Reliance and strengthening of regulatory systems: the EMA and Article 58

Plenary 1 - Regulation in promoting Universal Health access and coverage

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IX CPANDRH, San Salvador, 24-26 October 2018

DNM Medicamentos a tu alcance

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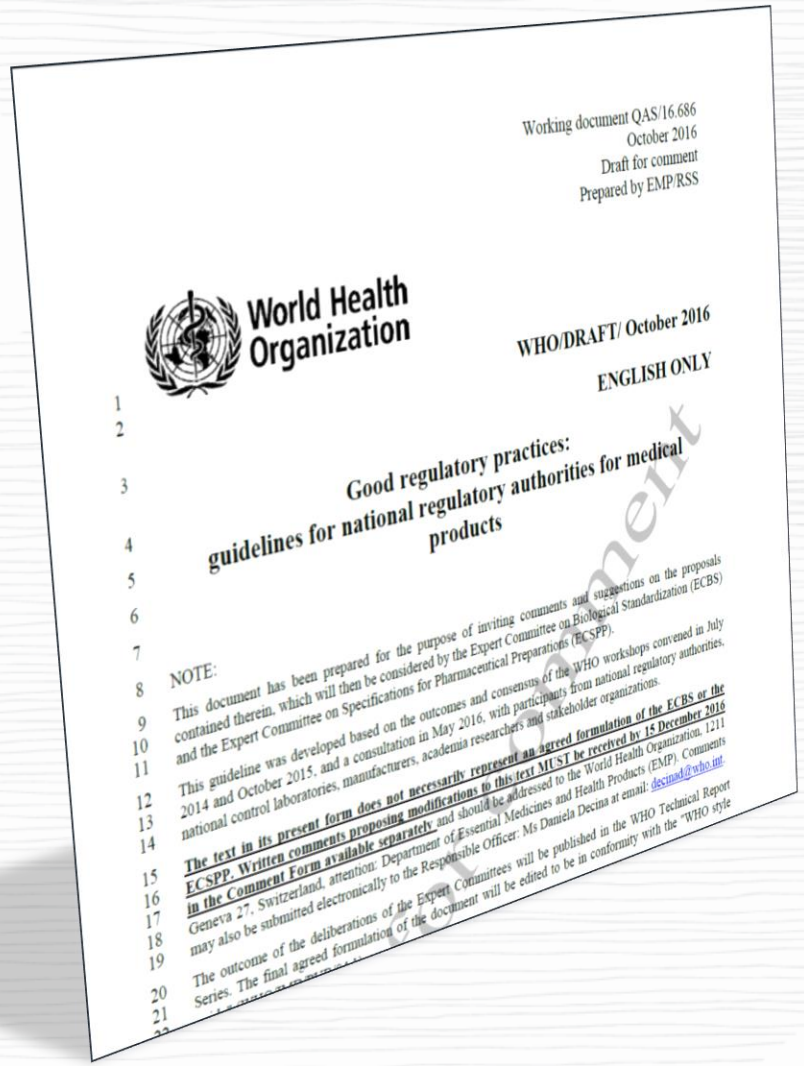
WHAT DOES RELIANCE MEAN?



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October 2016
Draft for comment
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World Health Organization

WHO/DRAFT/ October 2016

ENGLISH ONLY

Good regulatory practices:
guidelines for national regulatory authorities for medical products

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS) and the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).

This guideline was developed based on the outcomes and consensus of the WHO workshops convened in July 2014 and October 2015, and a consultation in May 2016, with participants from national regulatory authorities, national control laboratories, manufacturers, academia researchers and stakeholder organizations.

The text in its present form does not necessarily represent an agreed formulation of the ECBS or the ECSPP. Written comments proposing modifications to this text MUST be received by 15 December 2016 in the Comment Form available separately and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Department of Essential Medicines and Health Products (EMP). Comments may also be submitted electronically to the Responsible Officer: Ms Daniela Decina at email: decinad@who.int.

The outcome of the deliberations of the Expert Committees will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the "WHO style

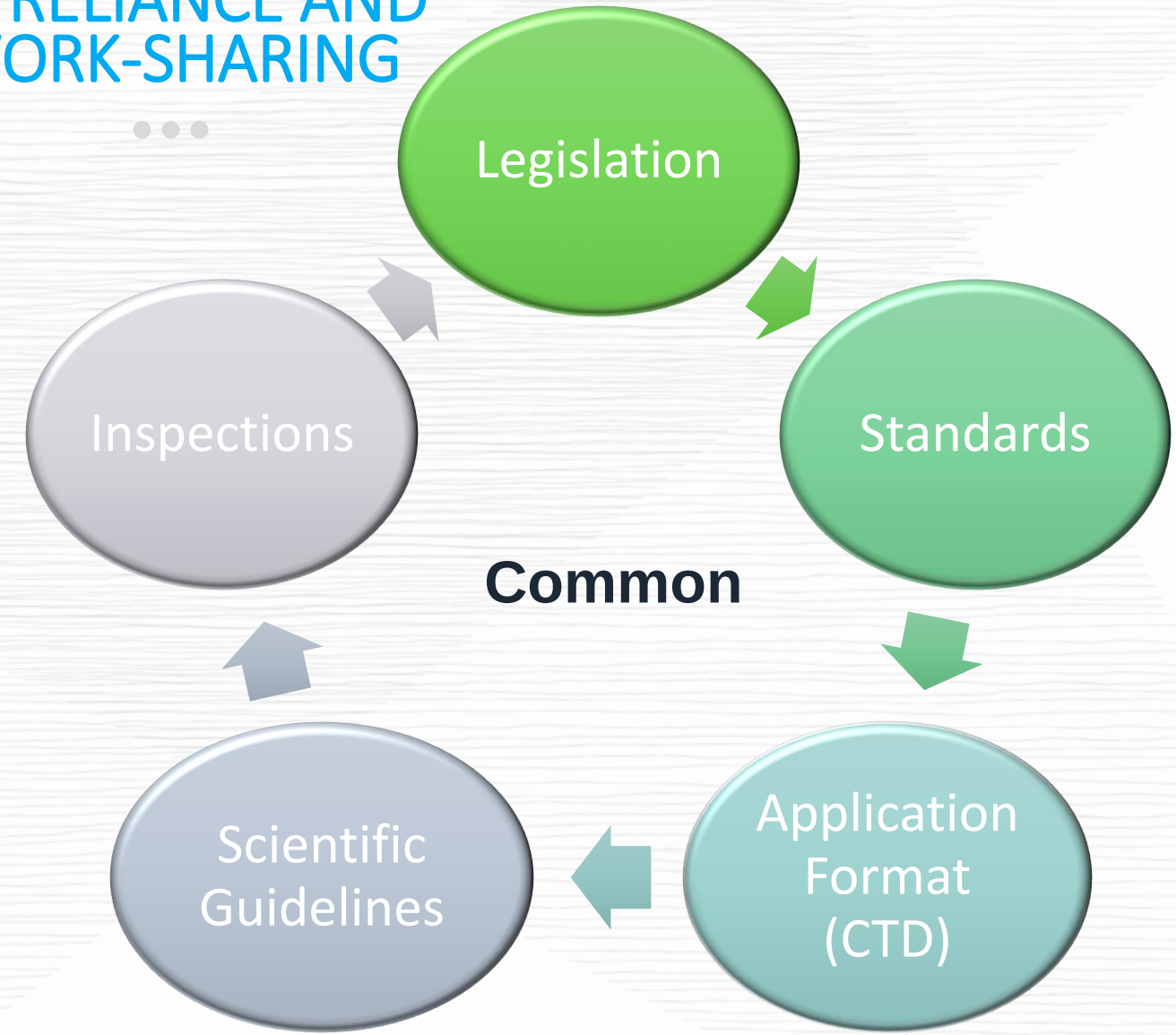
The WHO Good Regulatory Practice draft guideline
offers a helpful 2-step definition of reliance:

- take into account (partly or fully) assessment done by others
- retain responsibility for your own decision

http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf

EU RELIANCE AND WORK-SHARING

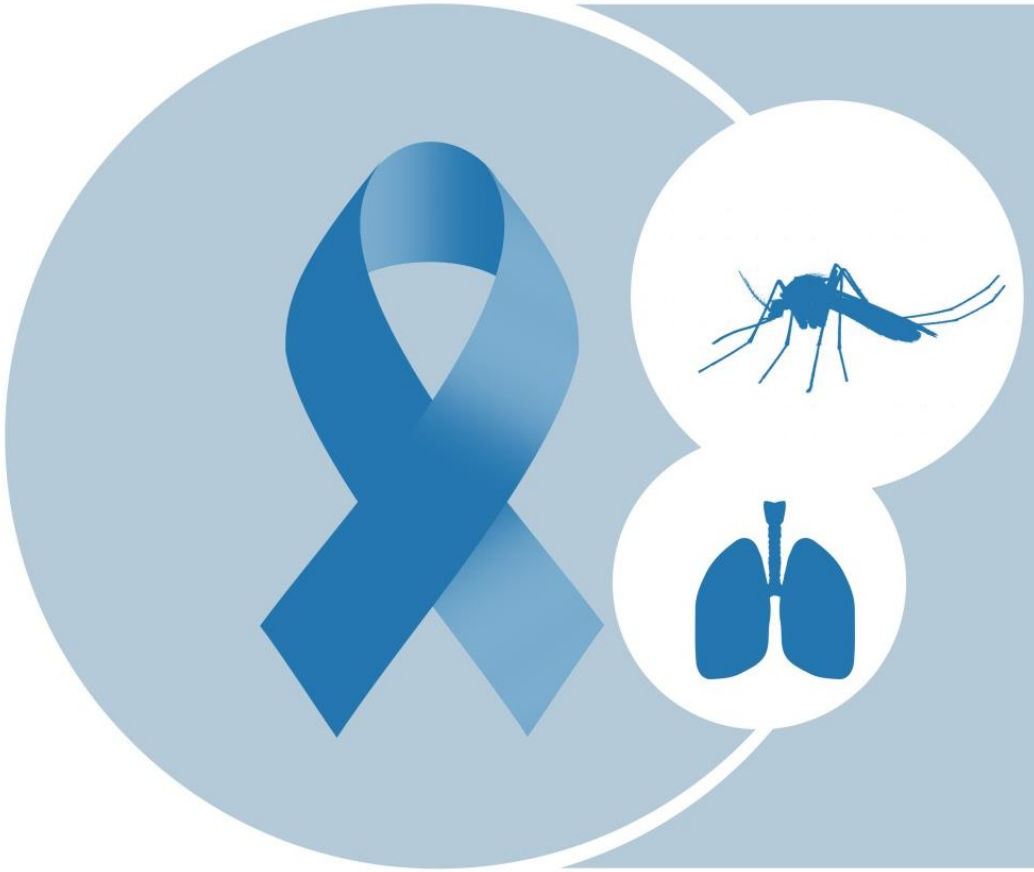
The EU regulatory system:
a single system based
on full transparency, reliance
and work-sharing



RELIANCE EXAMPLE #1:
Article 58 Procedure *('EU-Medicines4all')*

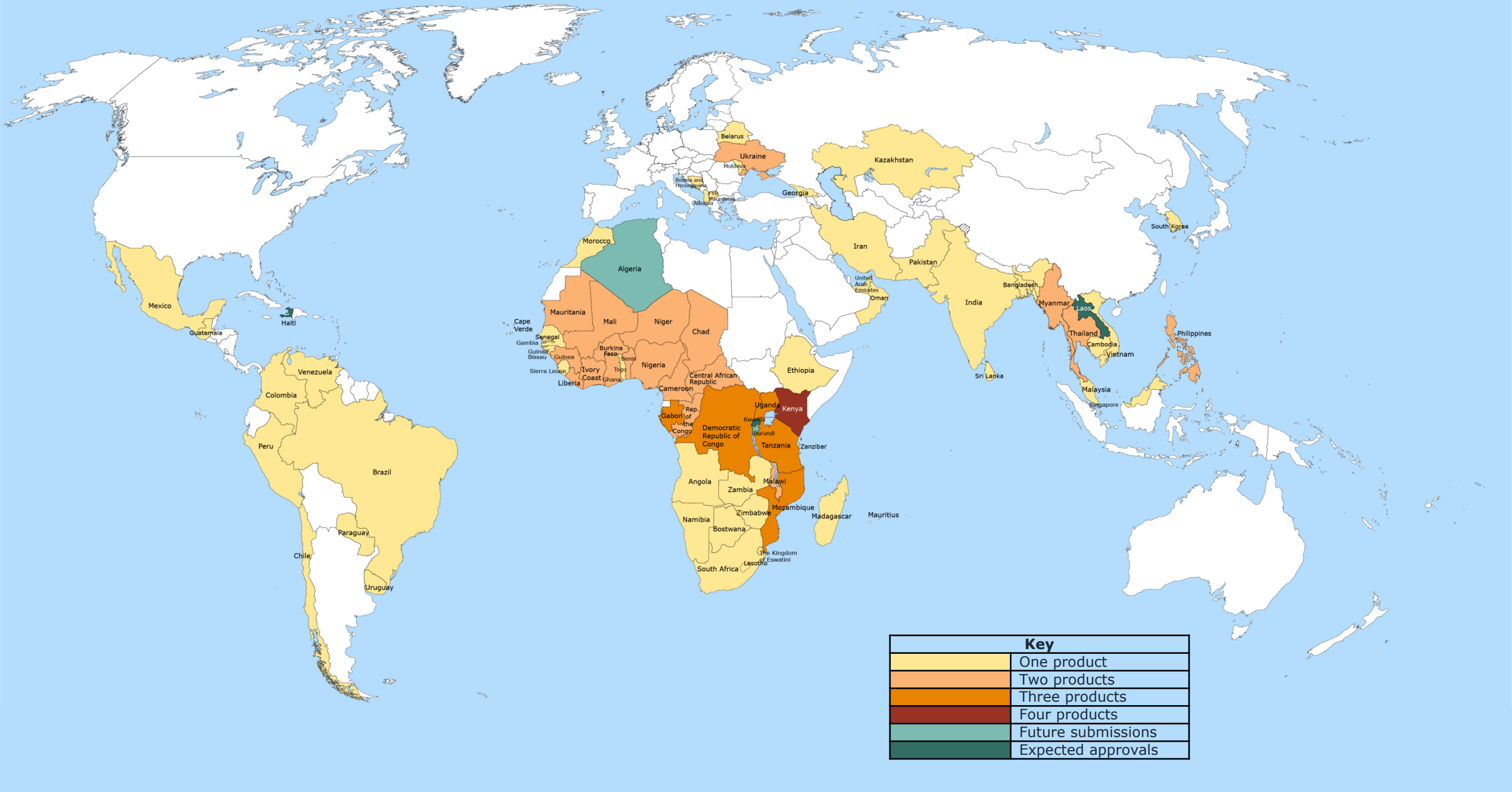
- EMA assessment of quality, safety and efficacy of a medicine or vaccine intended for use only outside the EU
- Evaluation carried out with the WHO and relevant 'target' non-EU regulatory authorities
- Same standards and procedures as for medicines marketed in EU
- Benefit-risk assessment targeted at intended non-EU population and indication
- Licensing decision taken by non-EU regulators in countries where the medicine or vaccine will be used

RELIANCE EXAMPLE #1:
Article 58 Procedure *('EU-Medicines4all')*



Vaccines or medicines used to prevent or treat public health priority diseases:

- Vaccines used in the WHO Expanded Programme on Immunization;
- Medicines for protection against diseases, such as HIV/AIDS, malaria and tuberculosis.
- Products of global public health interest, (Innovative, chemicals and biologicals, biosimilars, vaccines and generics)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Zanzibar
Angola
Zambia
Malawi
Mozambique
Zimbabwe
Namibia
Bostwana
South Africa
The Kingdom of Eswatini
Lesotho
Madagascar
Mauritius
Key
One product
Two products
Three products
Four products
Future submissions
Expected approvals

RELIANCE EXAMPLE #2:
Pilot WHO-EMA WLA Collaborative Registration Procedure

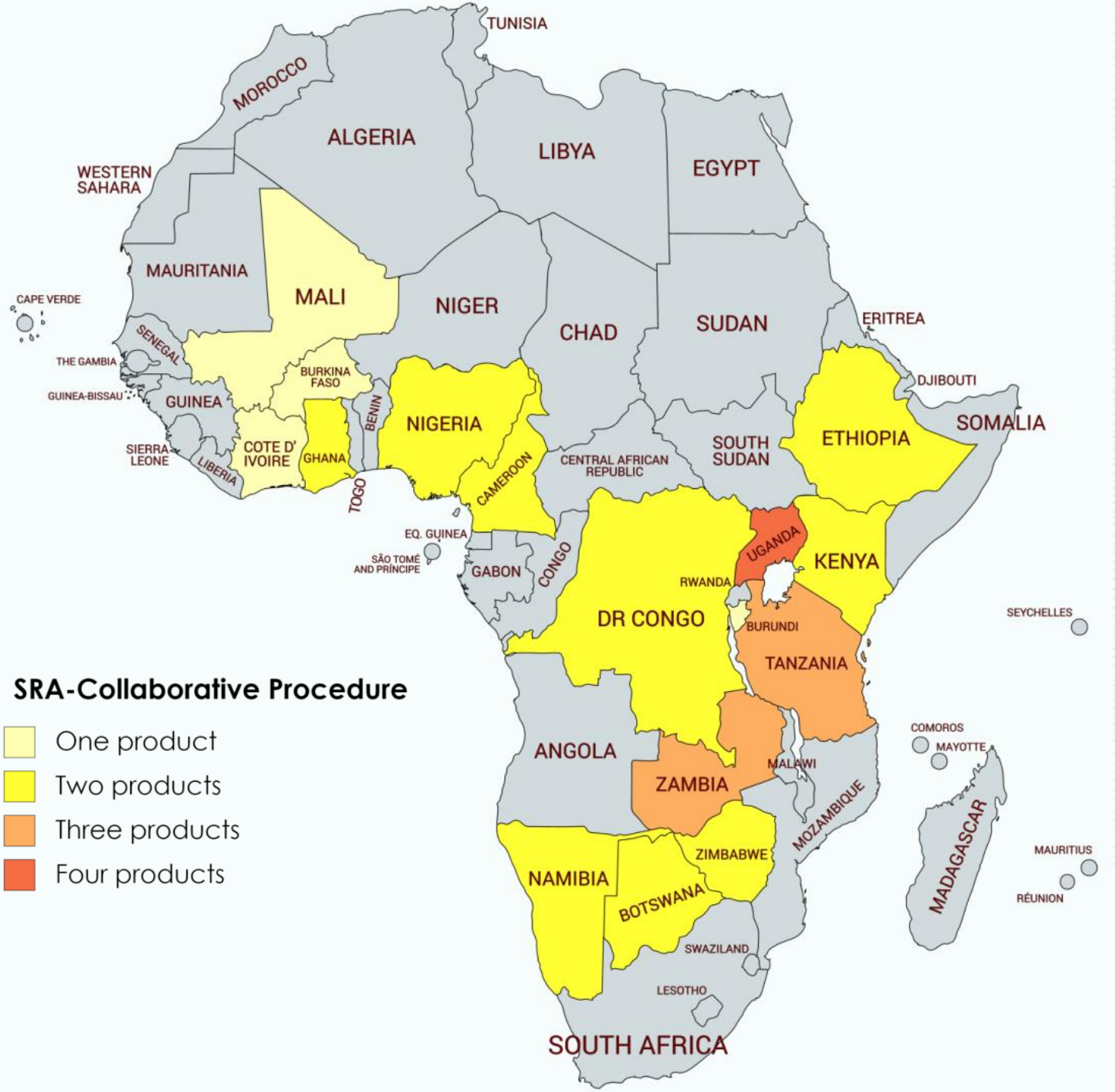
- Another option for sponsors looking for LMIC NRA approval
- Collaborative Registration aimed at facilitating and accelerating national registration of products assessed and pre-qualified by WHO
- Extended to medicines authorised by WHO Listed Authorities and pilot with EMA launched end 2014

Objective:

- Accelerate national approval process in countries where resources may be limited, based on the assessment work already carried out by the WLA
- Allows participating national authorities to retain their regulatory responsibilities and make own decisions

RELIANCE EXAMPLE #2:
Pilot WHO-EMA WLA Collaborative Registration Procedure

- 4 successful procedures + 2 ongoing
  (5 centrally-approved and one ‘Article 58’ product)
- Region-wide and single country reviews/approvals
- Products: HIV, tuberculosis, malaria, maternal and child health, haemophilia
- Participating NRAs commit to approval decision in defined timeframe
- Applicants must submit the same dossier
- Intentions to submit for another 2 products



Approvals granted in Africa based on pilot WHO-EMA WLA collaborative registration procedure

RELIANCE EXAMPLE #3:
International Pharmaceutical Regulators Programme (IPRP)

Pilot launched July 2014

Uses EU decentralised procedure as model for sharing assessment reports during scientific assessment

Shared by the EU agencies in real time with the participating non-EU authorities:

- During assessment procedures for generics participating in the pilot
- Upon request from the company applying for marketing authorisation
- Receiving authorities benefit from the information in the EU assessments but maintain their own regulatory responsibilities for decision-making

New website = http://www.iprp.global/home

RELIANCE ON ASSESSMENT REPORTS AND DECISIONS

- In addition to established cooperation programs, regulators outside the EU often request/allow applicants to provide EU assessment reports, which are used or considered while assessing products in the receiving country
- The possibility for this can be included in legislation or guidelines of the receiving countries, some examples:
  - Australia
  - Canada
  - CARICOM
  - Egypt
  - Jordon
  - Kuwait
  - Mexico
  - Saudi Arabia
  - Singapore
  - Switzerland
  - UAE

RELIANCE EXAMPLE #2:
Pilot WHO-EMA WLA Collaborative Registration Procedure

- Can reliance, cooperation and collaboration work? YES!
- No agency can do everything by itself
- Regulation through reliance is both efficient and effective
- There are many practical examples that show that it works
- Benefits regulators, industry and ultimately public health
- It’s not just about resources, but the way we work

BUT... does registration = access?

PAHO/WHO

Gracias, Thank You

Para más información / For more information:

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