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Developing Countries Vaccine Manufacturers Network

World Health Organization

Vaccines, a healthy future

Developing Countries Vaccine Manufacturer's Network
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Harmonization of regulatory approaches in African countries – WHO efforts

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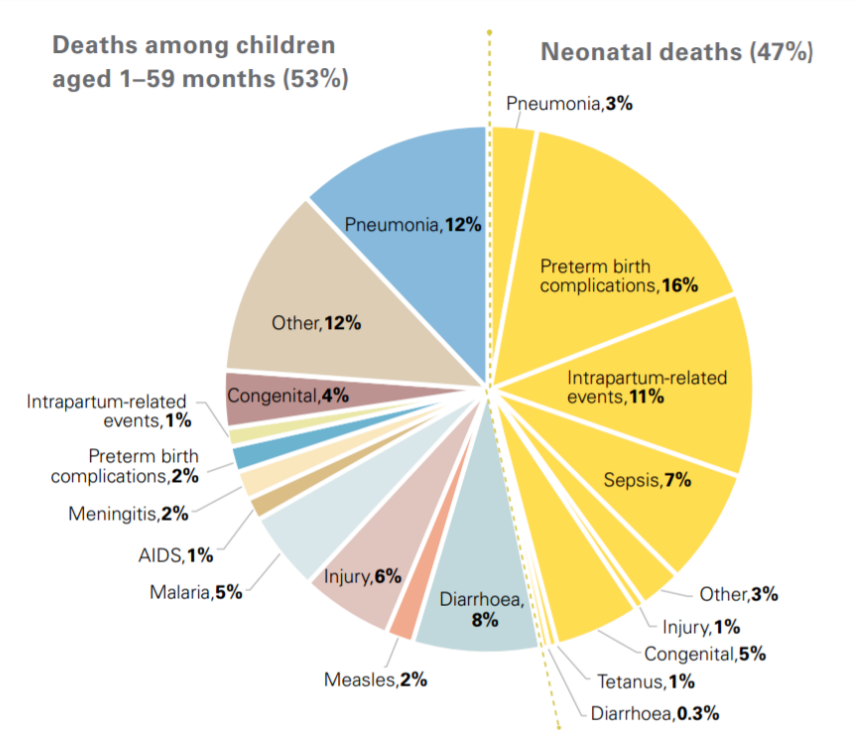
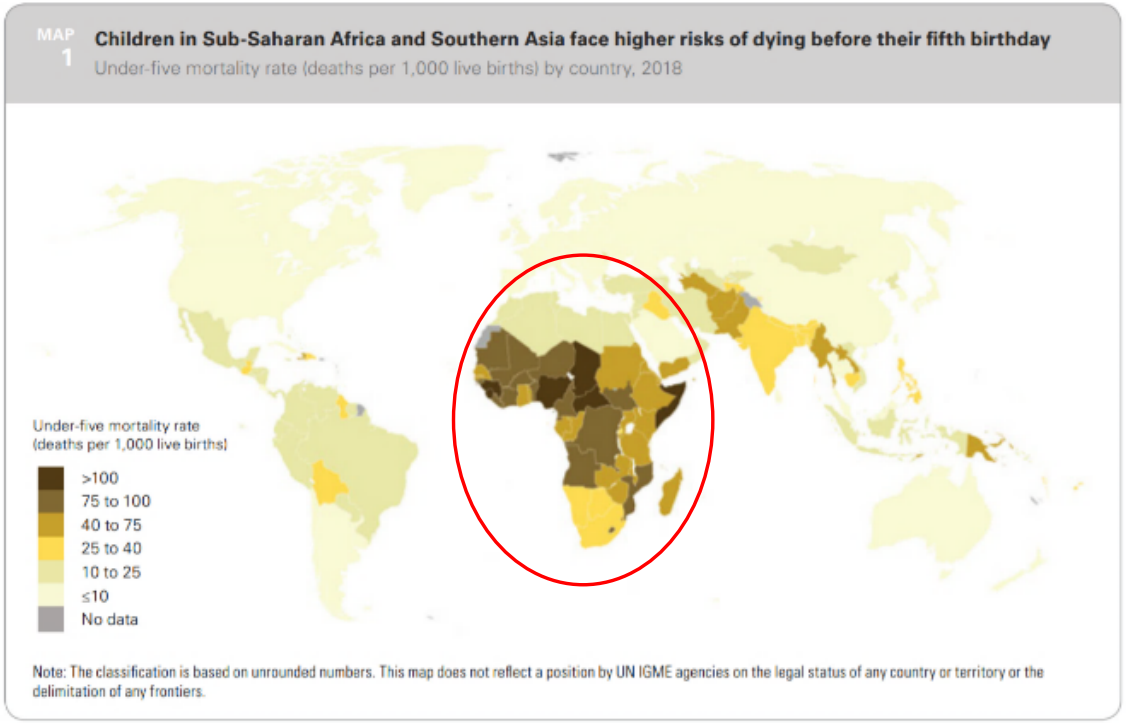
Infectious (preventable) diseases remain a leading cause of death among children under age 5



Global distribution of deaths among children **under age 5 by cause**, 2018



One child under age 15 died every five seconds in 2018
UN Inter-agency Group for Child Mortality Estimation

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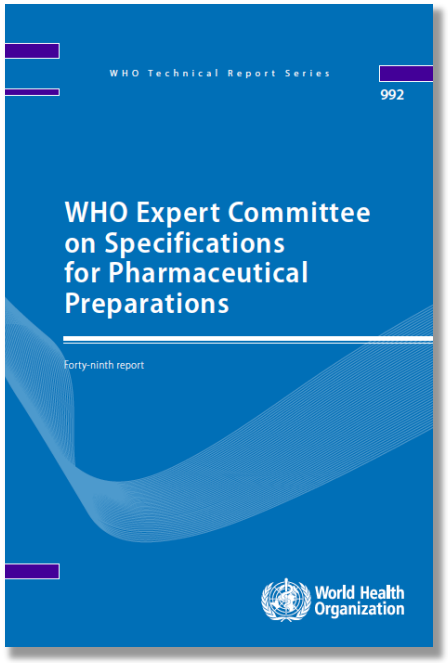
Access to medical products – global challenge

- In many low- and middle-income countries essential medical products are not always readily available and accessible;
- WHO estimate is that one third of the world's population have no or little access to essential medical products;
- This contributes to disparities in health and life-expectancy between low-income and high-income countries;
- One of the reasons is inadequate regulatory capacity and lack of collaboration and work sharing in medicines regulation.

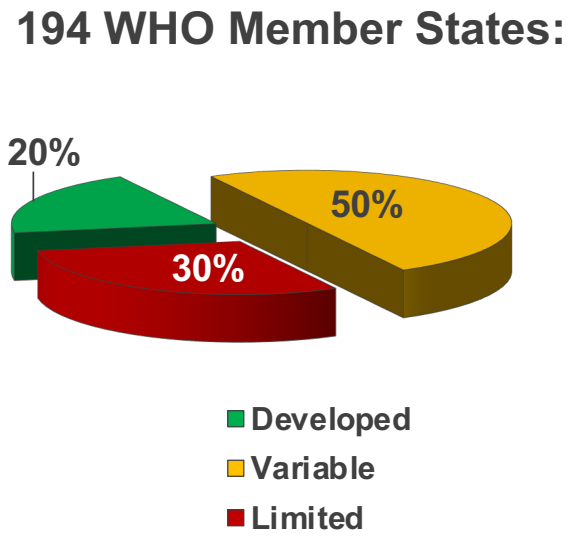
Globalization in medical products regulation

- All medical products should be used in the countries only after approval by the national or regional regulatory authority - **in line with current international standards** (WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010);
- There is no clear vision or policy about HOW to set up regulatory systems in times when it is unrealistic to manage all functions in one national setting – due to **globalization of regulatory science**;
- New medical products are likely more complex and sophisticated – demanding advanced health systems and "quality use".

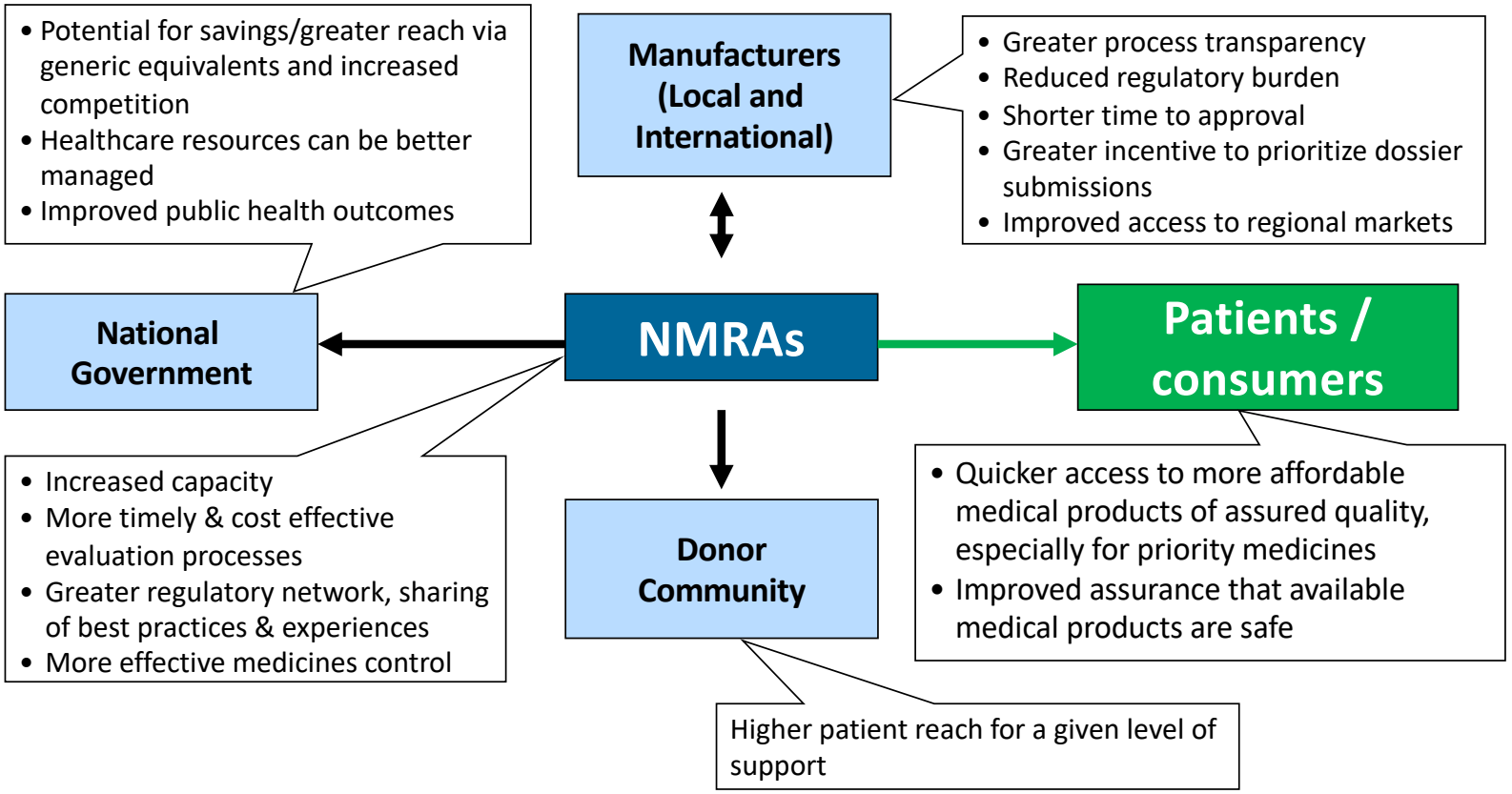


Gap in Regulatory Capacity

- **≈30% of NMRAs globally** have limited capacity to perform core regulatory functions
- Regulatory capacity gap between different countries (low- and high-income) in terms of:
  - Human and financial resources;
  - Regulatory functions effectively performed;
  - Expertise available for fulfilling regulatory functions;
  - Availability of proper systematic training for regulators.

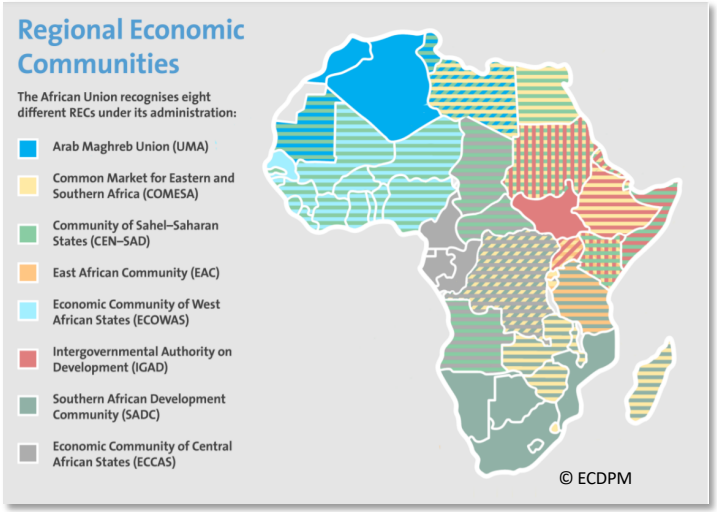


Why to support Regulatory Convergence and Harmonization?



African Medicines Regulatory Harmonization (AMRH) initiative

Launched in 2009 as a collaborative effort of a **Consortium of International Partners*** to respond to the challenges arising in harmonizing medicines regulation in Africa.



The overall objective of AMRH is:

To achieve a harmonized medicines regulation process in the countries belonging to the **Regional Economic Communities (RECs)**, based on common documents, processes and shared information systems at the RECs level.

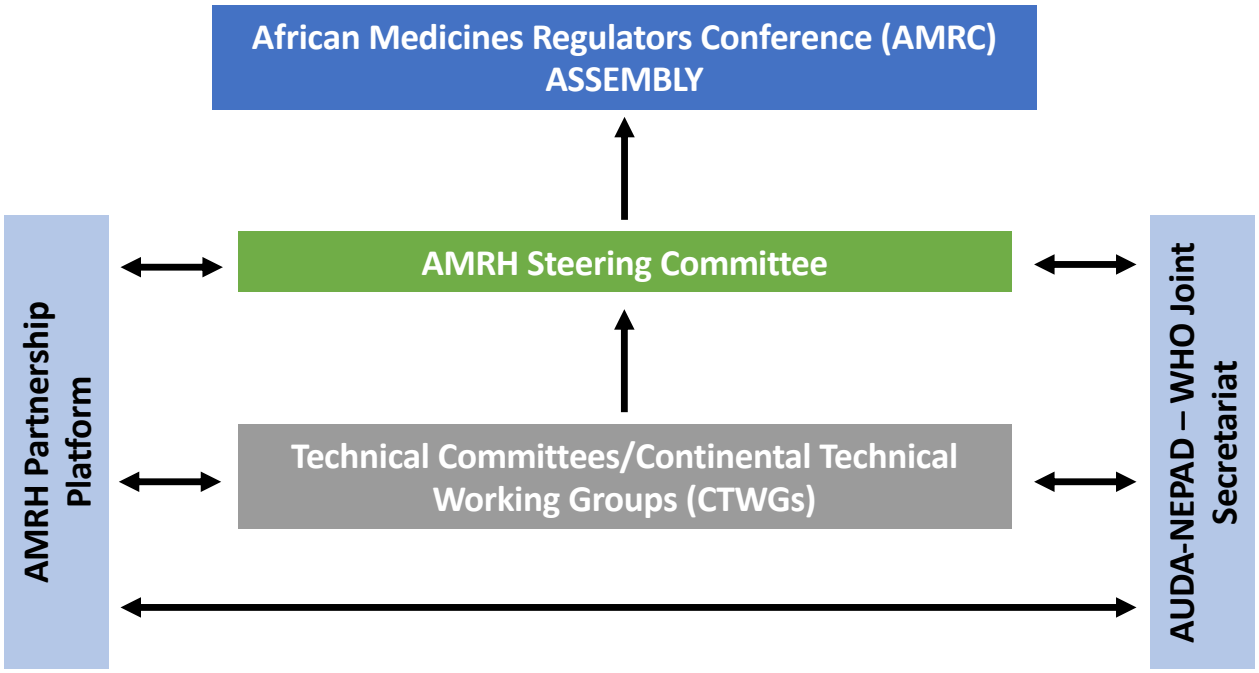
*African Union Commission, the Pan-African Parliament, the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD), WHO, Bill and Melinda Gates Foundation (BMGF), UK DFID and the CHAI

AMRH as a game changer in the Africa

All African RECs currently implementing Medicines Regulatory Harmonization Programmes/Projects:

- Development and implementation of Harmonized Technical Requirements/Common Technical Documents for medical products regulation;
- Development of Common Information Managements Systems;
- Implementation of joint activities – dossier assessments and GMP inspections;
- Impact monitoring and evaluation processes in place.

AMRH Governance Framework



AMRH Technical Committees:

- AVAREF;
- AMDF;
- ABRF;
- AMQF;
- Medicines Policy and Regulatory Reform.

Achieving AMRH vision

African people to have timely access to essential medical products and technologies that are safe, effective and of assured quality.

- Harmonized Technical Requirements/Common Technical Documents for medical products regulation were successfully developed and implemented in all RECs;
- A number of dossiers were jointly assessed and joint GMP inspections conducted in all RECs resulting in a number of essential medical products registered in the countries within a substantially shorter timelines;
- Important documents and procedures, including for addressing public health emergencies were developed and implemented by the AMRH Technical Committees, e.g., AVAREF, AMDF, ABRF, AMQF and others.

African Vaccine Regulators Forum (AVAREF) facing the COVID-19 pandemic

- AVAREF series of webinars to share information about products under development against COVID-19 and harmonization of the review and processing of COVID-19 clinical trial applications.
- AVAREF developed and adopted a critical document – the Strategy and Guidance for Emergency Preparedness;
  - The first application for an emergency joint review using this procedure commenced in July 2020.

African Medical Devices Forum (AMDF)

AMDF COVID-19 Task Force established with the working groups focusing on four key priority activities:

- List of COVID-19 IVDs which will be updated from time to time:
- List of medical devices and other products for prevention, control and case management:
- Mechanism to receive feedback on substandard and falsified IVDs, medical devices and personal protective equipment (PPEs) and inform NRAs;
- Donations.

Instead of conclusions - benefits of the harmonization and networking in Africa

Formation of effective networks between regulatory authorities nationally and internationally is beneficial in:

- Facilitating saving of scarce resources;
- Eliminating duplicative activities;
- Helping to build trust among the regulators in the continent;
- Pawing the way towards establishment and operationalization of the African Medicines Agency (AMA);
- Ultimately – in improving access to most needed essential medical products for the populations in Africa.

World Health Organization

www.who.int/medicines