

A collage of images showing a woman with a child, a surgeon, and a doctor, set against a map of Africa. The woman is smiling and holding a tablet. The surgeon is wearing a blue cap and mask. The doctor is wearing a blue jacket and stethoscope. The map of Africa is in the background.

# The African Medicines Agency:

towards a unified continental regulatory framework

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## What

# The Biopharmaceutical Industry supports the establishment of the African Medicines Agency (AMA).

We call upon all countries to ratify the AMA Treaty to enable the operational implementation of the continental regulatory system that will benefit patients, regulators, industry and healthcare systems in Africa. In addition to improving public health and life quality in Africa, a strong regulatory system will open perspectives for pharmaceutical industry, medical research and development.

AMA has the unique opportunity to become one of the most efficient and modern regulatory systems in the world. This opportunity can rapidly transform into reality, by using the experience gained from a decade of harmonization activities in the continent, learnings gained during the pandemic and the swift implementation of modern and innovative solutions.

- We support harmonization of all regulatory activities spanning the full product life cycle with clear roles and responsibilities at country, regional and continental level amongst all regulators (see page 6)
- We support AUDA-NEPAD's efforts at the country, regional and continental level to ensure that at least 15 countries ratify the treaty in a timely manner
- We appeal to all national regulators and healthcare stakeholders to advocate for AMA Treaty ratification and ensure that the AMA becomes a reality

“AMA has the unique opportunity to become one of the most efficient and modern regulatory systems in the world.”



## Why

AMA, as a modern regulatory system adopting digital and technology solutions and streamlined processes, will bring a series of advantages, including...

### Expanding timely access to medicines for patients

- Expands and accelerates access to new effective, safe, and quality medicines, through harmonized regulatory requirements leading to accelerated and simplified review processes
- Contributes to uninterrupted supply of quality medicinal products through predictable and transparent lifecycle management procedures
- Prevents exposure of patient to substandard and falsified medicinal products through enhanced market surveillance cross borders by coordination of information sharing among member states



### Facilitating collaboration between regulators that enables faster approval processes

- Implements Good Regulatory Practices
- Contributes to regulatory harmonization across Africa to enable collaboration, work-sharing and the use of reliance procedures
- Ensures scientific evidence-based regulatory decision-making and the implementation of global regulatory standards
- Builds regulatory capability and capacity through collaboration and education





## Why

### Building resilient healthcare systems that support a better quality of care

- Strengthens regulatory systems
- Reduces distribution of substandard and falsified medicinal products within national healthcare systems
- Contributes to improving life expectancy and quality of life of people in Africa



### Fostering a conducive environment for industry and innovation

- Creates environment for innovation and business development
- Accelerates and simplifies access to medicinal products through transparent assessments based on common standards and predictable, timely approvals
- Ensures continuous supply by streamlining management of regulatory submissions
- Supports capacity building by participating in education and investing in learning of other stakeholders
- Builds bridges between healthcare sector and economy enabling growth in both fields



## How

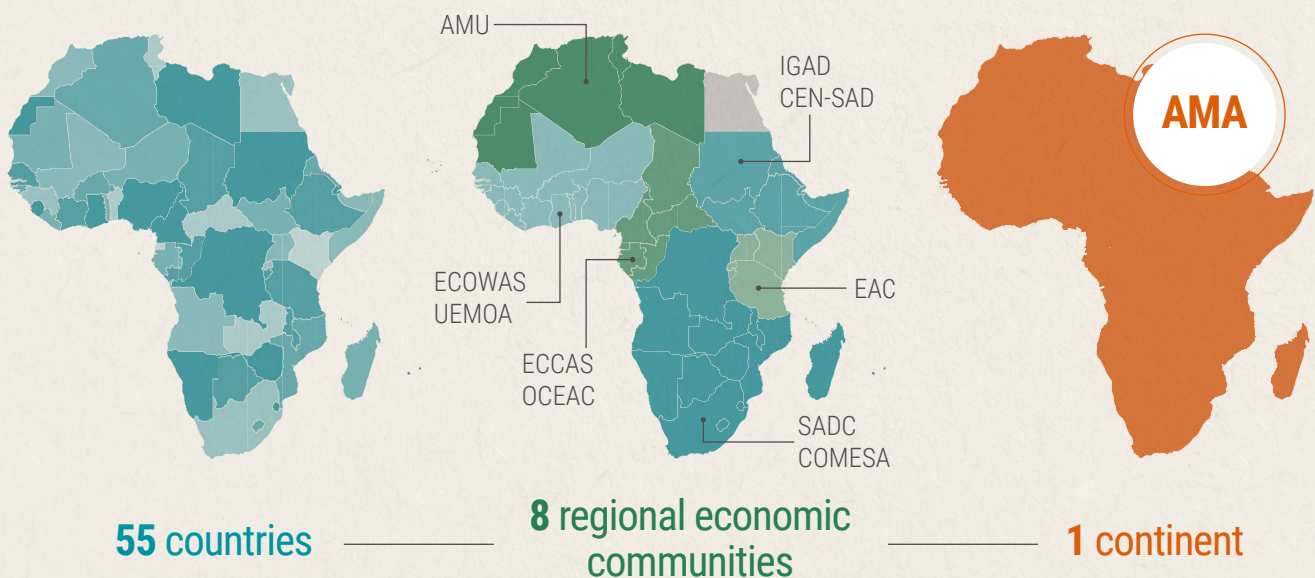
Both the African Medicines Regulatory Harmonization initiative and the Biopharmaceutical Industry are founded on the ground of collaboration and support for innovation.

Through engagement in AMRH's focus areas, the Biopharmaceutical Industry has contributed and continues contributing to regulatory reforms at the country, regional and continental levels to inspire the development of regulatory systems aligned with global standards.

We share knowledge and best practice experiences on key regulatory priorities (e.g., [Reliance](#), [GMP](#), [CPP](#), [Post-Approval Changes /samples](#), and Biotherapeutics). We also participate in various pilot projects to support the implementation of innovative systems to build experience and confidence across regulators.

## Call to Action

We invite all interested parties across the continent and beyond to join forces and support the AMA establishment within their area of influence.



# Roles and Responsibilities at National, Regional and Continental levels...

## National

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- Implement strong and effective regulatory systems based on Good Regulatory Practices and international standards.
- Perform market surveillance to regulate drugs circulation in the country and reduce counterfeit medicines circulation. Contribute to the pan-African information collection and sharing on substandard and falsified (SF) medical products coordinated by AMA to support the efforts of the African Union-recognized Regional Economic Communities (REC), Regional Health Organisations and Member States towards combating the presence of SF medical products.
- Use reliance pathways to avoid duplication of efforts and contribute to joint assessments.
- Share appropriately information within regulatory networks.
- Build capacity and provide technical support to REC and AMA.

## Regional

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- Continue the development and monitor the implementation of regional guidelines to align standards and strengthen ongoing regulatory harmonization activities.
- Implement joint assessments of new product applications and Post Approval Changes as well as joint Good Manufacturing Practices inspections.
- Use reliance on regulatory assessments taken by other WHO-listed Health Authorities.
- Ensure simplification and transparency of processes and accelerated and continuous access by patients to safe, efficacious and high-quality medicines and vaccines.
- Allocate /share adequate resources to fulfill regulatory activities including training and capacity-building.

## Continental

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- Coordinate and strengthen ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions.
- Carry out regulatory oversight of medicinal products by coordinating data collection and information sharing among Member States and RECs (product safety monitoring, market surveillance, clinical trials, inspections, etc.) to ensure product safety in the markets, while avoiding duplication of processes.
- Provide technical guidance to National Regulatory Agencies, national quality control laboratories and RECs, coordinate and network quality control laboratory services for national and regional regulatory authorities and support capacity building.
- Convene pooled scientific expertise and capacities in AMA joint assessments and inspections of complex new medicines and vaccines addressing priority diseases in Africa and strengthen networking for optimal use of the limited resources available.
- Foster scientific capacity across the continent, leverage Regional Centers of Excellence and develop scientific guidelines for medicines and vaccines for priority diseases across Africa.
- Ensure a concerted approach to fight substandard and falsified medicines and vaccines in Africa by coordinating Member States' market surveillance information sharing.
- Reduce the burden on AMA member states during pandemics by coordinating efforts and providing scientific expertise and guidance, fostering reliance and regulatory and legal harmonization.