualification of medical equipment according to ISO 13485 standard.

Result 4 : ANPP inspections in pharmaceutical establishments are optimized

The inspection of pharmaceutical establishments, as the registration of pharmaceutical products and the approval of medical devices, is part of the essential missions of ANPP. By adopting good practices in the conduct of inspection missions in accordance with the principles of ethics and transparency, ANPP will strengthen its capacities of market surveillance and conformity assessment of pharmaceuticals and medical devices placed on the market with the requirements of their registration/approval. By updating its pharmaceutical establishment inspection reference system and its inspection standards and grids, and by developing a classification of the reservations, ANPP will enhance the quality and efficiency of its inspections. In addition, the training of inspectors to ISO 1720 and 19011 standards will strengthen the Algerian certification system. By introducing the introduction of remote inspection of pharmaceutical establishments, ANPP acquires the capacity to continue its inspection activities not only in situations arising from constraints on travel and work meetings (for example, COVID -19 lockdowns) or the significant remoteness of distant and expensive travel that limits the number of inspections that can be performed.

Result 5 : laboratory capacities are strengthened in terms of quality management and research

ANPP laboratories are directly involved in the registration, counterpart and inspection processes. The quality of the assessments carried out by ANPP depends on the results of their analysis. As such, the strengthening of their organizational capacities in quality assurance of laboratories

according to ISO 17025 standards will give international recognition to ANPP assessments. Mastering the use of key technical equipment, in particular innovative equipment during the installation phase (i.e. analysis of biosimilar products), expression of results and interpretation and procedures of expertise and treatment of non-conformities, bacterial identification by proteomics by mass spectrophotometry as well as the implementation of an isoelectric focusing technique will strengthen and expand the control, analysis and interpretation capacities of ANPP. Similarly, by initiating research projects, ANPP will acquire a thorough knowledge of the most recent analysis techniques.

3.7. Means/input from the EU member state (s) administration (s)

Proposals submitted by the Member State should be concise and focused on the strategy and methodology, and on an indicative timetable underpinning them, the suggested administrative model, the quality of the expertise mobilized, the administrative structure and capacities of the institutions of the Member State. Proposals should be detailed enough to respond adequately to the Twinning Fiche, but should not contain a completed project. They should include sufficient detail about the strategy and methodology to indicate the sequencing of activities and identify key activities that will take place during the implementation of the project to ensure the achievement of the overall and specific objectives and mandatory outputs.

The Twinning partners ensure that the EU-funded twinning project has high and consistent visibility, in accordance with the provisions of the document "Communication and visibility of EU-funded external actions" available at the following address:

https://ec.europa.eu/international-partnerships/system/files/communication-visibility-requirements-2018_fr.pdf

The twinning project will be implemented through close cooperation between the partners in order to achieve the mandatory outputs in a sustainable manner.

The proposed activities will be developed with the twinning partners during the elaboration of the initial work plan and the successive rolling work plan every three months, bearing in mind that the final list of activities will be drawn up in consultation with the twinning partner.

Only the CVs of the Project Leader, Resident Twinning Advisor and Experts responsible should be included in the proposal.

3.7.1. Profile and tasks of the PL

The Member State Project Leader must be a high-ranking civil servant of the twinning Administration or an assimilated agent of a fully mandated body able to ensure an operational dialogue at the political level for the fulfilment of the objectives and able to solve problems with adequate solutions.

S/he will collaborate with her/his Algerian counterpart to guarantee leading and coordination of the whole project. S/he will have the capacity and responsibility to mobilise short-term experts to sustain proper implementation of expected activities. .

S/he will have:

- A university degree or an equivalent professional experience of 8 years
- A proven experience in the field of public administration and the management of an institution similar to the beneficiary institution and/or having taken charge the supervision and support of the provision of pharmaceutical products in a complete security

The MS Project Leader is responsible of the activities assigned to his/her administration in the work plan an must be available to the project during at least three days per month, with an on-site visit at least every 3 months in order to participate in the Project Steering Committees.
S/he will organise the quarterly Steering Committee meetings that they will chair jointly. The Steering Committee, which meets quarterly, will provide an update on the progress of the project in relation to the expected results.

S/he will be responsible in coordination with the Project Leader to submit quarterly and final reports to the UGP and (to the EU Delegation in Algeria).

3.7.2. Profile and tasks of the RTA

The RTA is a civil servant or employee of an institution or mandated body of the Member State for less than 3 years, s/he will ensure the twinning project implementation for the duration of the twinning, work full-time in Algeria. S/he will have:

- Masters 2 degree in medical sciences specializing in health management and/or pharmacy or at least eight years of professional experience in the health and/or pharmaceutical sector;
- specific experience, of minimum three years, in the field of pharmaceutical products and/or medical devices ;
- Knowledge of the requirements of the EU acquis and European good practices in the registration of pharmaceutical products, approval of medical devices and inspection of pharmaceutical establishments;
- Ability to manage a complex project, lead a team and ensure optimized communication;
- knowledge of both written and spoken French; The English language is also accepted;
- experience in the implementation of cooperation projects, particularly internationally (an asset) ;
- an experience in Algeria (an asset).

RTA may be required to provide scientific advice on pharmaceuticals and medical devices. S/he will be able to shed light on the general development strategy of a product in order to support the beneficiary administration in its organization and its processes in compliance with the regulatory framework and the requirements of the standards in force.

S/he is in charge of the day-to-day implementation of the twinning project. Specifically, in close collaboration with the project leader (PL) beneficiary country (BC), s/he:

- ensures the proper execution of the project work plan and activities in accordance with the planned outputs and time;
- coordinates and mobilizes short-term experts and ensures the good quality of the work provided;
- organises the launch, mid-term and closing conferences of the project and prepares the visibility documents in compliance with EU rules;
- ensures the proper management of the twinning activities, staff and logistics;
- provides the information necessary to prepare the documents as requested in the Twinning Manual (to be jointly countersigned by the PL of MS and BC), namely. side letters, contract amendments, payment requests , monitoring the consumption of the project budget;
- provides technical advice to ANPP within the framework of a predetermined work plan;
- participates in the writing and ensures the quality of the start-up, quarterly and final reports;
- organizes the steering committees with the PL of the BC, and attends them.

The RTA will be assisted by a full-time assistant who will be locally recruited after the project award and will be remunerated from the budget of the twinning contract. At this stage his/her Curriculum Vitae must not be part of the Member State's proposal.

Profile and tasks of results/outputs

For result/output 1, s/he will have:

- University degree or equivalent work experience of eight years;
- at least three years of specific experience in the field of public administration and/or public management and/or human resources management and/or training of civil servants.

For result/output 2, s/he will have:

- degree and experience in medical and/or pharmaceutical sciences with experience in the registration of pharmaceutical products

For result/output 3, s/he will have:

- degree and experience in medical and/or pharmaceutical sciences with experience in approval of medical devices

For result/output 4, s/he will have:

- degree and experience in medical and/or pharmaceutical sciences with experience in inspection and pharmaco-vigilance

For result/output 5, s/he will have:

- Engineering degree or pharmacist with experience in laboratory management and/or scientific research.

3.7.3. Profile and tasks of other short term experts

The Member State Will mobilize short-term experts (STEs). The desired general profile of STEs is as follows :

- have a university degree of higher level and equivalent professional experience of at least eight years in the specialties in accordance with the achievement of the five (05) outputs of the project;
- have pedagogical qualities in order to ensure the sharing of experience and a transfer of technical skills.

3.7.4. Translation and interpretation

If necessary, the Member State will provide a budget to cover translation and interpretation costs relating to the implementation of the activities.

4. Budget

€ 1 150 000

5. Implementation arrangements

5.1. Implementing body responsible for contracting and financial management

The Delegation of the European Union (DEU) is the contracting authority for this twinning project and provides administrative and financial management.

DEU is located at:

Domaine Benouadah, Rue du 11 décembre 1960, El Biar Alger
It is represented by **Mr Thomas ECKERT**, Ambassador, Head of the Delegation of the European Union.

Contact person: **Mrs Amina LAREDJ**

The National Coordinator of the Support Facility to Partnership Priorities EU-Algeria coordinates this twinning project, in compliance with Community procedures and in close relation with the EU Delegation in Algeria.

The contacts of the National Coordinator of the Support Facility to Partnership Priorities are :

Mr Abderrahmane SAADI,
Palais des expositions Pins Maritimes - Mohammadia - Alger
Tel. 213 23.79.50.01 / +213 23.79.50.02
Fax. +213 23.79.50.03
E-mail : Abderrahmane.SAADI@p »a-algerie.org

5.2. Institutional framework

The National Agency of Pharmaceutical Products (ANPP), located in Lot Géraud, Petit Staoueli (site of the new Pasteur Institut) -Dely Ibrahim, Alger, Algerie-, has various directorates and departments, including:

- Directorate of Pharmaceutical Registration
- Directorate of Approval of Medical Device
- Directorate of Technical monitoring, inspections and vigilance
- Directorate of Control and expertise
- Directorate of Laboratory and Scientific Research
- Directorate of Human Resources and Training
- Directorate of Finance and Accounting
- Directorate of Information Systems
- Internal Audit and Management Control Office.

5.3. Counterparts in the beneficiary administration

5.3.1. Contact Person

Doctor BELKACEMI Redha
Deputy- Director of economic assessment
Ministry of Pharmaceutical Industry
Sidi Hassen 16125, les Dunes Cheraga, Alger, Algérie.
Tel : +213661718867
Fax : +213(0)23.36.05.88
E-mail : r.belkacemi@miph.gov.dz

5.3.2. PL counterpart

Professor MANSOURI Kamel
General Director, Lot Géraud
Petit Staoueli (site du nouvel Institut Pasteur)
Dely Ibrahim, Alger, Algérie.
Tel : +213661311345
Fax : +213(0)23367523
E-mail : mansouri.kamel@anpp.dz

5.3.3. RTA counterpart

Doctor KHELEF Rym
Cooperation official
Petit Staoueli (site du nouvel Institut Pasteur)
Dely Ibrahim, Alger, Algérie.
Tel : +213661300956
Fax : +213(0)23367523
E-mail : khelef.rym@anpp.dz

5.3.4. Results/outputs responsibls

For output 1
Mrs BOUGUERRA Khadidja, Head of Internet Audit and Management Control Office
For output 2
Mrs TAHI Meriem, Director of Pharmaceutical Registration
For output 3
Doctor GHERAIEB Nabil, Director of Medical Device Approval
For output 4
Doctor BOUTARENE Nabiha Elkhaldia, Director of Technical Monitoring, Inspection and Vigilance
For output 5
Doctor BENAYAD CHERIF Ouatfa, Director of Laboratories and Scientific Research.

6. Duration of the project

24 months

7. Management and reporting [2]

7.1. Language

The official language of the project is the one used as contract language under the instrument (French). 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) oversees the implementation of the project. Its main tasks are to check the progress of the project and achievements of the mandatory outputs, ensure effective coordination between actors, finalize 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 of the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

8. Sustainability

It is about strengthening existing missions and the capacity of ANPP staff to better carry out the Agency's missions. The implementation of procedures, tools and methodologies, the training of trainers to ensure the sustainability of training is either a means of sustainability of the twinning outputs.

[2] Points 7.1 to 7.3 must be kept unchanged in all Twinning fiches Forms.

The regulatory framework for the ANPP's missions is recent and the twinning is likely to bring about minor but essential adaptations to supervise the rapid development of ANPP in terms of investments, workload as an increase in scientific, technical and administrative staff.

The twinning will allow the ANPP to develop its capacities for the mastery of all its missions and will bring a qualitative leap towards the upgrading of all its services in order to meet the national requirements of quality and safety of pharmaceutical products and recognition of its international controls and decisions.

The Contributions of the Member State will allow, in particular, to contribute to:

- a modern functional administrative organization supported by management tools focused on results and performance guaranteeing deployment of skills on a quality basis ;
- the staff trained in scientific techniques for the control and evaluation of pharmaceutical products;
- standards adopted to establish quality management and the operation of laboratories according to international standards;
- the dematerialized processes through the digitization of directorates;
- an inspection formed according to the guidelines and good practices of transparency and ethics accepted in the sector and at European and international levels;
- the appropriation of research methods capable of supporting the ANPP in ongoing innovations;
- the sustainability of outputs through the training of trainers in order to support the recruitment plans for young officials planned according to the development of the workload of ANPP and the pharmaceutical products sector.

9. Cross-cutting issues (equal opportunities, environment, climate, etc.)

Gender equality

Algeria fully supports gender issues. As for gender parity in the various sectors of activity, Algeria ranks first in the Arab world, ninth in Africa and 26th in the world. The State encourages the promotion of women to the responsibilities in the institutions, the public administrations and the enterprises.

More than 60% of the ANPP's staff are women, a considerable number of whom hold positions of responsibility and management (out of 9 directorates, 6 women are at their heads).

The twinning project will provide mechanisms to ensure that women, not only do they have full access to its resources, but they are actively involved in their allocations and these mechanisms are gradually being extended to all ANPP resources.

Democracy, good governance and rule of law

Overall, the twinning project falls within the framework of the values and principles set out and accepted in the Association Agreement between the EU and Algeria.

ANPP is directly concerned with issues related to good governance, transparency, the subjection of a public service mission to promote the best access to pharmaceuticals for citizens, while ensuring their safety.

Environment

As the Pharmaceutical Regulatory Authority, ANPP is the control structure in the pharmaceutical sector. As a result, ANPP has a role in raising awareness of the environmental impact due to the activities of the industries in the sector. To achieve this, it is imperative that pharmaceutical

manufacturers design their supply chains, production and distribution networks with a view to reducing the environmental footprint.

ANPP control inspections must also support this dimension.

10. Conditionality and sequencing

This twinning project is not conditioned by any specific preconditions, specific requirement, other than those expressly mentioned in the twinning fiche.

Proposals submitted by Member States must include activities to ensure that the results and deliverables listed in the fiche will be achieved.

The activities will be further developed with the twinning partners when drafting the twinning work plan, bearing in mind that the final list of activities will be decided in cooperation with the Member State.

In addition to the activities related to the three products and the quarterly meetings of the steering committee, it is planned to organise transversal activities aimed at ensuring the visibility of the project (launch seminar, mid-term conference, closing seminar, etc.).

11. Performance indicators

Result 1 : ANPP has an efficient organization capable of carrying out all its missions
- Organizational diagnosis performed
- An oriented human resources management, the forward management of jobs and skills is introduced
- A training plan is developed
- Percentage of digitization tools implemented
- Percentage of dematerialization of registration and approval processes
- A multi-media internal and external communication plan is put in place

Result 2 : ANPP optimizes its processes related to the registration of pharmaceutical products
- Percentage of online filing of procedures for applications for registration of pharmaceutical products and software adapted to the processing and monitoring of these applications.
- Percentage of staff dedicated to evaluation and trained in the evaluation of files submitted for registration
- Number of evaluator trainers trained
- Number of pharmaceutical product registration guidelines in place

Result 3 : ANPP optimizes processes related to the approval of medical devices
- Percentage of online filing of procedures for applications for approval of medical devices and software adapted to the processing and monitoring of these applications.
- Percentage of the staff dedicated to evaluation trained in the assessment of files submitted for approval
- Number of evaluator trainers trained
- Number of guidelines governing the approval of medical devices set up
- Number of assessors trained to ISO 13485:2020

Result 4 : ANPP inspections carried out in pharmaceutical establishments are optimized
- Number of inspectors trained in good pharmaceutical practices and inspections (ISO 17020, ISO19011 standards)
- Updated reference system of the inspection of pharmaceutical establishments

- Updated standards and inspection grids of pharmaceutical establishments
- A remote inspection of a pharmaceutical establishment carried out
- A classification of reservation (major, minor) with corresponding sanction criteria

Result 5 : laboratories capacities are strengthened in terms of quality management and research

- Percentage of engineers and laboratory technicians trained in control techniques
- Percentage of engineers and laboratory technicians trained in proteomics by mass spectrophotometry in bacterial identification
- ISO 17025 standard adopted

Available facilities

ANPP will provide the RTA and his/her assistant with a fully equipped office (hardware and software) as well as offices and meeting rooms for short-term experts.

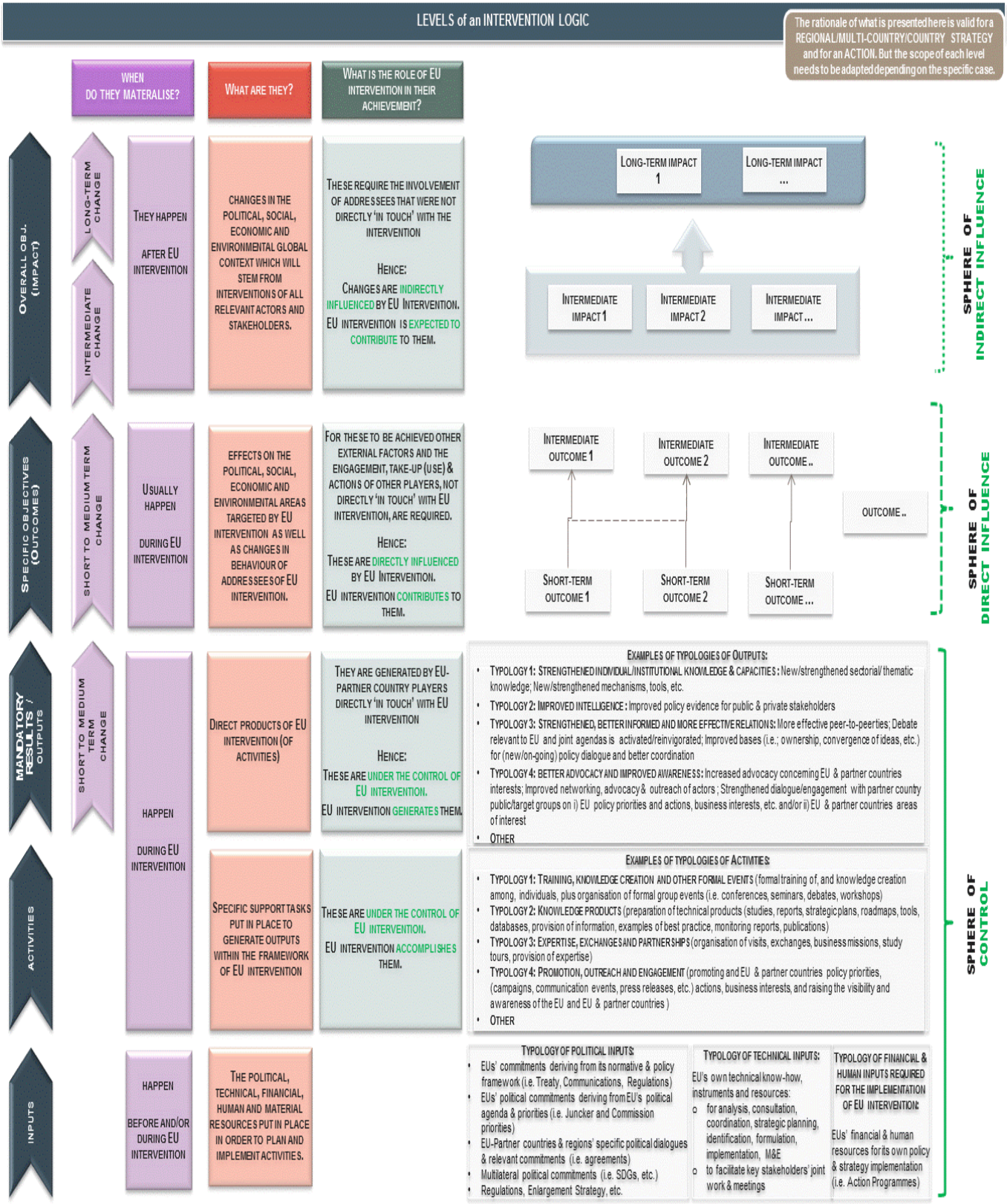
ANPP will cover the costs related to the implementation of the twinning project which would not have been mentioned in the twinning indicative budget.

[X]

ANNEXES OF THE TWINNING FICHE

1. Level of an intervention logic
2. Simplified logical framework
3. Summary table of directorates and their tasks

4. Annex I: Level of an intervention logic



AnnexII : Simplified logical framework

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Overall objective	Support to the implementation of the pharmaceutical policy set up by the Ministry of Pharmaceutical Industry, which aims in particular to improve health safety by strengthening the existing system in order to guarantee quality, safety and efficacy of pharmaceuticals and medical devices as well as their performance in order to protect public health.	Coverage rates for pharmaceuticals and medical devices Number of new pharmaceutical products registered Number of new licensed medical devices Decrease in pharmacovigilance and materiovigilance alerts	Activity report of the technical directorates of the Ministry of Pharmaceutical Industry PP and DM nomenclature ANPP Annual Reports and Reviews		

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Specific objective (s) (of the project)	Support to capacity building of the National Agency of Pharmaceutical Products to ensure its new missions of evaluation, audit, inspection and control of the quality and safety of pharmaceutical products and the performance of medical devices.	Number of files processed (at least + 10 %) File processing time (at least - 15 %) Processing time for the removal of reservations (at least - 15 %) Number of establishments inspected (at least + 10 %) Number of pharmacovigilance reports (at least - 10 %)	ANPP monthly internal activity Annual directorate review ANPP/MIPH websites ANPP scientific review ANPP scientific publications Twinning project reports	Non-availability of means Delays in the adoption of texts and decisions Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

	Results	**Indicators (with relevant reference and target data)**	**Sources of verification**	**Risks**	**Assumptions (project external factors)**
Output 1	ANPP has an efficient organization capable of carrying out all its missions	Organizational diagnosis (minimum 1 achieved) A management of human resources oriented Forward planning of employment, qualifications and skills is introduced Training plan (minimum 1 developed) Percentage of digitization tools implemented (at least 80%) Percentage of dematerialization of registration and approval processes (at least 80%)	ANPP monthly internal activity report Annual directorate review ANPP/MIPH websites Twinning project reports	Non-availability of means Delays in adopting organizational changes Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Output 2	ANPP optimizes its processes related to the registration of pharmaceutical products	Percentage of online filing of procedures concerning applications of registration of pharmaceutical products (at least 80%) Percentage of computerized processing and follow-up of applications regarding registration of pharmaceutical products (at least 80%) Percentage of personnel dedicated to evaluation trained in the evaluation of files submitted for registration (at least 80%) Number of evaluator trainers trained (minimum 10) Number of pharmaceutical product registration guidelines in place (minimum 3)	ANPP monthly internal activity report Annual directorate review Procedures Manuals ANPP/MIPH websites Twinning project reports	Non-availability of means Delays in the dematerialization of registration procedures Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Output 3	ANPP optimizes processes related to the approval of medical devices	Percentage of online filing of medical device approval application procedures (at least 80%) Percentage of computerized processing and tracking of medical device approval applications (at least 80%) Percentage of staff dedicated to evaluation trained in the evaluation of files submitted for approval (at least 80%) Number of evaluator trainers trained (minimum 10) Number of medical device approval guidelines in place (minimum 3) Number of assessors trained to the ISO 13485 standard (100%)	ANPP monthly internal activity report Annual directorate review Procedures Manuals ANPP/MIPH websites Twinning project reports	Non-availability of means Delays in the dematerialization of approval procedures Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Output 4	ANPP inspections carried out in pharmaceutical establishments are optimized	Number of inspectors trained in good pharmaceutical and inspection practices (ISO 17020, ISO 19011 standards) (at least 20) Pharmaceutical Establishment Inspection Guidelines (minimum 1 updated) Standards and inspection grids for pharmaceutical establishments (100% updates) Remote inspection of a pharmaceutical establishment (minimum 1 inspection carried out) Reservations (major, minor) (minimum 1 classification carried out)	ANPP monthly internal activity report Annual directorate review Inspection reports Inspection Guide List of reports Twinning reports	Non-availability of means Delays in the adoption of reference systems, standards and inspection grids Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

	Results	Indicators (with relevant reference and target data)	Sources of verification	Risks	Assumptions (project external factors)
Output 5	laboratories capacities are strengthened in terms of quality management and research	Percentage of engineers and laboratory technicians trained in new control techniques (at least 80%) Percentage of engineers and laboratory technicians trained in proteomics by mass spectrophotometry in bacterial identification (at least 20%) ISO 17025 standard adopted (minimum 1 pre audit)	ANPP monthly internal activity report Annual directorate review Quality Assurance Manual and Guides Non-conformity handling manual and guidelines Laboratory Functional Audit Manual Collection of research works Twinning reports	Non-availability of means Delay in preparing of the implementation of the ISO 17025 standard Non-availability of the concerned teams	The Covid 19 pandemic is largely mitigated Adherence of managers to the corrective measures to be taken Stability and management involvement

Annex III : ANPP Estimated schedule

	Quarter 1			Quarter 2			Quarter 3			Quarter 4			Quarter 5			Quarter 6			Quarter 7			Quarter 8		
RTA																								
RTA and twinning start day																								
RTA assistant selection																								
Horizontales Activities																								
Preparation of initial work plan																								
Steering Committees																								
Visibility and Communication																								
Kick-off Meeting																								
Closing Conference																								
Mandatory Results/Outputs																								
O1 ANPP has an efficient and a modern organization capable of carrying out all its missions																								
O2 ANPP optimizes its processes related to the registration of pharmaceutical products																								
O3 ANPP optimizes processes related to the approval of medical devices																								
O4 ANPP inspections carried out in pharmaceutical establishments are optimized																								
O5 laboratories capacities are strengthened in terms of quality management and research																								