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Regulatory Pathways for Registration of New Vaccines

World Health Organization

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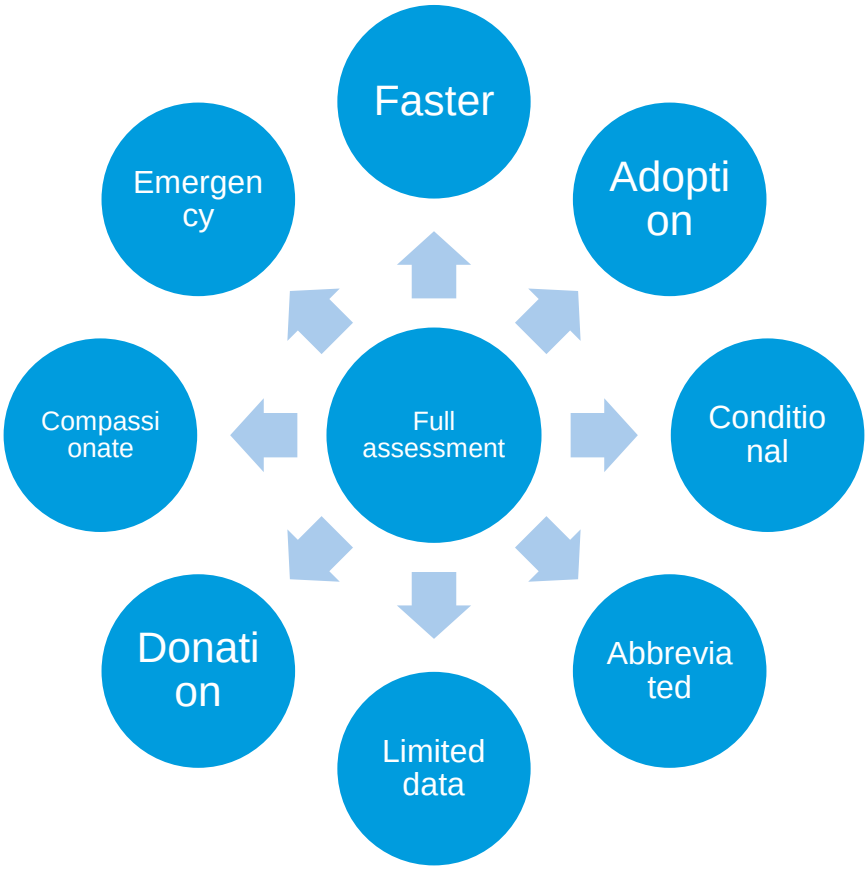
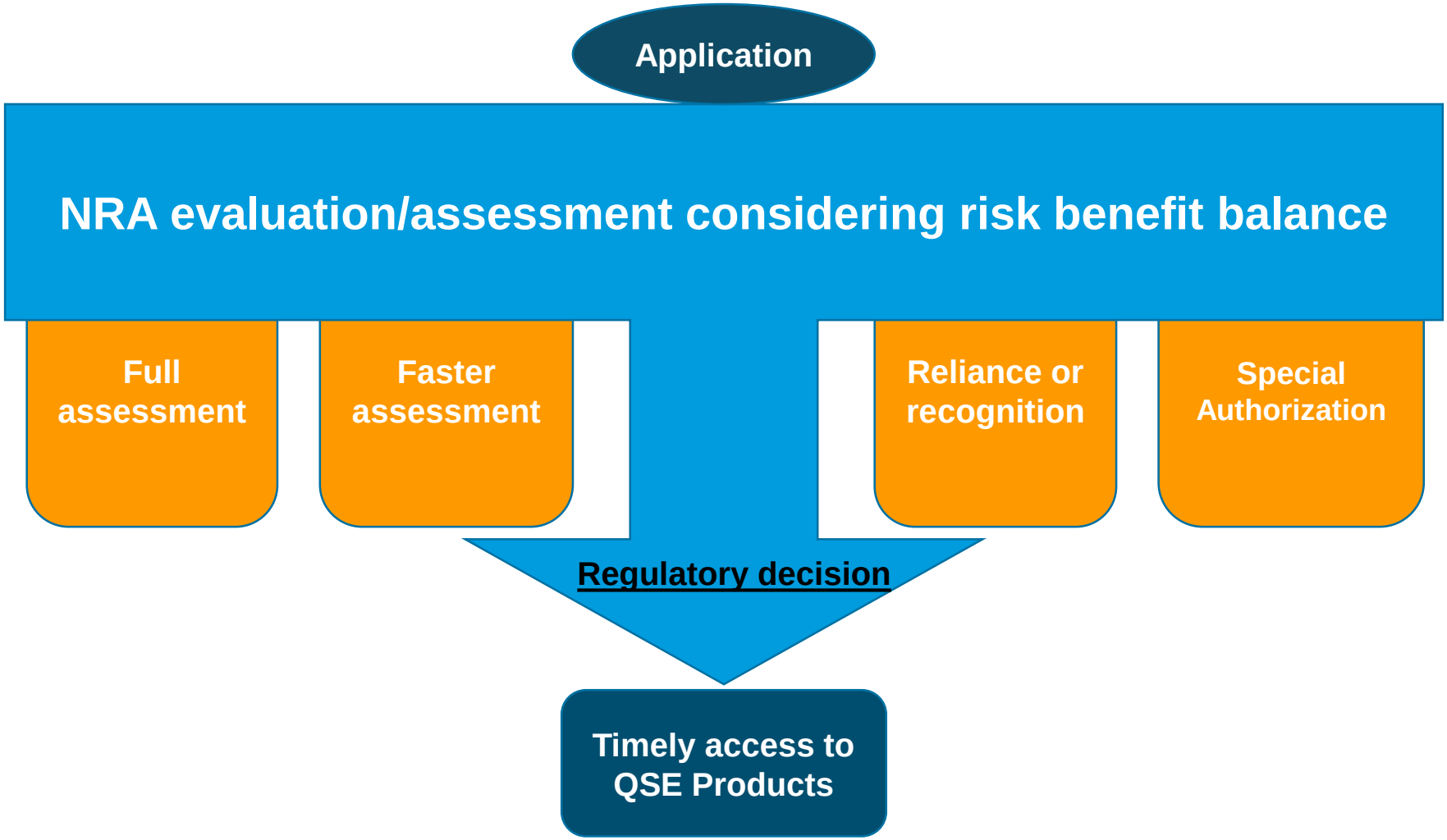
Outline of presentation

- Regulatory pathways to provide timely access to assured quality vaccines
- Tools to accelerate vaccine registration in transitioning countries
  - Facilitating registration (guidelines and standards)
  - Prequalification and emergency assessment procedures
  - Aassisted registration
  - Collaborative procedures and joint assessments
- Contributing to Coalitions
- Major challenges
- Conclusion

Types of Regulatory Pathways for Access to Medicines/Vaccines




Application
NRA evaluation/assessment considering risk benefit balance
Full assessment
Faster assessment
Reliance or recognition
Special Authorization
Regulatory decision
Timely access to QSE Products

Tools to accelerate vaccine registration in developing countries

- Facilitating registration (guidelines and standards)
- Prequalification and emergency assessment procedures
- Assisted registration (Parallel Review, EMAs article 58, US FDA PEPFAR process, Swiss medic MAGHP process)
- Collaborative procedures and joint assessments

WHO written standards: ECBS

Written standards (e.g., Guidelines, Recommendations) - Vaccines

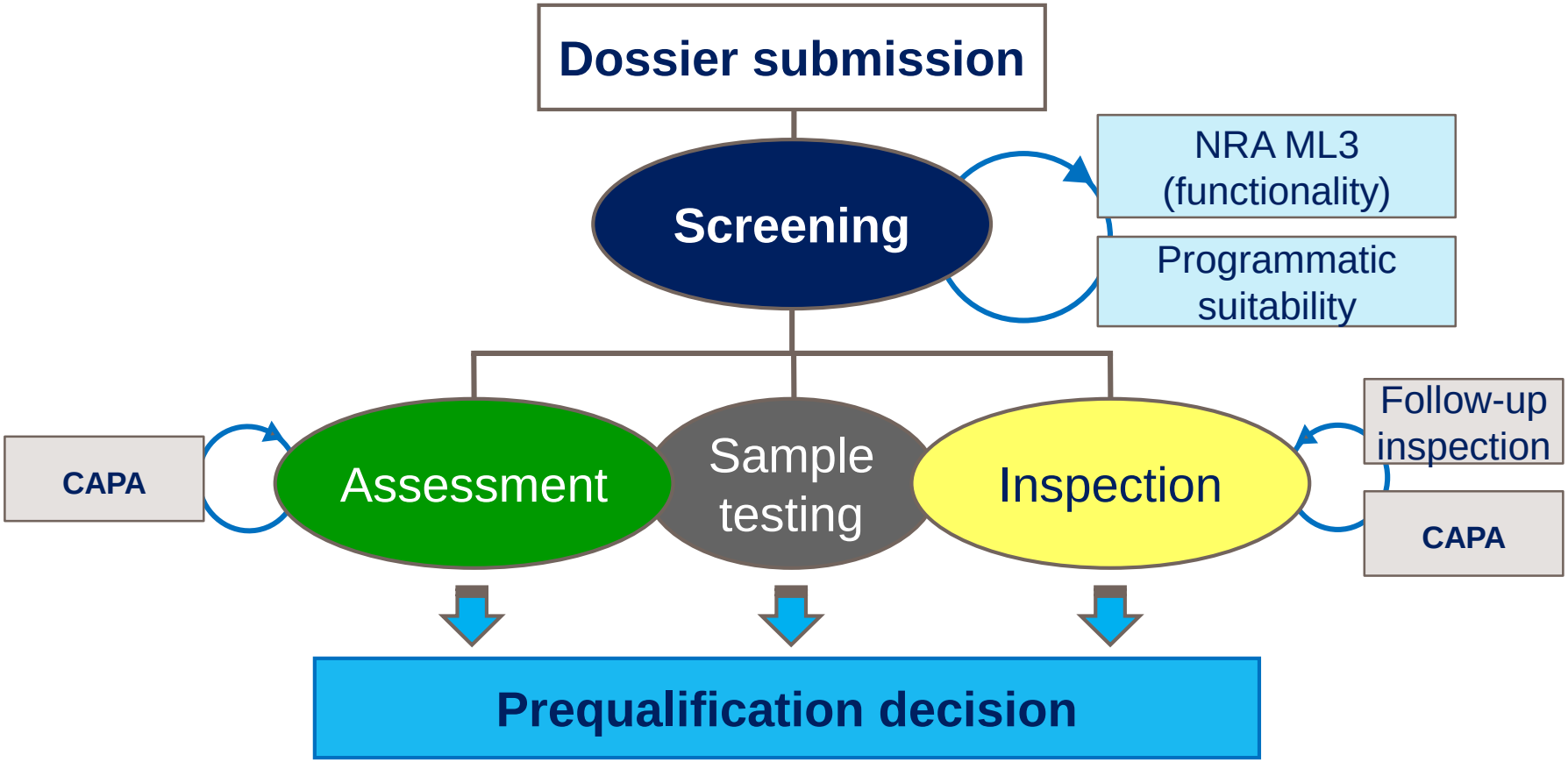
- Guidelines on the quality, safety and efficacy of Ebola vaccines
- Guidelines on procedures and data requirements for changes to approved biotherapeutic products
- WHO Recommendations, Guidelines and other documents related to the
- manufacture and quality control of biological substances used in medicine
- WHO good manufacturing practices for biological products
- Regulatory assessment of approved rDNA-derived biotherapeutics
- Recommendations to assure the quality, safety and efficacy of recombinant human papillomavirus virus-like particle vaccines

Prequalification (PQ) of Vaccines by WHO

- Response to the need of procurement agencies and Member States for quality-assured health products, by creating and applying quality-assurance mechanisms
- PQ of Vaccines
  - started 1987, originally request by UNICEF and PAHO to evaluate quality, safety and efficacy of vaccines in the context of national immunization programmes,
  - 148 vaccines prequalified to-date
- Facilitates registration in developing countries
- Countries can rely on PQ assessment, inspection, lot testing, etc.

Source: http://www.who.int/immunization_standards/vaccine_quality/progress_report_who_pqp_june2013.pdf?ua=1

Vaccine Prequalification workflow



Emergency Use and Assessment Listing (EUAL) for candidate vaccines – not prequalification

- A time-limited special procedure for assessment of candidate products under special public health emergencies
- Used for UN procurement decision-making
- Intended to support highly impacted countries in their regulatory decision-making

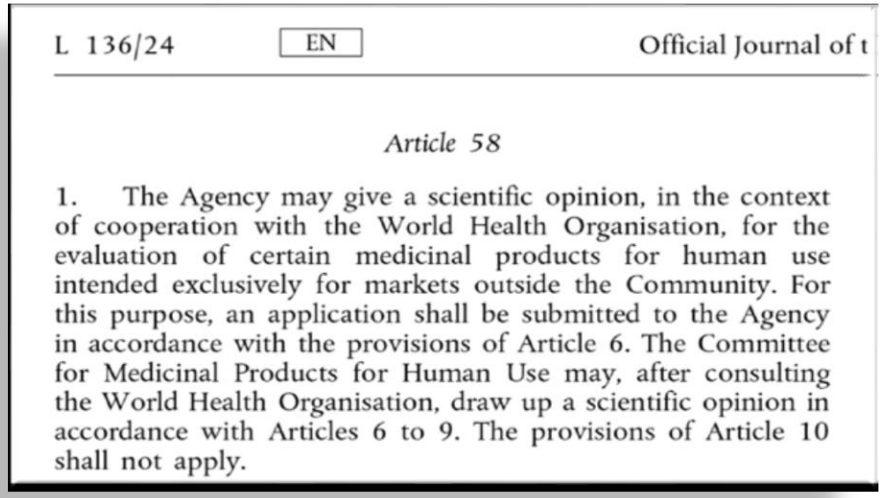
Consultation meeting May 2017

- Revision of the procedure based on the experience gathered
- Idea of a Pre-EUAL process
  - Could use PIP and Smallpox experiences as input on vaccine side
- Mapping of regulatory requirements for emergency use

For http://www.who.int/medicines/news/public_consult_med_prods/en/

EMAs Article 58

- Introduced in 2004 as a tool to help to expand LMIC access to new medicines and improve public health
- Involvement of NRA experts and observers from ‘target’ countries
- Cooperation with WHO
- Assessment of quality/safety/efficacy
- Scientific opinion on use outside the EU



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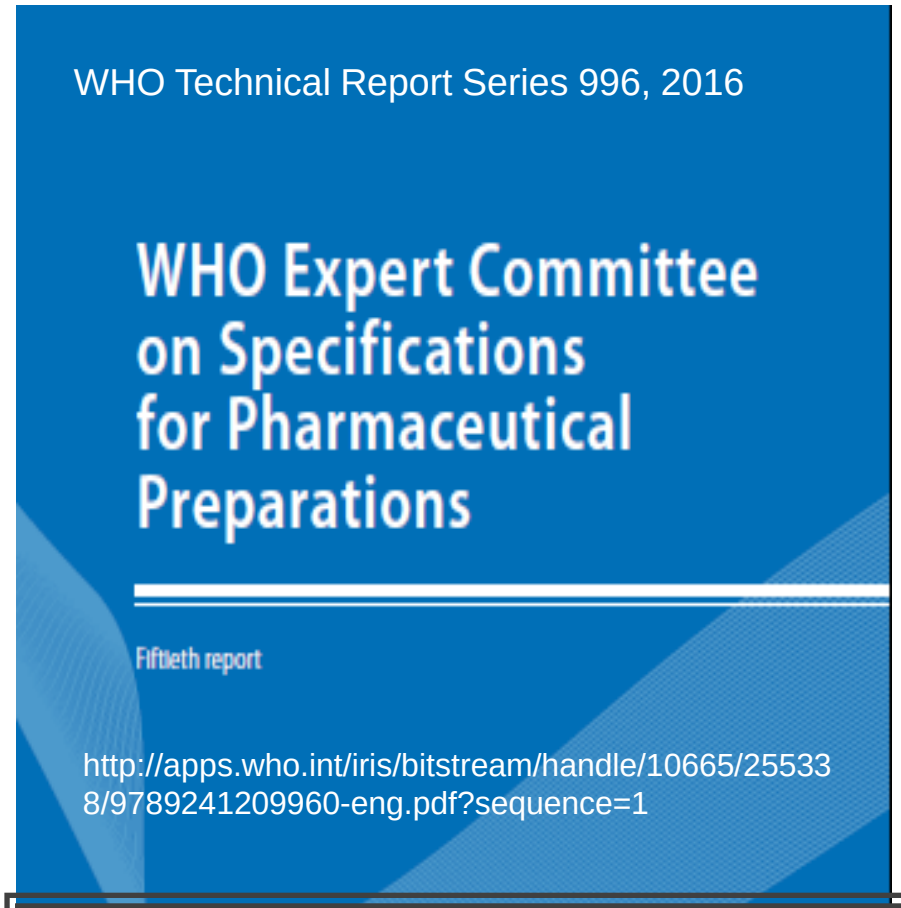
Article 58

1. The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the evaluation of certain medicinal products for human use intended exclusively for markets outside the Community. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 6. The Committee for Medicinal Products for Human Use may, after consulting the World Health Organisation, draw up a scientific opinion in accordance with Articles 6 to 9. The provisions of Article 10 shall not apply.



Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

Applicable guidelines for CRP

Objective and Principles of WHO PQ Collaborative Registration Procedure (CRP)

- **Objective:** Accelerate access to prequalified products by reducing duplication of efforts, optimizing use of resources, promoting collaboration and reliance concepts
- **Principles:** Voluntary
- Product and registration dossier in countries are 'the same' as **prequalified by WHO.**
- Shared confidential information to support NRA decision making in **exchange for accelerated registration process (90-day commitment)**
- Harmonized product status' is monitored and maintained

Collaborative procedures and joint assessments – facilitating and accelerating registration of vaccines

- R&D Blueprint : preparing the ground
- African Vaccine Regulatory Forum (AVAREF) - successful model for joint reviews of clinical trials
- Regional Harmonisation Networks (e.g. AMRH, SEARO, WPRO, GCC, CRS) facilitate registration
- Joint assessments of vaccines
- Collaborative Registration Procedure

KEY Principles of WHO PQ CRP

- Voluntary
- Product and registration dossier in countries are 'the same' as **prequalified by WHO.**
- Shared confidential information to support NRA decision making in **exchange for accelerated registration process**
- 'Harmonized product status' is monitored and maintained

Contributing to Coalitions

- Coalition of Epidemic Preparedness Innovations (CEPI)
  - Regulatory group, Standards group
  - Supporting Tabletop exercise on emergency access to products (Ghana, November 2017)
- Coalition of Interested Partners (CIP)
  - WHO led initiative to coordinate and collaborate across donors and other stakeholders
- International Coalition of Medicines Regulatory Authorities (ICMRA)
  - Contribution to Crisis management, Vigilance work and Track and Trace

Major Challenges

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Technical Challenges

- New and complex products that has never been registered before
- Competency and knowledge gap
- Other regulatory activities to be completed (CT, testing, inspection) as part of MA
- Lack of proper regulatory oversight during the post marketing phase (AEFI)

Administrative Challenges

- Diversity in country MA requirements
- Slow and long regulatory pathways
- Multilayer decision making processes
- Rigid regulatory framework

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Conclusion

- ✓ Enabling Access to Vaccines and other medical products a priority for WHO
- ✓ Multiple initiatives underway to facilitate registration of vaccines
- ✓ Evolving principles of joint assessments and reliance concepts
- ✓ Success of Collaborative Registration Procedure for medicines needs to be extended to Vaccines
- ✓ Importance of creating synergies and avoiding duplication
- ✓ Collaboration and Communication across stakeholders essential

Thank you

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Regulatory Systems Strengthening (RSS)

Regulation of Medicines and Other Health Technologies (RHT)

World Health Organization (Geneva, Switzerland)

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