WHO collaborative registration procedure to assure access to modern DR-TB medicines

World Health Organization
REGIONAL OFFICE FOR Europe

Webinar of the Collaborating Network

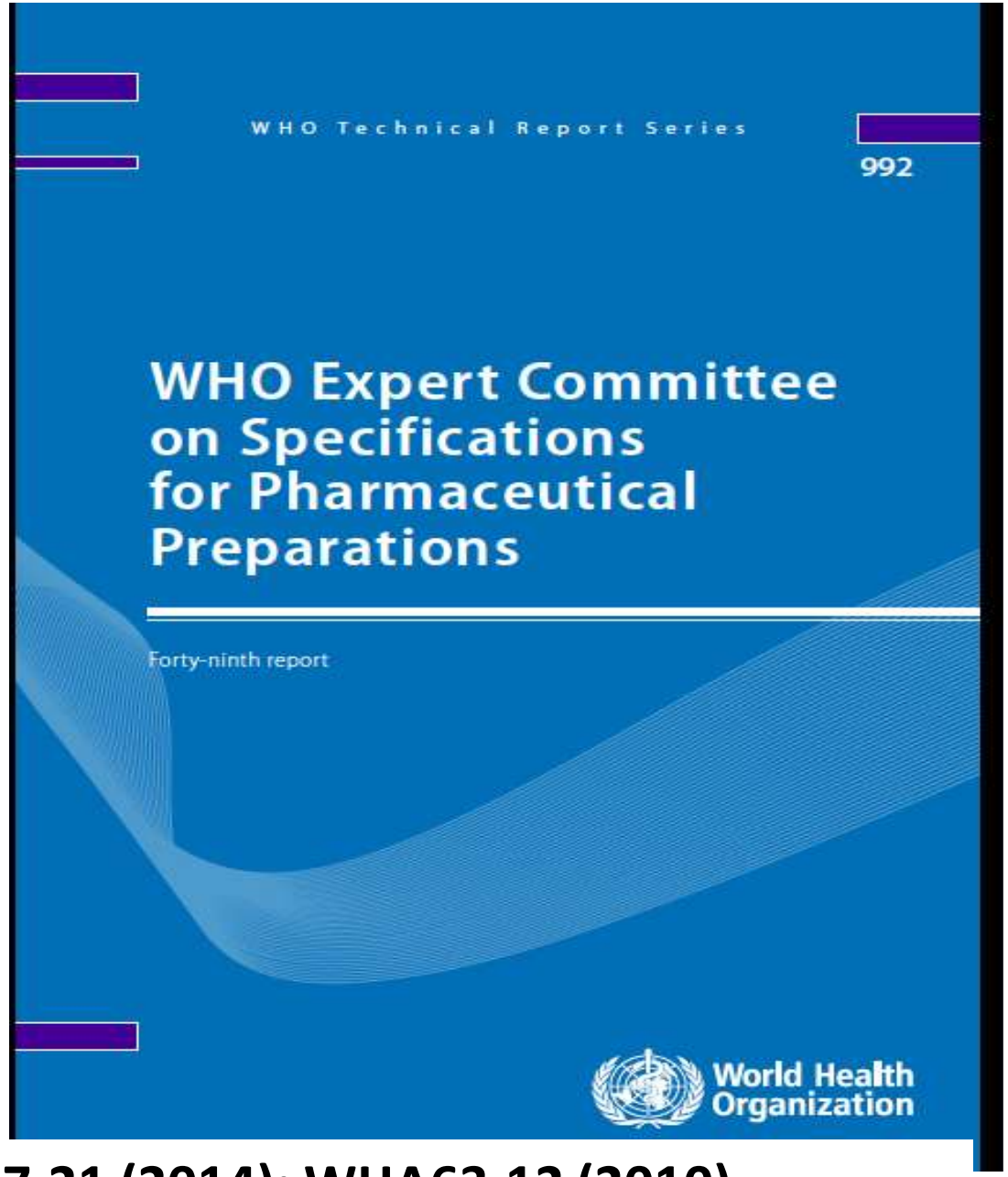
December 2, 2020

All pharmaceutical products, including multisource products, should be used in a country **only after approval** by the national or regional authority. Regulatory authorities should require the documentation of a multisource pharmaceutical product to meet the following:

— GMP;

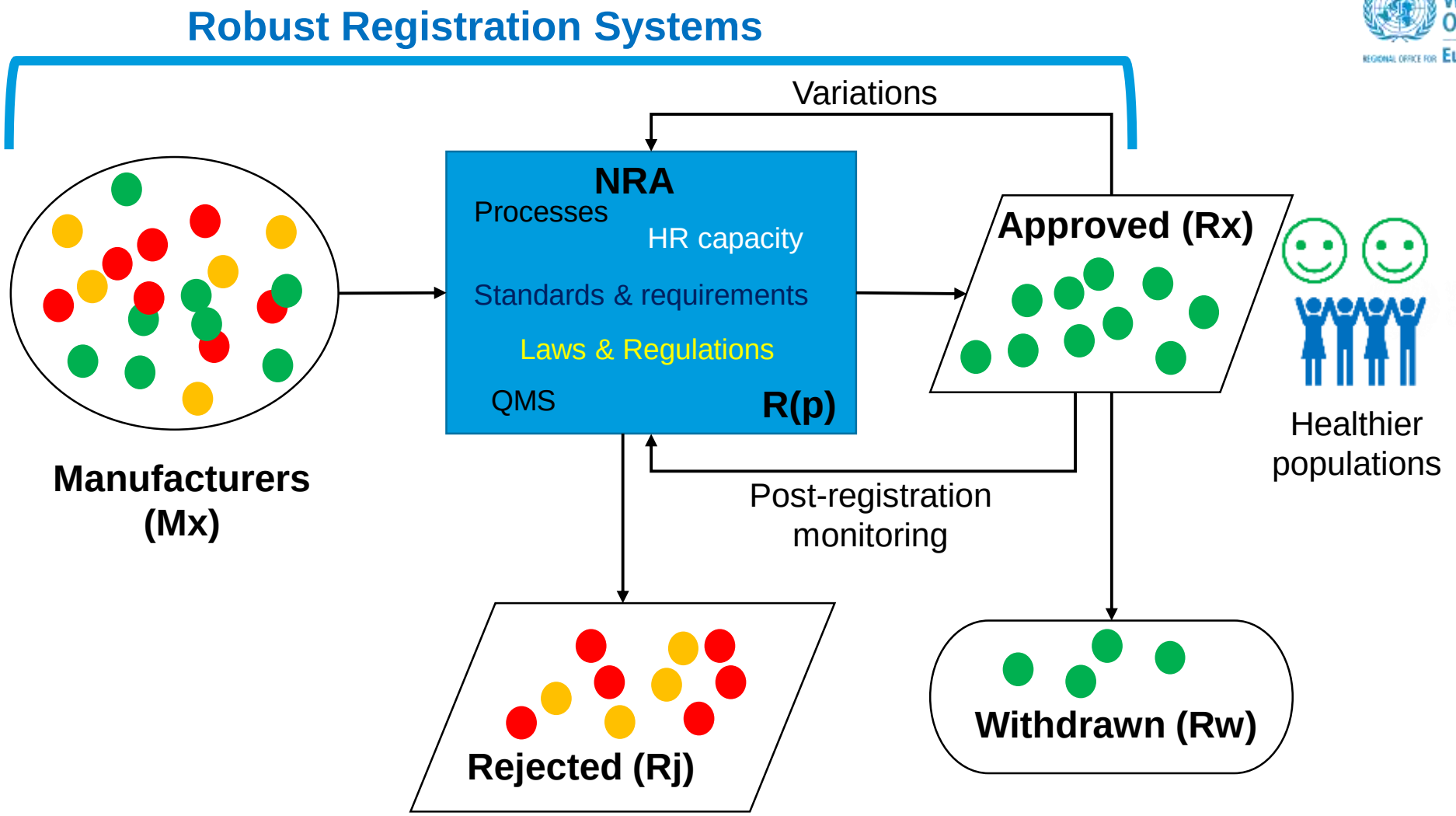
— QC specifications;

— **pharmaceutical product interchangeability**



WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010)

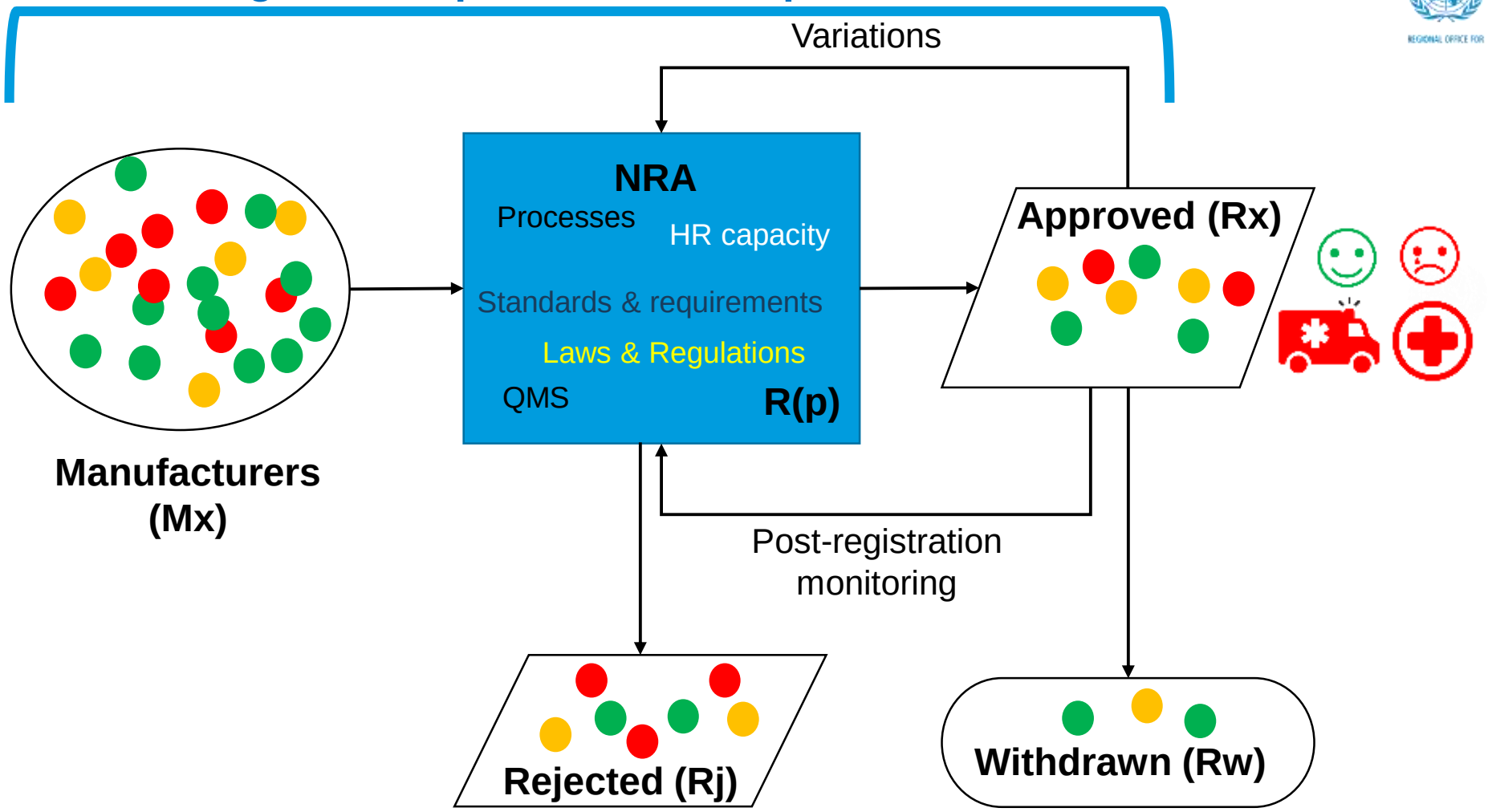
IDEAL SITUATION



Medicines Regulation Process Flow

REALITY

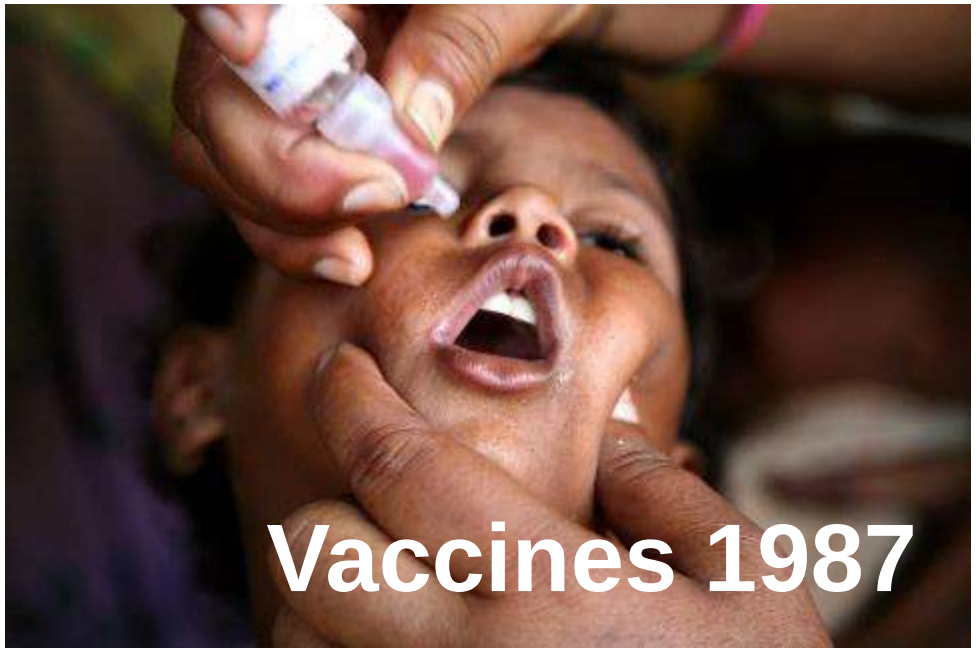
Registration processes not optimized



Medicines Regulation Process Flow

WHO Prequalification

In vitro Diagnostics 2010
HIV test kit evaluation 1988



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

WHO PQ Process

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INPUTS

Expression of Interest

Dossier

WHO Guidelines

Assessors/ Inspectors

Testing

PROCESS

Assessment of Dossier

+

Inspections (API, FPP, CRO)

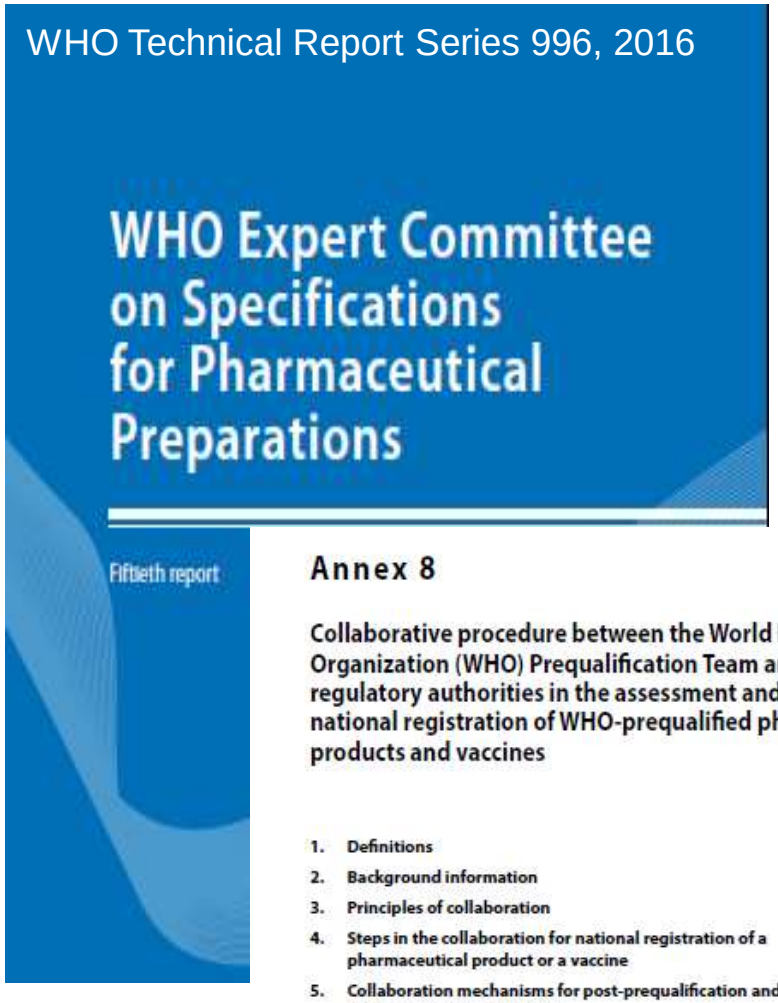
Assessment/ Inspection/Lab Reports

OUTPUTS

List of Prequalified products

WHO Public Reports

WHO Technical Report Series 996, 2016

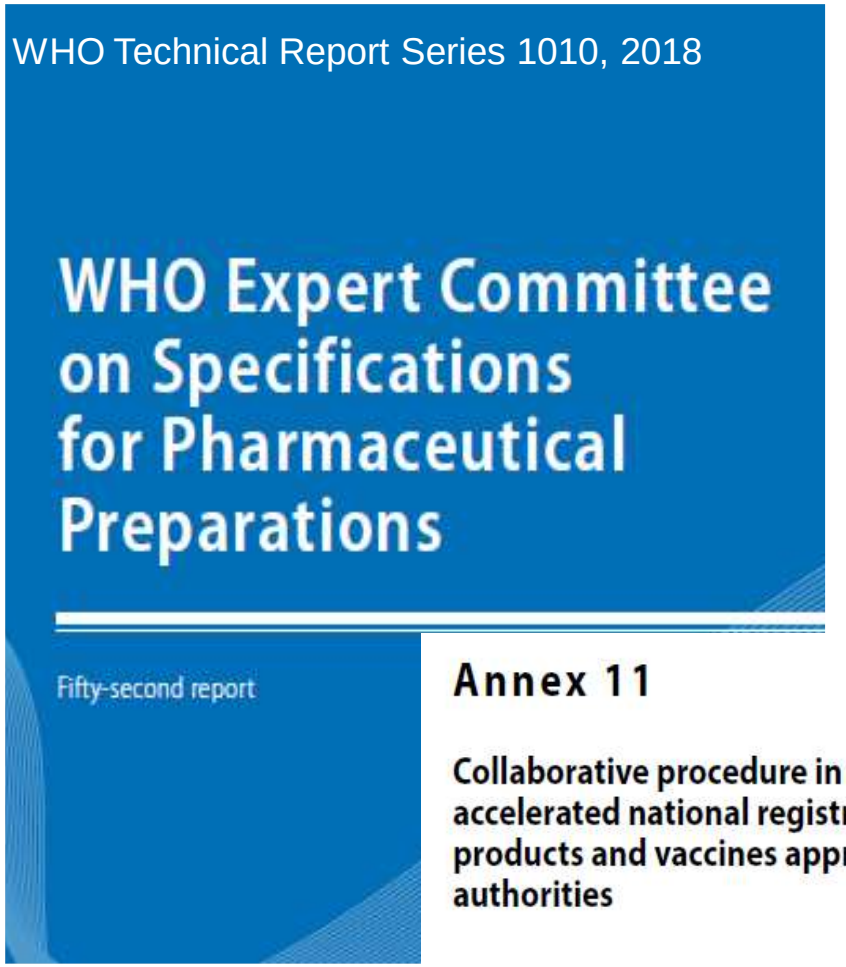


Annex 8

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

http://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1

WHO Technical Report Series 1010, 2018



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Annex 11

Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

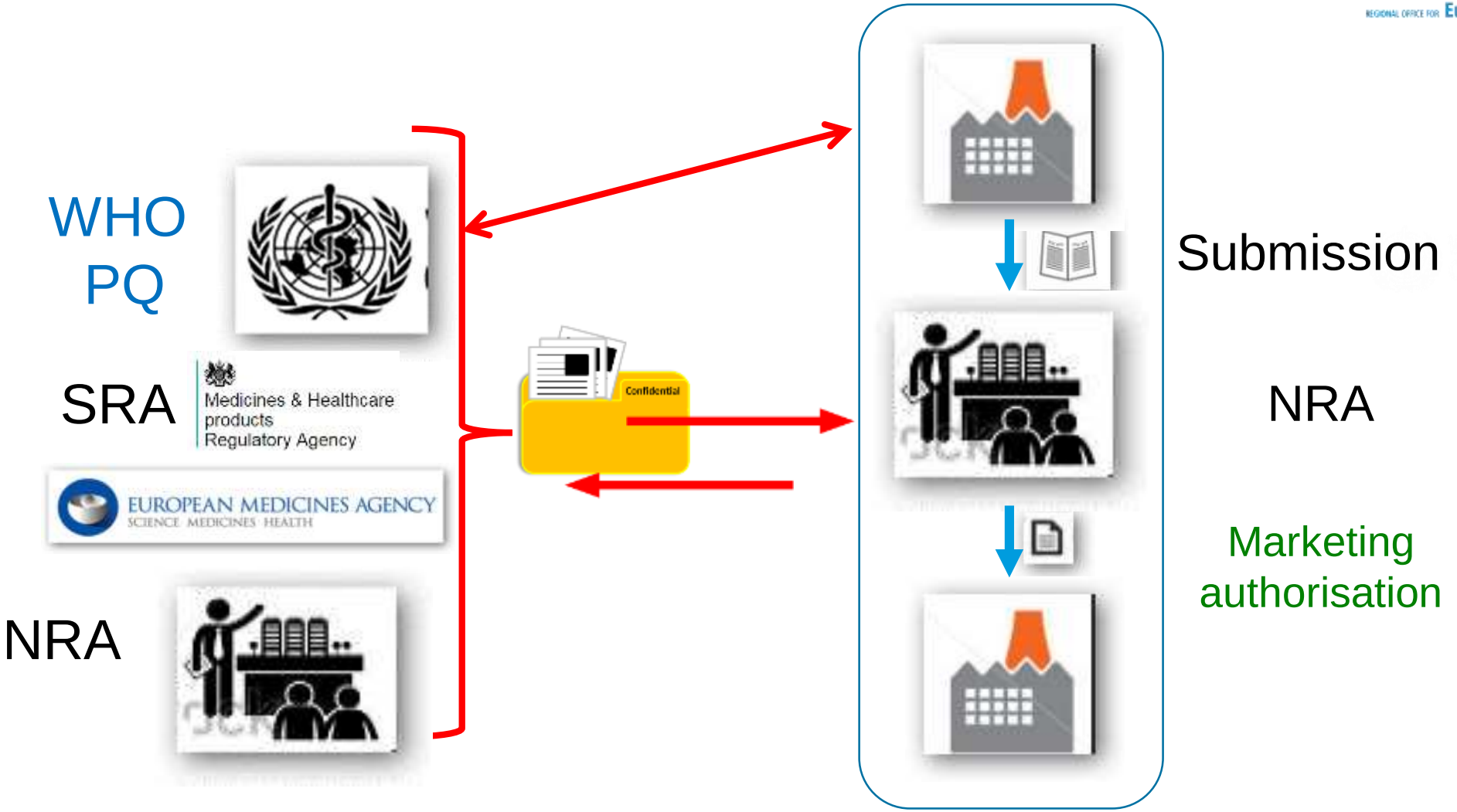
http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf?ua=1

Concept of facilitated registrations (Reliance)

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)
- Having the same product
- Having same essential technical data
- National legislation and sovereignty are not affected
- Respect confidentiality of commercially sensitive information
- Manage properly regulatory follow-up

How does the collaborative procedures works?



Win-win outcomes for all stakeholders

NRAs

- Having data well organized in line with PQ requirements
- Availability of unredacted WHO assessment and inspection outcomes to support national decisions and save internal capacities
- Having assurance about registration of 'the same' product as is prequalified (in this case, US FDA approved/tentatively approved products)

Manufacturers

- Harmonized data for PQ and national registration
- Facilitated interaction with NRAs in assessment, inspections
- Accelerated and more predictable registration
- Easier post-registration maintenance

WHO

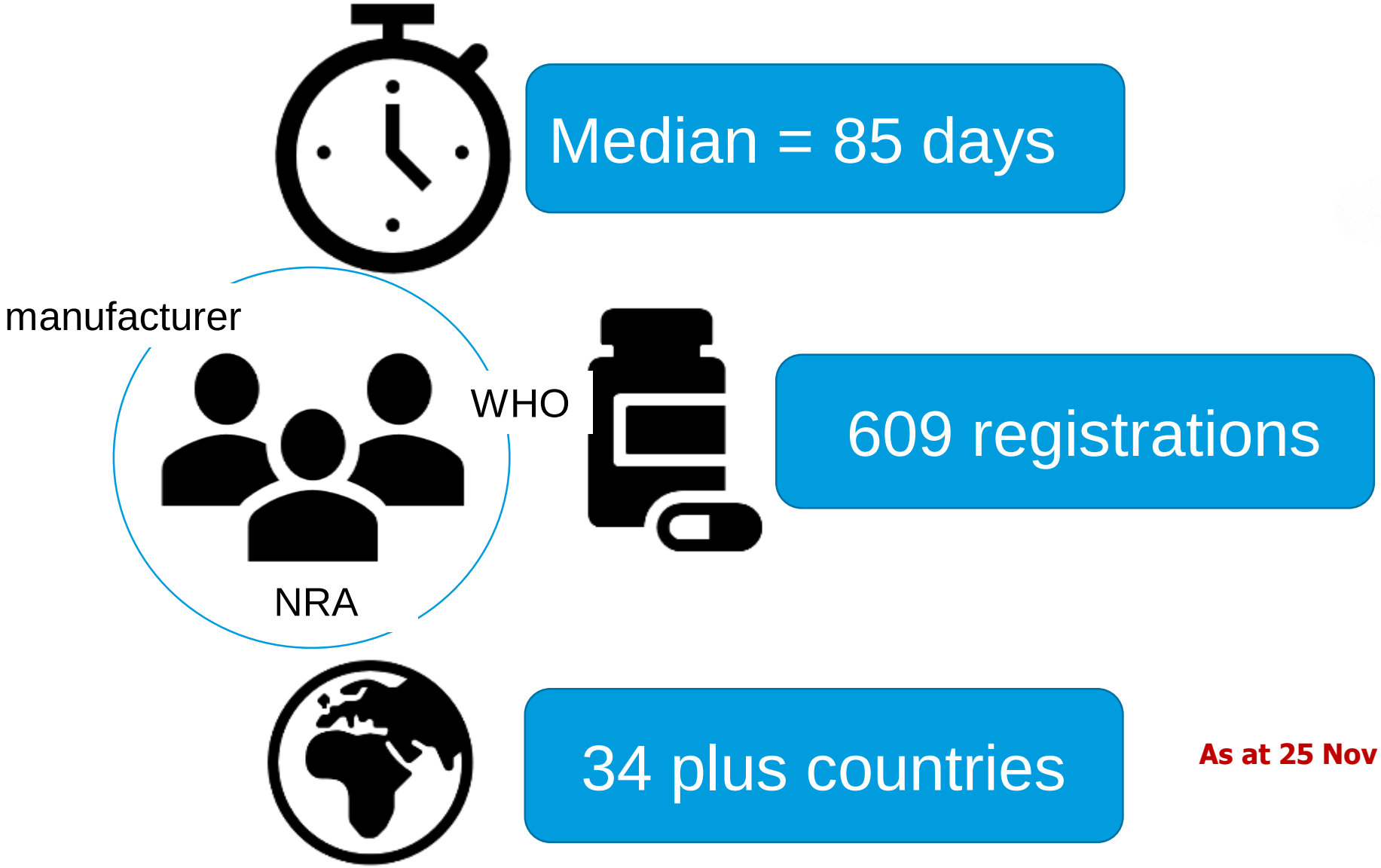
- Prequalified products are faster available to patients
- Feed-back on WHO prequalification outcomes

Procurers

- Time,
- Assurance,
- Availability

NTP

WHO PQ CRP



As at 25 Nov 2020

https://extranet.who.int/prequal/content/collaborative-registration-faster-registration

Participating NRAs

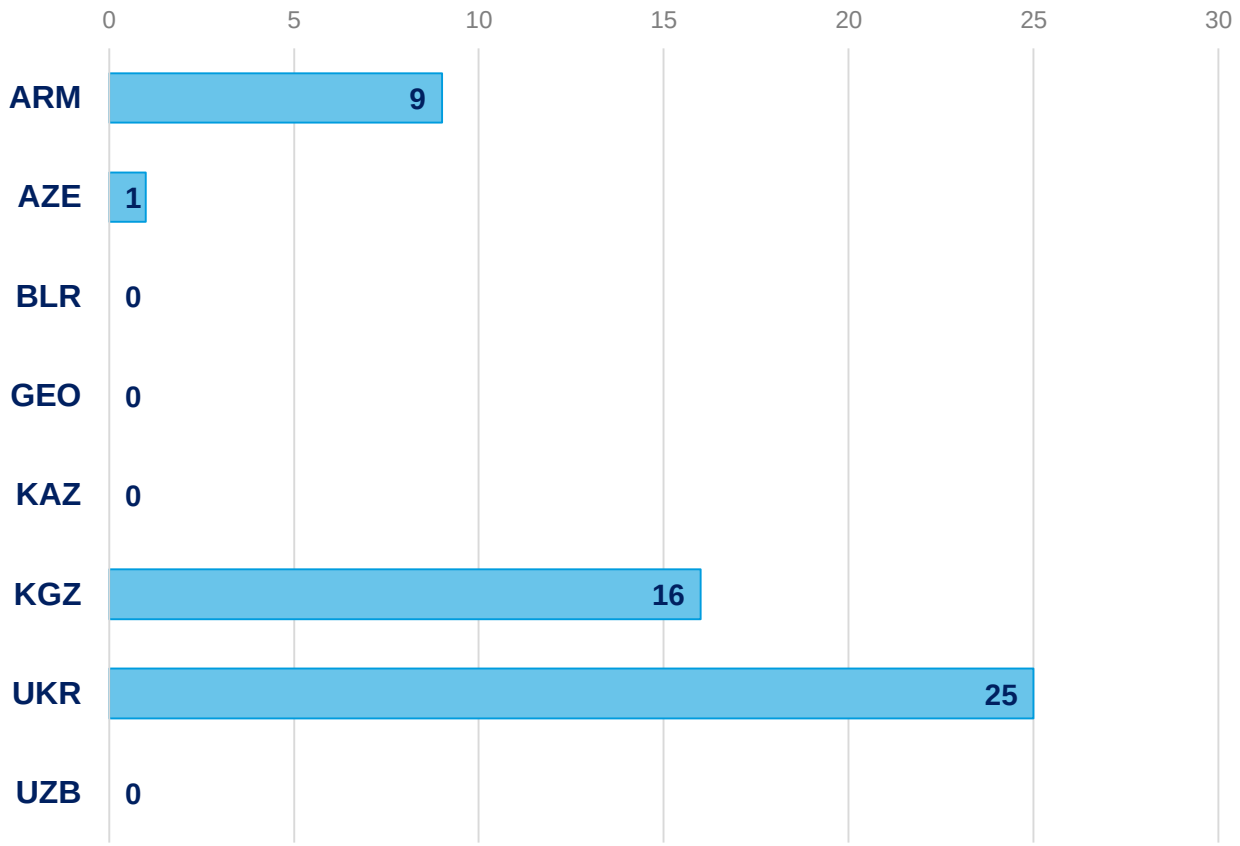
- **Armenia**
- **Azerbaijan**
- **Belarus**
- Bhutan
- Botswana
- Burkina Faso
- Burundi
- Cameroon
- Caribbean Community (CARICOM)
- Comores
- Côte d'Ivoire
- Democratic Republic of the Congo
- Eritrea
- Ethiopia
- **Georgia**
- Ghana
- **Kazakhstan**
- Kenya
- **Kyrgyzstan**
- Lao People's Democratic Republic
- Madagascar
- Malawi
- Malaysia
- Mali
- Mozambique
- Namibia
- Nigeria
- Pakistan
- Philippines
- Rwanda
- Senegal
- Sierra Leone
- South Africa
- Sri Lanka
- Sudan
- Tanzania
- Thailand
- Togo
- Uganda
- **Ukraine**
- **Uzbekistan**
- 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

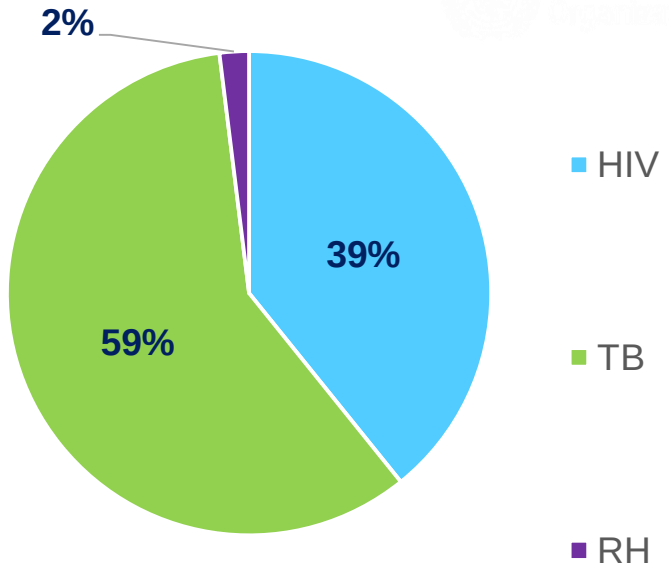
As at 1 Dec 2020

WHO European Region

Countries



Therapeutic area



Total registrations: 51 (As at 25 Nov 2020)

Thank you

WHO Regional Office for Europe

UN City
Marmorvej 51
Copenhagen Ø
Denmark

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Organisation mondiale de la Santé
BUREAU RÉGIONAL DE L' Europe

Всемирная организация здравоохранения
Европейское региональное бюро