



Pharmaceutical industry in Tunisia, challenges and perspectives

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Introduction

The pharmaceutical industry in Tunisia constitutes a dynamic market in perpetual growth capable of making our country a platform for the export of health products

Promising sector considered as a driver of economic and social development

The interest is based on strategic directions with an action plan aimed at promoting the country as an export hub and as an investment site

Introduction

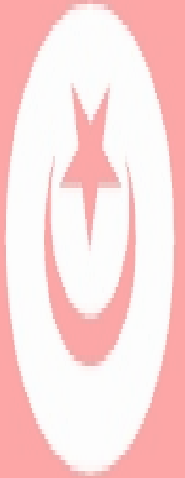
Quality management systeme

Objective: insure quality, safety and efficacy

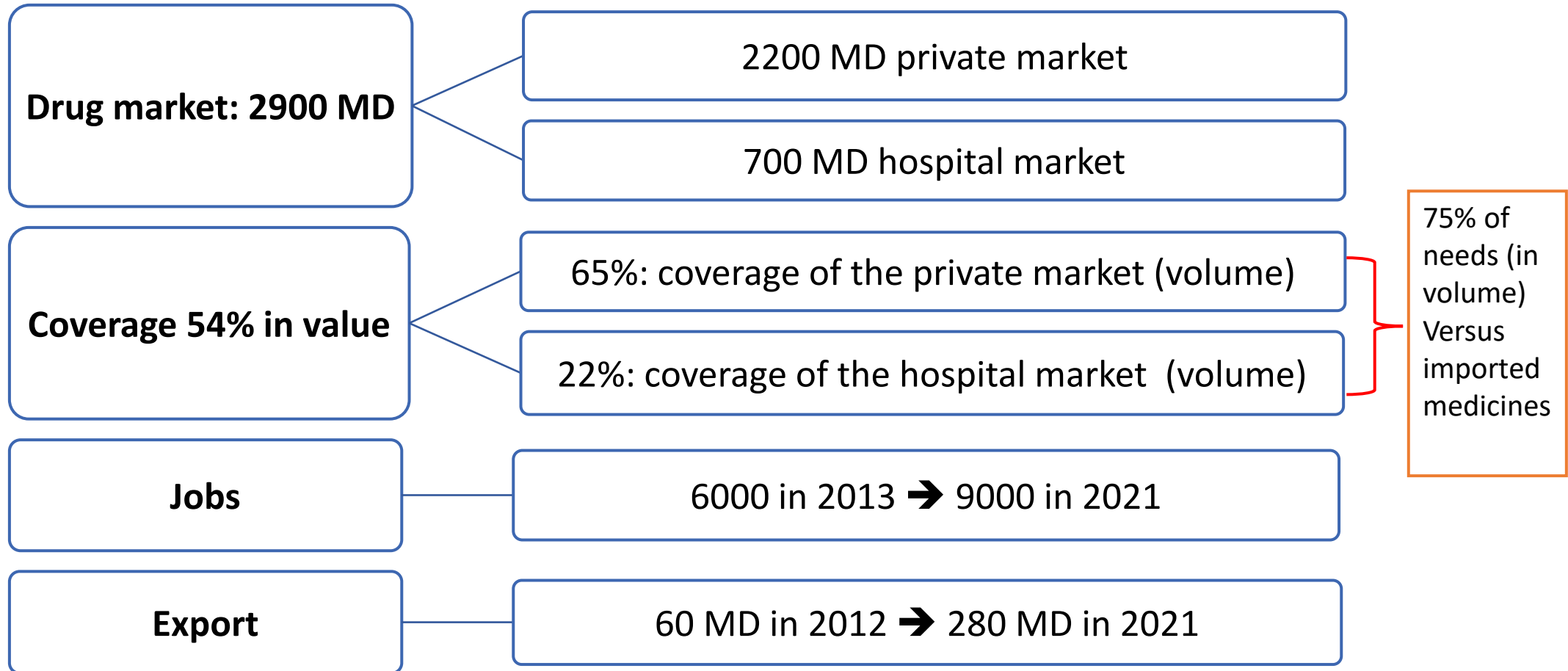
Harmonization with ICH

Harmonization with the African Agency

Effective, stable and strong regulatory system



Pharmaceutical sector: high added and strategic value



Export countries

- **Africa:**

Ivory Coast, Senegal, Algeria, Libya, Mauritania, Morocco, Uganda, Sudan, Chad, Gabon, Mali, Congo, Burkina Faso, Cameroon, Rwanda, Benin, Djibouti, Madagascar, Niger, Guinea, Burundi...

- **Asia:**

UAE, Iraq, Jordan, Oman, Saudi Arabia, Lebanon...

- **Europe:**

France, Malta, Italy, Spain, Switzerland...



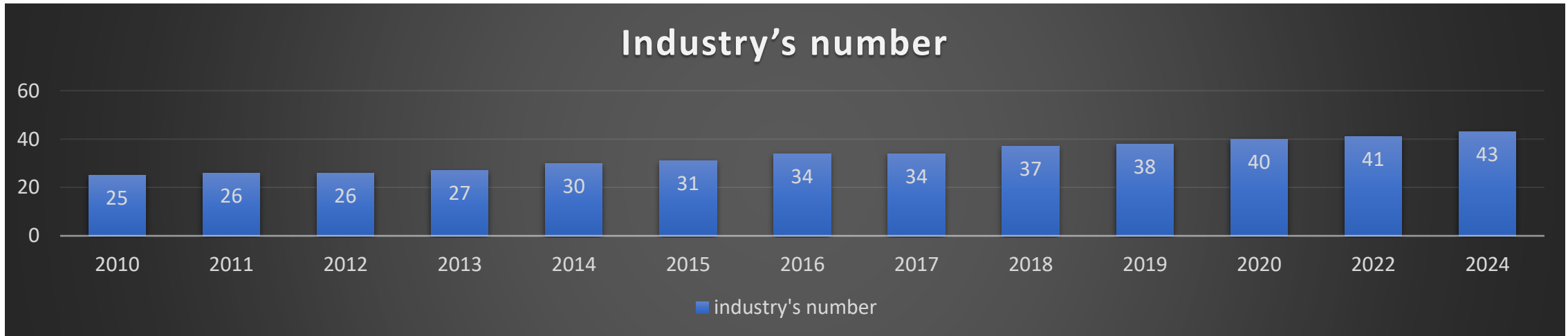
Africa Market (80 MD)

Laboratoires exporting to Africa:

Adwya - TERIAK - MEDIS - SAIPH - Berg Life Science – Cytopharm - Dar
Essaydaly- Dorcas – Galpharma – Ibn Al Baytar – Infomed Pharma – IPS said –
Medicef – Opalia Pharma – Pfizer Tunisie – Pharmacare – Pierre Fabre
Médicament Production Tunisie – Sanofi Aventis Pharma Tunisie – SIPHAT –
Winthrop Pharma Tunisie.

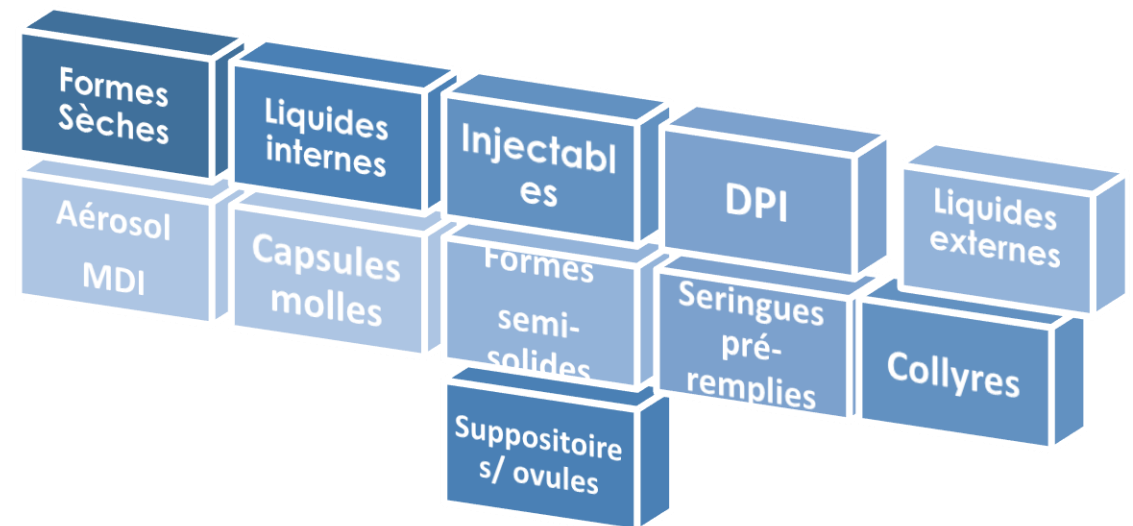


Eclectic industrial landscape



Evolution of the number of medicines industries in Tunisia, DPM

- Generics,
- Licensed originators
- Biosimilars
- Vaccins & serums



Foreign pharmaceutical industries established in Tunisia

- Partenariat joint-venture with SIPHAT :

Les laboratoires Pierre Fabre (France)

Les laboratoires Pfizer (US)

High export potential especially for Africa.

- Tunisien laboratories manufacturing under licence (TERIAK, ADWYA, IPS, SIMED, SIPHAT, SAIPH...)

Pharmaceutical industries of subsidiaries established outside the country

- **Les laboratoires TERIAK :**

CINPHARM au Cameroun

Under licence with french laboratories : SERVIER, IPSEN et SANOFI (avec la possibilité d'exporter à partir de la Tunisie)

- **Les laboratoires MEDIS :**

- INTHA-MEDIS en Algérie

- MEDIS-Sénégal à Dakar

- MEDIS République tchèque

- **Les laboratoires SAIPH :**

- Saiph-Ivoire en Côte d'Ivoire « Projet de construction en cours / terrain 35 000 m² »



Strengths: Pharmaceutical Industry



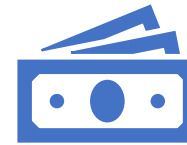
Regulatory framework: since the 1970s, covering all aspects of drug manufacturing, registration, and distribution:
<http://www.dpm.tn/industrie/reglementation>.



The geographical location of Tunisia and the airport and ground infrastructure



Qualified human potential: High-level executives as well as technicians graduated from the faculty of pharmacy, engineering schools, health schools, and biotechnology sciences



State encouragement: A new legal framework that encourages investment: financial incentives + tax incentives:
<http://www.tunisieindustrie.nat.tn/fr/>

Ifriqiya

Name Arabic
(Latin Africa) of Tunisia
until the 13th century



Investment promotion

République Tunisienne | Ministre de l'Industrie, de l'Énergie et des Mines

English Italiano عربي

Agence de Promotion de l'Industrie et de l'Innovation

PORTAIL DE L'INDUSTRIE TUNISIENNE

Bienvenue sur le
www.tunisieindustrie.nat.tn

Chercher... Chercher

W.S.A. WINNER 2011

ACCUEIL INCITATIONS ET AVANTAGES CRÉATION D'ENTREPRISES INFORMATIONS INDUSTRIELLES ETUDES ET MONOGRAPHIES INNOVATION SERVICES EN LIGNE

Qui sommes-nous ? | Informations pratiques | FAQ | Contactez-nous Publications de l'API | Monographies sectorielles | Documents utiles

Accueil > Incitations et avantages > Nouveau cadre juridique de l'investissement

Nouveau cadre juridique de l'investissement

Le nouveau cadre juridique est régi par les textes réglementaires suivants :

- ▶ Loi n°2016-71 du 30 Septembre 2016, portant loi de l'investissement;
- ▶ Loi n°2017-8 du 14 Février 2017, portant refonte du dispositif des avantages fiscaux ;
- ▶ Décret 2017-389 du 9 Mars 2017, relatif aux incitations financières au profit des investissements réalisés dans le cadre de la loi de l'investissement.

Quels sont les avantages et incitations prévus par le nouveau cadre juridique de l'investissement ?

- ✓ **La prime de l'augmentation de la valeur ajoutée et de la compétitivité**
- ✓ **Développement Régional**
- ✓ **La prime du développement durable**
- ✓ **Les participations au capital**
- ✓ **Projets d'intérêt national**
- ✓ **Encouragement de l'Exportation et des Secteurs Innovants**
- ✓ **Les secteurs prioritaires et les filières économiques dans l'Industrie et les services**
- ✓ **Autres Avantages Fiscaux**

- ✓ Financial incentives
- ✓ Tax incentives

Annexe 1 : Liste des secteurs prioritaires

- ▶ l'agriculture, la pêche, l'aquaculture, et les services liés
- ▶ les activités de première transformation des produits de l'agriculture et de la pêche
- ▶ Industries de nanotechnologie
- ▶ Industries de biotechnologie
- ▶ Textile et habillement
- ▶ Industries électroniques
- ▶ Plastique technique et produits composés
- ▶ Industries automobiles, aéronautiques, maritimes et ferroviaires, et composantes
- ▶ Industries pharmaceutiques et dispositifs médicaux
- ▶ Les centres de recherche et développement et de recherche clinique
- ▶ Industrie des équipements industriels
- ▶ Industries militaires
- ▶ Industries culturelles et créatives
- ▶ L'assemblage, la valorisation, la transformation et le traitement des déchets solides et liquides
- ▶ Les projets de protection et de valorisation des filières naturelles, de biodiversité et de lutte contre la désertification
- ▶ La production des énergies renouvelables
- ▶ Les technologies de la communication et de l'information
- ▶ Les services logistiques prêtés dans les zones logistiques
- ▶ Le tourisme : les projets d'hébergement et d'animation touristique réalisés dans le cadre du développement du tourisme culturel, écologique, de santé, du désert et le tourisme du golf
- ▶ Les centres sportifs et de loisirs



National Regulatory Authority : Technical administration of the Ministry of Health



Quality control of drugs and pharmaceuticals

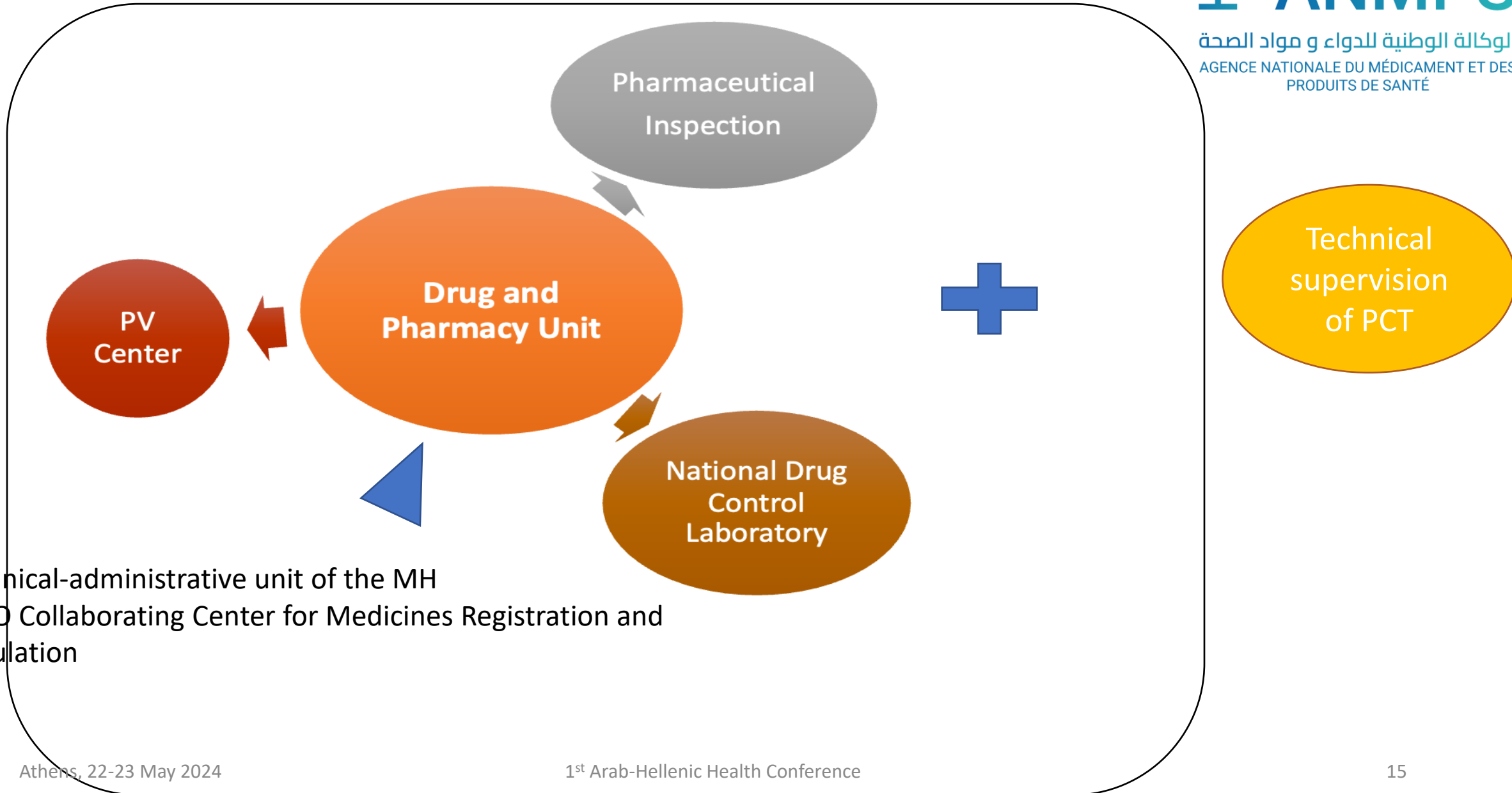


Monopoly of drugs import and supply of public structures



**Pharmacovigilance, post-marketing follow-up
Bioequivalence studies**

National Regulatory Authority:



- Technical-administrative unit of the MH
- WHO Collaborating Center for Medicines Registration and Regulation

Missions of the DPM Decree n°2007-30017 of 27/11/2007

1. National Narcotics Bureau + Drug Addiction Commission
2. Technical Committee for Pharmaceutical Specialties (CTSP);
3. Specialized commissions for reviewing MMA application files (17,)
4. National Commission for Veterinary Medicine
5. National Commission for the Granting of Operating Authorizations for Establishments Manufacturing Medicines for Human Use
6. National Drug Advertising Control Commission
7. National Commission for the Promotion of Infant and Child Nutrition
8. Hemodialysis Filter Approval Commission
9. Medicines and Vaccines Observatory

National Regulatory Authority missions

Pharmaceutical industries

licencing and agreement of industries
licencing of pharmacists

Human and Veterinary drugs

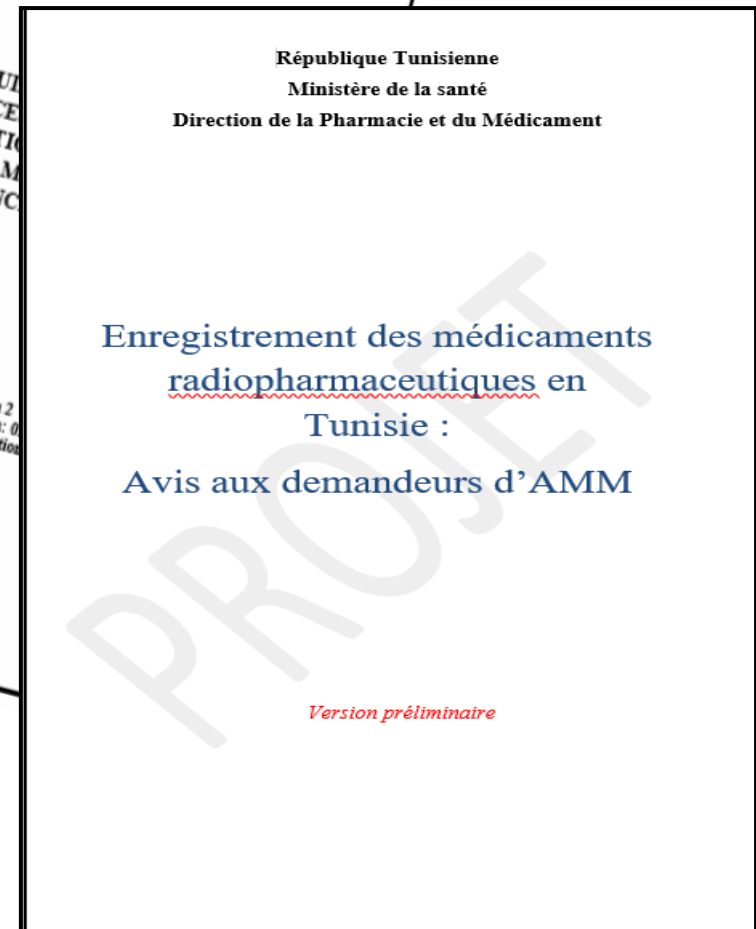
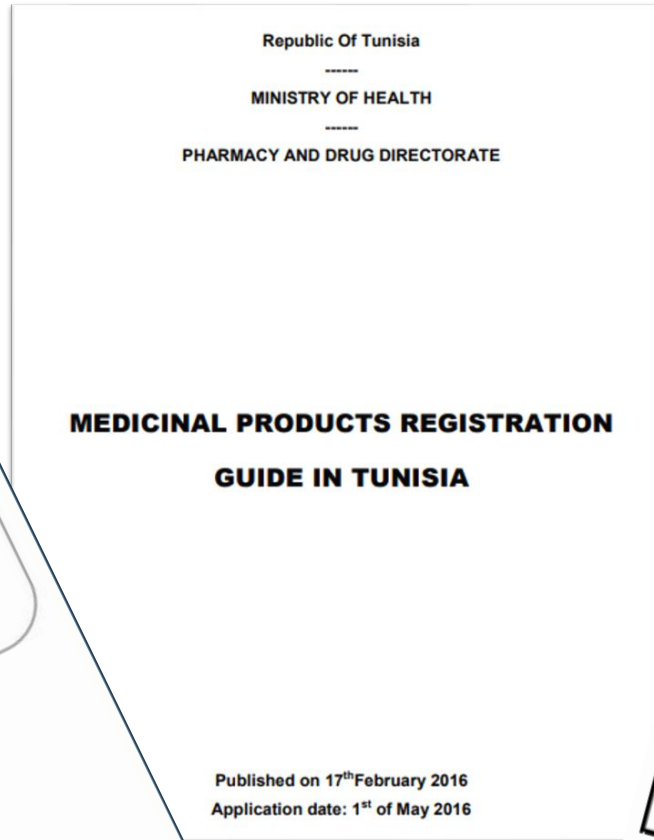
Registration
Clinical trials
Drug publicity
Autorisation of importation and exportation of drugs

Medical devices and Health Products (Food Supplements, Cosmetics, infant formulas)

Technical control of importation of medical device, cosmetics

Pharmacy and wholesalers distributors

- licencing and agreement of pharmacy
- Creation and transfert of pharmacy
- Agreements of Whosalers distributors



Towards a New Information System for the Drug Agency in Tunisia

Law No. 2023-2 of July 12, 2023, establishing the National Agency for Medicines and Health Products.

- Reducing the timeframes for obtaining MAs.
- Modernizing the registration process.
- **RIMS of the drug agency**
- Ensuring transparency."

Digitalization

e-CTD

KEY PROCESS STEPS FOR DIGITALIZATION



1-CURRENT SITUATION



2- DIGITALIZATION PREPARATION



3- DEVELOPEMENT & ACQUISITION



4- DEPLOYMENT



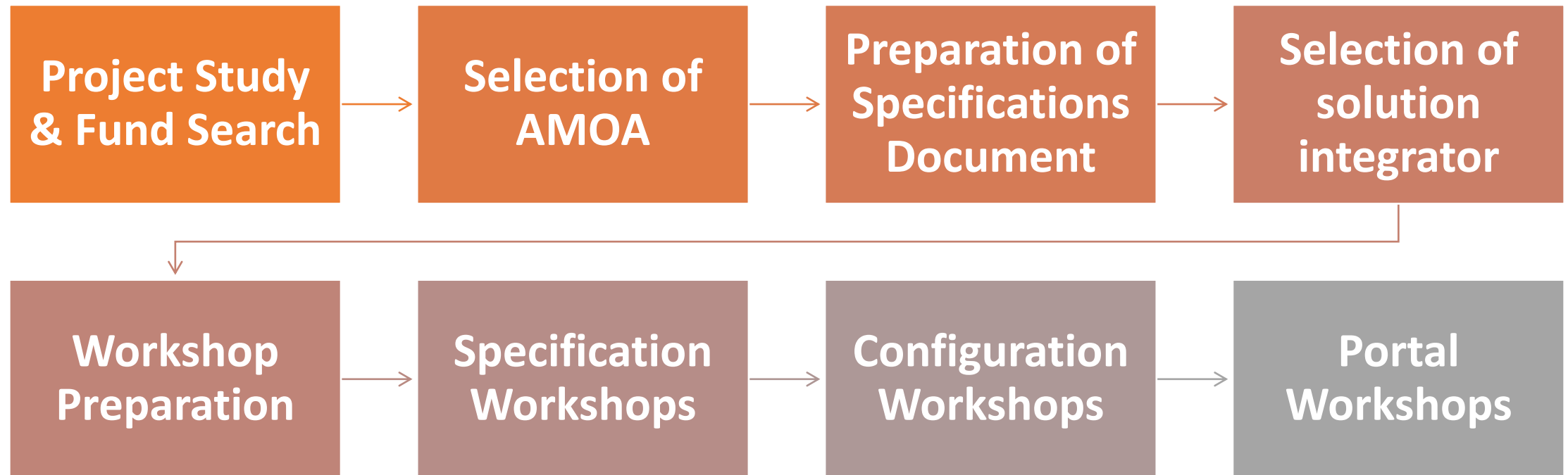
- Assessment of Current Systems
- Process Optimization and Modeling
- Target Quality Document System
- Cost Estimation
- Specifications Document



Athens, 22-23 May 2024

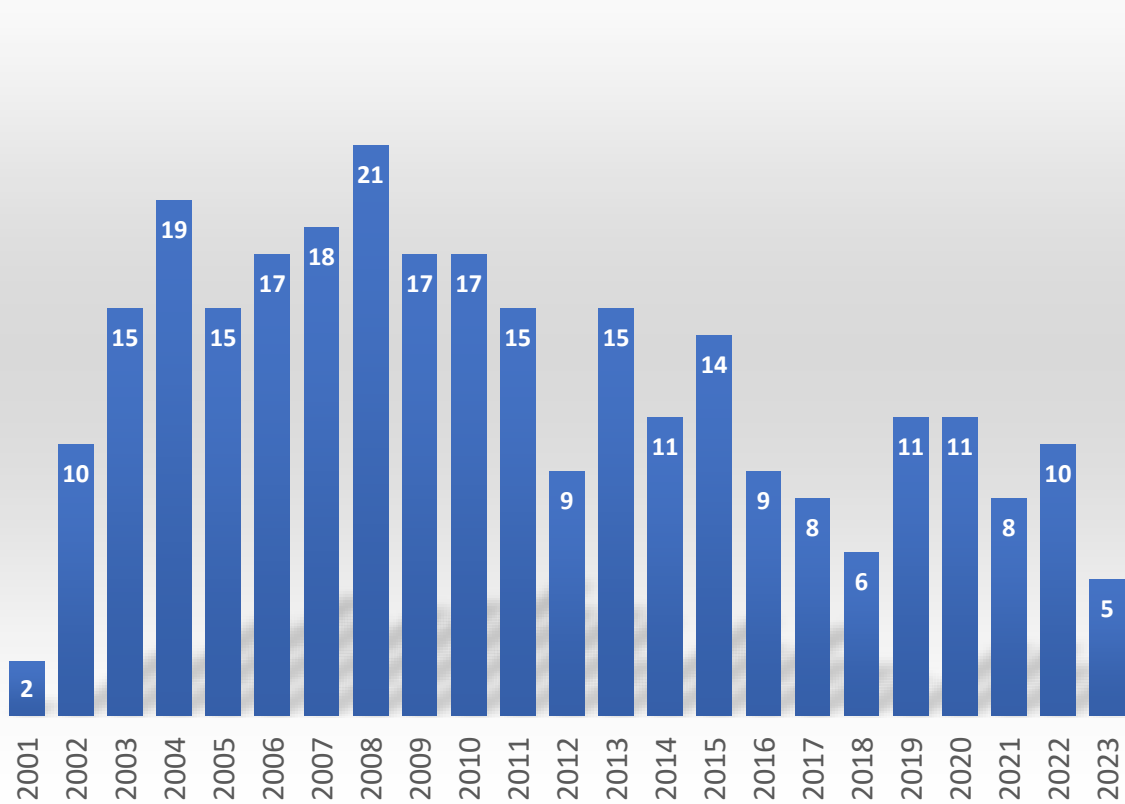


ROAD MAP OF E-CTD PROJECT

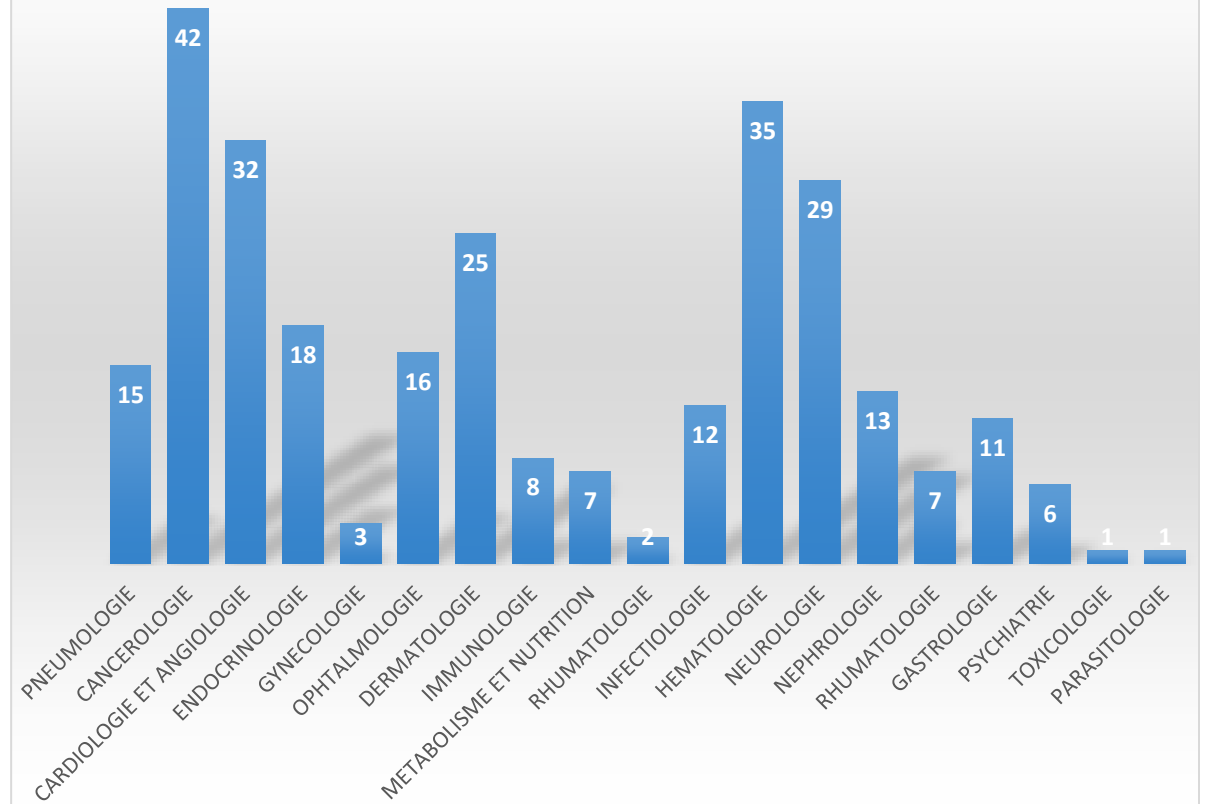


Clinical trials in Tunisia

Distribution of the number of clinical trials registered with the DPM from 2001 to 2023



Distribution of clinical trials by medical specialties between 2001 and 2023.





Regulatory framework

- Tunisia is one of the first Arab and African countries to have clear regulations regarding clinical trials adapted to international standards (Good Clinical Practices - ICH).
- Tunisia remains a pioneer in Africa and the MENA region concerning the protection of personal data through Organic Law 2004-63 of July 27, 2004."



Attractiveness of Tunisia for the clinical trials

Factors enhancing its competitiveness in the MENA region:

Regulatory context

Patient pool (presence of treatment-naïve patients)

Healthcare professionals' expertise

Infrastructure and environment"



Intellectual Property in Tunisia

- The protection of inventions by patents is very old in Tunisia since 1888 : the beylical decree of December 26, 1888
- Has been updated on August 24, 2000 : The law N° 2000-84 on patents and its application decrees were published
- It is compatible with the requirements of the WTO Agreement and in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Law No. 2000-84 of August 24, 2000, on Patents¹

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Intellectual Property in Tunisia



- Tunisia is member of the World Intellectual Property Organization (WIPO) and signatory to several international conventions on intellectual property:
 - WIPO Patent Cooperation Treaty;
 - Madrid Protocol for the International Registration of Marks;
 - Paris Convention for the Protection of Industrial Property and Trademarks;
 - UNCTAD Agreement on the Protection of Patents and Trademarks;
 - Agreement with the EU that allows automatic patent protection in Tunisia for European patent applications through the European Patent Organization.

Vaccine supply



Pasteur institute of Tunis:

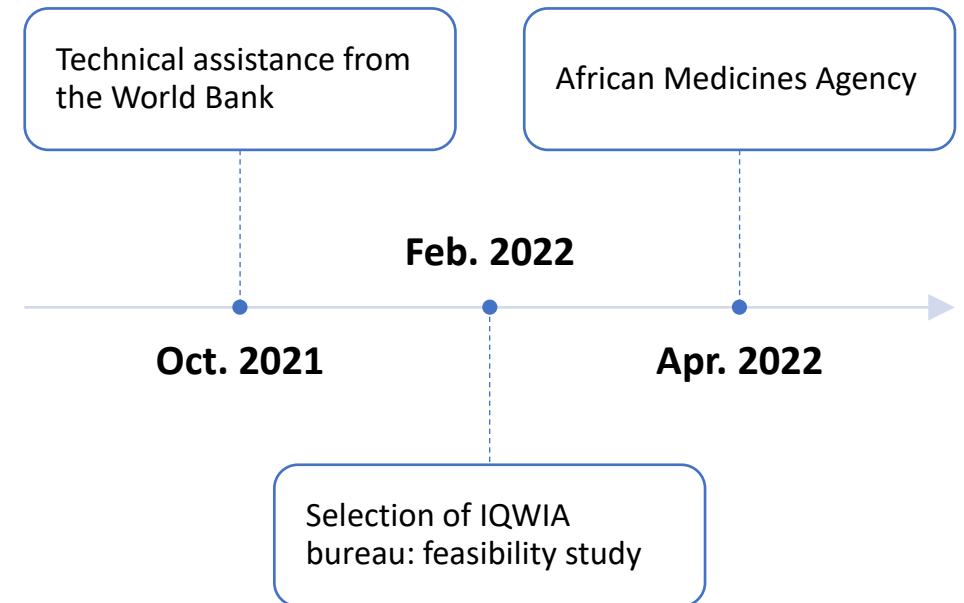
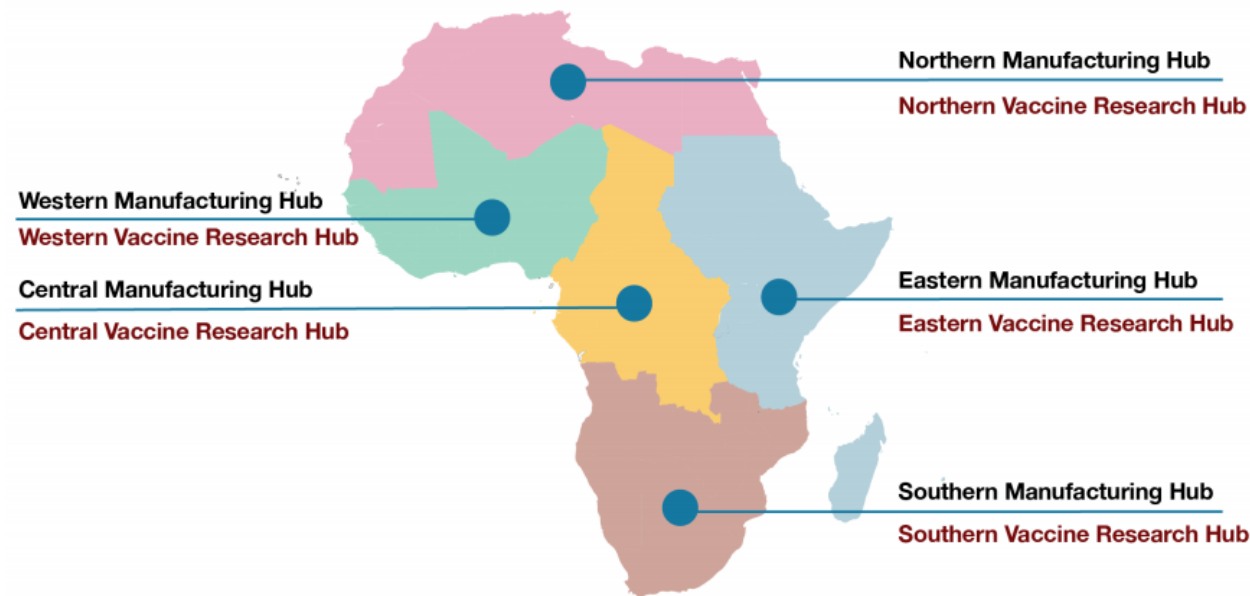
Manufacture of vaccines and serums

- ✓ Intradermal BCG
- ✓ Immun BCG
- ✓ SAV antiviperin serum
- ✓ SAS antiscorpionic
- ✓ SAR antirabic

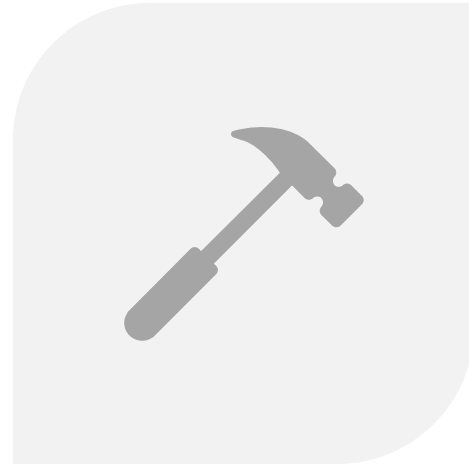
Opportunity : vaccin manufacturing

Tunisia has expressed its interest in joining the North African Hub for vaccine manufacturing and has received support from the World Bank."

AFRICA UNION'S GOALS | REGIONAL VACCINE RESEARCH AND MANUFACTURING HUBS



Challenges : Preparing the prerequisites."



REGULATORY AUTHORITY: LEVEL 3 MATURITY
ACCORDING TO THE WHO'S GLOBAL
BENCHMARKING TOOL (GBT).



ECONOMIC DIPLOMACY.

A silhouette of a person running on a rocky ledge against a sunset background. The person is in a dynamic, forward-leaning pose, suggesting movement and challenge. The background features a bright sun low on the horizon, creating a warm, golden glow that transitions into a clear blue sky above. The overall scene conveys a sense of determination and readiness for a task.

Ready for the challenge

➔ Tunisian quality pharmaceutical industry (mRNA vaccines and drugs)























