Regulatory Harmonisation and International Collaboration on Medicines

XIV Encuentro RedEAMI
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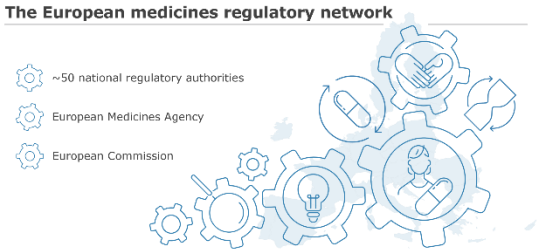
The European Medicines Regulatory Network: reliance in action



EMA in the EU

Who do we work for?

zdrowie zdravie
zdravlje Gesundheit
salud υγεία saúde
tervist veselība
salute здраве saħħa
terveys sundhed
health hälsa sláinte
egészség’
zdravje zdraví
gezondheid
sveikata
santé sănătate

27 member states

23.9% of global sales of medicines

24 official languages

Who we are

~4000 scientific experts from across Europe

7 Scientific Committees

- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

1 Management Board

27 Member States' representatives

4 Civil society representatives

2 European Commission representatives

2 European Parliament representatives

1995 EMA established

~900 staff members

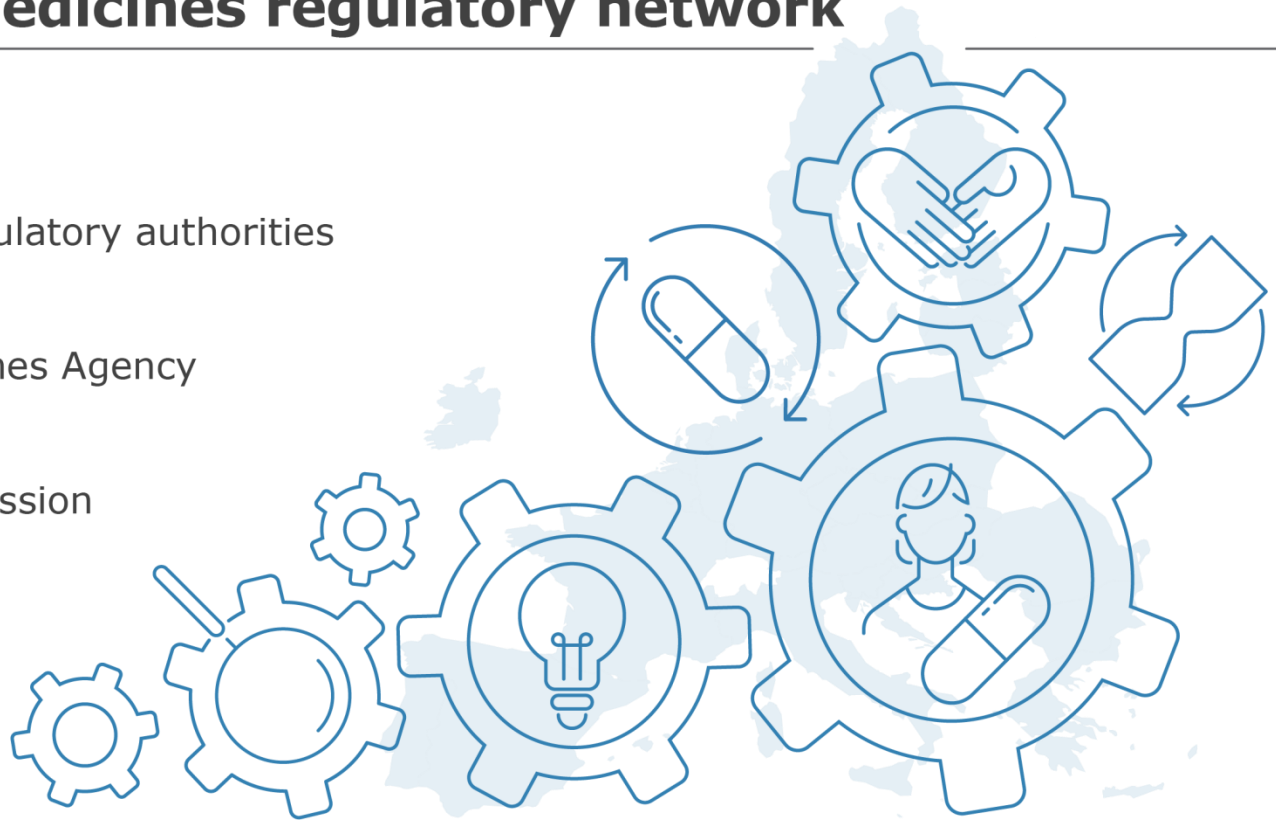
What we do

Protect human and animal health

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- ABC XΨΩ Provide reliable information on human and veterinary medicines to patients and healthcare professionals

The European medicines regulatory network

- ~50 national regulatory authorities
- European Medicines Agency
- European Commission

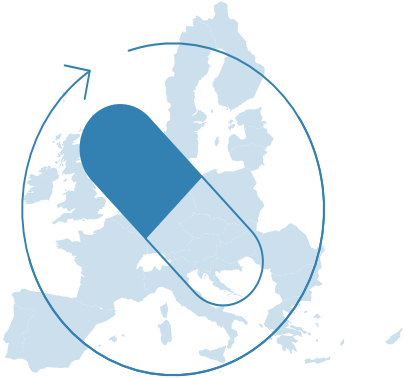


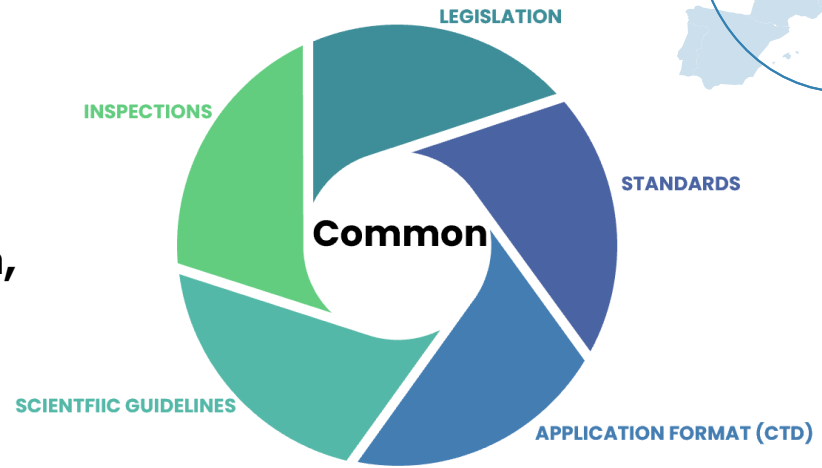
Reliance in action: European medicines regulatory network

An effective and efficient way of regulating medicines based on full transparency, **reliance, work-sharing and recognition**.

All European authorisation pathways based on **single assessment**, that can be used as a basis for reliance by another agency.

Single assessment and single market is possible thanks to **common legislation, common rules and common dossier requirements**.





EMA: Promoting International Collaboration

EMA in the global environment

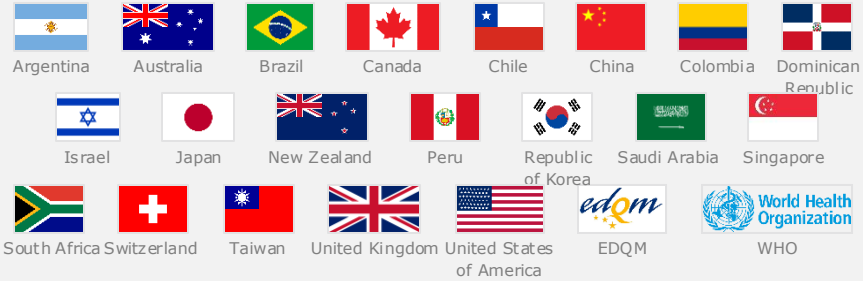
Engagement and exchange with international regulatory authorities is part of EMA's daily work.

International collaboration is key to:

- **Avoid duplication** of work
- **Release scarce resources** for more critical areas
- **Facilitate alignment** of regulatory approaches between international authorities
- **Speed up access** to new and/or affordable medicines
- **Support regulators** outside the EU who may **lack resources** and/or specific competences

Mechanisms for international collaboration

Bilateral relations



International Liaison Officers

Confidentiality Arrangements (CA)

Ad Hoc CA

Mutual Recognition Agreements (MRA)

Clusters

Multilateral relations

ICH harmonisation for better health

OPEN

PIC/S

IPA project

ICMRA

EU-M4all

IPRP International Pharmaceutical Regulators Programme

SRA CRP

AMA project

VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

IPA: Instrument for Pre-accession Assistance
AMA: African Medicines Agency

Bilateral International cooperation at EMA

- We talk regularly, on a daily basis, with other Regulatory Authorities (in particular Regulators with CoA)
- All divisions/departments are involved
- **~80% of all products** going through EMA committees have some discussion at international level
- Growing interactions through multilateral ‘Clusters’

Overview of EMA / US FDA collaboration mechanisms

Confidentiality arrangement (2003)

EU-US MRA (2017, vet in 2023)

Clusters (currently 34, some multilateral)

Ad hoc collaboration and exchanges

Parallel scientific advice

Fellowships & visits

EMA-US FDA Liaison Programme

Inspection of Manufacturers of Medicinal Products located in 3rd countries outside EU (Mutual Recognition)

The EU has signed international agreements with countries covering mutual recognition of each others GMP Inspections.

- EU recognises outcome of GMP inspections of these authorities and NCA's do not perform inspections in these countries (some caveats apply).
- GMP compliance of sites is checked during Marketing Authorisation application but no inspection by EU NCA (unless caveat applies) and no EU GMP Certificate or Statement of Non-compliance is entered in EUDRAGMDP.

Benefits for industry

- Fewer duplicative inspections
- Waiving of re-testing upon importation
- Encourage greater international harmonisation

Benefits for regulators:

- Better use of inspection resources
- Focus on manufacturers of higher risk
- Encourage greater international harmonisation

EMA assessment reports: a tool for Reliance

European Public Assessment report includes:

- information about the product
- approved product information
- conditions to the MA
- scientific discussion (based on CHMP assessment report)
- information on the post-authorisation procedures

- EMA publishes information on medicinal products at various stages of their life cycle
- This guidance helps stakeholders know what kind of publications to expect.

  Guide to information published on human medicines
- Transparency enables many regulatory authorities to rely on EMA's assessment of medicines.

Opening our Procedures at EMA to Non-EU authorities - OPEN

Non-EU experts were invited to attend and contribute to EMA evaluations of COVID-19 products while keeping full scientific and regulatory independence.

The WHO EUL (Emergency Use Listing) for one vaccine led to more than 100 approvals within 2 weeks based on this EMA collaborative assessment

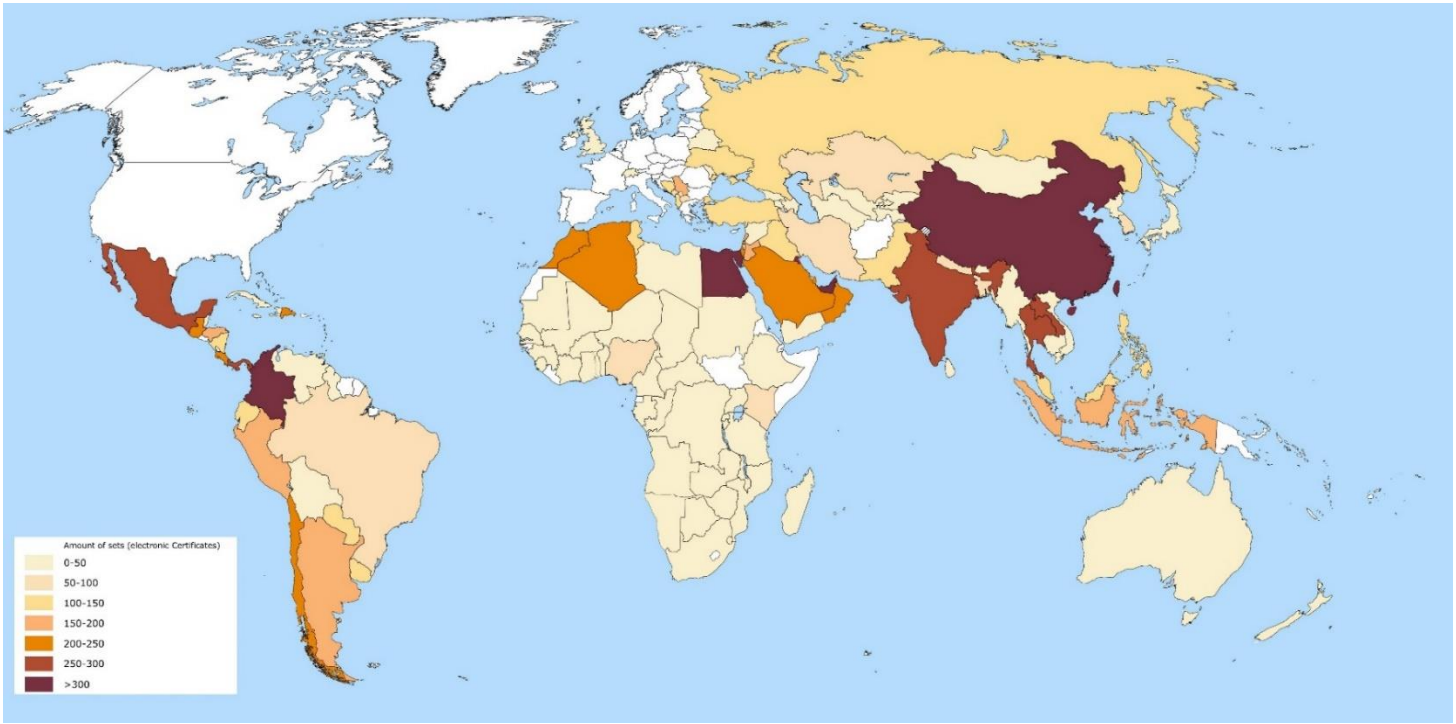
After success of COVID-19 pilot, OPEN pathway now expanded to identified areas:

- Antimicrobial resistance (AMR) *global threat where progress requires a collective effort for human and veterinary products*

- Priority medicines designated under the **PRIME scheme (temporarily <u>not</u> including ATMPs products)** and PRIME-type products which **address high unmet need** (e.g. Alzheimer,)

- Medicinal products responding to health threats or **public health emergencies**

EMA and eCPPs: a tool for reliance



(e)Certificates of Pharmaceutical Products provide **assurance**, confirm marketing authorisation **status** of a medicinal product and that is produced in accordance with **GMP** standards.

EMA is probably biggest issuer of (e)CPPs. EMA issues > 11000 certificates each year

European medicines network designated as WHO listed authority

- On 20 May 2024, EMA, EC and 30 NCAs were designated as WHO Listed Authorities (WLAs) that can be relied on for fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines.
- Decision was based on technical evaluations by WHO, confirming consistency of advanced performance by all these authorities.
- This recognition enables reliance on trusted regulatory authorities, promoting confidence and fostering regulatory convergence, harmonization of approaches, and international cooperation.
- Currently, EMA and the network are already broadly used as reference agency to apply reliance amongst companies.


World Health Organization

NEWS RELEASE

Largest number of regulatory agencies for medical products approved as WHO Listed Authorities

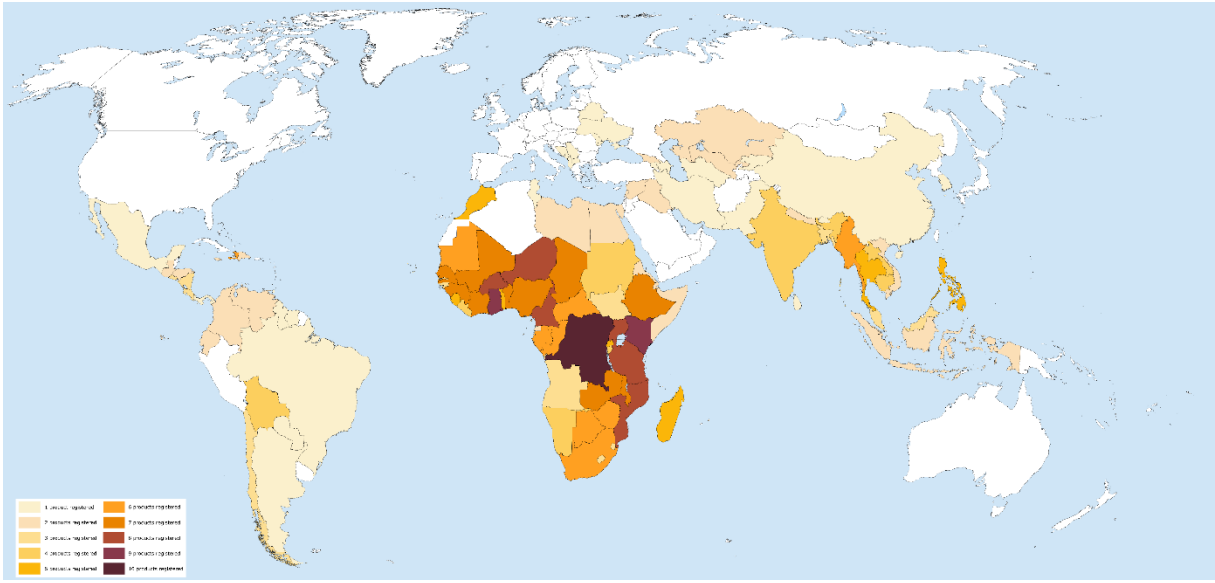
EU-Medicines for all (EU-M4all)

EMA supports the global regulatory system through collaboration with **WHO** using two main regulatory mechanisms that **facilitate registration and capacity building:**

1. EU-M4all (Art. 58):

EMA evaluates and gives an opinion, in cooperation with **WHO**, on medicinal products for human use intended for markets outside of the EU.

Since 2021, this procedure can also be performed in parallel to a centralised procedure to accelerate medicines access at a global scale.



17 medicines with an EU-M4all scientific opinion*

115 countries worldwide

394 Marketing Authorisations

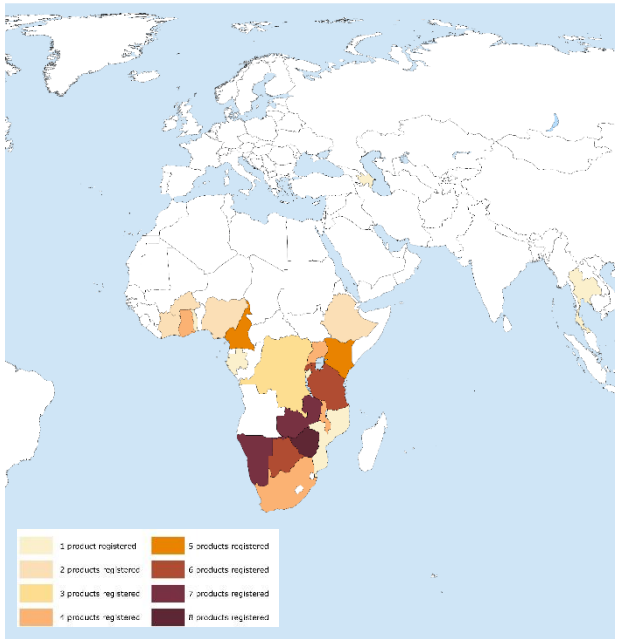
*7 of which have been withdrawn or surrendered and 1 pending as of September 2024

WHO Collaborative Registration Procedure (CRP)

2. WHO SRA CRP:

Accelerates national approval in countries where resources may be limited, based on the regulatory work already carried out by Stringent Regulatory Authorities (SRAs), such as EMA.

This facilitates earlier access to essential medicines for patients worldwide, improving global public health.



13 medicines with EU marketing authorisation

23 countries

83 marketing authorisations via CRP

As of June 2024

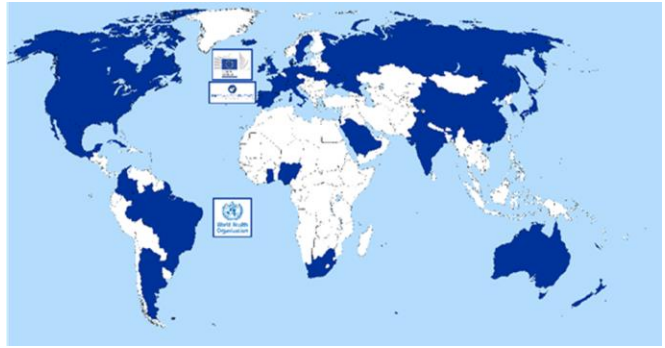
EMA/WHO Post Authorisation Reliance Pilots

- Building a more efficient model for the management of Post Authorisation Commitments
- Accelerating timelines for approval of PAC
- Promoting harmonization of requirements
- Ensuring continuation of supply

International Coalition of Medicines Regulatory Authorities

ICMRA is a voluntary, executive-level strategic coordinating advocacy and leadership entity of regulatory authorities that work together to

- Address **current and emerging regulatory and safety challenges**
- Provide **strategic direction for common activities**
- Identify areas for **synergies**
- **Leverage** existing initiatives



[International Coalition of Medicines Regulatory Authorities (ICMRA) |]

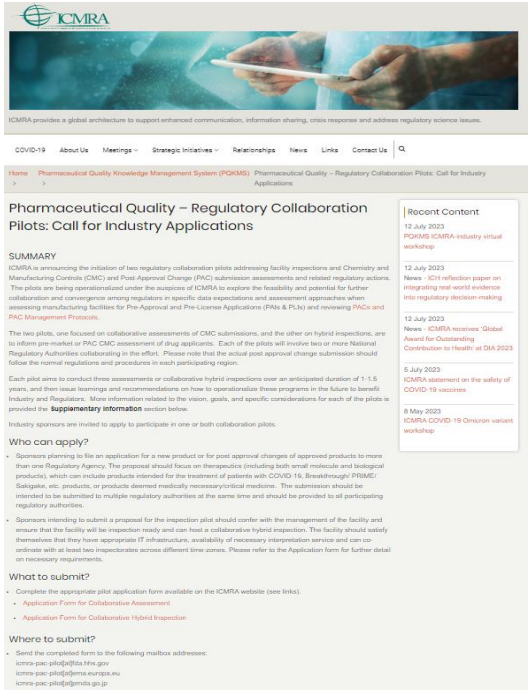
The **Coalition** supports**:**

- Enhanced communication and information sharing
- Crisis response
- Regulatory science issues

Representation from across all continents and regions

Regular Policy TCs and workshops ensure sharing of information and promote convergence in regulatory approaches

ICMRA - Regulatory collaboration pilots



Pharmaceutical Quality – Regulatory Collaboration Pilots: Call for Industry Applications | International Council of Medicines Regulatory Authorities (ICMRA)

One focused on collaborative assessments of CMC post-approval submissions, and the other on hybrid inspections to

- ✓ facilitate convergence in assessment practices for key products
- ✓ develop collaborative assessment approaches
- ✓ promote multi-agency GMP inspections

Multi-agency collaborative assessment of Post Approval Change Management Protocols (PACMP):

- *5 cases have been reviewed collaboratively*
- ***Same submission*** *submitted to all Authorities*
- *Participating Reg Authorities up to 4; Observers up to 6*
- *Synchronised approval across multiple regulatory regions in 120 d*
- *Harmonised technical assessments with limited regional specific considerations*
- *No additional regulatory burden as a result of the pilot*

European Medicines Regulatory Network support to the African Medicines Agency and African Regulators

EMA's AMA Project

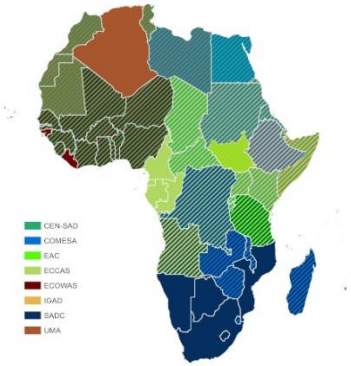
EMA and the EMRN support to the AMA will focus on the following key objectives:

1. Support the operationalisation of AMA and the framework for collaboration among African regulators.
2. Strengthen the scientific and regulatory expertise of the African regulatory network.
3. Align the efforts of the European Medicine Regulatory Network supporting African regulators.

National Regulatory Agencies (NRAs)

55 countries

Regional Economic Communities (RECs)



8 regions

African Medicines Agency (AMA)

1 continent

Support AU **joint assessment and inspection pilots**

Design and deliver **training strategy** for African Regulators

Support **regional assessment and reliance**

Take away messages

- Drug development is global
- Medicines regulation poses cross-border challenges: regulators need to think and act both locally and globally.
- All regulators face many challenges, including **increased workload** and **limited resources.**
- **Collaborative pathways** and **reliance** avoid duplication of work and promote regulatory harmonisation, capacity building, transparency and trust, and earlier access.
- International collaboration and reliance is a need, not a choice. It brings **benefits for regulators, industry and in particular to patients** who can have access to high quality, safe and effective medicines.

No one agency, no matter how big, can do it all by themselves

Reliance is a modern 21st Century way of doing regulatory business

Thank you for your attention

Further information

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