WHO PQ Collaborative Registration Procedure and
SRA Collaborative Procedure

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Changing regulatory paradigm – questions to answer

- Can all national regulators assess and inspect all the *products* that come to their markets?
- Does *repetitive* assessment and inspections give *added value*?
- How to build confidence in scientific assessments/inspections carried out by other parties?
- How regulators can best contribute to the public health with the (limited) resources they have?
How regulators can best contribute to the public health with the (limited) resources they have?

- Avoid doing things that do not give added value, concentrate on things that **do give added value**;
- Concentrate on **high risk areas/products**;
- Be pragmatic:
  "Nice to know" – **forget it**, "Need to know" – **get it**!
  And learn making difference between the two;
- Cooperate with partners in order to **increase regulatory capacity by elimination of duplicated activities** - facilitated by comparable standards and administrative requirements.
Collaborative Mechanisms

- Collaboration is defined as a process that enables independent individuals and organizations to combine their human and material resources so they can accomplish objectives that are difficult to bring about alone.¹

- Various terms have been used in literature to describe this process of coming together, such as partnership, alliances, collaboration and teamwork²,³

Both reflect "taking account of" the output of other regulatory authorities;
- Increasing prevalence/necessity, even with most mature/resourced NRAs;
- Prerequisite: regulatory system and functions that can then be the object of reliance or recognition;
- May be both unilateral or mutual

NB: sovereignty of decisions maintained in both cases
Variety of approaches - new regulatory pathways

- WHO PQ Collaborative registration procedure;
- Facilitated registration procedure of SRA approved medicines (SRA pilot);
- EU Article 58 procedure;
- US PEPFAR;
- Canada's Access to Medicines Regime;
- Swissmedic MAGHP procedure;
- ZaZiBoNa process;
- EAC joint assessment process;
- ASEAN Joint Assessment Process;
- etc...
WHO PQ Collaborative Registration Procedure
(Collaborative Procedure Between WHO and National Regulatory Authorities in the Assessment and Accelerated National Registration of WHO-prequalified Pharmaceutical Products and Vaccines)

The procedure has been developed to:

- enhance *timely access to prequalified products in countries*;
- to ensure that the product in countries is the same as the one which is prequalified and to provide a model for regulatory information exchange among countries;
- first piloted in June 2012 and is currently in use;
- also benefits manufacturers of prequalified pharmaceutical products and vaccines through faster and better harmonized regulatory approvals in participating countries.
KEY Principles of the Collaborative Procedure

- Voluntary;
- Product and registration dossier in countries are the same as prequalified by WHO;
- Mutually beneficial: shared confidential information to support NRA decision making in exchange for accelerated registration process;
- "Harmonized product status" is monitored and maintained.
Steps of the procedure:

Agreement

- NRA confirms to WHO PQT its interest to participate in collaborative procedure and respect its conditions;
- One or two focal persons are designated at each interested NRA, sign confidentiality undertaking and are given access to the WHO managed restricted access platform (MedNet).

Registration

- Manufacturer submits MA application to participating NRA for the PQ-ed medicine and informs the authority about the interest to follow the collaborative procedure. Same data submitted as for PQ;
- Manufacturer informs WHO PQT about the application for national registration and, for each product, provides written agreement to exchange of information between the participating NRA and WHO PQT;
Steps of the procedure: Registration

- Participating authority confirms to WHO PQT its interest to apply the procedure for given medicinal product;
- Within **30 days**, WHO PQT provides focal person(s) in the participating NRA with assessment and inspection reports via restricted-access website (MedNet) and provides additional explanation, if requested;
- **Within 90 days** participating NRA decides upon the national registration, informs WHO PQT about the outcome of national registration and, when divergent from PQT decision, provides explanations;
- **Within 30 calendar days** of having taken its decision, the participating authority informs WHO/PQT and the applicant of this decision;
- WHO PQT **lists products registered by participating NRAs** according to this procedure on its public website.
### Participating NMRAs

<table>
<thead>
<tr>
<th>Armenia</th>
<th>Georgia</th>
<th>Philippines</th>
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<tbody>
<tr>
<td>Botswana</td>
<td>Ghana</td>
<td>Senegal</td>
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<td>Kyrgyzstan</td>
<td>South Africa</td>
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<td>Cameroon</td>
<td>Lao PDR</td>
<td>Tanzania</td>
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<tr>
<td><em>Caribbean Community</em> (CARICOM)</td>
<td>Madagascar</td>
<td>Uganda</td>
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<tr>
<td>Cote d'Ivoire</td>
<td>Malawi</td>
<td>Ukraine</td>
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<td>Eritrea</td>
<td>Namibia</td>
<td>Zanzibar</td>
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<td>Ethiopia</td>
<td>Nigeria</td>
<td>Zimbabwe</td>
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*CARICOM*

**Member States:** Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago

**Associate Member States:** Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

As at 19 Sept 2017
Total registrations: 257
(As at 19 Sept 2017)
## Pipeline of applications in countries

As at 19 Sept 2017

No products registered or under review yet: Georgia, Lao PDR, Sierra Leone, Zanzibar

<table>
<thead>
<tr>
<th>Country (when started)</th>
<th>No of submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philippines (Mar-16)</td>
<td>0-20</td>
</tr>
<tr>
<td>Tanzania (Oct-13)</td>
<td>0-20</td>
</tr>
<tr>
<td>Mali (Feb-16)</td>
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<tr>
<td>Mozambique (Jan-...)</td>
<td>0-20</td>
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<tr>
<td>Botswana (May-14)</td>
<td>0-20</td>
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<tr>
<td>Malawi (Sep-15)</td>
<td>0-20</td>
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<tr>
<td>Uganda (Nov-12)</td>
<td>0-20</td>
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<td>Namibia (May-13)</td>
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<td>DRC (Jan-16)</td>
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<td>Cameroon (Jan-15)</td>
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<tr>
<td>Kenya (Dec-12)</td>
<td>0-20</td>
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<tr>
<td>Madagascar (Jan-15)</td>
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</tbody>
</table>

- **Registered**
- **Under review**
- **Dossier awaited**
Pipeline of applications, by company

- Macleods Pharmaceuticals Ltd...
- Strides Shasun Limited (Mar-15)
- Cipla Ltd (Jan-14)
- Hetero Labs Limited (May-13)
- Jai Pharma (formerly: Famy...)
- Mylan Laboratories Ltd (Nov-12)
- Lupin Ltd (Jun-16)
- Cipla Ltd, Cipla (May-17)
- China Resources Zizhu...
- Acme Formulation Pvt. Limited...
- Ajanta Pharma Ltd (May-15)
- Strides Pharma Global Pte Ltd...
- DNDi, Switzerland (Cipla Ltd is...)
- Hetero Labs Ltd (Mar-17)

As at 19 Sept 2017

Registered
Under review
Dossier awaited

Company (when started)

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<tr>
<td>0  20  40  60  80  100 120 140 160 180</td>
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Pipeline of applications, by company
Median time to registration

*Including regulatory time and applicant time

As at 19 Sept 2017
Where do you find the information?

WHO Website: Prequalification

- List of prequalified medicinal products (FPPs)

- List of prequalified APIs
  - Can be used by FPP manufacturers to assure the quality of APIs.
  - Can be used by NMRAs who wish to verify (to a certain extend) the potential standard of APIs that have been used to manufacture nationally registered medicines.

- List of prequalified QC laboratories
  - The list may be used by any organization to ensure that testing for quality monitoring is done to an acceptable standard

- Public Assessment Reports (WHOPAR) and Public Inspection Reports (WHOPIR)
Win-win outcomes for all stakeholders

NMRAs

• Having data well organized in CTD in line PQ requirements;
• Availability of WHO assessment and inspection outcomes to support national decisions and save (scarce) internal resources;
• Opportunity to learn from PQ assessors and inspectors;
• Demonstrating NMRA efficiency;
• Having assurance about registration of "the same" medicine as is prequalified;
• Quality control by same methods and specifications;
• Easier post-registration maintenance;
• Having a model process for mutual co-operation in registrations.

WHO

• Prequalified medicines are faster available to patients;
• Feed-back on WHO prequalification outcomes.
Win-win outcomes for all stakeholders

Manufacturers

• Harmonized data for PQ and national registration;
• Facilitated interaction with NMRAs in assessment and inspections;
• Accelerated and more predictable registration;
• Easier post-registration maintenance.

Procurers

• Faster start of procurement and wider availability of PQ medicines;
• Assurance about "the same' medicine as is prequalified.
SRA Collaborative Procedure

Collaborative Procedure in the Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities (WHO-EMA Collaborative Registration Pilot)

The concept

ZERO duplication of effort in whatever form
KEY Principles of SRA Collaborative Procedure

• Voluntary

• Applicable both to SRA approved innovative and generic medicines;

• Product and registration dossier in countries are "the same" as approved by SRA.

• Shared confidential information to support NRA decision making in exchange for accelerated registration process

• "Harmonized product status" is monitored and maintained
Principal roles of the participating parties (1)

- Participating NMRAs express their interest to participate in the Procedure, their commitment to respect principles of the Procedure and their confirmation of confidential treatment of commercially sensitive information;

- Participating SRAs do not object to share their assessment reports and inspection reports with applicants/authorization holders to support access to needed medicines in line with principles of the Procedure;

- Participating companies submit applications to NMRAs and provide assistance necessary to finalize the application in line with the Procedure.
Principal roles of the participating parties (2)

- **WHO-PQT** assists in execution and maintenance of the Procedure, posts lists of participating NMRAs and SRAs (including SRA conditions with information sharing) on its website and collects information about performance of the Procedure;

- Should the medicine be highly therapeutically relevant for WHO supported treatment programs, WHO actively facilitates information exchange among involved SRAs and participating NMRAs.
## 20 Participating NMRAs in the pilot SRA procedure

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**Rwanda & Madagascar participated in one of the meetings/procedures (as an observer)**

**Participating SRAs:**
1. European Medicines Agency (EMA)
2. UK Medicines and Healthcare products Regulatory Agency (MHRA)

As at 02 Nov 2017
Country registrations & therapeutic area

Total registrations: 34
(As at 02 Nov 2017)
Status of product in countries

As at 2 Nov 2017

<table>
<thead>
<tr>
<th>Product</th>
<th>Status</th>
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<tbody>
<tr>
<td>SIRTURO 100MG TABLETS</td>
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</tr>
<tr>
<td>SAYANA PRESS 104MG/0.65ML INJECTION</td>
<td></td>
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<tr>
<td>PYRAMAX 60/20 GRANULES</td>
<td></td>
</tr>
<tr>
<td>PYRAMAX 180/60MG TABLETS</td>
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<tr>
<td>PREZISTA 400MG TABLETS</td>
<td></td>
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<tr>
<td>PREZISTA 100MG/ML SUSPENSION</td>
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<tr>
<td>INTELENCE 25MG TABLETS</td>
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<tr>
<td>EURARTESIM 320/40MG TABLETS</td>
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<tr>
<td>EURARTESIM 160/20MG TABLETS</td>
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Variety of registration pathways or options

- Full assessments and inspections by NRA
  - Decisions based on information generated (100%) by NRA
- Recognition of decisions made by other NRA
  - e.g., EU Mutual recognition
- Abridged review processes
  - Secondary or tertiary reviews of primary reports from other regulatory agencies e.g. SRA or WHO PQ
- Work-Sharing
  - e.g., EU decentralised, Zazibona
- Joint assessments or inspections
  - e.g., WHO-EAC Joint Assessments/inspections;
  - e.g., ASEAN Joint Assessments.
www.who.int/medicines