Swissmedic MAGHP Procedure: Progress update and lessons learned

World Health Organization

Overview of collaborative procedures and initiatives to register therapeutic products

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Access to medical products – a global challenge

- WHO Constitution: "…the highest attainable standard of health is a fundamental right of every human being."
- Good health is impossible without access to medical products.
- Universal Health Coverage depends on the availability of quality-assured affordable health technologies in sufficient quantities.
- An estimated **two billion people have no access to essential medicines**, effectively shutting them off from the benefits of advances in modern science and medicine.
- Reasons for limited/insufficient access are numerous – including inadequate regulatory capacity and lack of collaboration and work sharing in medicines regulatory area between countries.

WHO Benchmarking of National Regulatory Authorities (NRAs)

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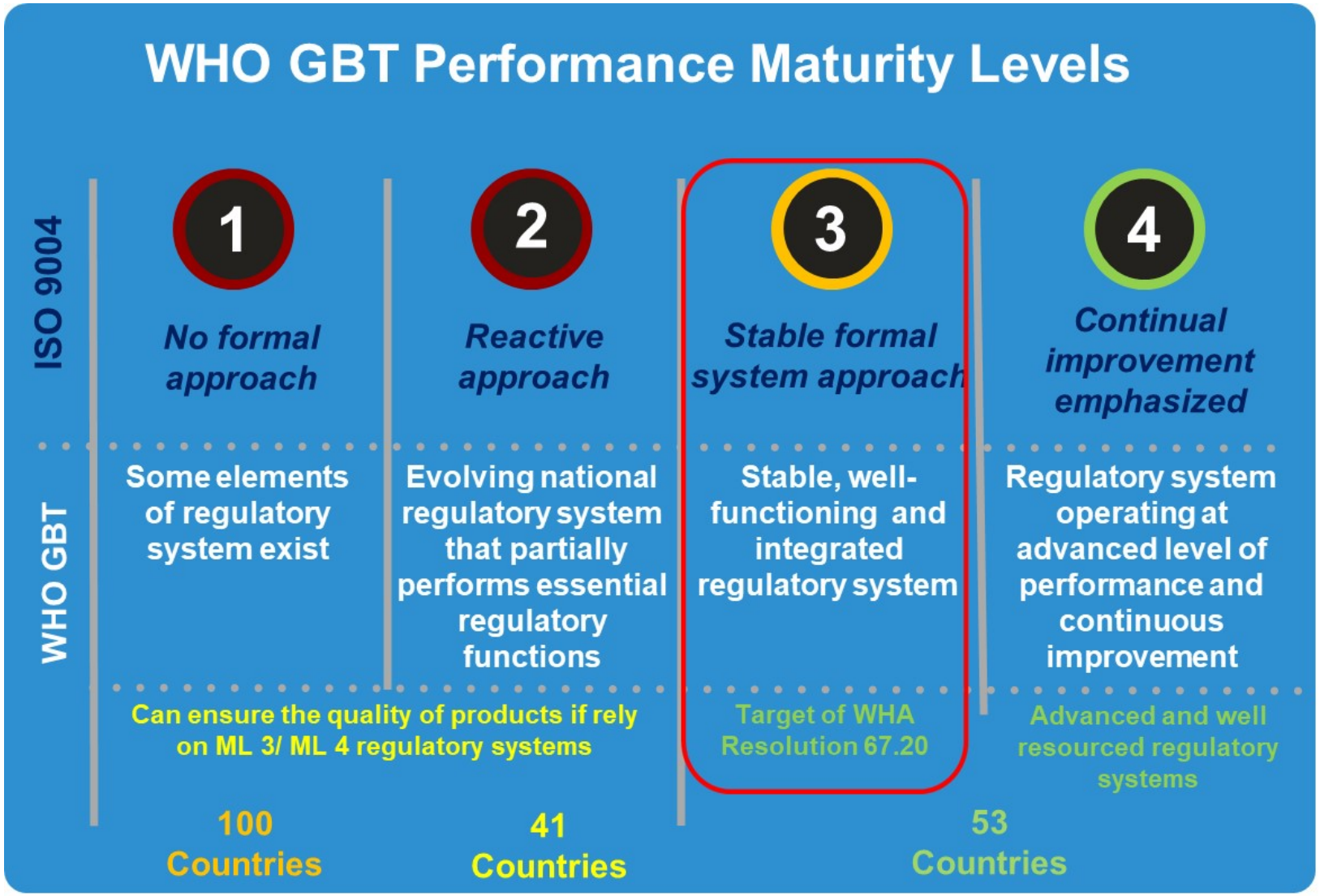

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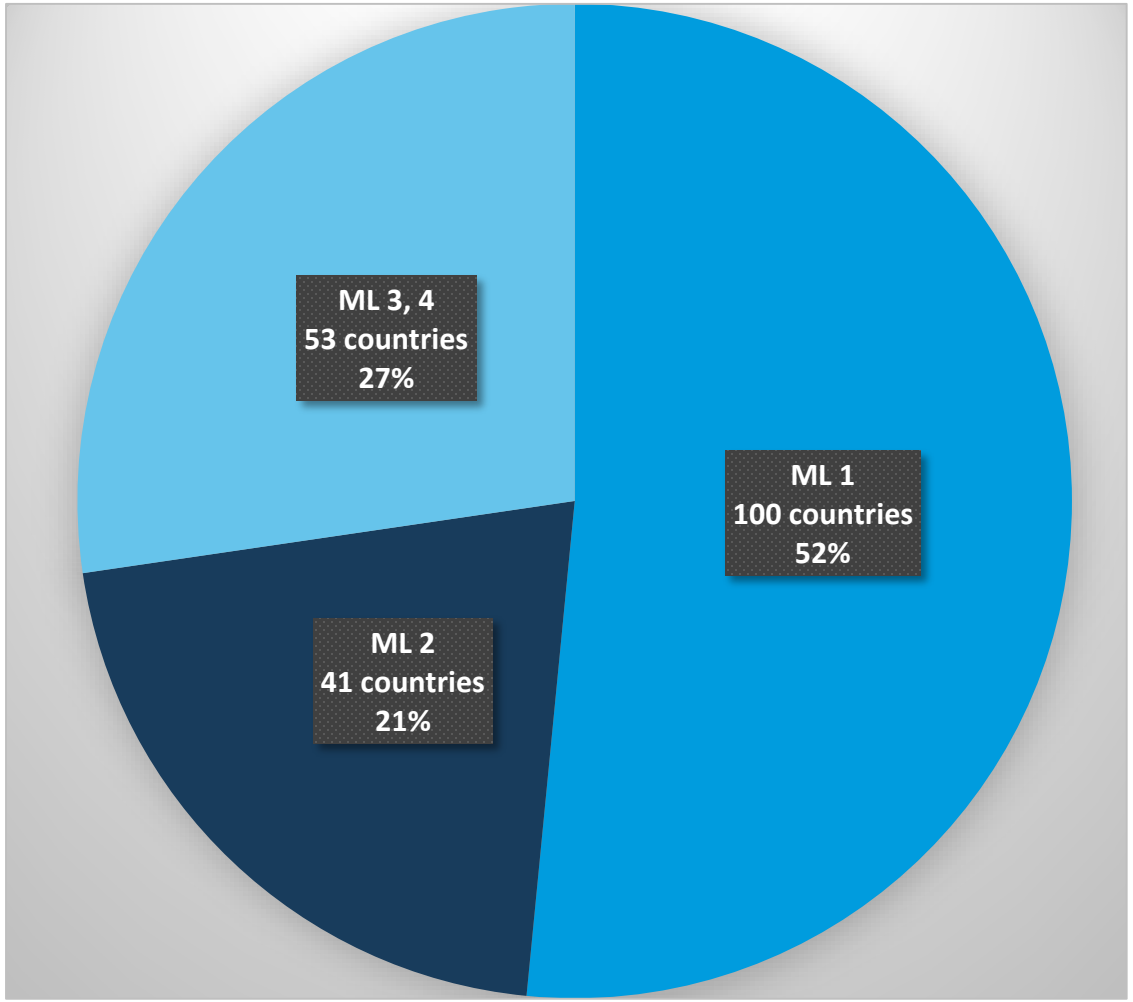
WHO Benchmarking of National Regulatory Authorities (NRAs)



2020

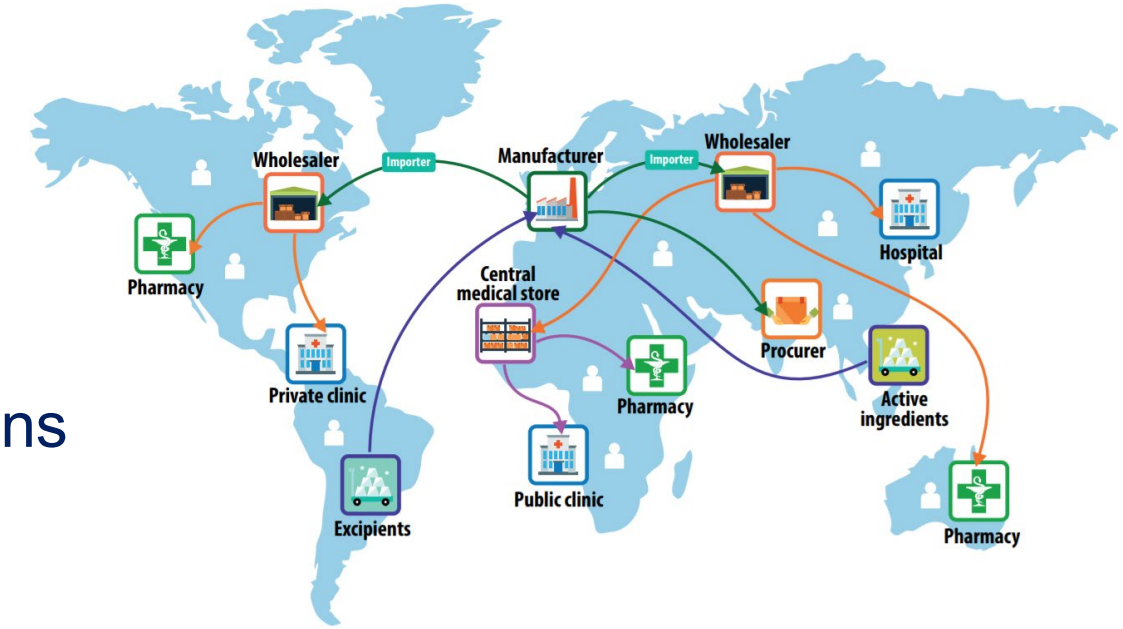
How to “transfer/translate” the regulatory information from trusted sources to facilitate in-country approval?

The Sixty-seventh World Health Assembly resolution 67.20 recognized that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products

- WHO Prequalification and approval by “SRAs” provide good basis for informed national authorisation
- How do we get the prequalified and “SRA”- approved product to the patients faster, and more efficient?
- How do we ensure continued supply of quality-assured products post-authorisation?

Evolving Science and Regulatory Challenges

- Globalization of markets
- Sophistication of health technologies
- Rapid evolution of regulatory science
- Increasing complexity of supply chains
- Transparency and growing public expectations
- Lack of global regulatory resources



Importance of international cooperation to ensure the safety, quality and efficacy/performance of locally used medical products

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed

Adopting a smart regulatory approach

Strengthening regulatory systems to ML 3 - Primary focus of WHO efforts – baseline for effective regulation.

Principle of reliance is central to WHO's approach to regulatory system strengthening and effective regulation regardless of the size and maturity of the authority.

Reliance as a vital strategy in confronting the challenges posed by global regulatory environment.

Regulatory cooperation and reliance are built on trust and confidence.

A framework for designating regulators as WHO Listed Authorities (WLAs) will provide a transparent and evidence-based pathway to be globally recognized.

WHO Good Reliance Practices

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Promote a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life-cycle

Definition: The act whereby the regulatory authority in one jurisdiction takes into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions, assessments and information of others.

Regulatory information and knowledge could be transferred through facilitated pathways

MAIN PRINCIPLES:

- **Sharing information / expertise** (assessment, inspection and testing results or expertise) that serve as basis for authornational decisions – avoiding duplication.
- **Voluntary participation** – reference authorities, participating ities and manufacturers/sponsors

WHO PQ collaborative registration procedure

Vaccines: 2004

- Medicines: Started in 2012
- Diagnostics: Pilot 2019
- Vector control: Pilot 2020

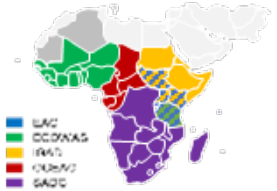
"SRA" collaborative registration procedure

Initiated in 2015

- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- 20 African NRAs

Regional networks

African Medicines Regulatory Harmonization Project (AMRH)



ASEAN SIAHR Project

→ Swissmedic MAGHP & Swissmedic involvement in regional activities in Africa

Facilitated registration based on reliance

Regulators worldwide can benefit from already conducted scientific assessments and inspections to support the national registrations, if:

- Have access to regulatory expertise from trusted party (complete assessment and inspection reports)
- Have the same product
- Have the same essential technical data
- Understand validity of B/R for local environment

Important to mention that:

- National legislation and sovereignty are not affected
- Confidentiality of commercially sensitive information is respected
- Post-approval changes are properly managed.

Win-win outcomes for all concerned stakeholders

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NRAs

- Having data well organized in line with PQ requirements
- Availability of unredacted assessment, inspection and performance evaluation outcomes to support national decisions and save internal capacities
- Having assurance about registration of “the same” product as is prequalified

WHO

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

Manufacturers

- Harmonized data for SRA or PQ and national authorisation
- Facilitated interaction with NRAs in assessment, inspections, performance evaluations
- Accelerated and more predictable authorisation
- Easier post-authorisation maintenance

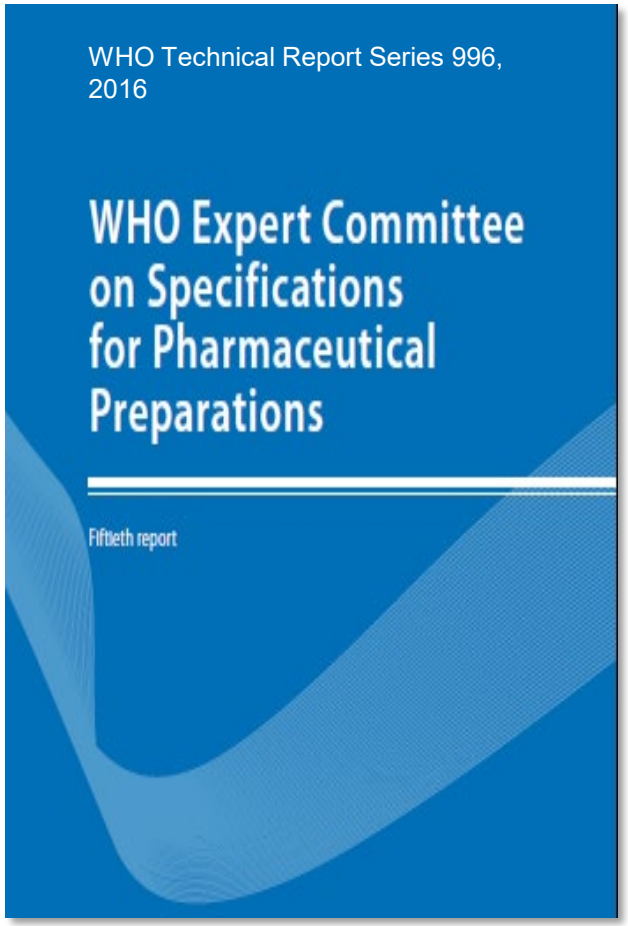
Procurers

- Time, assurance, availability

Patients

- Timely access to quality-assure, safe and effective medical products

The Collaborative Registration Procedure (CRP)



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

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

1.	**Definitions**	264
2.	**Background information**	265
3.	**Principles of collaboration**	267
4.	**Steps in the collaboration for national registration of a pharmaceutical product or a vaccine**	274
5.	**Collaboration mechanisms for post-prequalification and/or post-registration variations**	279
6.	**Withdrawals, suspensions or delistings of prequalified pharmaceutical products or vaccines and national deregistrations**	280
References		281
Appendix 1	National regulatory authority participation agreement and undertaking for national regulatory authority focal point(s)	282
Appendix 2	Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure	292
Appendix 3	Expression of interest to national regulatory authority (NRA) in the assessment and accelerated national registration, acceptance by NRA and notification of Procedure outcomes	295
Appendix 4	Report on post-registration actions in respect of a product registered under the Procedure	303

44 Participating NRAs, plus 1 Regional Economic Community (Medicines)

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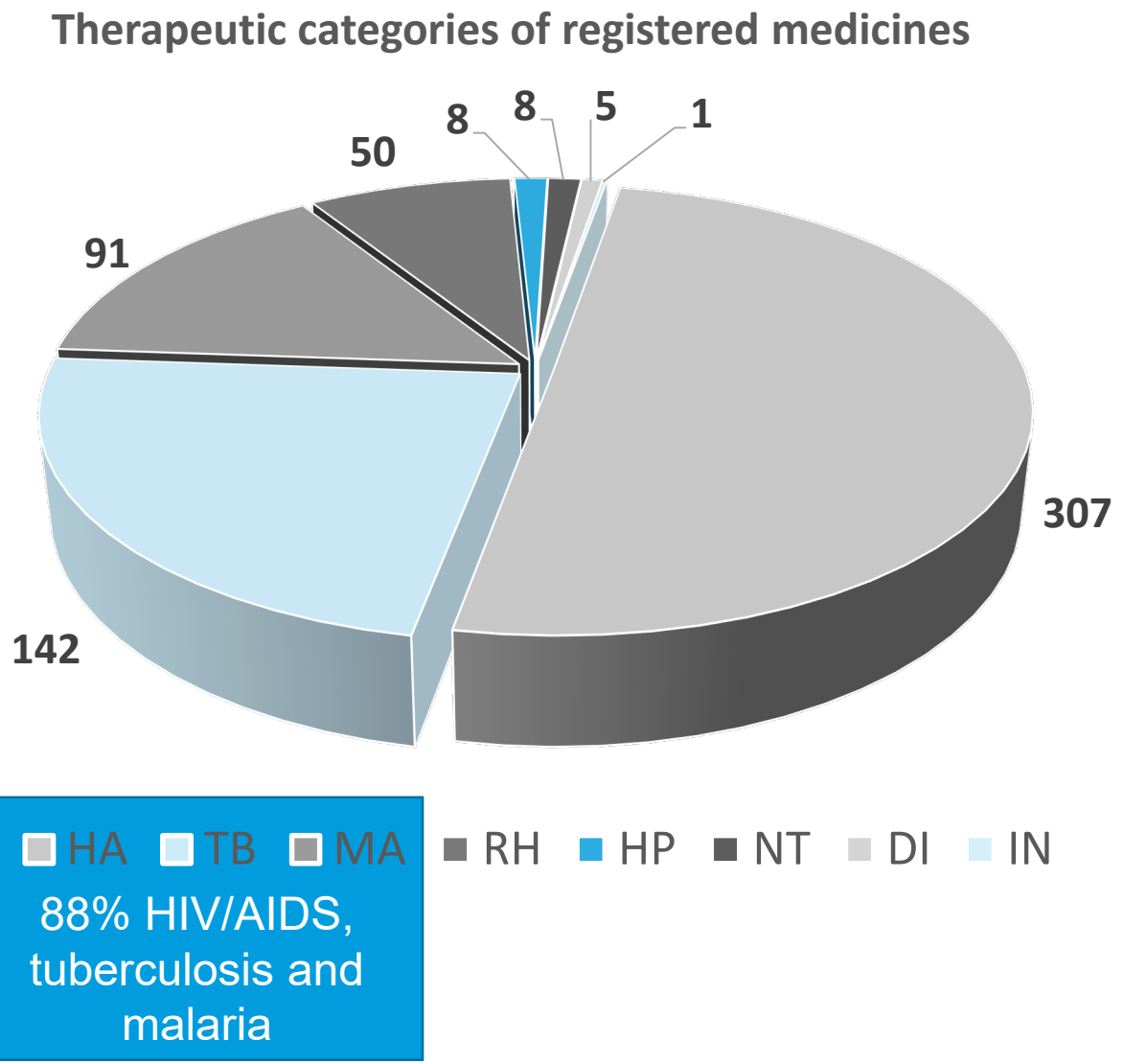
As at 30 Nov 2020

Armenia
Azerbaijan
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
*Caribbean Community (CARICOM)
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malaysia
Malawi
Mali
Mauritania
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

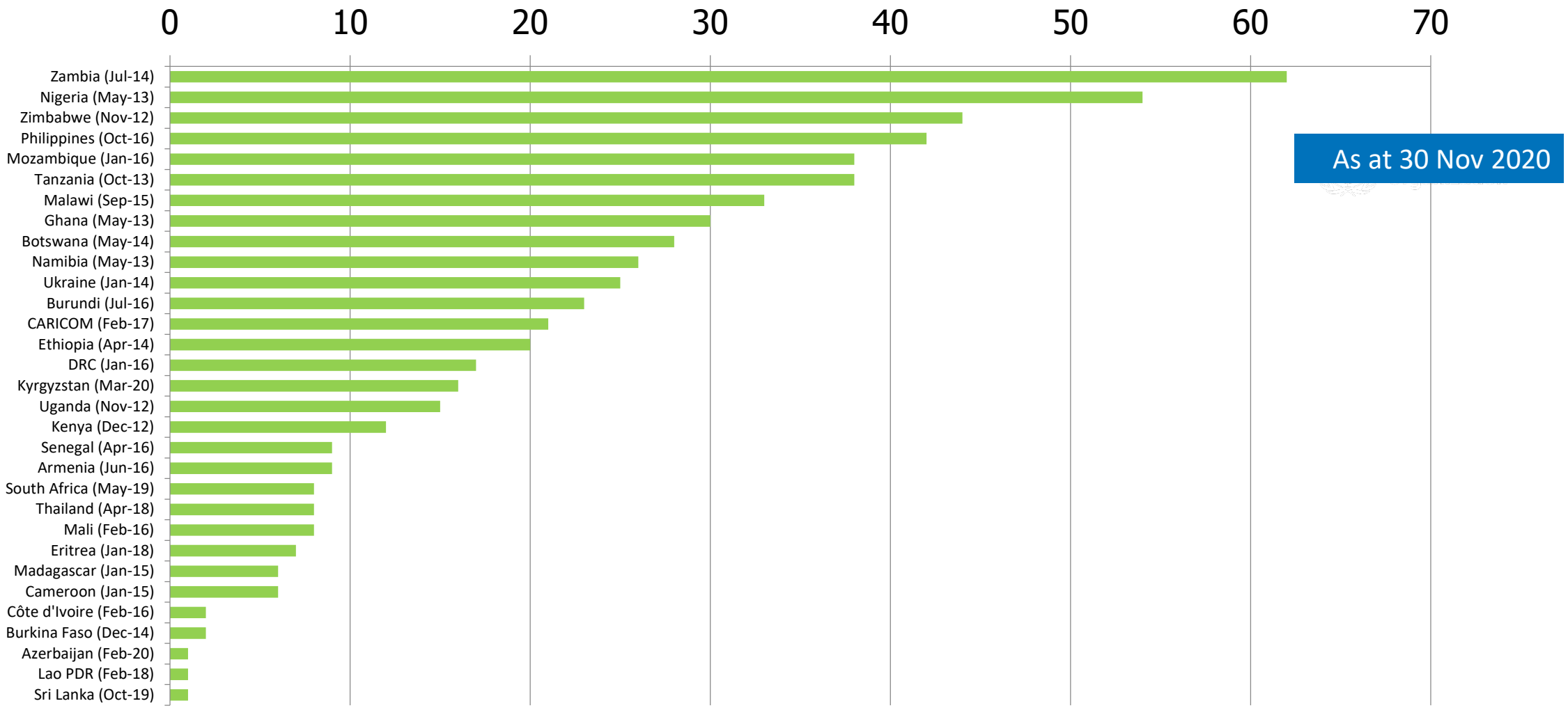
Registrations by therapeutic area



Total registrations: 612

As of 30 Nov 2020

Registrations by country

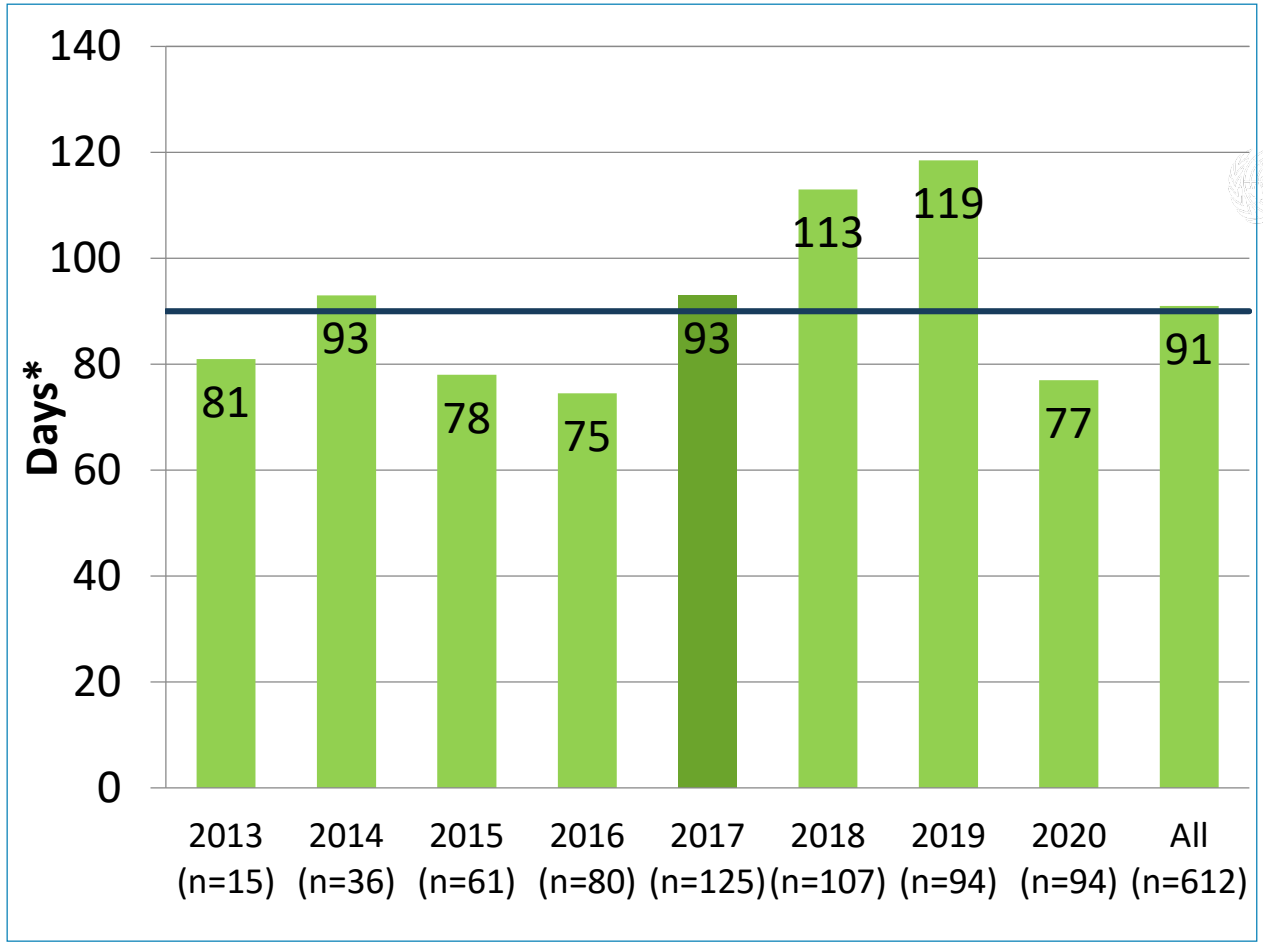


Median time to registration

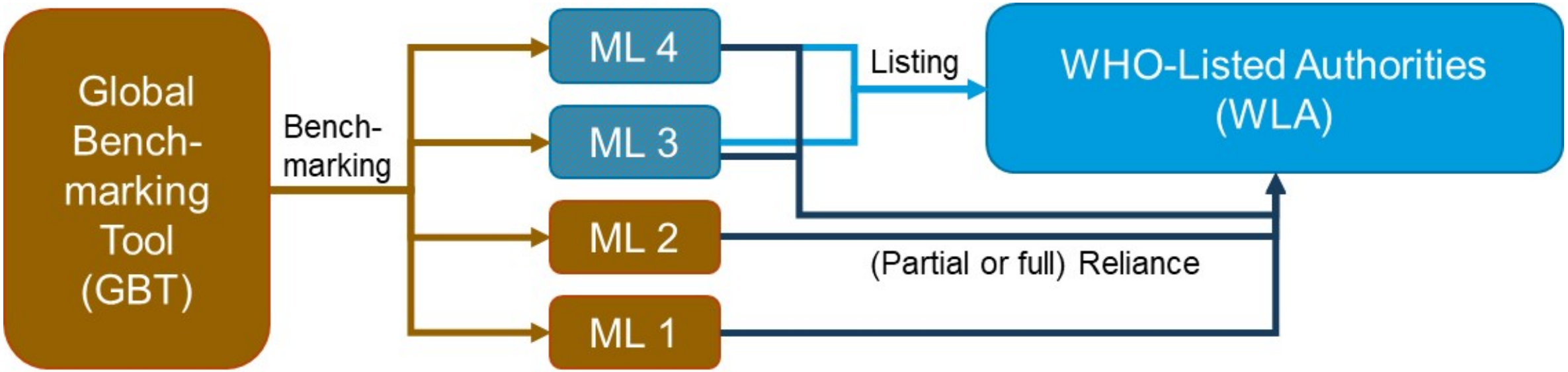
*Including regulatory time and applicant time

As at 30 Nov 2020

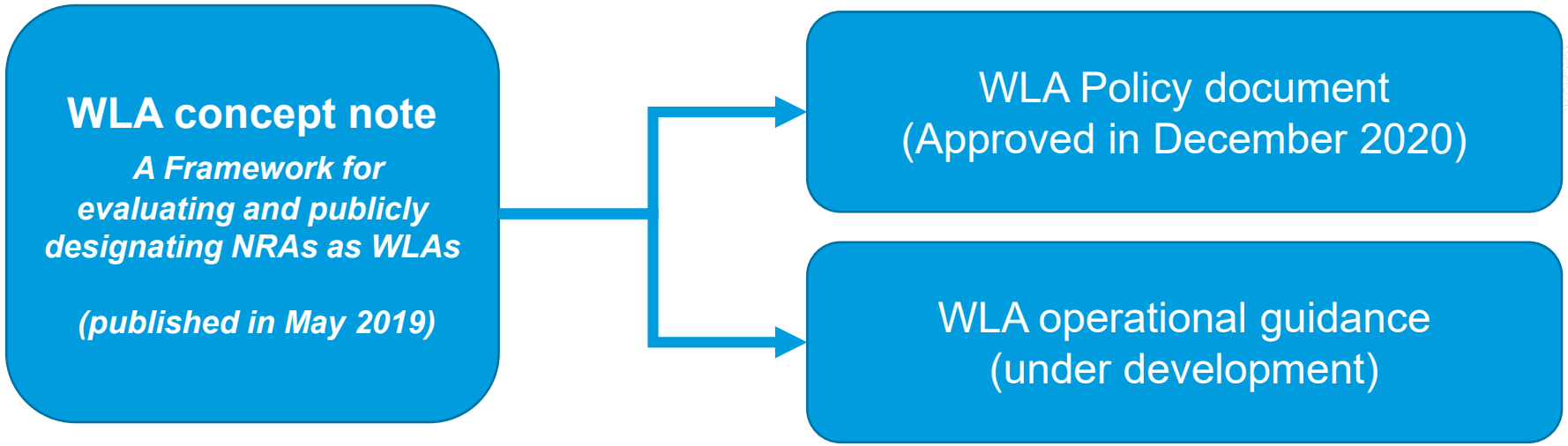
90 days TARGET



WHO Benchmarking and listing of regulatory authorities as WHO Listed Authorities (WLAs)



The WLA Framework



The WLA framework (policy and operational guidance) is envisaged to be operational in 2022

Definition of a WHO Listed Authority

Adopted by the ECSPP in October 2020

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process

Conclusions

- Timely access to medical products – a never-ending challenge?
- Not a single regulator anymore can fulfil all regulatory work alone
- To generate quality national decisions regulators globally must collaborate and must take into consideration the information available from other regulatory authorities
- Not using the outputs and outcomes from other regulatory authorities means lost opportunity, duplication of efforts, increased regulatory burden and waste of scarce resources.
- Concept of reliance is central for the regulatory strengthening systems activities and to increase efficiency of the global regulation of medical products.
- The WLA framework will provide a transparent and evidence-based pathway to be globally recognized.
- Time is right with unprecedented level of collaboration between National Regulatory Authorities.

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