WHO collaborative registration procedure

World Health Organization
REGIONAL OFFICE FOR Europe

Webinar of the Collaborating Network

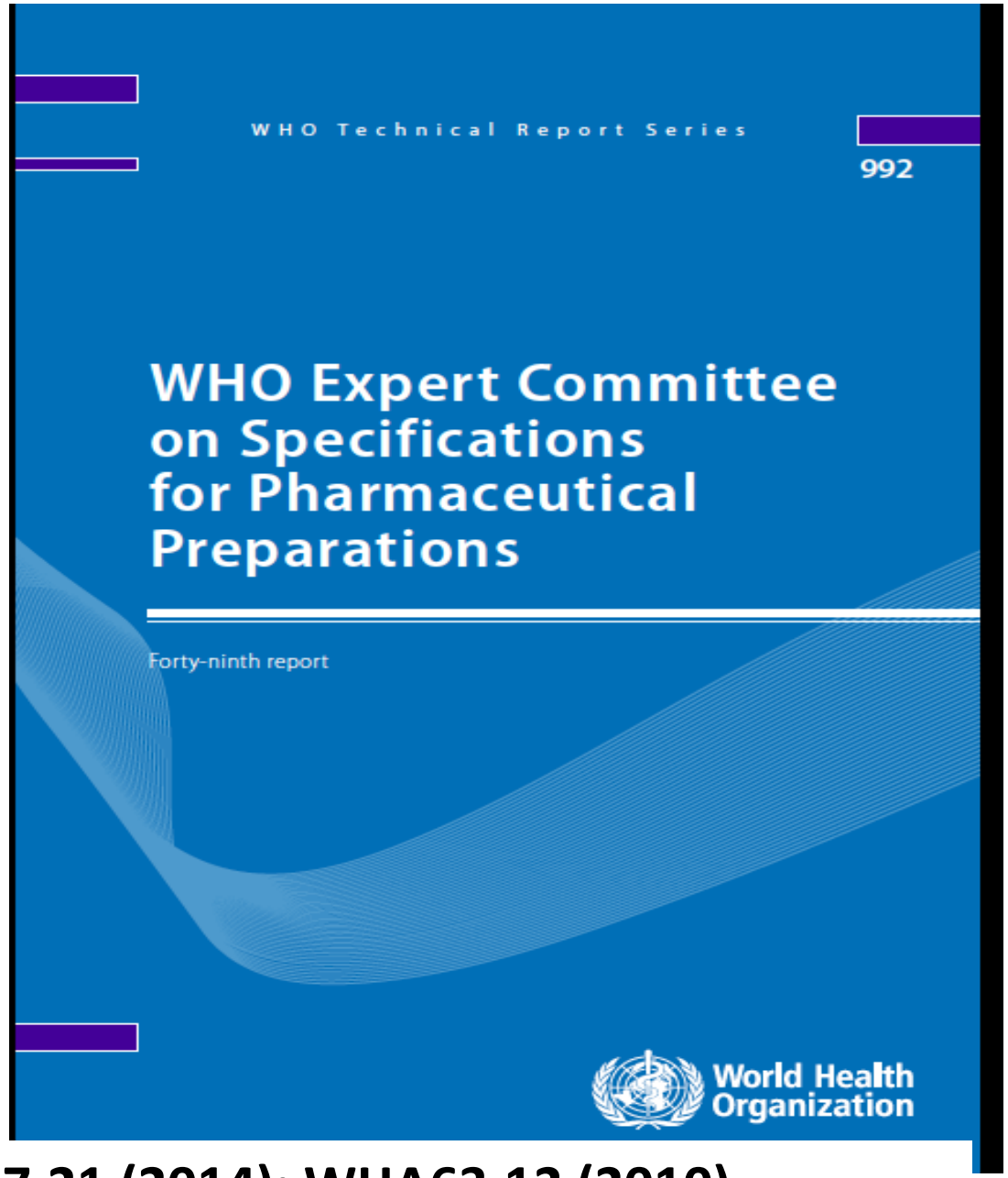
December 7, 2021

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)

WHO Prequalification

In vitro Diagnostics 2010
HIV test kit evaluation 1988

World Health Organization
REGIONAL OFFICE FOR Europe

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

WHO PQ Process

World Health Organization
REGIONAL OFFICE FOR Europe

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 PQ Collaborative Registration Procedure

(Collaborative Procedure Between WHO and National Regulatory Authorities in the Assessment and Accelerated National Registration of WHO-prequalified Pharmaceutical Products and Vaccines)

The procedure has been developed to:

- enhance *timely access to prequalified products in countries*;
- to ensure that the product in countries *is the same as the one which is prequalified* and to provide a model for regulatory information exchange among countries;
- first piloted in June 2012 and is currently in use;
- also benefits manufacturers of prequalified pharmaceutical products and vaccines through faster and better harmonized regulatory approvals in participating countries.

KEY Principles of the Collaborative Procedure

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

Steps of the procedure:

Agreement

- NRA confirms to WHO PQT its interest to participate in collaborative procedure and respect its conditions;
- One or two focal persons are designated at each interested NRA, sign confidentiality undertaking and are given access to the WHO managed restricted access platform (MedNet).

Registration

- Manufacturer submits MA application to participating NRA for the PQ-ed medicine and informs the authority about the interest to follow the collaborative procedure. Same data submitted as for PQ;
- Manufacturer informs WHO PQT about the application for national registration and, for each product, provides written agreement to exchange of information between the participating NRA and WHO PQT;

Steps of the procedure: Registration

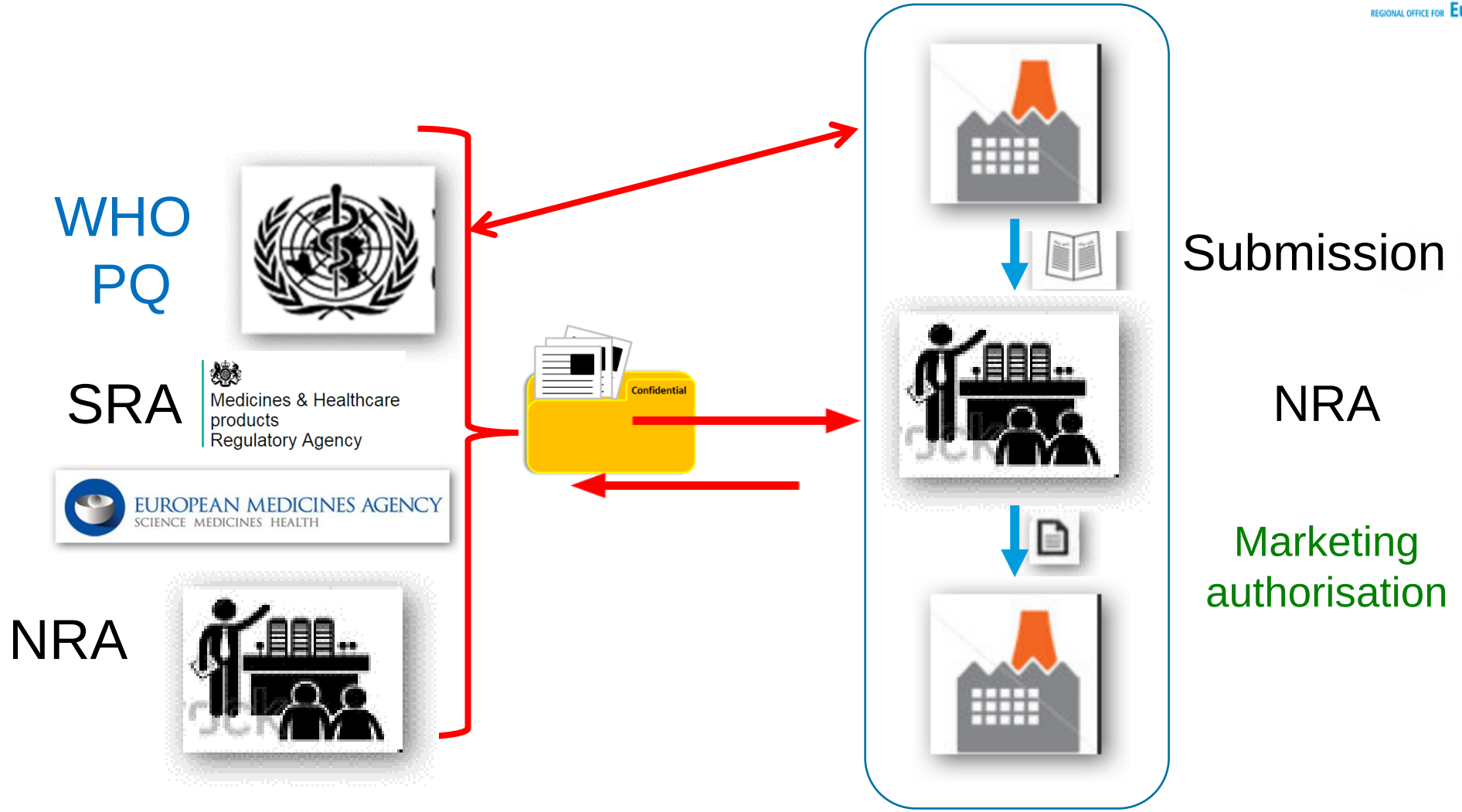
- Participating authority confirms to WHO PQT its interest to apply the procedure for given medicinal product;
- Within **30 days**, WHO PQT provides focal person (s) in the participating NRA with assessment and inspection reports via restricted-access website (MedNet) and provides additional explanation, if requested;
- **Within 90 days** participating NRA decides upon the national registration, informs WHO PQT about the outcome of national registration and, when divergent from PQT decision, provides explanations;
- **Within 30 calendar days** of having taken its decision, the participating authority informs WHO/PQT and the applicant of this decision;
- WHO PQT **lists products registered by participating NRAs** according to this procedure on its public website.

Concept of facilitated registrations (Reliance)

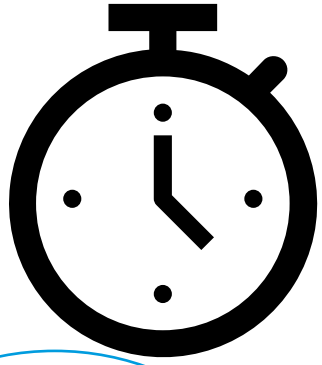
To support the national registrations, regulators can benefit from already organized scientific assessments and inspections, if

- 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

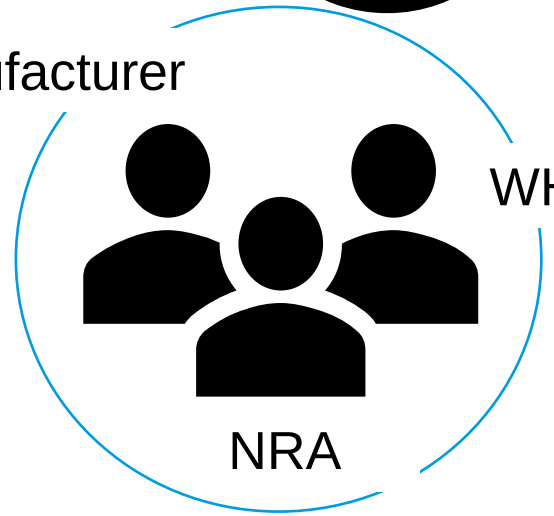
How does the collaborative procedures works?



WHO PQ CRP



Median = 85 days



695 registrations + 83 new

36 plus countries + 2 new

2 Jul 2021

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

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)

WHO

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

Manufacturers

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

Procurers

- Time,
- Assurance,
- Availability
- Faster start of procurement and wider availability of PQ medicines;
- Assurance about "the same' medicine as is prequalified.

WHO Technical Report Series 996, 2016

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Fiftieth report

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

WHO Expert Committee on Specifications for Pharmaceutical Preparations

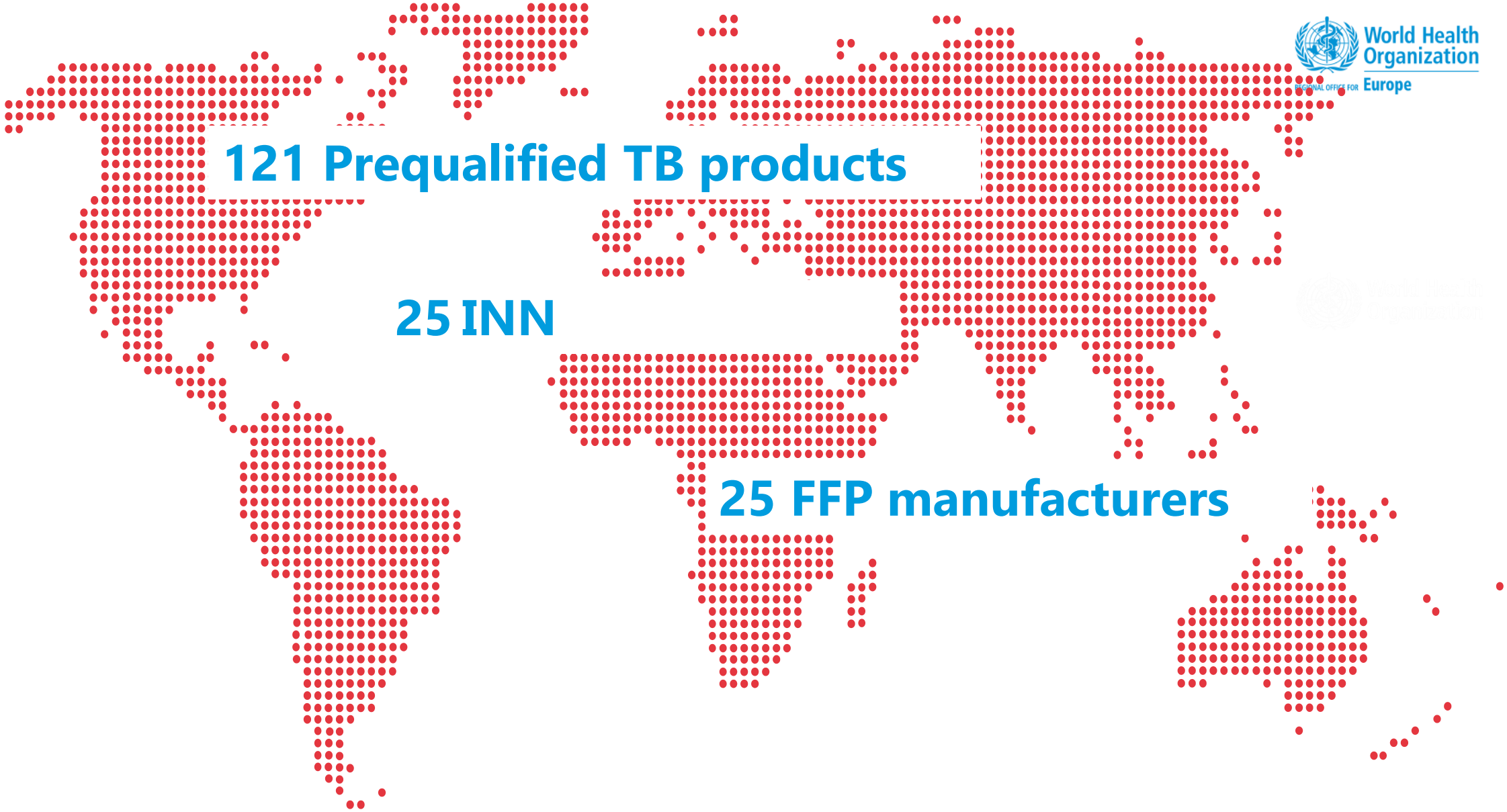
World Health Organization
REGIONAL OFFICE FOR Europe

Fifty-second report

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



World Health Organization
REGIONAL OFFICE FOR Europe

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

Participating NRAs

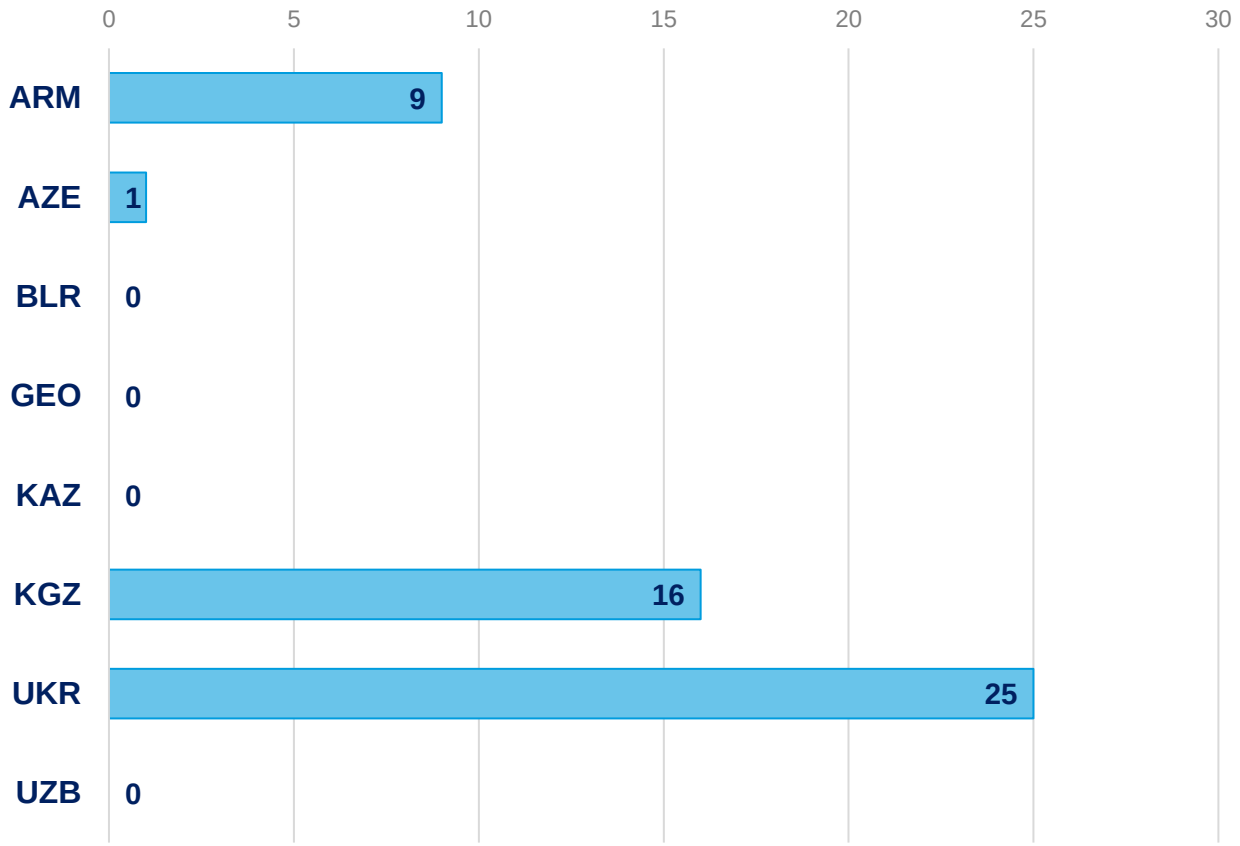
- **Armenia**
- **Azerbaijan**
- **Belarus**
- Bhutan
- Botswana
- Burkina Faso
- Burundi
- Cameroon
- Caribbean Community (CARICOM)
- Comores
- Côte d'Ivoire
- Democratic Republic of the Congo
- Eritrea
- Ethiopia
- **Georgia**
- Ghana
- **Kazakhstan**
- Kenya
- **Kyrgyzstan**
- Lao People's Democratic 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

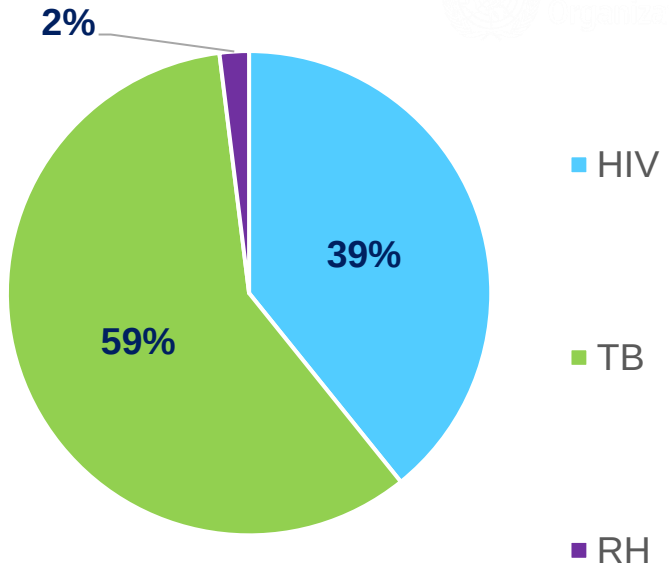
As at 1 Dec 2021

WHO European Region

Countries



Therapeutic area



Total registrations: 51 (As at 6 Dec 2021)

Thank you

WHO Regional Office for Europe

UN City
Marmorvej 51
Copenhagen Ø
Denmark

WHO_Europe

facebook.com/WHOEurope

instagram.com/whoeurope

youtube.com/user/whoeuro

World Health Organization
REGIONAL OFFICE FOR Europe

Weltgesundheitsorganisation
REGIONALBÜRO FÜR Europa

Organisation mondiale de la Santé
BUREAU RÉGIONAL DE L' Europe

Всемирная организация здравоохранения
Европейское региональное бюро