

# Approaches to recognition of GMP certificates between the countries of Middle East

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**Jordan Food and Drug Administration (JFDA) was established in 2003 by Provisional law #31, it is responsible for protecting the public health by ensuring the safety, efficacy, and security of Pharmaceutical products, Food and medical devices**

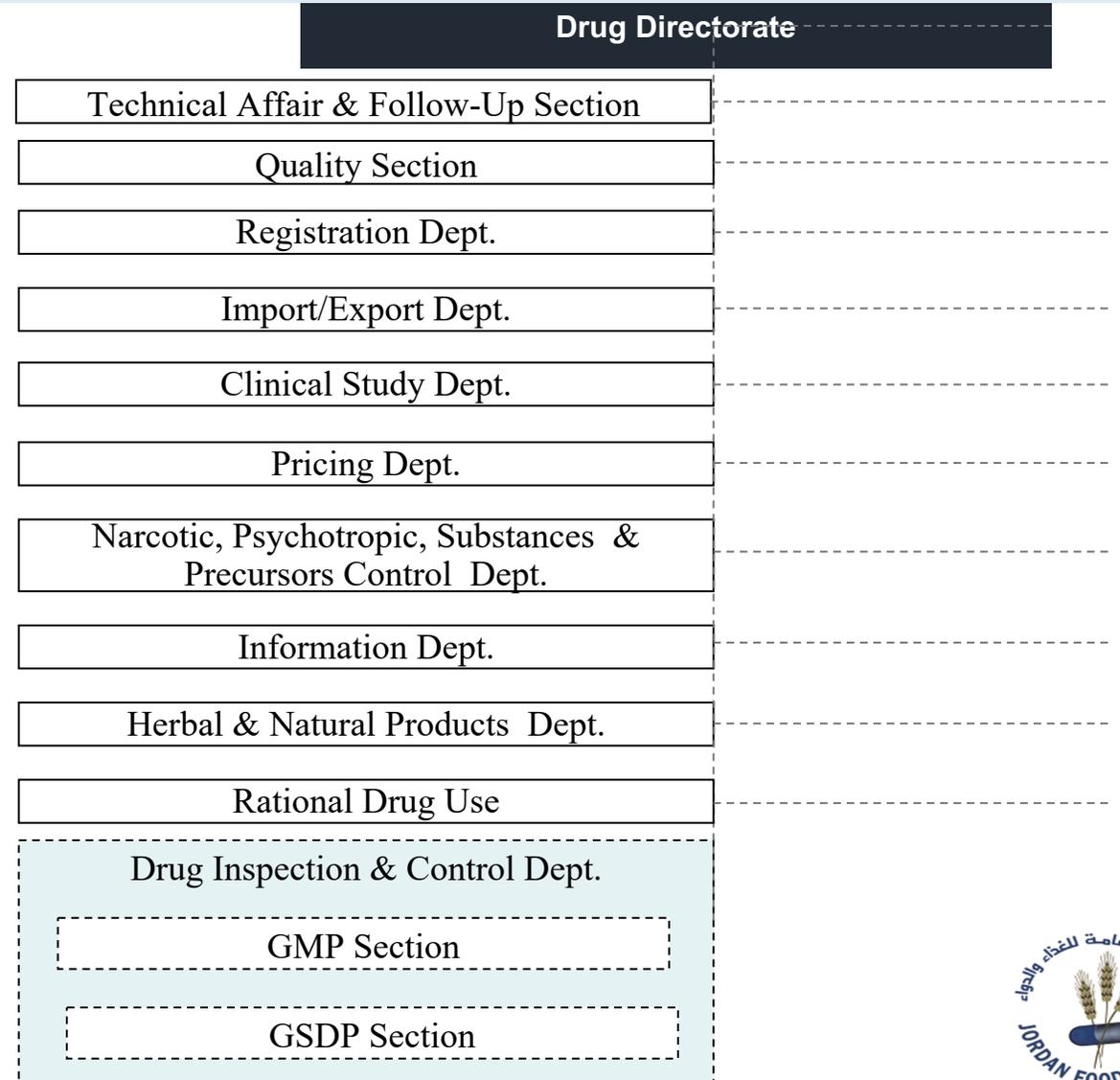
# Drug Directorate



- The only official body responsible for regulating all aspects related to medicines throughout their full lifecycle.
- Aim to maintain safety, quality, efficacy and availability of medicines at affordable prices.

## Scope of Activities

- Medicinal Product registration
- Lot release
- Post-marketing surveillance
- Monitoring and inspections of Manufacturing Sites
- Clinical trials monitoring
- Price regulation
- Regulating Exportation/Importation of Pharmaceuticals
- Raising public awareness



# Drug Directorate Core values

## Patient focused & Trust

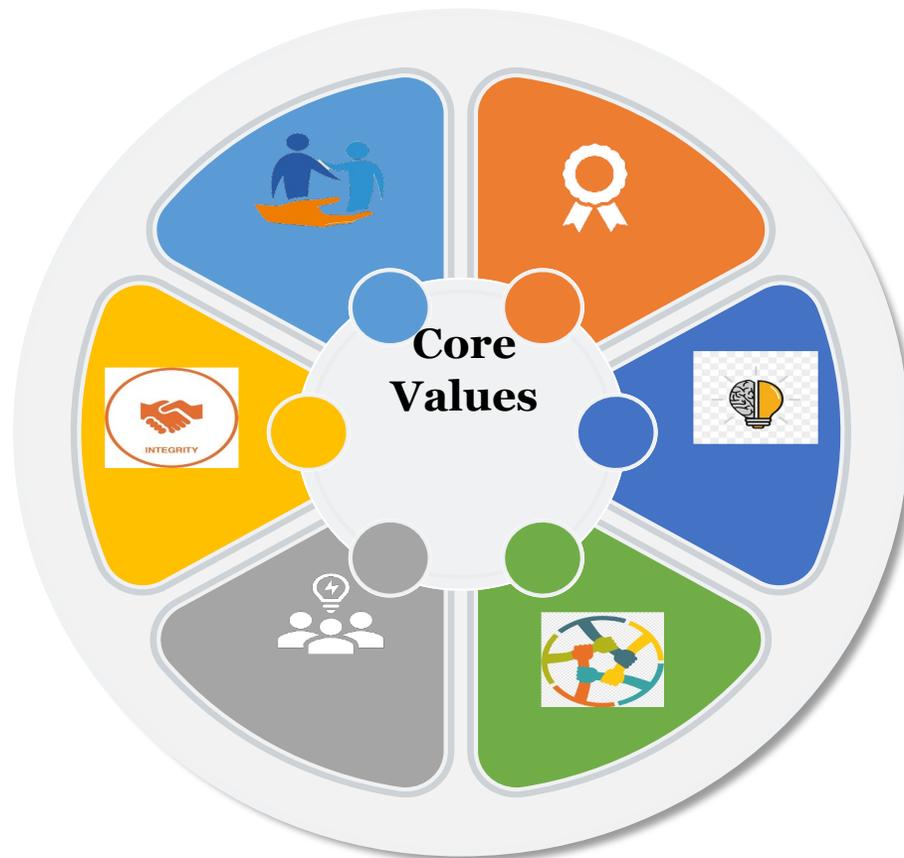
Build institutional legitimacy , strengthen social acceptance & improve performance

## Integrity

We are independent, accountable & transparent

## Collaboration

With all stakeholders



## Excellence

Committing to high standards

## Perspicacity & Innovation

As essential trait to success , we learn, we adapt , we improve

## Team work & Responsibility

It's the pillar & we anchor each other to excel & serve

# Drug Directorate Core values

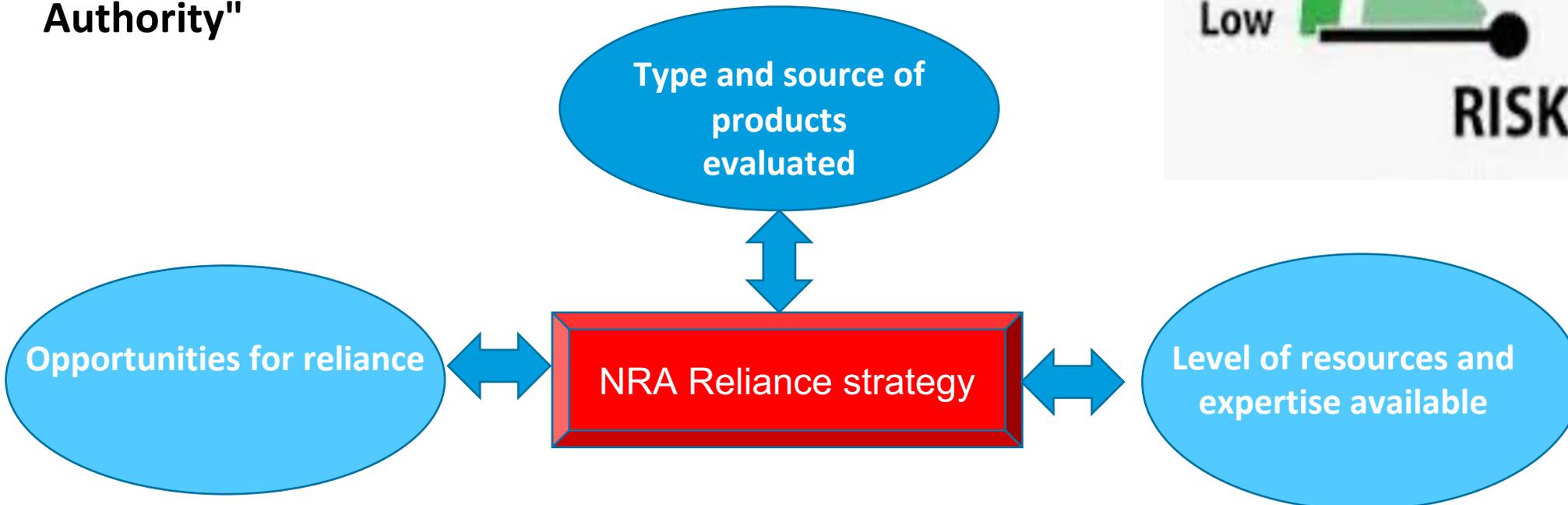


- Licensing & accreditation of local Pharmaceutical Manufacturing sites and accreditation of overseas manufacturing sites
- Enforce the proper implementation of laws and regulations related to the manufacturing and distribution of medicines in Jordan
- Inspecting pharmacies, drug stores and manufacturing facilities (local & overseas) to ensure the safety, effectiveness and quality of medicines
- Recommend legal action against entity found to be in violation

# Our reliance approach at JFDA (Risk-Based Approach)



“Regulatory systems with fewer resources can be as effective as those with more resources if they use a risk-based approach, take advantage of the work and decisions of other regulatory authorities and focus their resources on essential, value-added activities that can be provided only by the regulatory Authority”

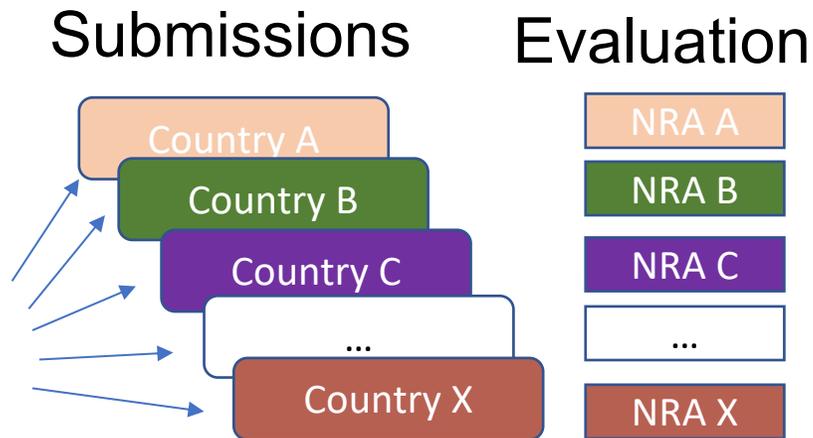


# Reliance for a more efficient use of global resources

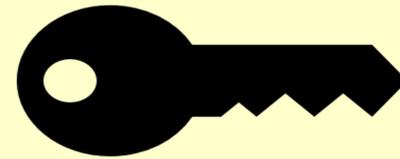


INCREASING WORKLOAD

LIMITED GLOBAL REGULATORY RESOURCES



## SOLUTIONS



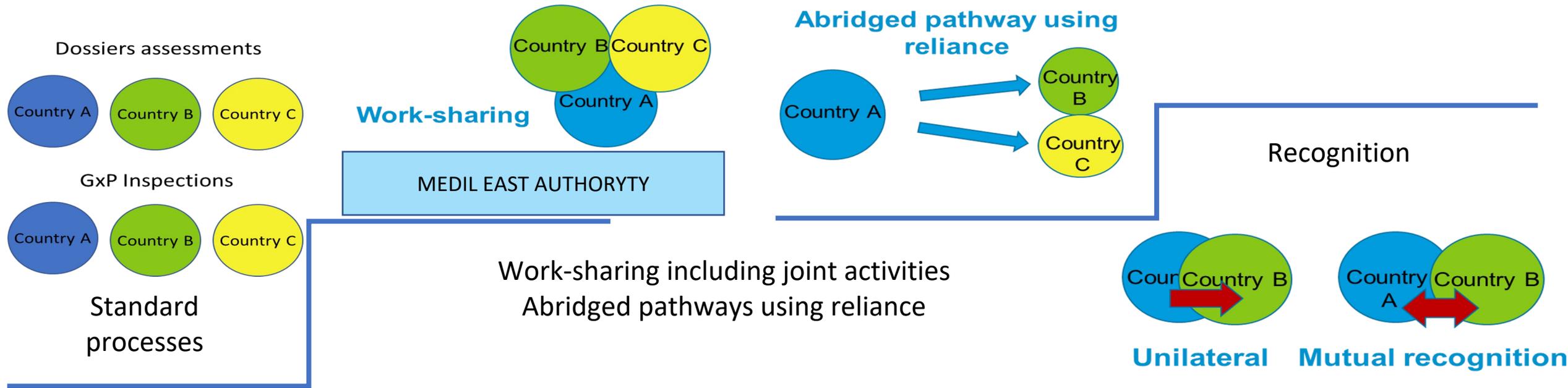
Work-sharing,  
Joint assessment,  
Abridged pathways,  
Strengthened collaboration,  
etc.

Implementation of reliance

Are we using the global regulatory resources as best as we can?



# Why Reliance



**Independent decisions**  
based on its own reviews and/or inspections

**Leveraging regulatory work**  
Performed by other competent and trusted authorities to reduce the workload

**Unilateral or mutual recognition**  
based on treaties or equivalent

Building trust between NRAs, increasing reliance and efficiency



# JFDA PIC/S accession



- PIC/S aims to lead the international development, implementation and maintenance of **harmonized GMP standards and quality systems of regulatory authorities** .
- **Main benefits to JFDA :**
  - Training opportunities.**
  - International GMP harmonization.**
  - Networking.**
  - High standards:** Preparing for the accession to the Scheme (or reassessment) forces improvements in the GMP inspection system and procedures. This results in increased efficiency.
  - Sharing of information:** effective use of inspection resources through the voluntary sharing of GMP inspections reports.
  - Rapid Alert System:** The PIC/S Alert and Recall System is part of a wider system, which includes the Alert and Recall System of EU/EEA/MRA partners.
  - Facilitating the conclusion of other Agreements:** e.g. Mutual Recognition Agreements, between Members at various levels Reduced duplication of inspections
  - Cost savings;
  - Export facilitation;
  - Enhanced market access.

# JFDA benchmarking by the WHO Global Benchmarking Tool (GBT)



- The quality safety & efficacy of pharmaceutical products is entrusted to JFDA in Jordan.
- Effective, efficient and transparent regulatory systems are consequently an essential component of overall health systems and contribute to desired public health outcomes and to innovation and investment
- The WHO GBT is the first globally agreed-upon framework for evaluating the capacity of a national regulatory system.
- JFDA finished the self-benchmarking ,
- What are the benefits?

Its an exercise to us that will help identify our strength points, upgrade our system & fill the gaps

It helps Devising an institutional development plan that lays out the pathway to strengthen the system

Reaching maturity level 3 will help boosting pharmaceutical sector, through allowing local pharmaceutical manufacturers to apply for WHO-prequalification , continuing promoting access and supply of safe, effective and quality medical products.



# 1st JFDA International Congress Recommendations in Oct/2016



Creating harmony, and simplifying procedures in the Arab region, and North Africa.

Establishing a union which joins all regulatory bodies in the Middle East and North Africa.

In march/2023 the Council of Arab Health Ministries announced the approval of establishing the Arab Medicines Agency (WAAD):

- Helping to achieve pharmaceutical sustainability for all Arab countries.
- Opening new markets for medicinal products & medical Devices manufactured within Arab countries.
- Support Arab economies, achieving economic growth.
- Helping to develop common standards in the field Medicinal products registration & inspection of pharmaceutical factories.
- Aiming to facilitate cooperation and networking between competent authorities, and regional and international organizations, thus increasing mutual confidence.





VIII ALL-RUSSIA  
GMP CONFERENCE

ORGANIZERS



GENERAL PARTNER



STRATEGIC PARTNER



GENERAL  
INFO PARTNER



GENERAL INFO AND  
ANALYTICAL PARTNER



STRATEGIC  
INFO PARTNER

