

Accelerated procedure for registration  
of WHO-prequalified medicines

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Collaboration Procedure between the  
WHO Prequalification Programme and  
NMRA

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PREQUALIFICATION OF  
MEDICINES PROGRAMME  
A UNITED NATIONS PROGRAMME  
MANAGED BY WHO



World Health  
Organization

Copenhagen, September 2012

QUALITY MEDICINES FOR EVERYONE

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# Background reasoning (1)

- Although WHO prequalified medicines are thoroughly assessed and manufacturers are inspected according to WHO/international standards, to be used in recipient countries they have to be registered by NMRAs.
- Re-assessment and re-inspections of prequalified medicines place demands on NMRAs.
- Slow registration delays availability to patients.
- Specific national registration requirements sometimes discourage manufacturers to import needed medicines.



## Background reasoning (2)

- Registration of prequalified medicines may be facilitated by closer co-operation among WHO, NMRAs and manufacturers
- Prerequisite of facilitated national registration is the communication of confidential data and therefore procedure must be well defined and agreed by all participating parties
- Common assessment and inspections are useful practice, but not always are applicable



# Survey organized during the PQP Assessment training in January, 2011

Armenia

Belarus

Botswana

Cuba

Ethiopia

Georgia

Ghana

Kenya

Mozambique

Namibia

Oman

Saudi Arabia

Sudan

Tanzania

Thailand

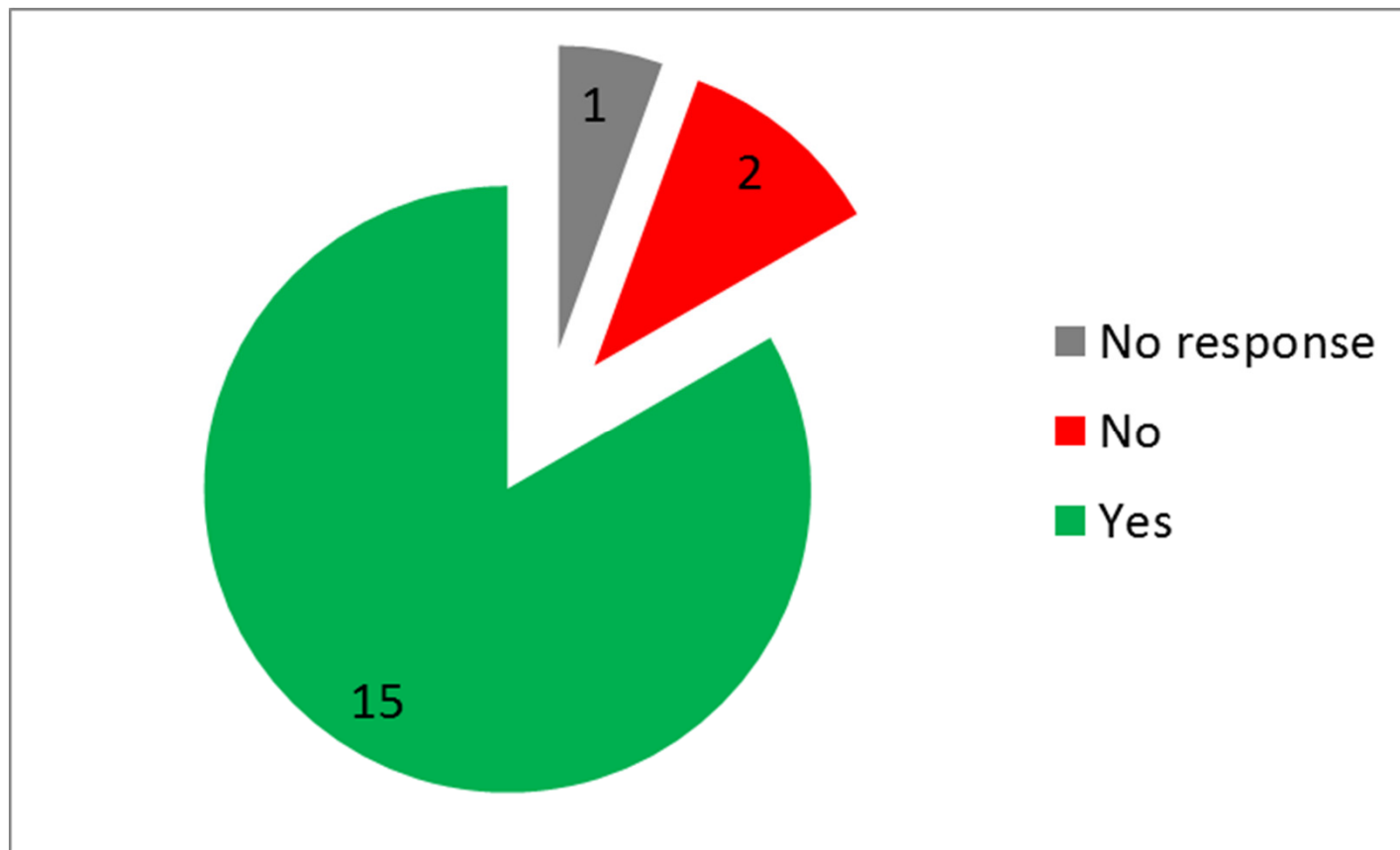
Uganda

Zambia

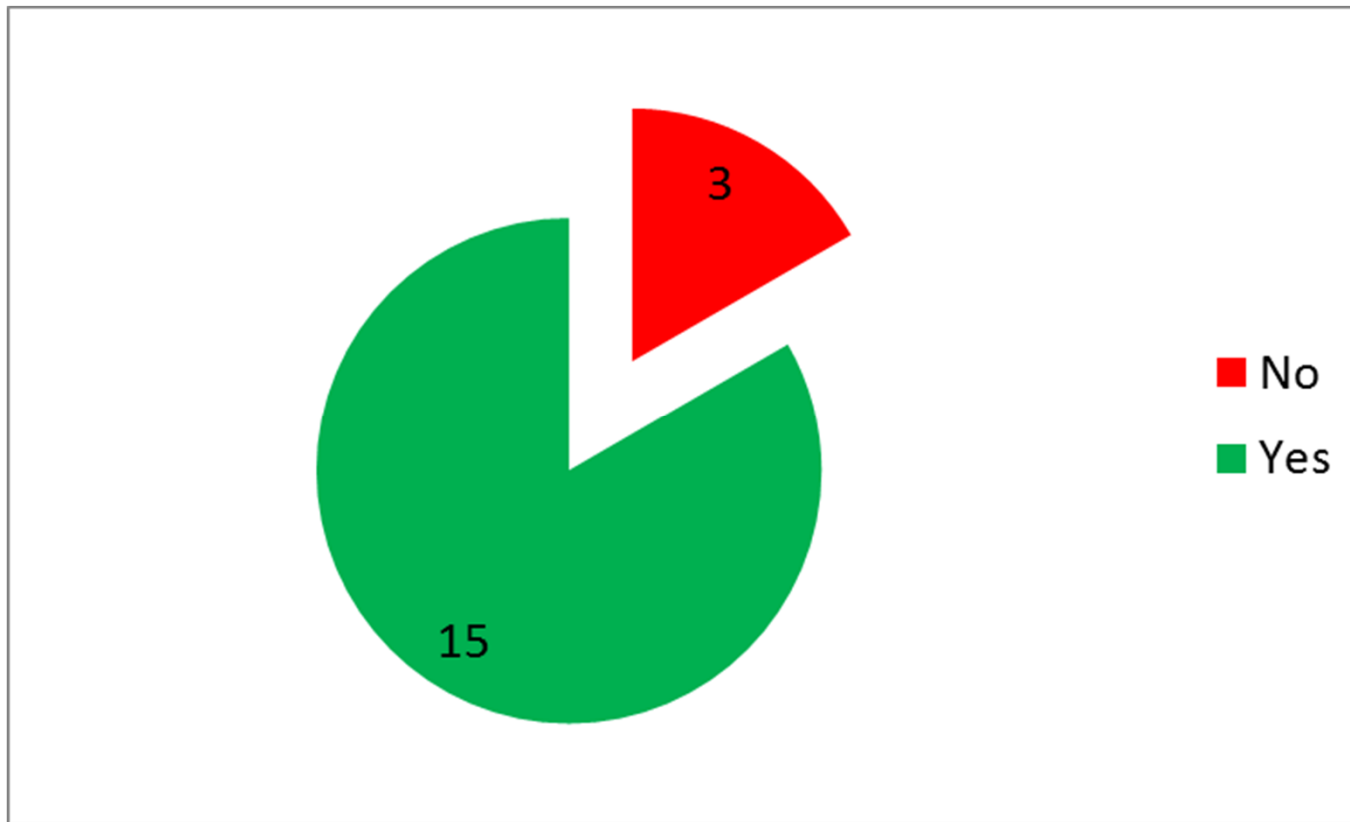
Zimbabwe



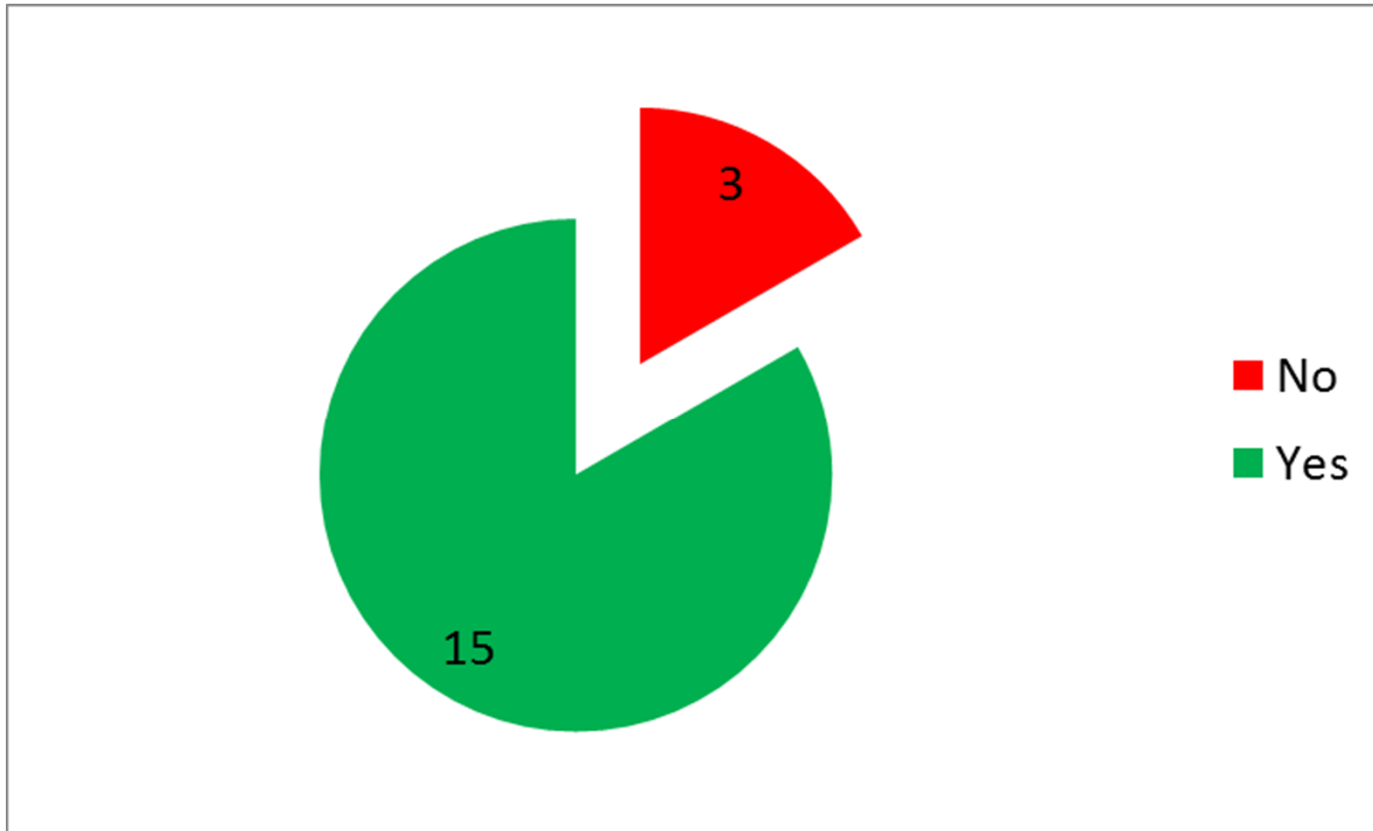
# CTD format of dossier is mandatory or accepted



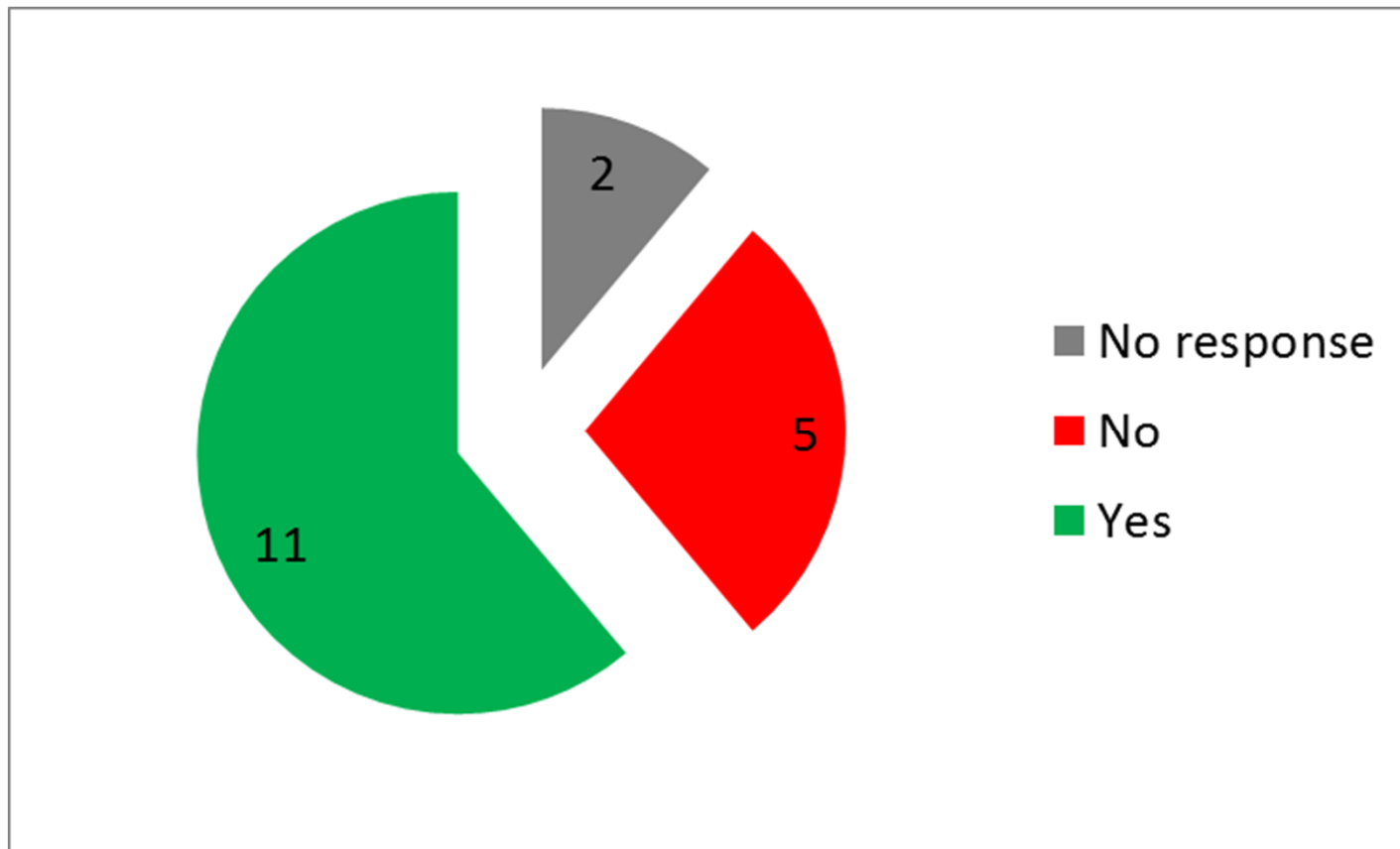
# Requirements on documentation of bioequivalence (concerning both demonstration of bioequivalence in vivo and in vitro) are in principle close to PQP



# GMP standard required by country regulations for manufacturers of finished dosage forms is equivalent to WHO or PIC/S GMP

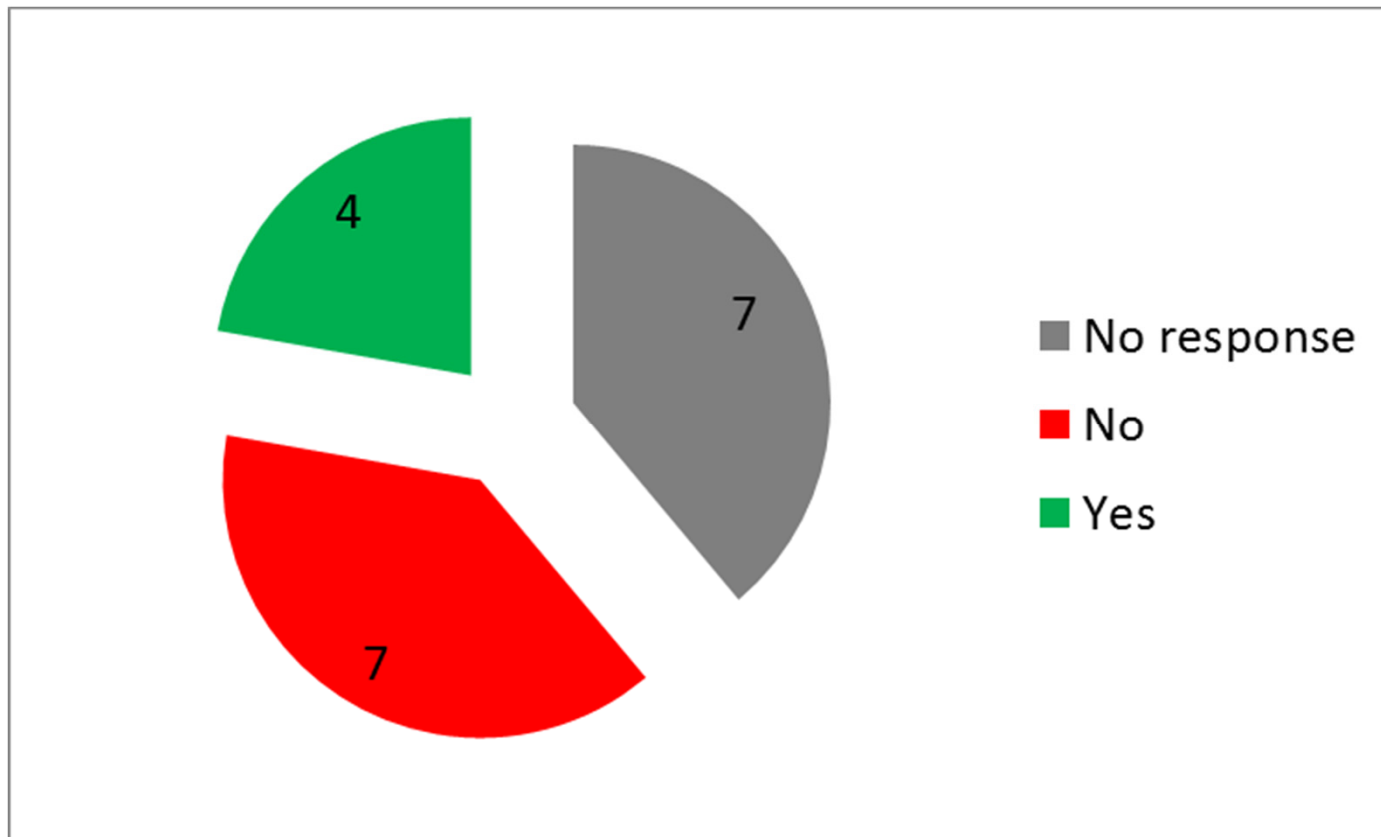


**In the practice of your authority, does exist the difference between registration process of medicines, which are WHO prequalified or approved by stringent authorities, and other medicines?**

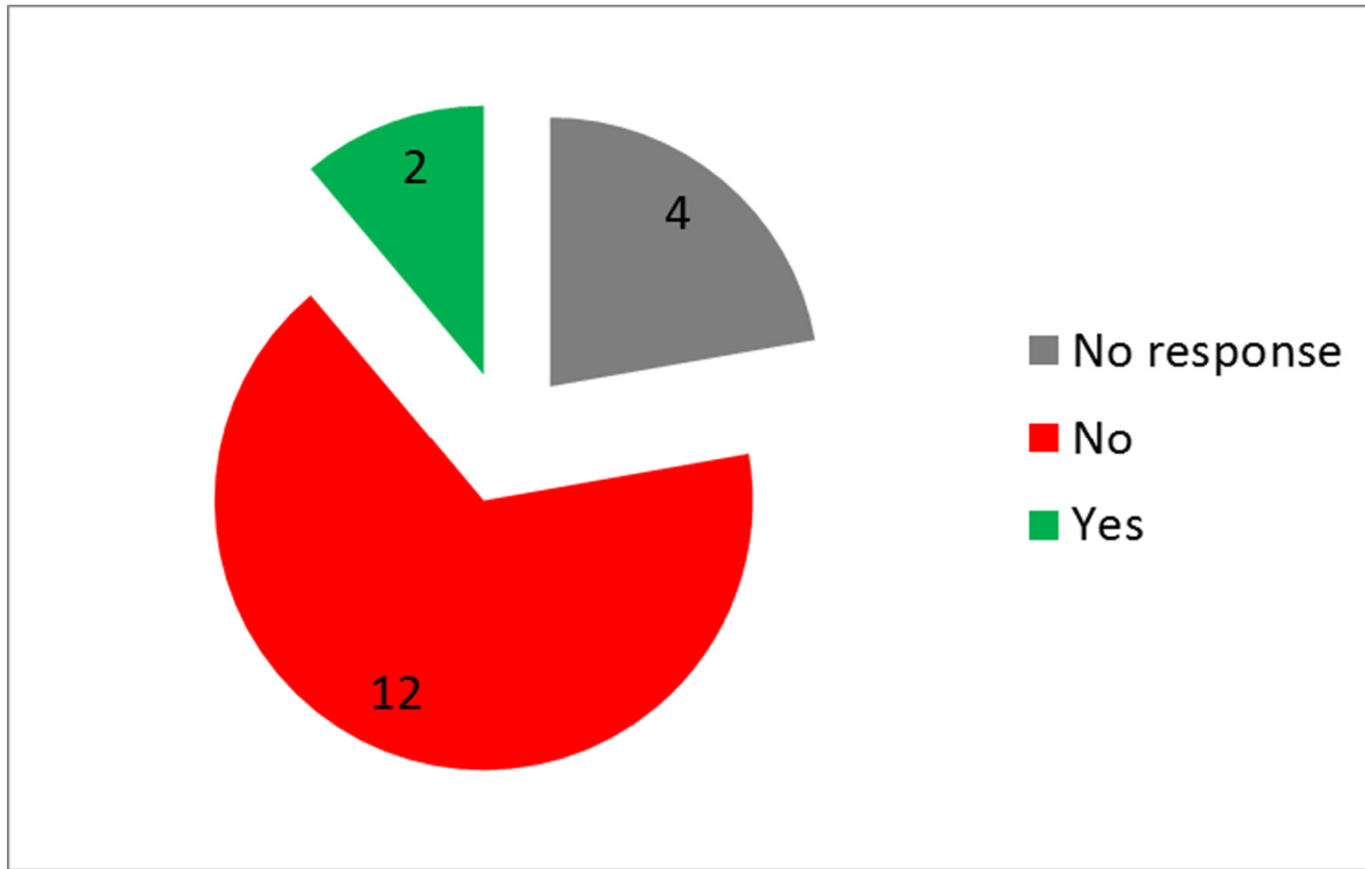




# Do you utilize WHO Public Assessment Reports (WHOPARs) in support of taking decision about national registration



# Does any publicly available document exist explaining the difference?



# Principles of proposed process

1. Procedure voluntary for manufacturers and NMRAs and providing benefits to both parties.
2. Being asked by PQP holder (manufacturer), full PQP assessment and inspection outcomes and advice will be shared with interested NMRAs to facilitate national regulatory decisions making (registrations, variations, withdrawals). Applicable only for medicines assessed by PQP.
3. No interference with national legislation, decision making process and regulatory fees – availability of PQP expertise.



# Principles of proposed process

4. Co-operation among PQP holder (manufacturer), NMRA in interested country and PQP necessary to overcome confidentiality issues, assure information flow and product identity. Registration dossier in countries in principle the same as approved by PQP.
5. Each participating authority commits to adopt registration decision within 90 days from having available full PQP assessment and inspection outcomes and has the right to
  - decline to adopt procedure for individual medicines
  - decide differently from PQP, but keep PQP informed and clarify the reasons for deviation.



## Procedure drafted in wide consultation and available for comments:

[http://www.who.int/entity/medicines/areas/quality\\_safety/quality\\_assurance/PQProcedure-assessmentandacceleratednationalreg-QAS12-497\\_01062012.pdf](http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/PQProcedure-assessmentandacceleratednationalreg-QAS12-497_01062012.pdf)

Pilot testing starting with 10 interested countries:

- Botswana
- Ghana
- Kenya
- Namibia
- Nigeria

- Tanzania
- Uganda
- Zambia
- Zanzibar
- Zimbabwe

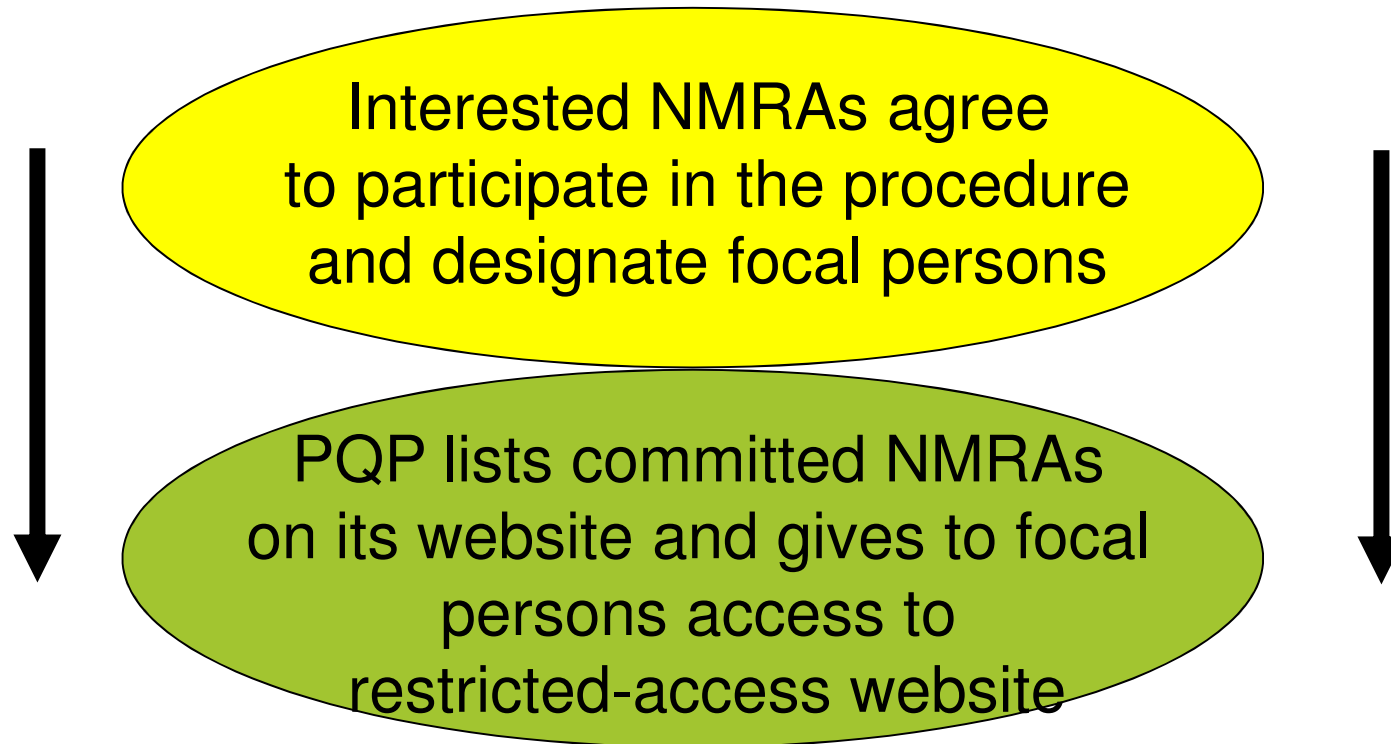


# Steps of the procedure: agreement

- NMRA confirms to WHO PQP its interest to participate in collaborative procedure and respect its conditions (*Annex 1A*)
- One or two focal persons are designated at each interested NMRA, sign confidentiality undertaking and are given access to the WHO managed restricted-access web-site (*Annex 1B*)



# Steps of the procedure: agreement



# Steps of the procedure: registration /1

1. Manufacturer submits to participating authority the application for national registration of the medicinal product, which underwent WHO PQP assessment/ inspections and is prequalified, and informs the authority about the interest to follow the collaborative procedure. Same data submitted as for PQP. (*Annex 3, Part A*)
2. Manufacturer informs WHO PQP about the application for national registration and, for each product, provides written agreement to exchange of information between the participating authority and WHO PQP (*Annex 2*)



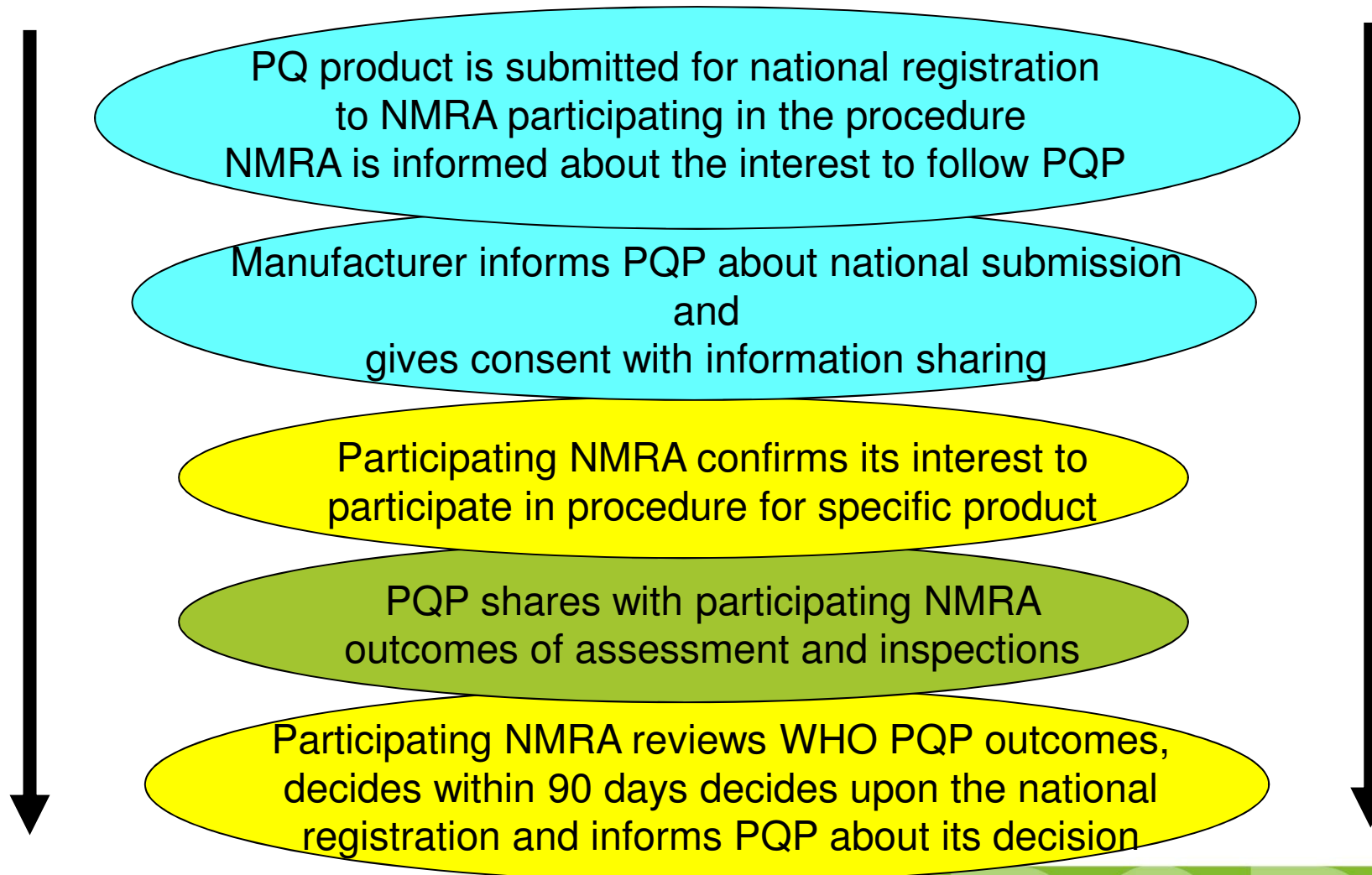


# Steps of the procedure: registration /2

3. Participating authority confirms to WHO PQP its interest to apply the procedure for given medicinal product (*Annex 3, Part B*).
4. WHO PQP provides focal person (s) in the participating authority with the assessment/inspection outcomes via restricted-access website and provides additional explanation, if requested.
5. Participating NMRA having WHO PQP assessment and inspection outcomes decides within 90 days upon the national registration. Participating NMRA informs WHO PQP about the outcome of national registration and, when divergent from PQP decision, provides explanation (*Annex 3, Part C*).



# Steps of the procedure: registration



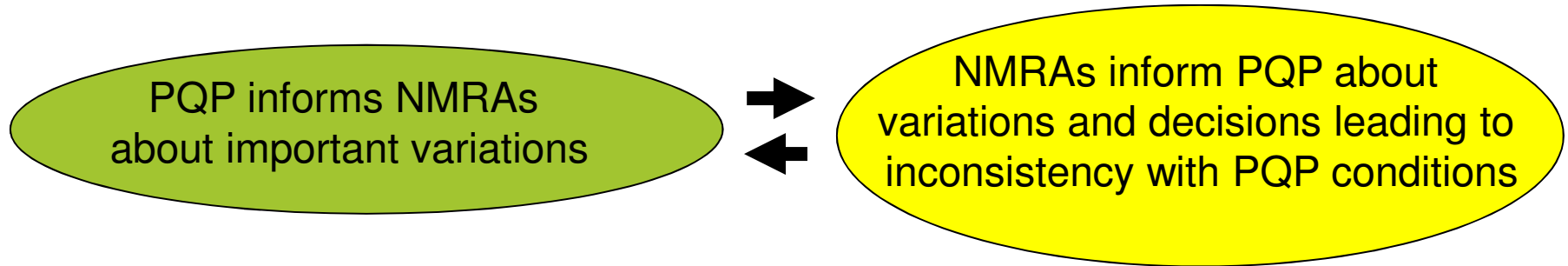
# Steps of the procedure: post-registration

1. PQP provides participating authorities with variation assessment reports and post-prequalification inspection reports, when regulatory action is deemed to be justified
2. Participating authorities inform PQP about the outcome of national variation procedures, if they have reached a decision different from that reached by PQP, or they reached a decision which results in national registration conditions being inconsistent with prequalification conditions
3. WHO PQP informs participating NMRA about withdrawals, suspensions or de-listings of prequalified medicinal products
4. Participating authority informs PQP about national de-registration (for any reason) of a prequalified medicinal product.

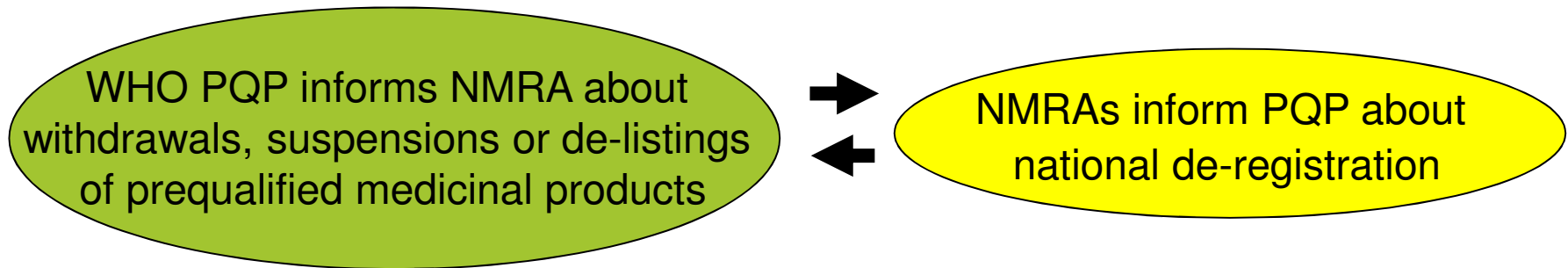


# Steps of the procedure: post-registration

## Variations



## De-registrations and de-listings



# Pilot phase and adoption of the procedure

- 10 countries and 2 prequalification holders interested to participate in the pilot. Experience from the pilot planned to be reviewed at the meeting with participating countries and manufacturers.
- Procedure posted for public comments and submitted for adoption to the WHO Expert Committee on Specifications for Pharmaceutical Preparations (10-11 October 2012).



# Win-win outcomes for all stakeholders

- NMRAs
  - Availability of WHO assessment and inspection outcomes to support national decisions
  - Opportunity to learn from PQP assessors and inspectors
  - Saving internal capacities
  - Demonstrating NMRA efficiency
  - Having assurance about registration of 'the same' medicine as is prequalified
  - Easier post-registration maintenance
- WHO
  - Prequalified medicines are faster available to patients
  - Feed-back on WHO prequalification outcomes



# Win-win outcomes for all stakeholders

- Procurers
  - Faster start of procurement and wider availability of PQ medicines
  - Assurance about 'the same' medicine as is prequalified
- Manufacturers
  - Harmonized data for PQ and national registration
  - Facilitated interaction with NMRAs in assessment and inspections
  - Accelerated and more predictable registration
- Ultimate beneficiaries are patients!



# Thank you for the attention

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