IX PAN-RUSSIAN GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP : Tunisian Experience

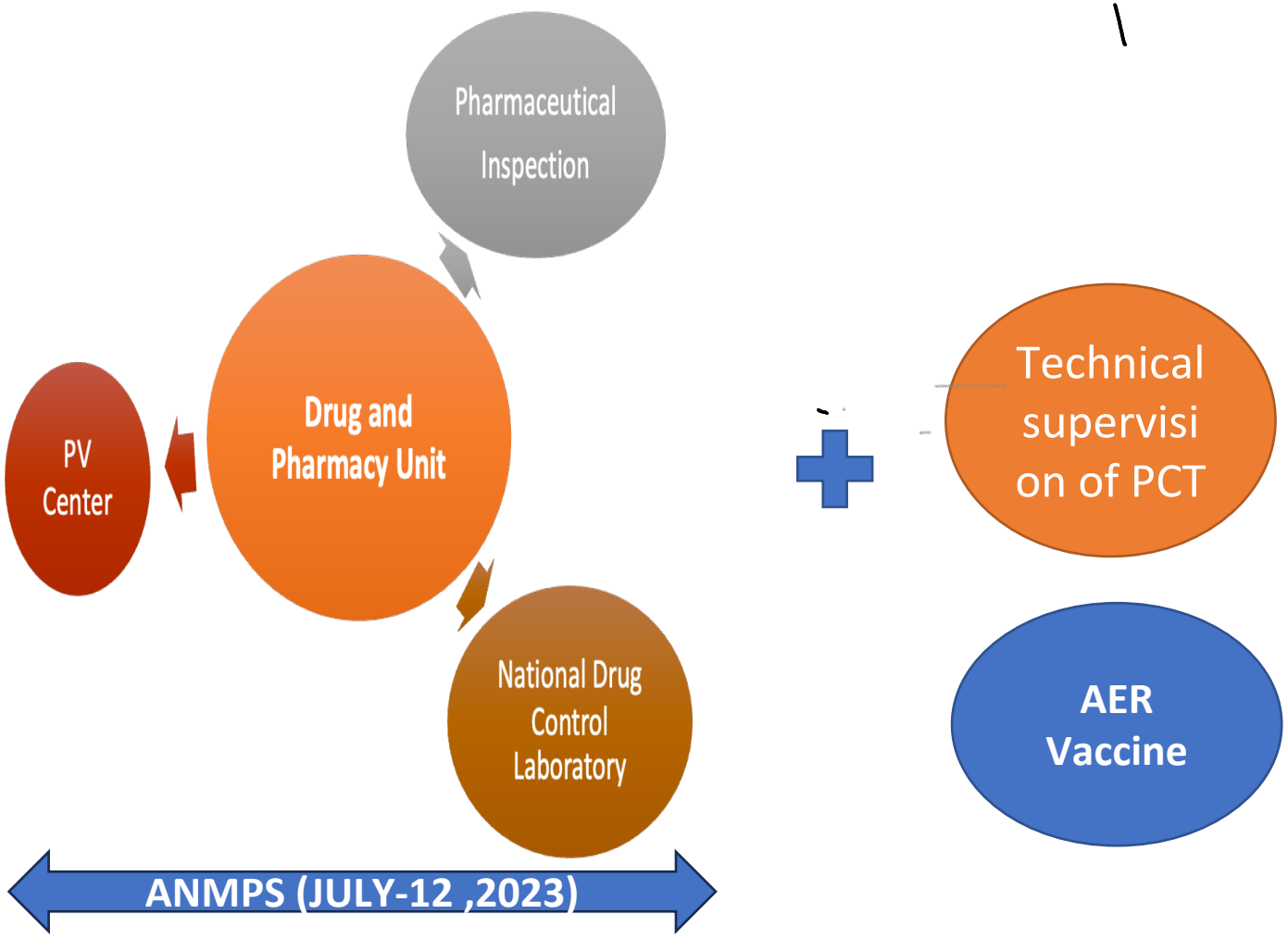
Pr Ai Mrabet Ministry of health Tunisia

Objectives of the National pharmacèutical policy

National Regulatory Authority National agency of Drugs and Health products)

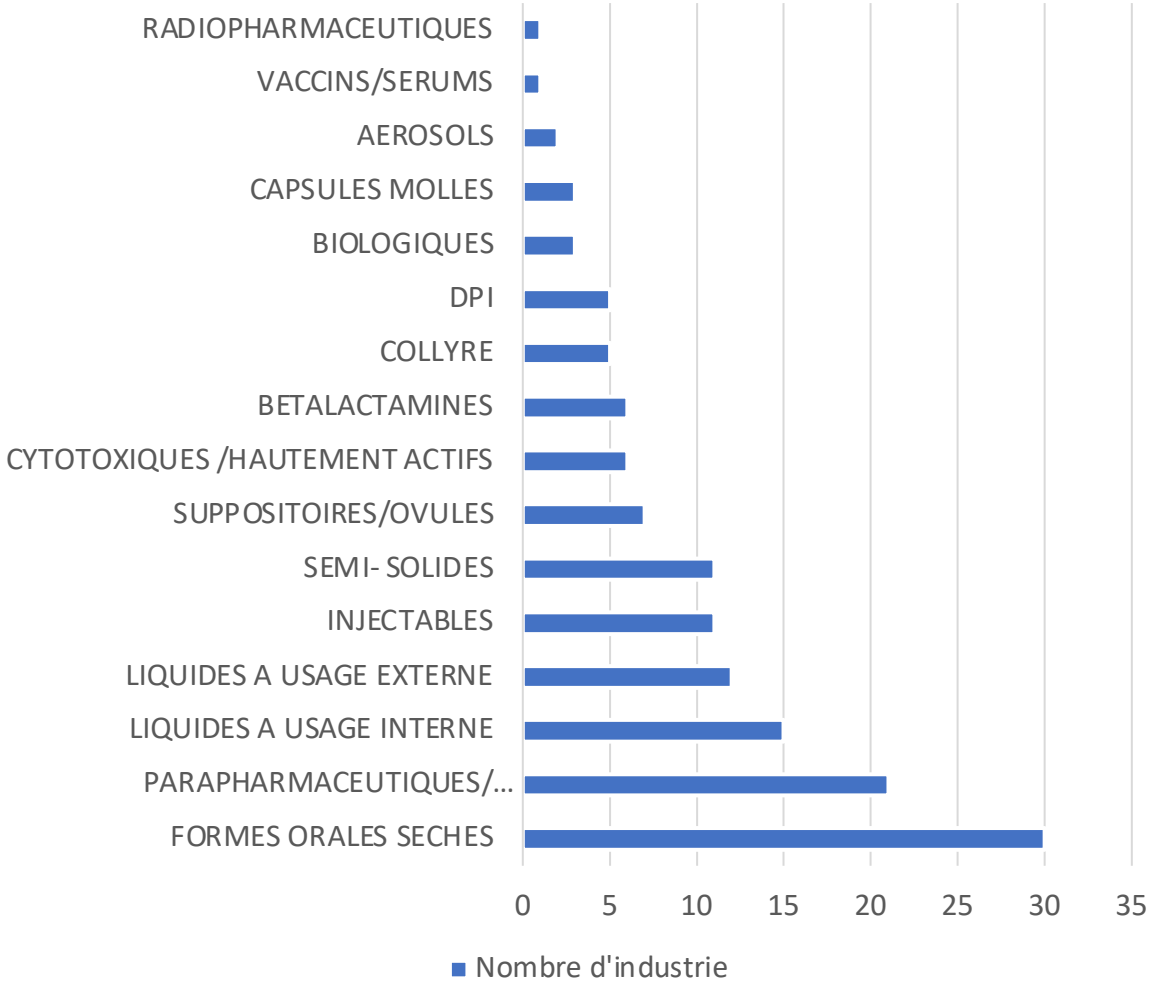
The main objectives of the national pharmaceutical policy are :

- **Guaranteeing equitable patient access to quality, safe and effective essential medicines and medical devices**
- **To ensure the conformity of the pharmaceutical act to the whole chain by following international standards**
- **To ensure the national security of medicines through an efficient local pharmaceutical industry and innovative services**



Number of plant per pharmaceutical dosage form

Pharmaceutical industries



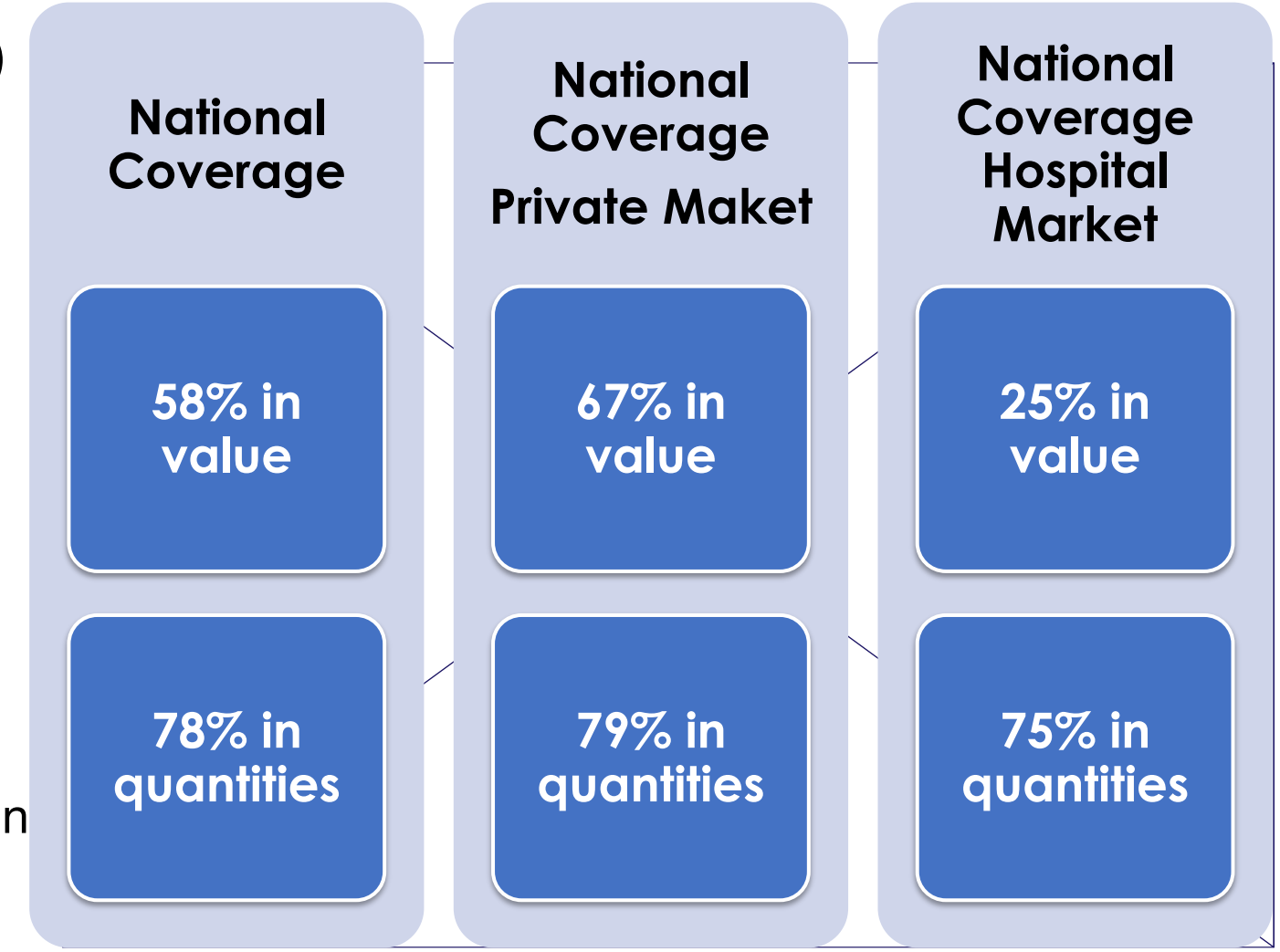
Pharmaceutical industries:62	
Human drugs	**43** • 15 generic companies (100%) • 6 under license 100% • 22 is mixed : generics + under license
Veterinary drugs	**7**
Medical devices	**12**

Exportation and compagnies invested

Pharma Market: Coverage 2023

•**Export of Drugs: 295 million dinars in 2023 (compared to 282 in 2022, i.e. +5%)**

- **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…
- **Exportation through platforms from Europe**
- Tunisian Companies invested in plants in Africa :**Algéria** (Medis , pharmaghreb), **Cameroon** (Teriak) **Ivory Cost**(Teriak, Saiph (in process) ,le **Senegal** (Medis)

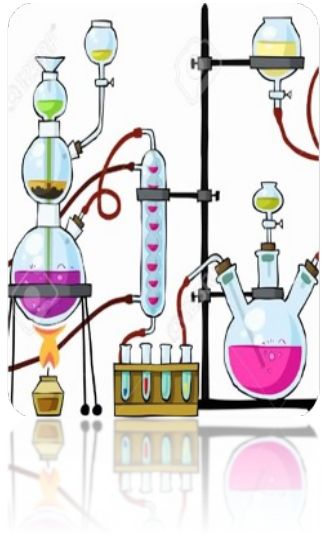


Data sources: CNIP, IQVIA and DPM

Marketing authorization procedure for Generics

DPM (MoH)
Application submission

Administrative Informations
(Module1)



LNCM
(Module 3 : Quality Aspects)

MAA

Experts
(Module 4 and 5 Safety and Efficacy data)

Assessment and Testing

Specialized Scientific Commission

Technical Committee for Proprietary Medicinal Products

Minister of Health

AMM

Procedure for granting the operating license

1-Application file (DPM)	• An operating License • An extension of the operating license • In accordance with the order of the Minister of Public Health of December 15, 1990
2-Site inspection (DIP)	• Ensured by inspectors from the Pharmaceutical Inspection • Visit to premises + examination of documents • Check GMP compliance: • Decree 90-1400: rules for Good Manufacturing Practices • Guide to European Good Manufacturing Practices • Inspection report: submitted for the opinion of the accreditation commission
3-Licensing approval commission (DPM)	• Composition (12 Members)/operating rules defined by decree of November 11, 2009 / meeting every 2 to 3 months • Operating license order: Minister of Health • Orders of Responsible Pharmacists (PRT, PRP, PRCQ): Minister of Health • Certificate of Good Manufacturing Practices: DPM

PRT :pharmacist technical manager **PRP:** pharmacist manufacturing **PRCQ :** pharmacist quality system

GBT3 : Global benchmarking tools

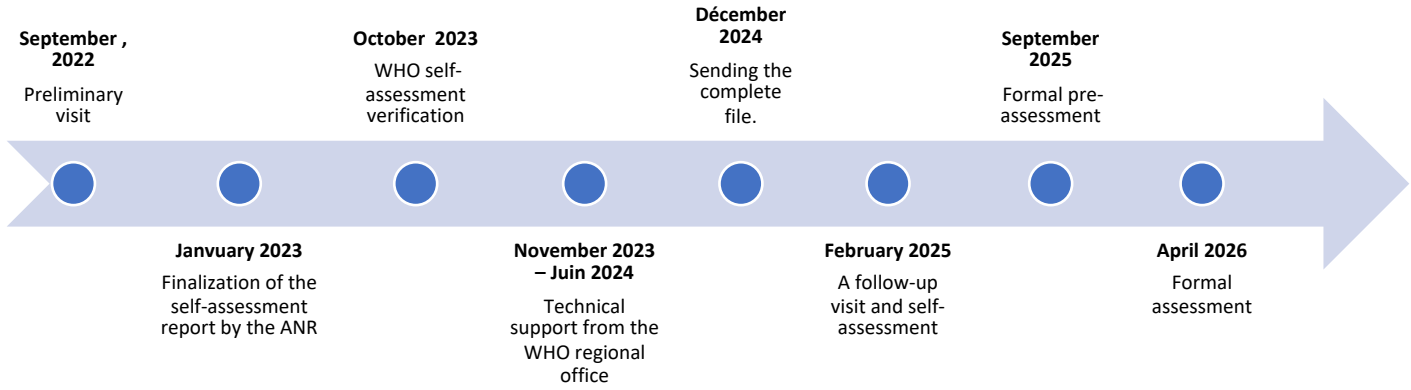
- Purpose of the resolution

Stable, Efficient and Integrated regulatory system

GBT3 Approach to stable and formal system , main functions:

1. General regulatory system,
2. Grant of license,
3. Registration and marketing authorization,
4. Market surveillance and control
5. Regulatory inspection,
6. Vigilance, surveillance and control of the market,
7. Laboratory tests,
8. Supervision of clinical trials,
9. batch release

ANMPS Roadmap for formal evaluation



Project of Cooperation Agreement between Tunisian regulateur Agency ANMPS and FEDERAL State Institution “State Institute of Drugs and good Practices ” of the ministry of Industry and trade of the Russian Federation

- **Areas of Cooperation :** The cooperation between the Parties shall be carried out in the following areas, but is not limited to:
- a) participation in international roundtables, conferences, symposia, congresses and other similar events organized by the Republic of Tunisia and the Russian Federation for the participants of the pharmaceutical industry and regulatory authorities;
- b) capacity building in mutually agreed areas, including training for **GMP inspectors** and other educational activities;
- c) collaboration between ANMPS(DIP) and the FSI “SID&GP” on mutual recognition **of the results of GMP inspections;**
- c) any other areas of cooperation carried out during the pharmaceutical inspections of the manufacturing sites.

Thank you

ORGANIZERS

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

GXP SID& GP

S GROUP

GENERAL PARTNER

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Gedeon Richter
Health is our mission

GENERAL INFORMATION PARTNER

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