2008 - 2018: looking back and looking forward for building universal access to quality-assured medicines

Be cause HEALTH Seminar

Alain PRAT, Quality Assurance Team, Sourcing & Supply Chain Department
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The Global Fund

Quality Assurance Team

Mission

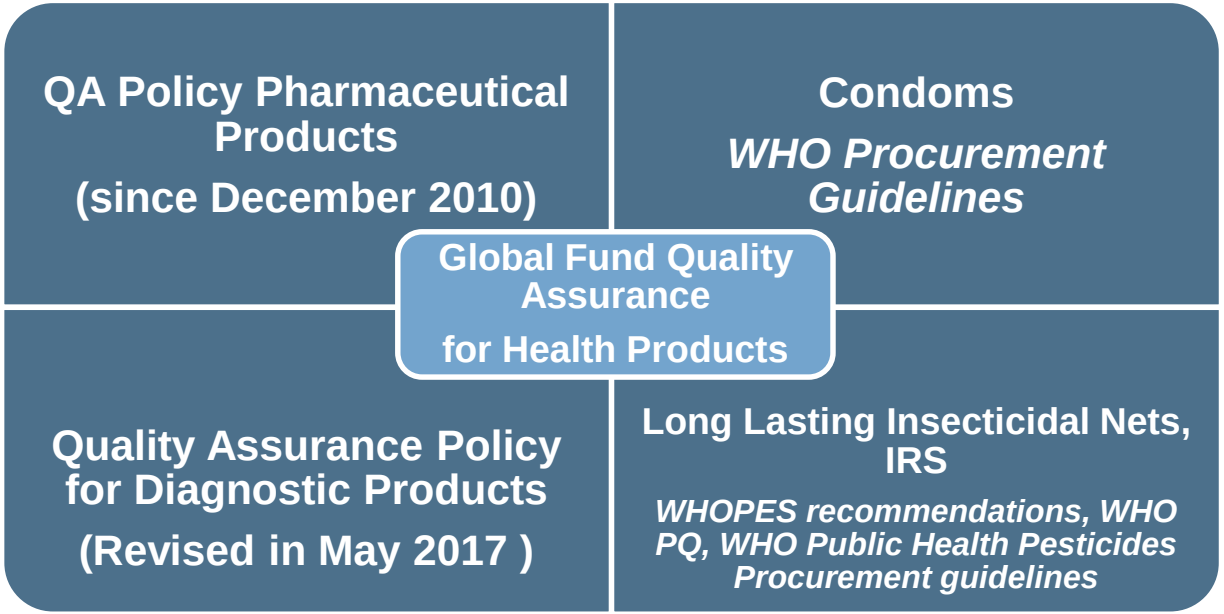
Enable procurement of the health products complying to internationally-recognized norms and standards, assure continuity of supply, and facilitate access to innovative products through policies, communications with countries, data sharing and compliance verification exercise

Value driver	Description of value
Safety	• Ensure products procured with GF funds are safe, efficacious and of assured quality
Access	• Support introduction to innovative products through Expert Review Panel (ERP) process
Availability	• Work to ensure continuity of supply
Compliance	• Guarantee that products procured with GF funds adhere to GF internal policies and guidelines

In full alignment with TGF 2022-2017 Strategy :
Maximize impact against HIV, TB and Malaria

Quality Assurance requirements

Developed under a framework of Policies and Guide making reference to WHO internationally recognized guidance and few educational guidelines for Recipients – Policy and guide are mandatory as part of GF regulation



QA Policy for Pharmaceutical Products

Three pillars of quality assurance policy

1. Clinical Criteria

- ✓ Medicines listed in WHO EML or national or institutional Standard Treatment Guidelines
- ✓ Require applicants/ recipients to provide justification for selection of unlisted products in one of the STGs

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2. Quality Criteria

- ✓ For all products:

➡ Authorization for use in the recipient countries

- ✓ For ARVs, anti-TB and anti-malarial products

➡ Specific requirements

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3. Monitoring Quality

- ✓ Monitoring quality of products all along the supply chain

4. Implementing Pharmacovigilance

- ✓ Monitoring ADRs of pharmaceutical products

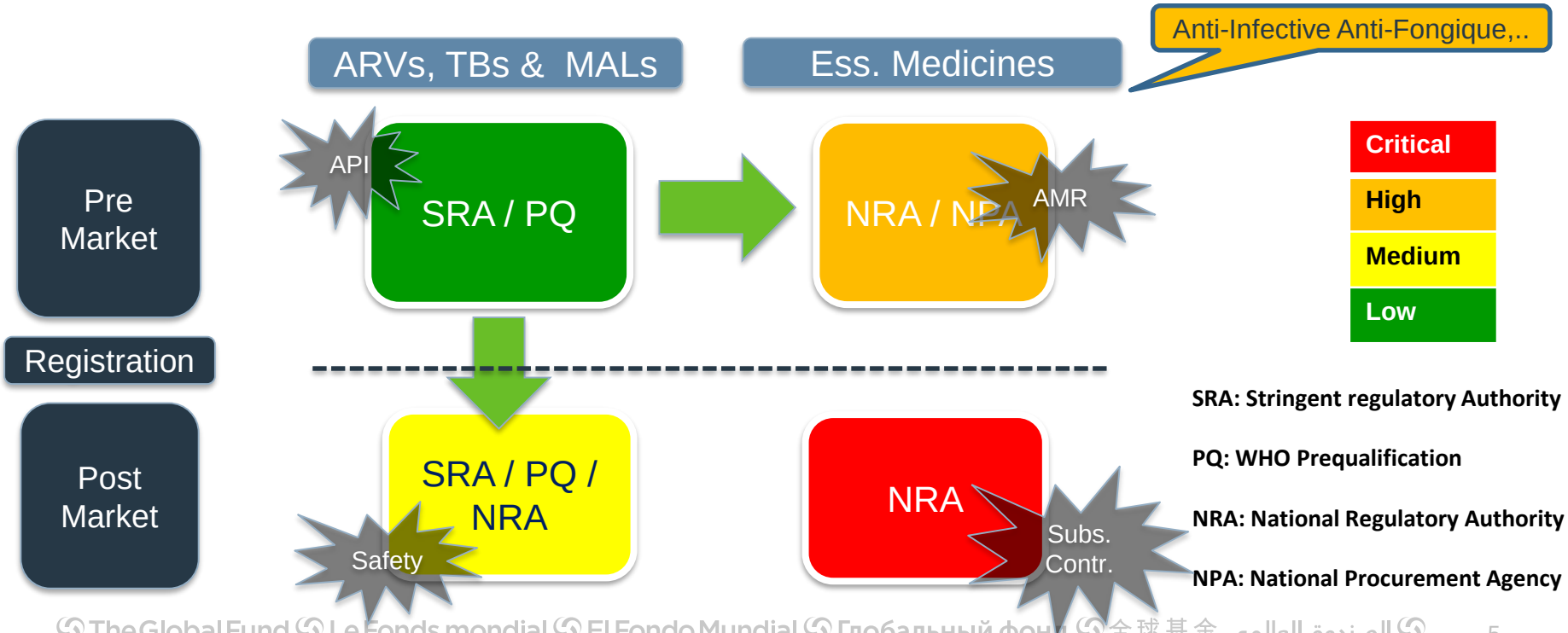
Marketing Authorization of core FPPs: ARVs, TBs & Malaria Products

Reliance on stringent mechanism in addition to national mechanism

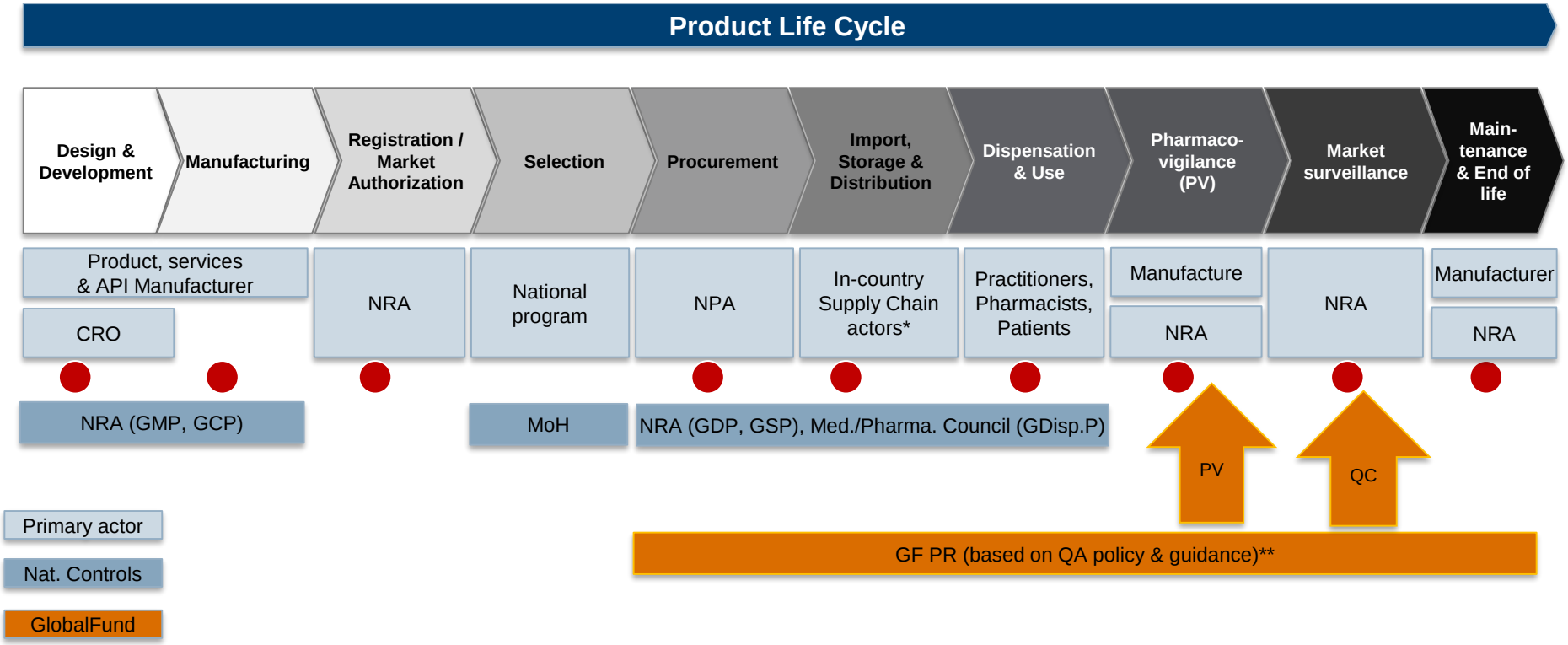
MA MECHANISM	DESCRIPTION	AUDIT PRACTICES
Stringent Drug Regulatory Authorities (SRA)	• Robust legal/regulatory environment • ICH Requirements • Experienced & Skilled Staff in Q/S/E	• Regular GMP inspection as per related regulation • Mutual Recognition Agreement • **Prioritization based on risks**
OR		
WHO PQ program	• Programme managed by WHO which prequalifies medicines considered by GF to be acceptable for procurement • WHO requirements • Experienced & Skilled Staff in Q/S/E	• Regular GMP inspection as per WHO PQ Procedure • Consideration of SRA decision • **Prioritization based on risks**
OR		
Expert Review Panel (ERP)	• Alternative mechanism used upon GF request • Panel of external technical experts reviewing the potential risks/ benefits to use an FPP that is not yet WHO-prequalified or SRA-authorized • Typically used for innovative products • Supported by WHO	• Proof of GMP Compliance but no Routine Inspection • Consideration of SRA & WHO PQ & PICS related countries Inspections

Risk for the quality of pharmaceutical products

Continuously review current risk assessment related to quality of health products and adequacy of risk mitigations



Primary role of the National Regulatory Authority

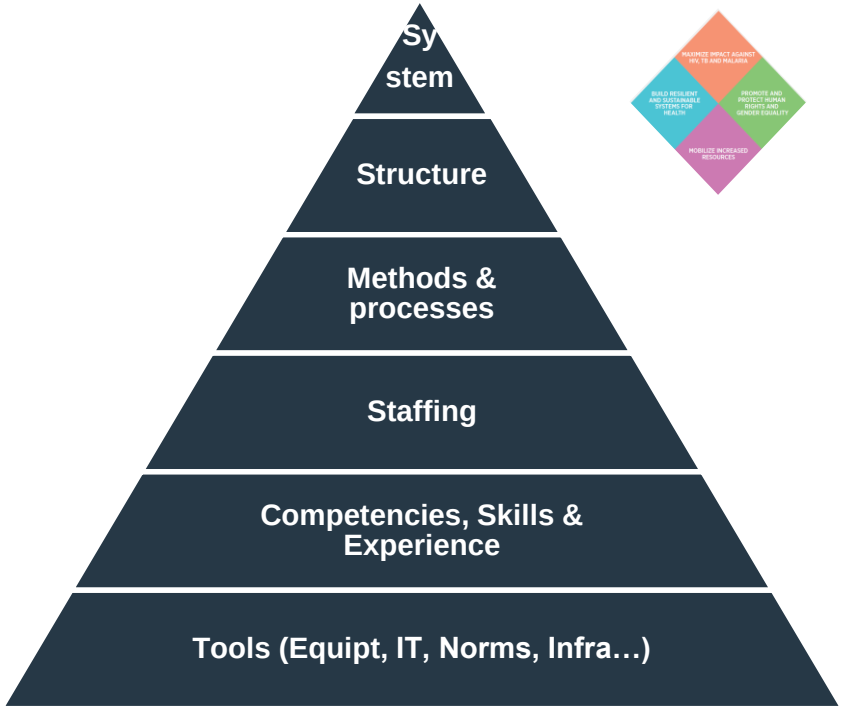


Building Resilient Regulatory System

Challenges

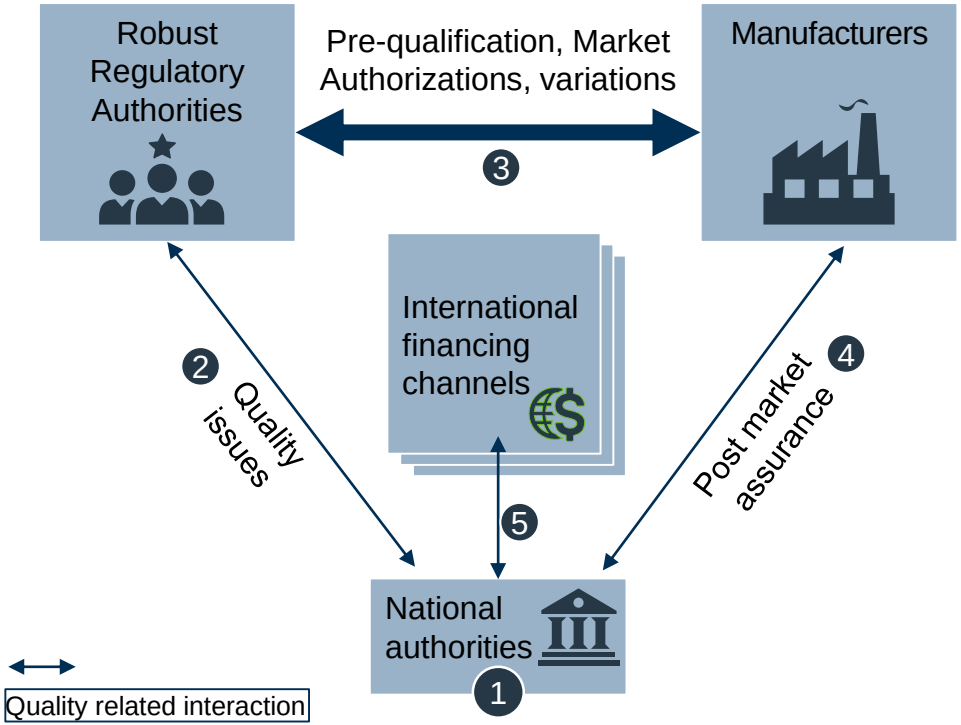
- Multiple structure/institutions in place, overlapping responsibilities
- Not adequate structure in place, no distribution of authority, unclear line of authority & reporting
- No processes in place, lack of documentation
- Not adequate number of staff to perform technical and administrative tasks
- Lack of competencies to execute regulatory & scientific tasks
- Lack of adequate tools, IT System, Reference documentation

Supporting Regulators to satisfy their hierarchy of need



Communication Challenges in the QA Echosystem

Quality assurance ecosystem



Challenges

1. **Limited capacity of countries to generate adequate information in a timely manner**
2. **Insuficient quality information from the field reach the SRA to effectively act up**
3. **Manufacturers informing predominantly RRA and only partially countries on quality & safety issues**
4. **Very limited quality information from the field reach the manufacturer**
5. **Limited sharing of information between countries and partners**

Source: GF

Thanks for your attention