World Health Organization

WHO PQ Collaborative Procedure for Accelerated Registrations

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How do WE get the prequalified product to these patients faster, and more efficient?

PREQUALIFICATION PROGRAMME
A United Nations Programme managed by WHO

US FDA Tentative approval process, EU Article 58; Canada Health Access Initiative

ICH harmonisation for better health

IGDRP International Generic Drug Regulators Programme

PIC/S

edqm European Directorate for the Quality of Medicines & HealthCare

Caribbean Regulatory System

Gulf Central Committee for Drug Registration / Harmonisation

ASEAN Pharmaceutical Product Working Group

AMRH → **AMA**

PANDRH

ZAZIBONA **EAC MRH** **ECOWAS**

World Health Organization

Concept of collaborative registrations

To support the national registrations, regulators can benefit from already organized scientific assessments and inspections, if

- Having access to regulatory expertise from trusted party (complete assessment and inspection reports and possibly an expert assistance)
- Having the same product
- Having same essential technical data
- Understanding validity of expertise for their environment
- National legislation and sovereignty are not affected
- Respect confidentiality of commercially sensitive information
- Manage properly regulatory follow-up

How does the PQ collaborative procedure works?

WHO PQ Process

INPUTS

Expression of Interest

Dossier

WHO Guidelines

Assessors/ Inspectors

PROCESS

Assessment of Dossier

+

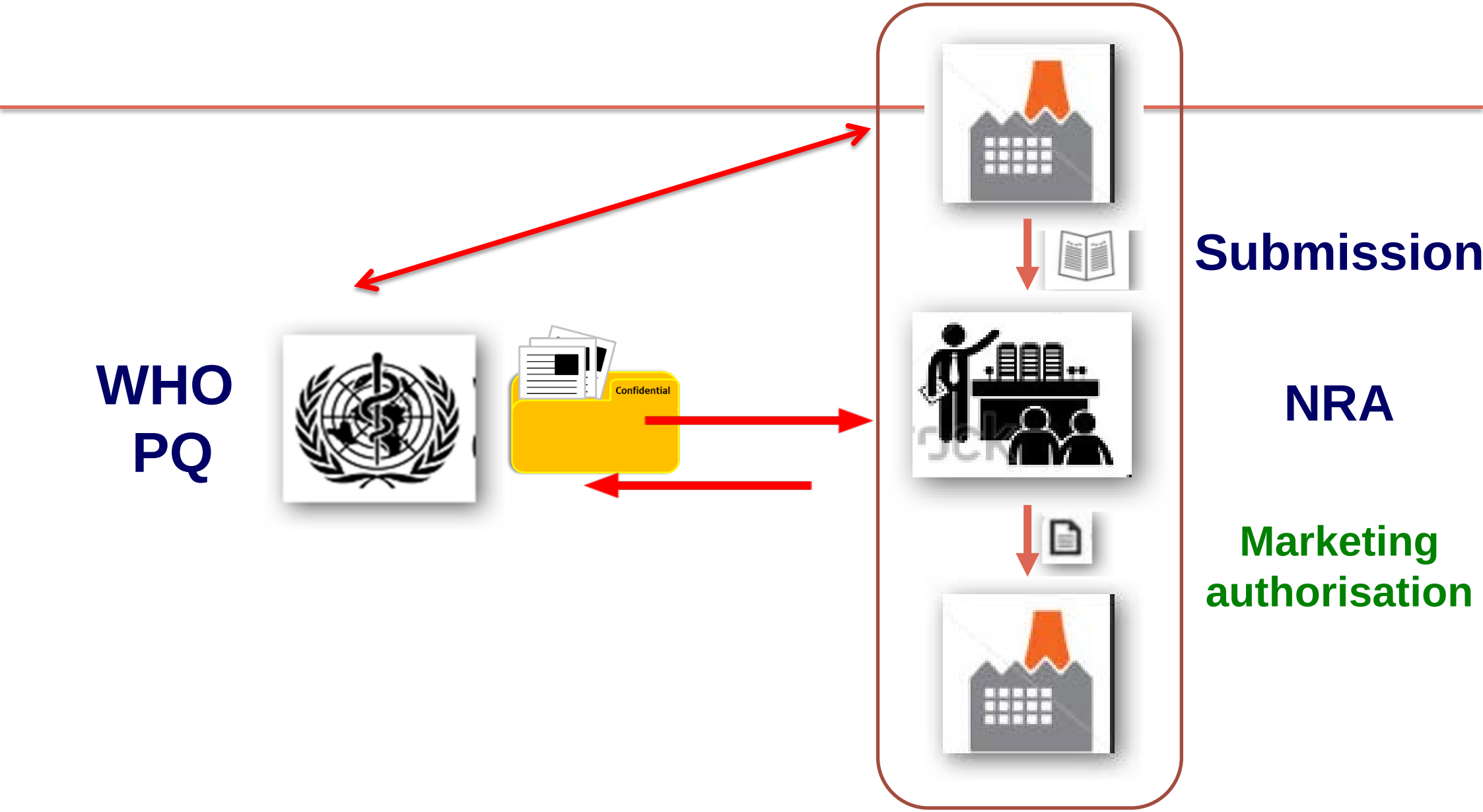
Inspections (API, FPP, CRO)

Assessment/ Inspection Reports

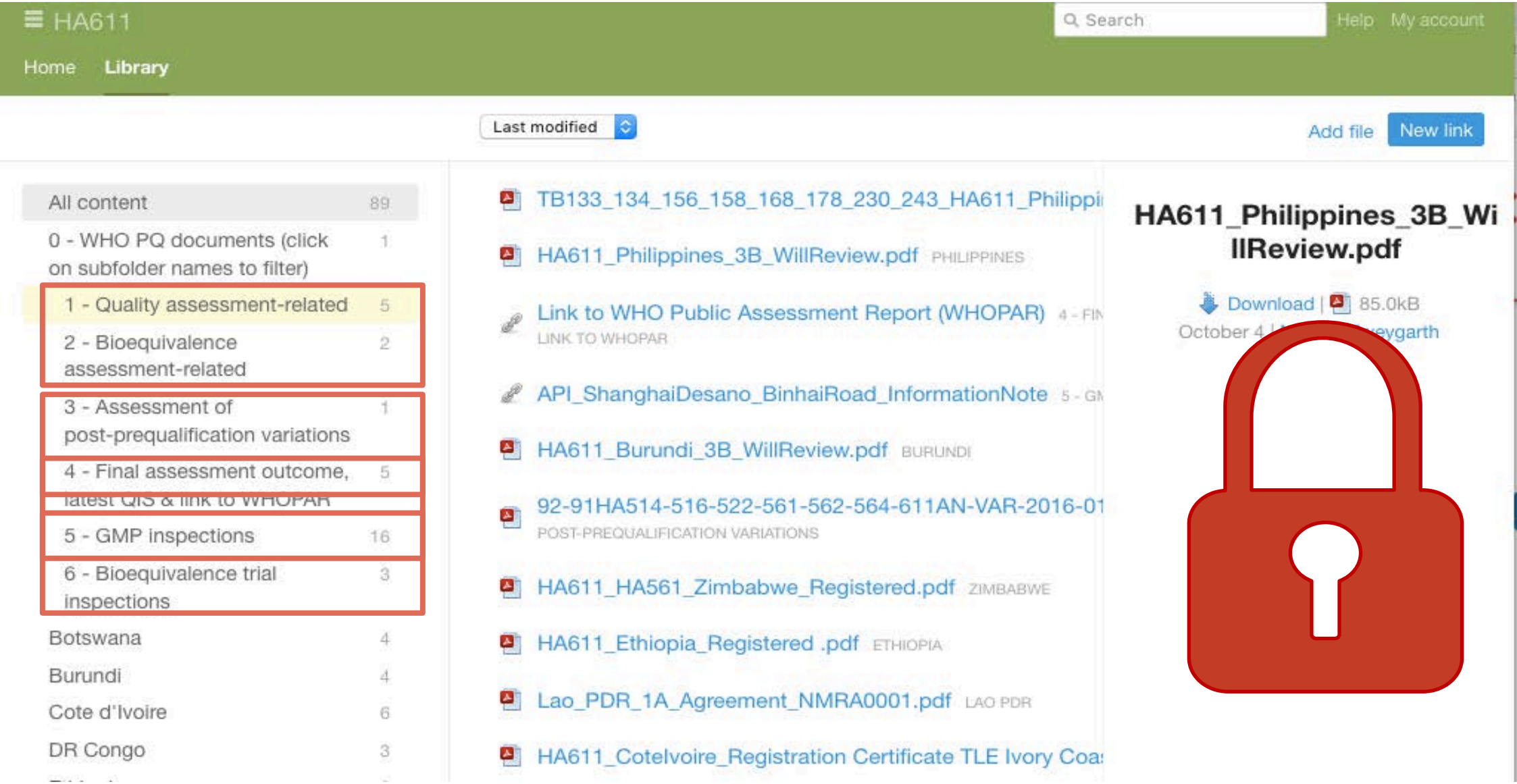
OUTPUTS

List of Prequalified products

WHO Public Reports


WHO
PQ
Confidential
Submission
NRA
Marketing
authorisation

Collaborative procedure: Documents shared



KEY Principles of WHO PQ Collaborative Registration Procedure

- 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

Options for participating regulators

- **Decide on use of the process for individual products**
  - Recognize
  - Verify
  - Organize R/B second review and inspections
  - Consider in decision making
  - Use as quality assurance of national assessment and decision
- **Conclude differently from WHO PQ - justify**
- **Benefit from shared information for harmonization and training**

BUT

- **Accelerate the national decision**
- **Keep WHO informed about the national decision**

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 internal capacities
  - 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 (website)

WHO PQ CRP Status update

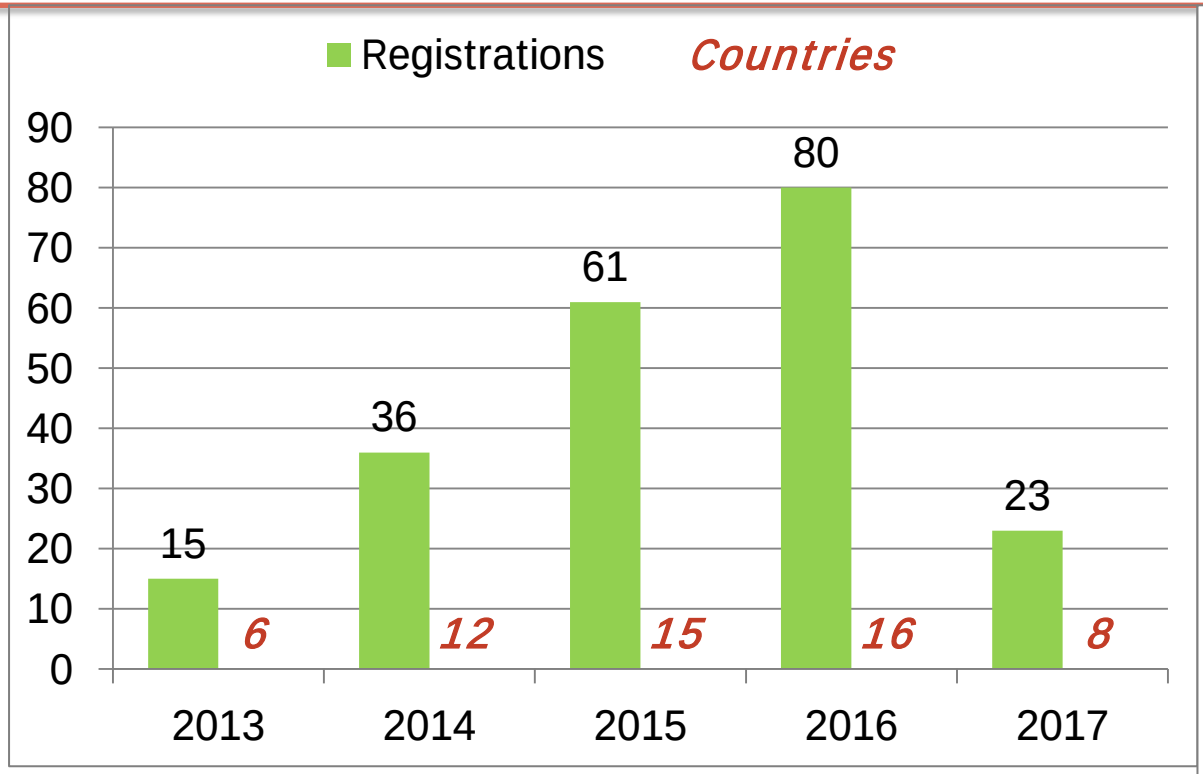
Participating NMRAs

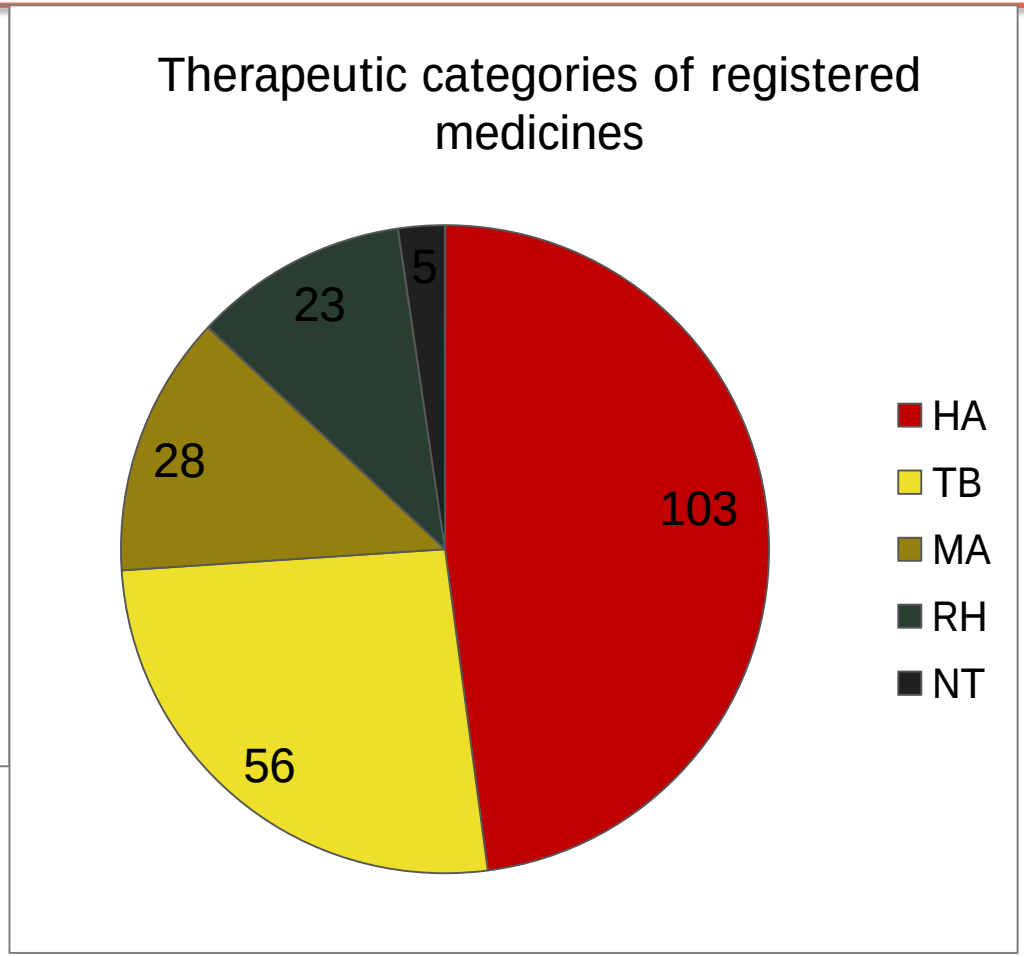
Armenia
Botswana
Burkina Faso
Burundi
Cameroon
*Caribbean Community (CARICOM)
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malawi
Mali
Mozambique
Namibia
Nigeria
Philippines
Senegal
Sierra Leone
South Africa
Tanzania
Uganda
Ukraine
Zambia
Zanzibar
Zimbabwe

* 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 12 May 2017

Country registrations & therapeutic area

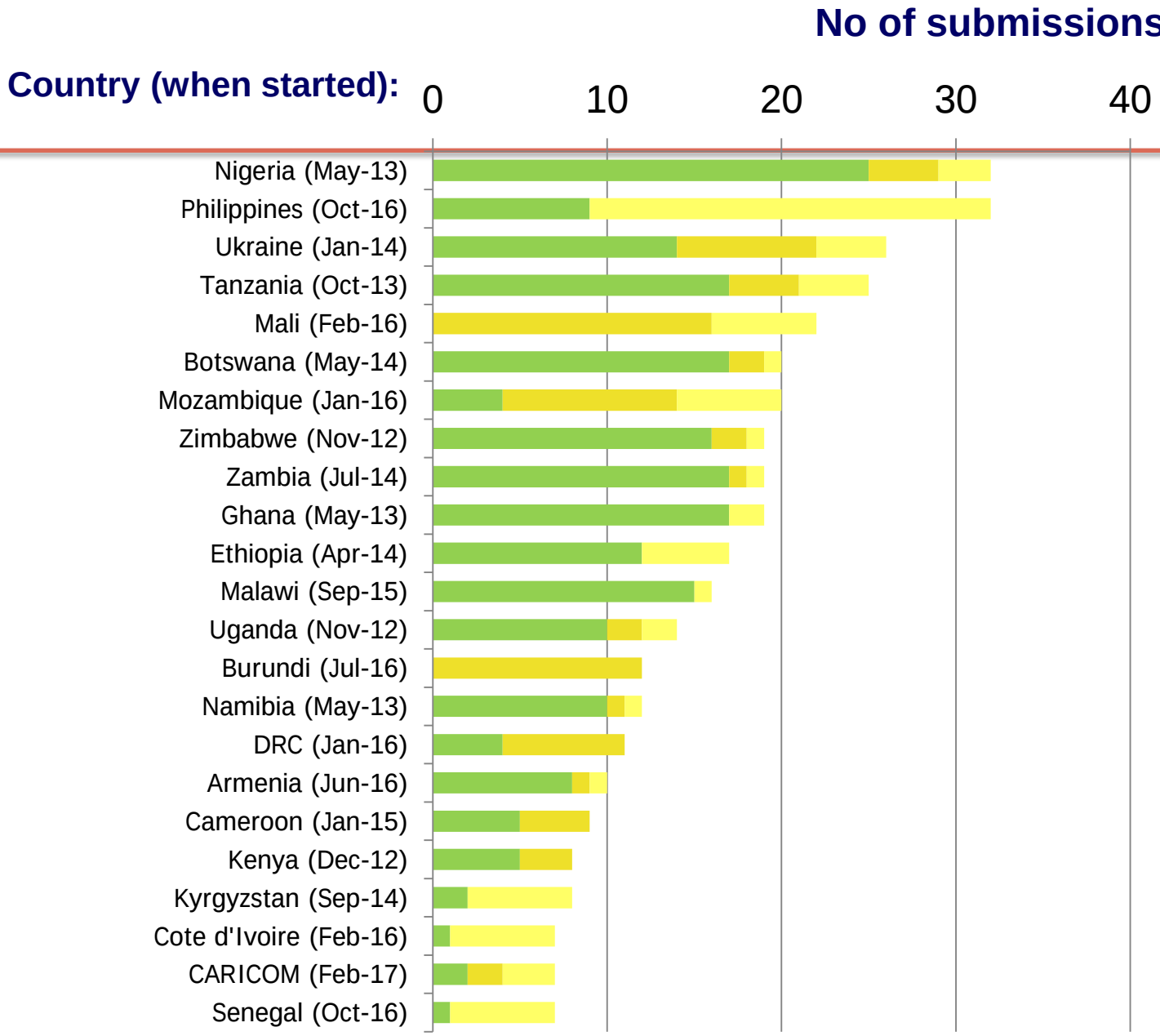




Total registrations: 215
(As at 12 May 2017)

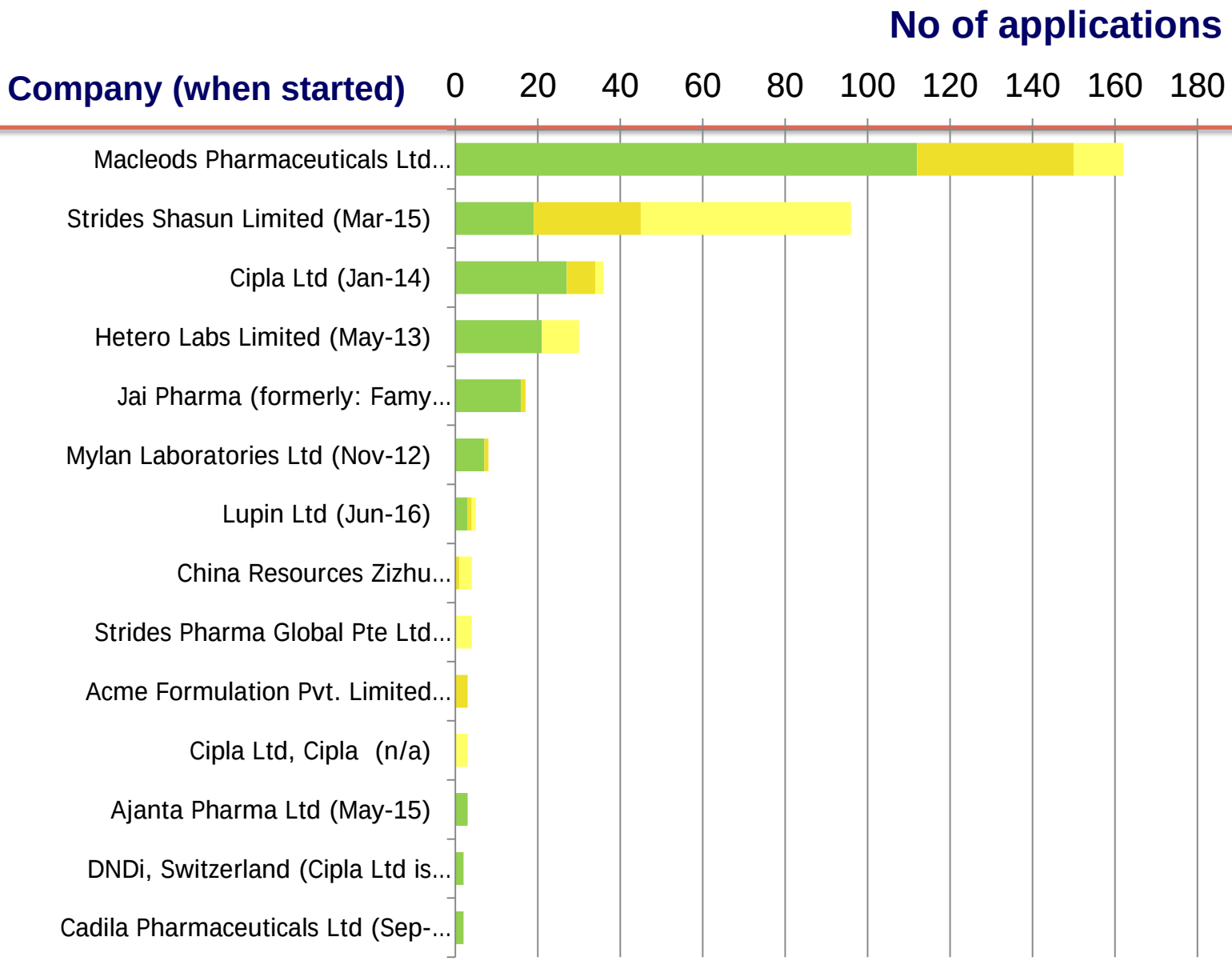
Pipeline of applications in countries

As at 12 May 2017



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

Pipeline of applications, by company

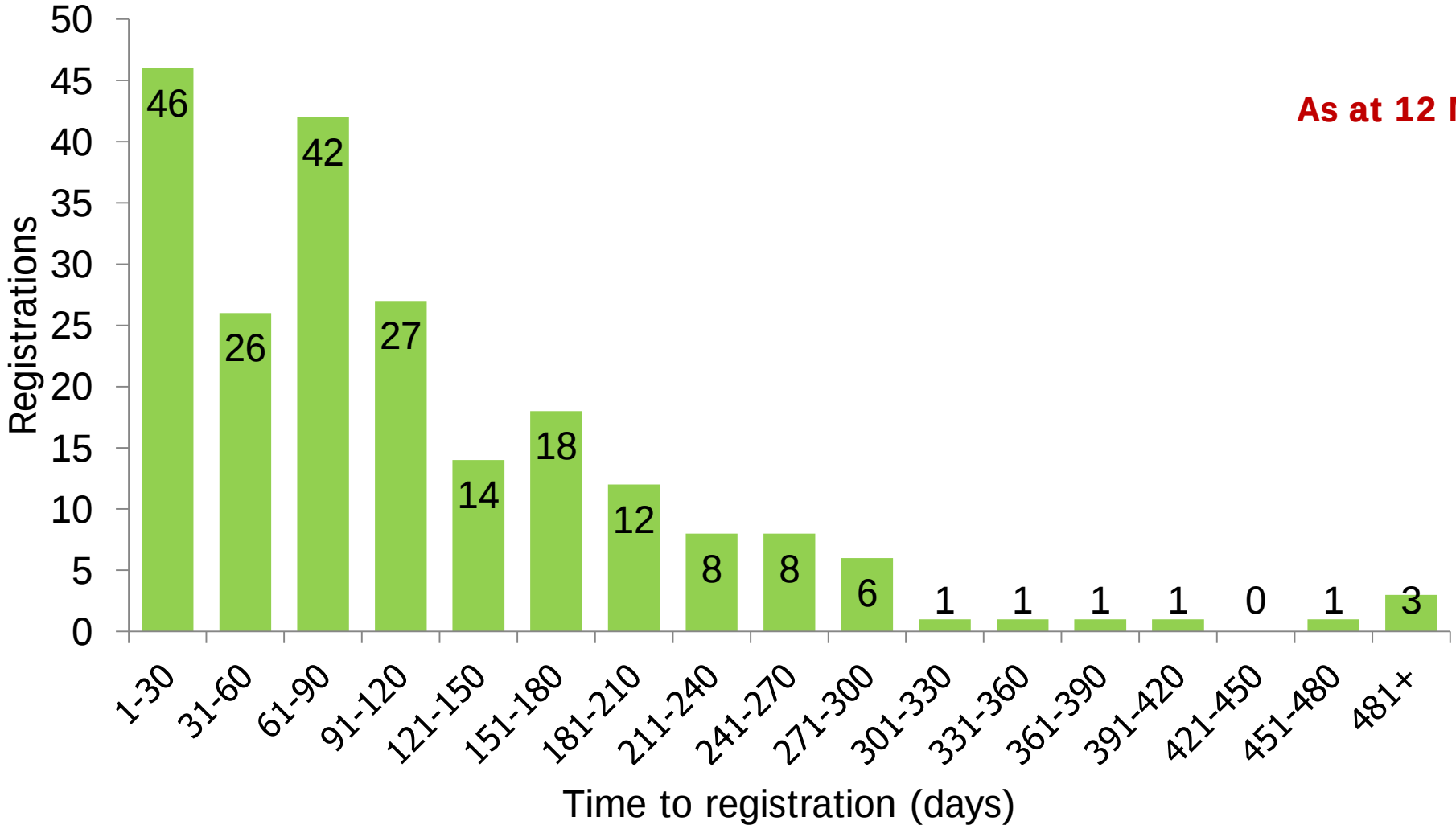


As at 12 May 2017

Time to registration

(to date, n=215 2017 – 2013)

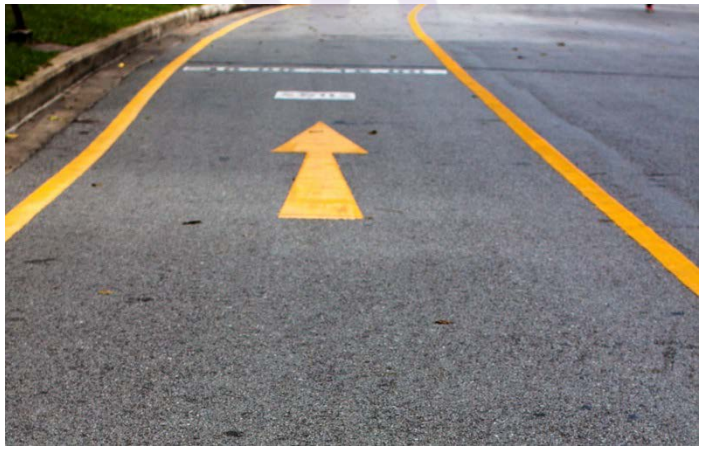
Including regulatory time and applicant time

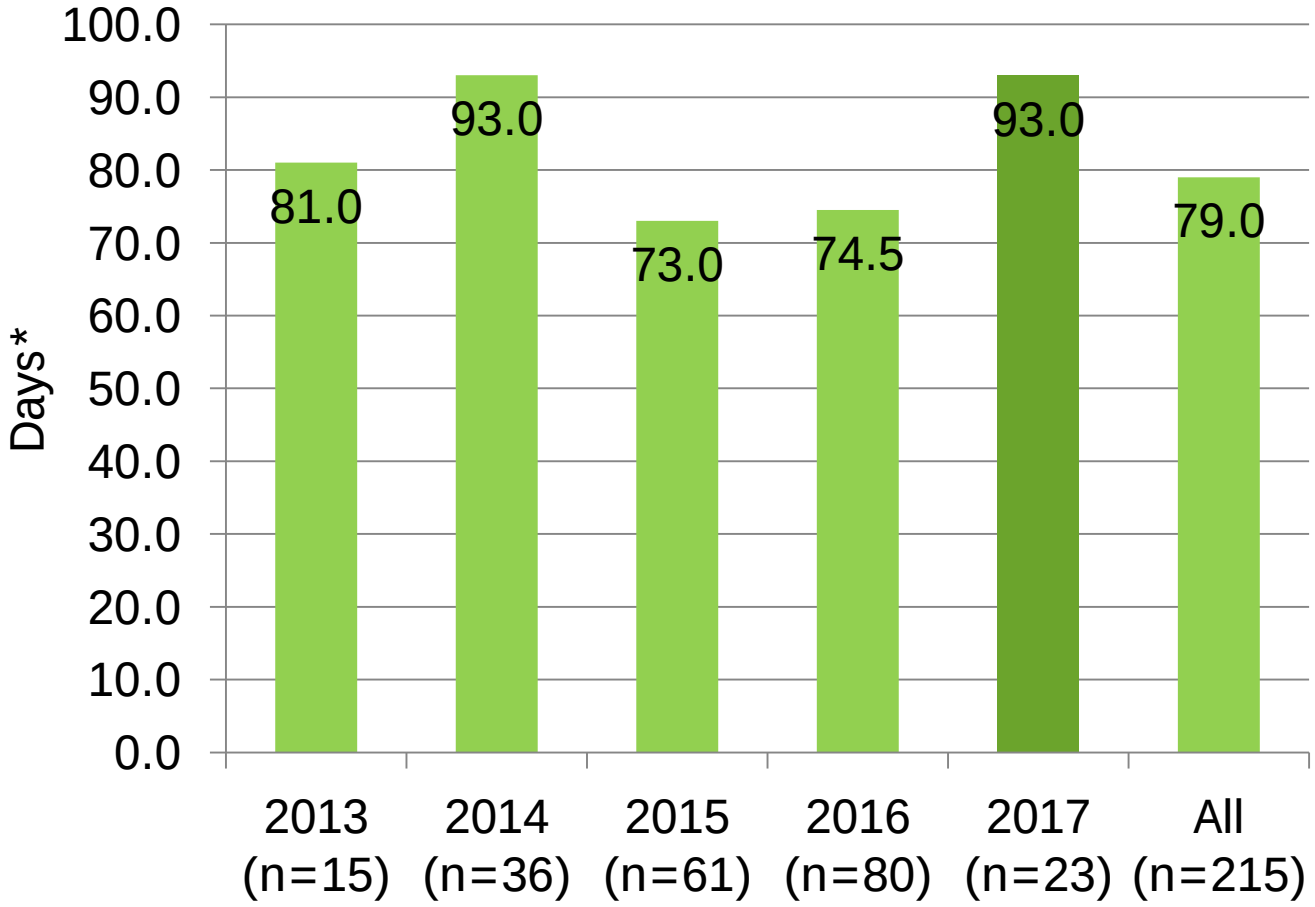


Median time to registration

Including regulatory time and applicant time*

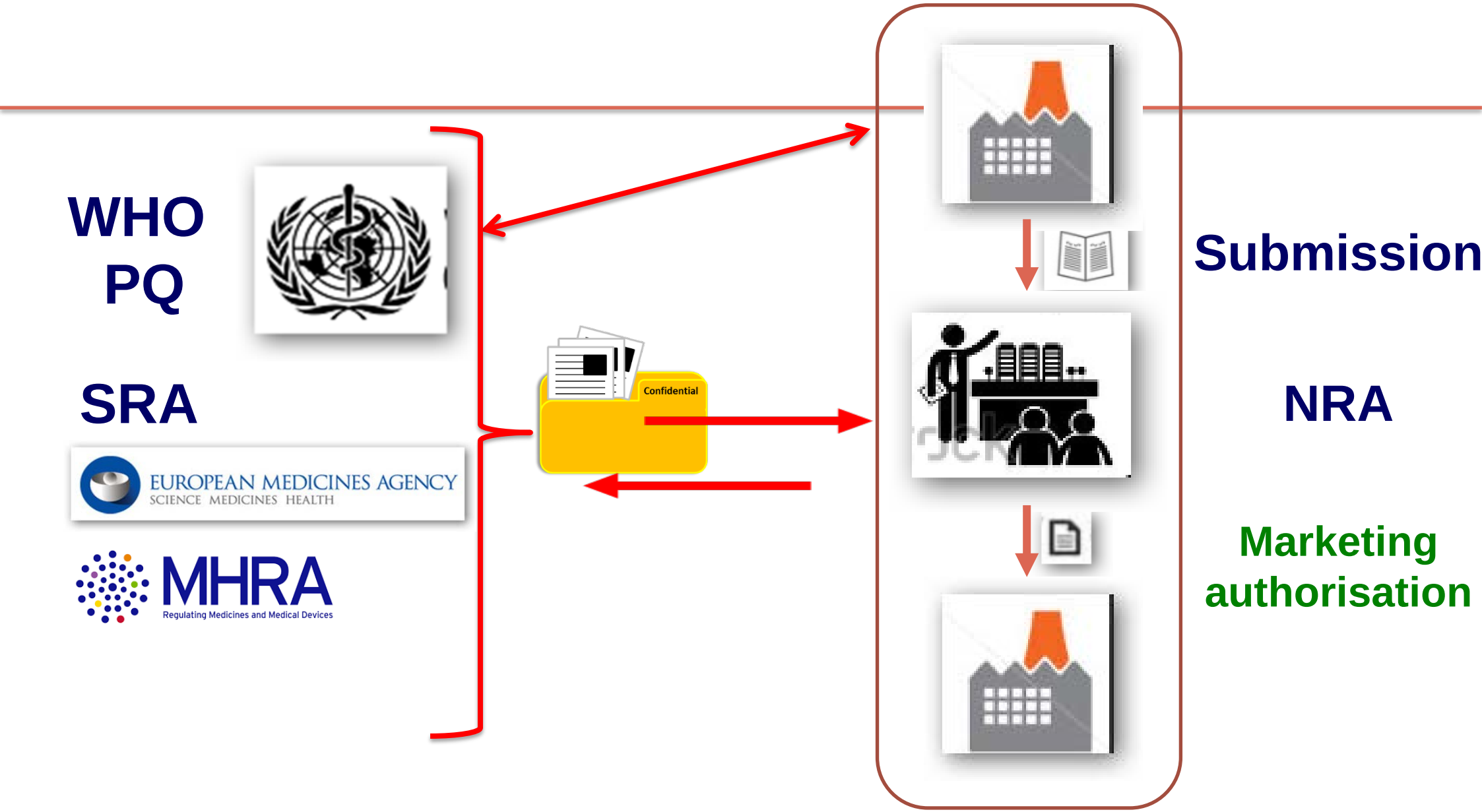
Days





As at 12 May 2017

Pilot SRA Collaborative Procedure

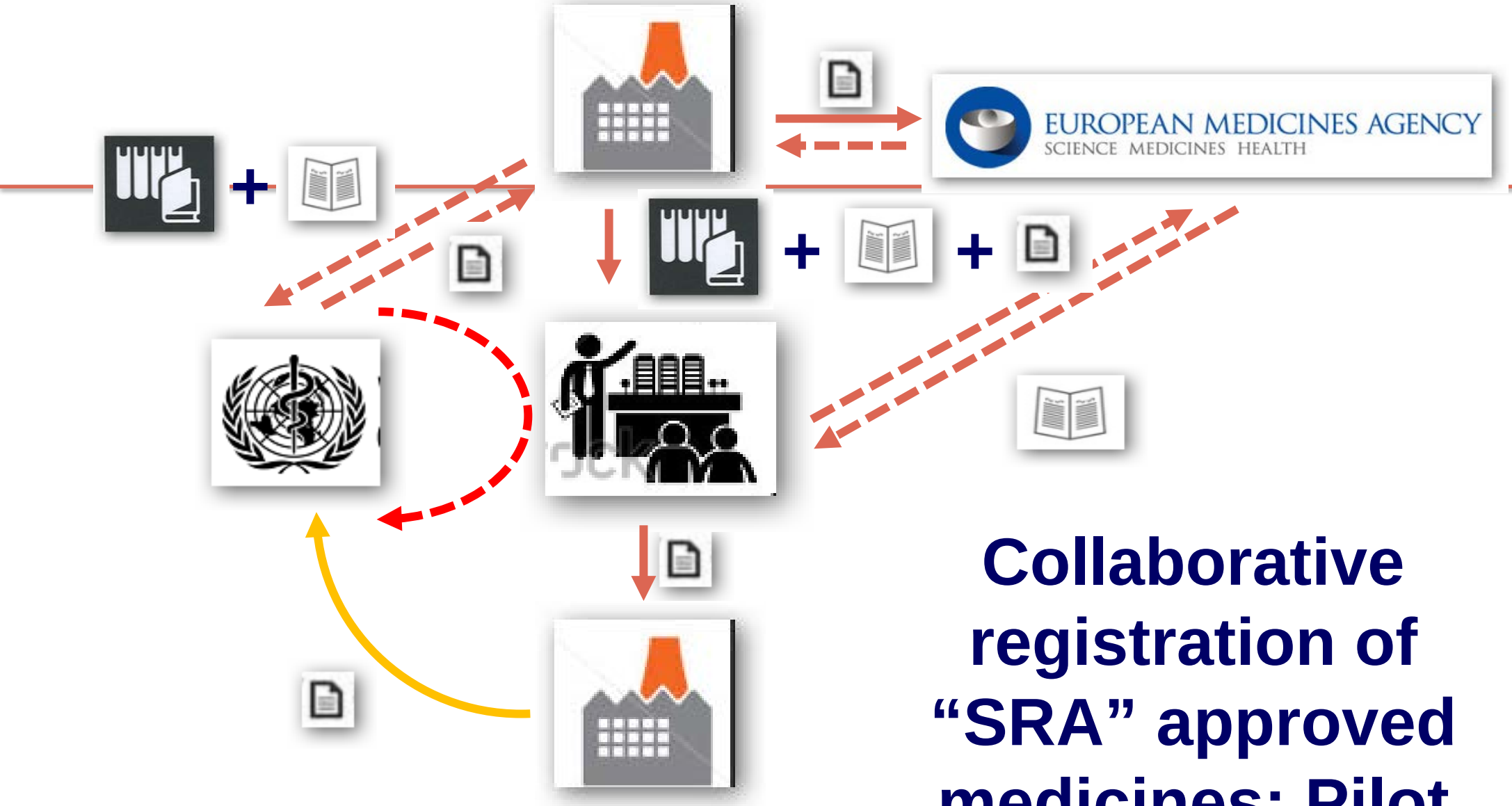

WHO
PQ
SRA
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
MHRA
Regulating Medicines and Medical Devices
Confidential
Submission
NRA
Marketing
authorisation

SRA Collaborative Procedure

- Platform serving to all kinds of medicines
    - Generics and innovators
    - Different therapeutic categories
    - Both authorized medicines and those with special status (e.g. EU Art.58, PEPFAR)
- Internationally applicable without interference with national legislation
- Aiming to support regulatory collaboration, networking, work-sharing, harmonization and capacity building

KEY Principles of SRA Collaborative Procedure

- Voluntary
- 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



Collaborative registration of "SRA" approved medicines: Pilot Scheme

WHO as a facilitator

- Facilitation of agreements with NMRAs and SRAs
- Selection of products deserving special attention
- Organization of assisted assessment meetings with participation of relevant experts
- Quality assurance and facilitation of common national positions and questions to applicants
- Facilitation of communication between applicants for registration and NMRAs
- Progress monitoring and problem solving
- Collection of experience to improve the process

Experience

- Improved registration timelines
- EMA consolidated assessment reports do not provide sufficient details in Q part
  - **QIS recognized as an important instrument. Verification of QIS by SRA can be useful**
  - **Bridging report is useful for innovative products**
- Agreement on common list of questions among countries is possible


If you want to go quickly, go alone.
If you want to go far, go together. ~
African proverb

Additional slides - backup

Step 1 of CRP

Appendix 1

Agreed and accepted for pharmaceutical products and vaccines.

Nationa
and und
focal po

Appendix

Agreement
Health Org
regulatory
registration

WHO Technical Report Series No. 996, 2016

For the NRA

Signature: _____

Name: _____

Title: _____

Place and date: _____

Attachments:

Signed Undertaking(s) of NRA focal point(s) (Appendix 1, Part B)

Focal point for inspections

If applicable, this should be the same focal point as for the "WHO/PQT Collaborative Procedure with NRAs in inspection activities" (http://who.int/prequal, "Inspections"). The same person should be designated for inspections of pharmaceutical products and vaccines

1.
Mr/Ms/Dr
First name (
Surname/fai
Title in NRA
Email: ____
Telephone:
☐ A signed

Focal point(s) for dossier assessment

For dossier assessment, different persons can be nominated for pharmaceutical products and vaccines. The same person may be nominated to be the focal point for inspections and dossier assessment. If additional person(s) are nominated for dossier assessment, please complete the details below.

2.
Mr/Ms/Dr as a focal point for dossier assessment of
pharmaceutical products only ☐
pharmaceutical products and vaccines ☐
First name (and initials): _____
Surna
Title i
Email
Telepl
☐ A s

3.
Mr/Ms/Dr as a focal point for dossier assessment of vaccines
First name (and initials): _____
Surname/family name: _____
Title in NRA: _____

Appendix 1, Part B

Undertaking for NRA focal point(s)

The undersigned:

Mr/Ms/Dr

First name (and initials): _____

Surname/family name: _____

Title in NRA: _____

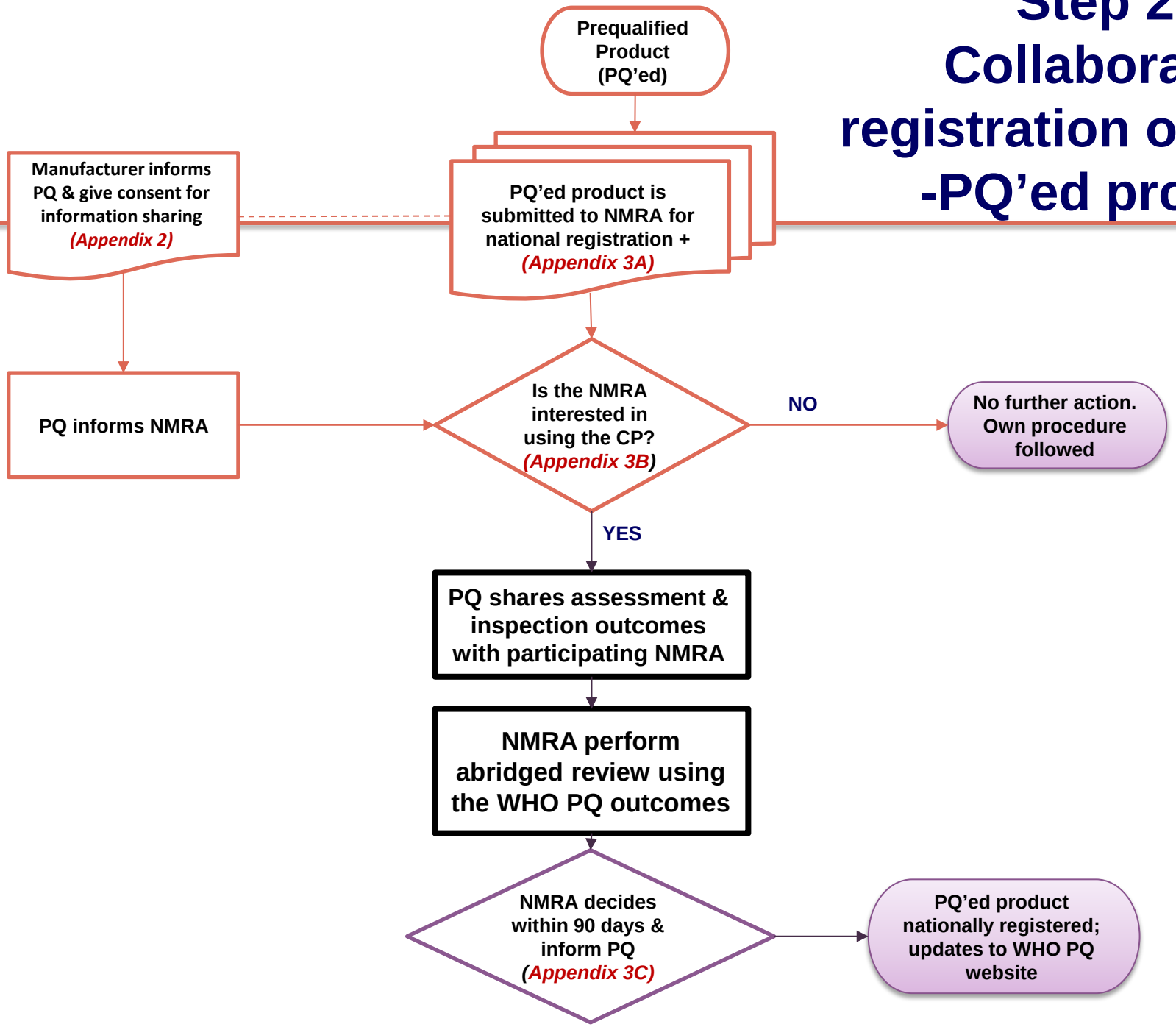
Name of NRA: _____ ("the NRA")

Country: _____ ("the Country")

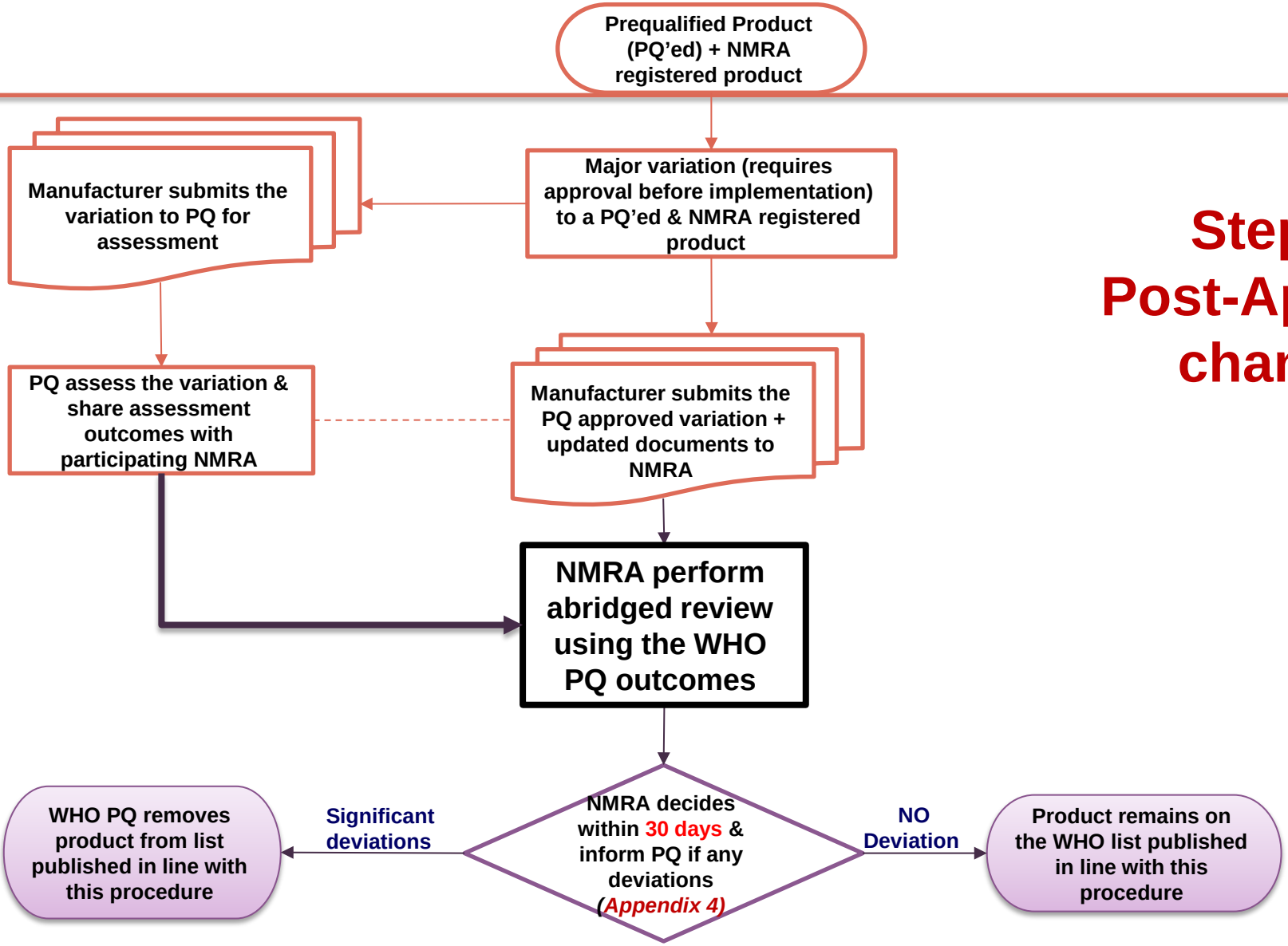
Email: _____

Telephone: _____

Step 2: Collaborative registration of a WHO -PQ'ed product



Step 3: Post-Approval changes



Step 4
Registration Maintenance