Who are we?

- Essential Medicines and Health Product [EMP]
- Regulation of Medicines and other Health Technologies [RHT]
  - Innovation, Access and Use [IAU]
  - Technologies Standards and Norms [TSN]
  - Regulatory Systems Strengthening [RSS]
  - Prequalification Team [PQT]
  - Safety and Vigilance [SAV]
What is the goal?

For manufacturers

A common regulatory dossier for manufacturers?

- At submission: common standards
- Over time: common standards and common procedures

For agencies

Quality products, supported by quality dossiers

Faster assessments

For WHO

Increased reliance among regulators, avoiding duplication of effort
Harmonisation of standards

WHO Activities

- ICH
- IGDRP-IPRF
- WHO Expert committees
- Regulatory strengthening activities

Observations

- Different bioequivalence and biowaiver requirements
- Different acceptable reference products in different countries.
Reliance among Regulators
Reliance among Regulators

Information sharing and reliance

Reliance verses recognition within WHO-RHT

Recognition

The PQT - SRA procedure
Listing of PEPFAR, EU Art 58 products
Use of EDQM CEP to support Drug Product applications.
EU oversight of manufacturing sites

Reliance

Use of other regulators assessment reports to conduct abridged assessments
Use of other regulators GMP Inspection reports to undertaken Desk reviews to establish compliance
WHO PQT Collaborative Registration procedure
WHO SRA Collaborative procedure pilot
WHO PQ Collaborative Registration Procedure

WHO CRP

- It is for manufacturers of Prequalified Drug Products, to accelerate registration in-country
- It is voluntary
- Shared confidential information to support NRA decision making in exchange for accelerated registration process
- NRA decision within 90 days (Y/N)
- Product and registration dossier in countries are 'the same' as prequalified by WHO.
- 'Harmonized product status' is monitored and maintained
WHO PQ Collaborative Registration Procedure

WHO
PQT

Submission
NRA
Marketing authorisation
Participating NRAs

Armenia  Georgia  Philippines
Botswana  Ghana  Senegal
Burkina Faso  Kenya  Sierra Leone
Burundi  Kyrgyzstan  South Africa
Cameroon  Lao PDR  Tanzania
*Caribbean Community (CARICOM)  Madagascar  Uganda
Cote d'Ivoire  Malawi  Ukraine
Eritrea  Mozambique  Zanzibar
Ethiopia  Namibia  Zimbabwe

As at 12 May 2017
WHO PQ Collaborative Registration Procedure

Median time to registration

*Including regulatory time and applicant time

As at 12 May 2017

Days*
Reliance among Regulators

Lessons learned

Reliance and recognition does not mean:

• A loss of sovereignty
• A loss of jobs
• A loss of income
Reliance among Regulators

Lessons learned

- Maintaining the sovereignty of countries to assess and approve medicines
- Must have trust in the reference regulator - Getting to know each other
- Overcoming issues of confidentiality of information
- Make sure all stakeholders are on-board and have the same information – familiarity with procedure and the role each party plays.
- Availability of reports/information to support the NRAs decision making process
- Ensure there are suitable processes in place within the NRA that support the reliance process
- Dedicated resources and priority within the agency for reliance process.
Section introduction

Building relationships between regulators
Building relationships between regulators

Trust in:

- Procedures and oversight
- Technical outcomes
- People

WHO Good regulatory practices guideline: Guidelines for national regulatory authorities for medical products

Finding a suitable Regulator

- ICH?, PIC/s?
- WHO Global Benchmarking Tool
Building relationships between regulators

WHO Regulatory Benchmarking Tool

WHO has been benchmarking and working with member states to strengthen regulatory systems since 1997

Goals:

• Strengthen regulatory systems to a level that represents a well-functioning, stable system, and

• Promote regulatory cooperation, convergence, networking, work-sharing and reliance

A regulator need not be a reference for every type of product, or every type of activity.

The benchmarking tool is aiming to provide regulators with information to enable collaboration.
WHO Global Benchmarking Tool

NRA assessment visits

- Green: NRA assessment conducted
- Blue: NRA assessment not conducted

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries.

Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization, Immunization Vaccines and Biologicals (IVB) Updated as of 5 June 2013
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization in collaboration with P&B CONSULTING
WHO Global Benchmarking Tool

Maturity Levels

1. **No formal approach**
   - Some elements of regulatory system exist

2. **Reactive approach**
   - Evolving national regulatory system that partially performs essential regulatory functions

3. **Stable formal system approach**
   - Stable, well-functioning and integrated regulatory system

4. **Continual improvement emphasized**
   - Regulatory system operating at advanced level of performance and continuous improvement
Building relationships between regulators

Trust cannot simply be mandated from on-high. It will require regulators to work together to establish a relationship.

Establishing trust between regulators is a prerequisite to reliance and recognition.

RHT’s success with the CRP relies in large part to work with:

- EAC Regulators - East African Community
- SADC Regulators - Southern African Development Community

Via:

- Trainings and interventions
- Attendance at PQT assessment sessions
- Use of PQT rotational positions
Harmonization, Reliance and recognition is well underway

To move forward regulators must recognise this as a legitimate alternative to inward focused regulation

There must be political willingness to undertake these activities.

Reliance and Recognition must move from being “side projects”

Procedures require integration, resources, it needs to be practised.

There are probably still several key technical barriers preventing maximum benefit

WHO are playing a catalytic role in global reliance
Many Thanks!

Regulation of Medicines and other Health Technologies [RHT]

WHO

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