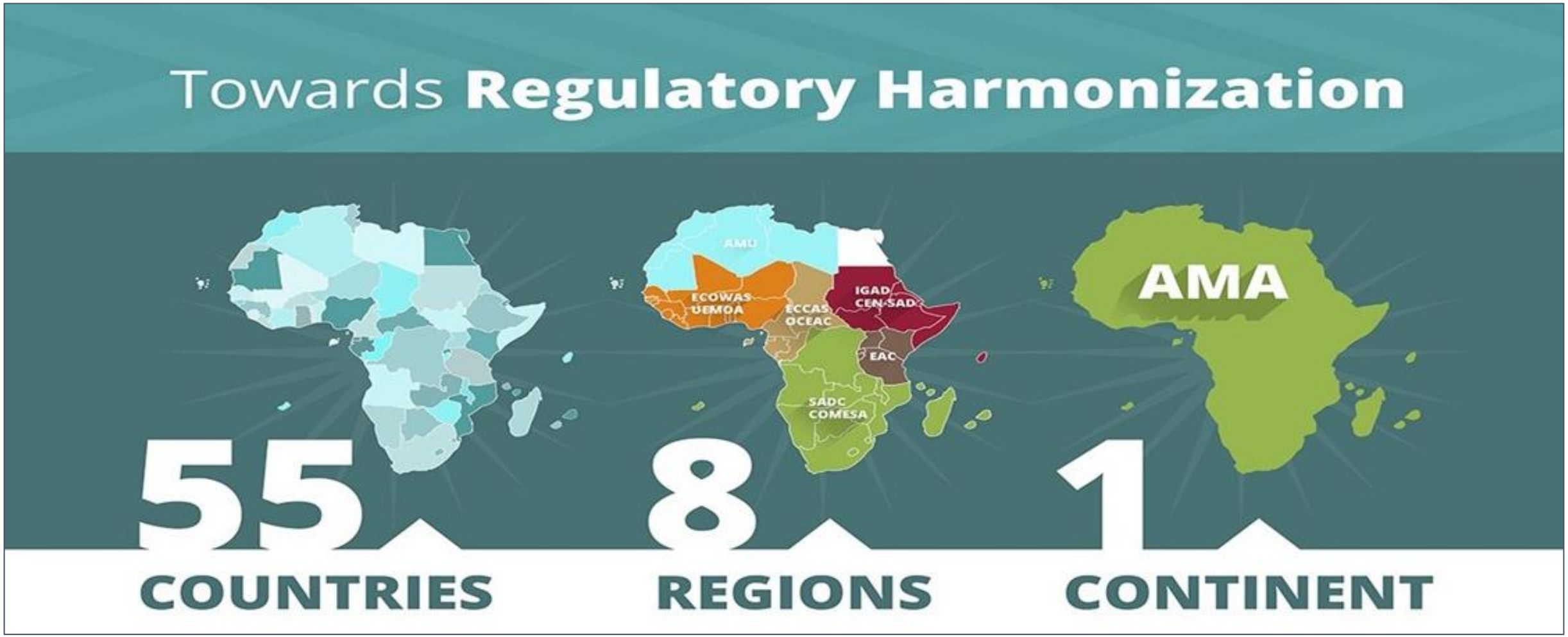
African Medicines Agency - Unpacked

Dr Judy Coates

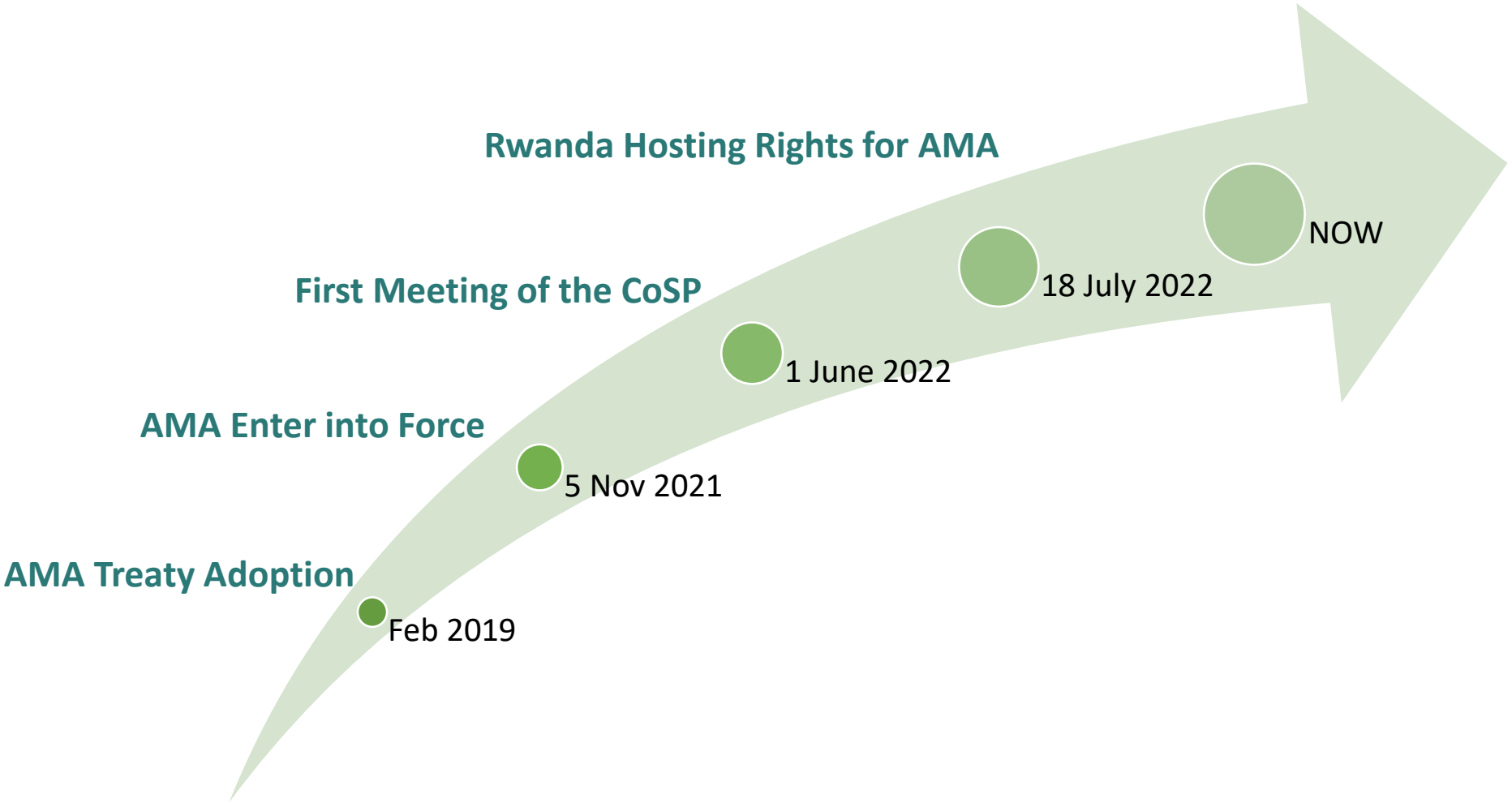
3 August 2022

SAAPI



African Medicines Agency

AMA Progress



AMA African Medicines Agency

African Union

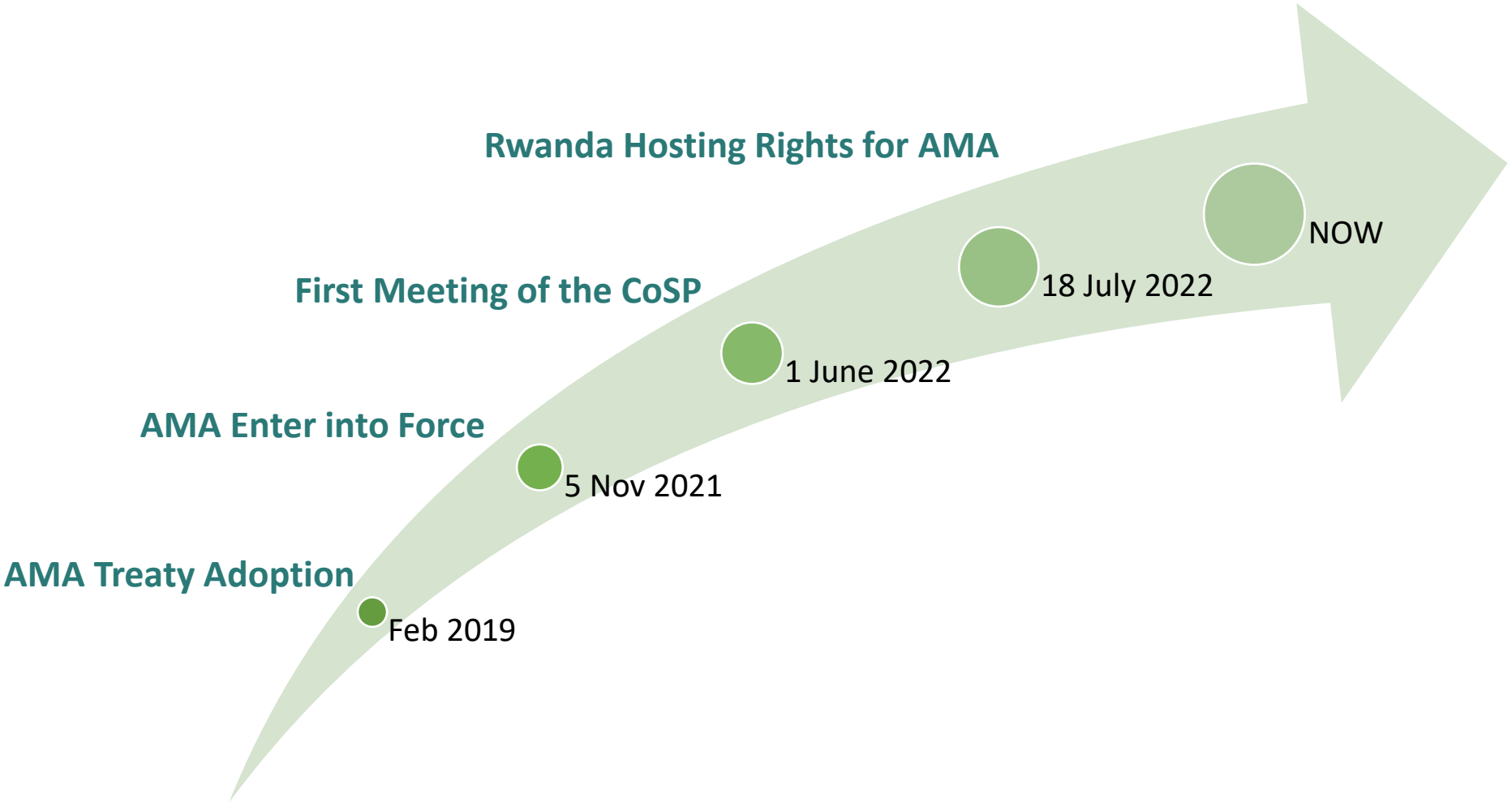
African Medicines Agency (AMA)

The Treaty for the establishment of the African Medicines Agency (AMA) was adopted in February 2019, by the 32nd Session of the Assembly of Head of State and Government. The Assembly further called on its Member States to sign and ratify the Treaty in order for the Treaty to enter into force as soon as possible (Assembly/AU/Dec.735 (XXXII).

AMA will be the second continental health agency after the Africa Centres for Disease Control and Prevention (Africa CDC), that will enhance the capacity of States Parties and Regional Economic Communities (RECs) to regulate medical products in order to improve aceess to quality, safe and efficacious medical products on the continent. AMA will also promote the adoption and harmonization of medical products regulatory policies and standards, as well as provide scientific guidelines and coordinate existing regulatory harmonization efforts in the African Union recognized RECs and Regional Health Organizations (RHOs).

African Medicines Agency

AMA Progress

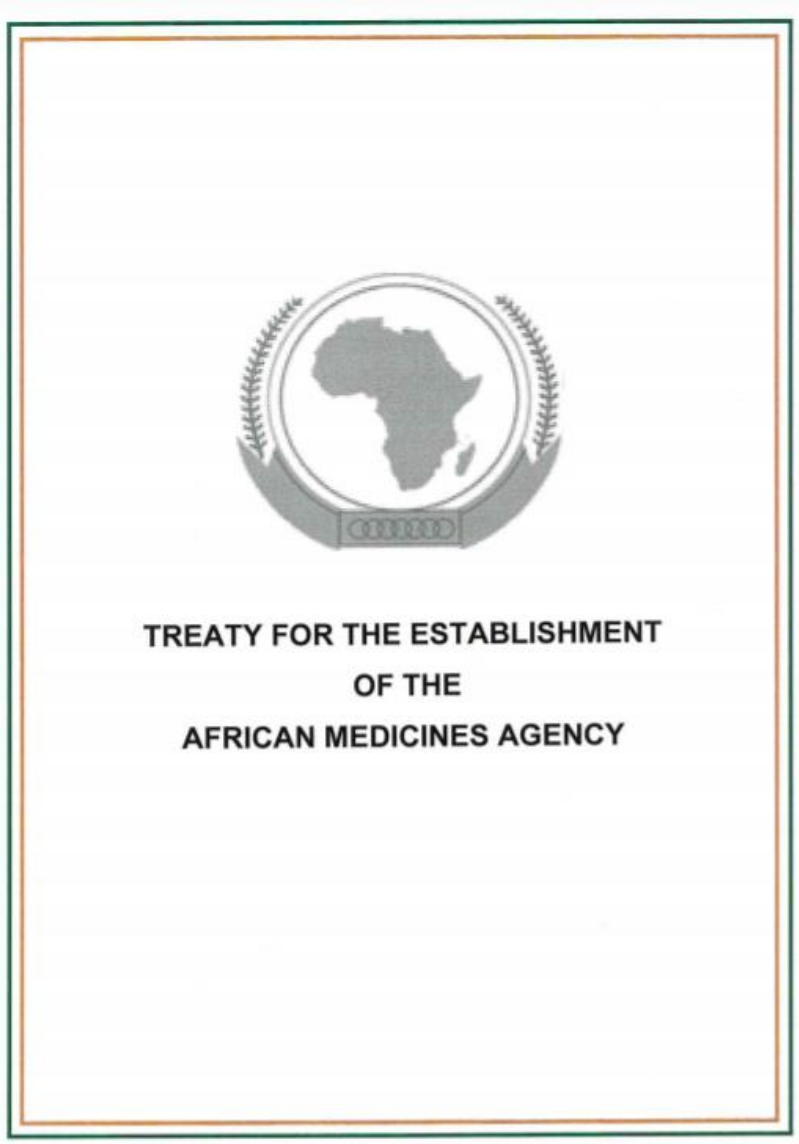


AMA African Medicines Agency

The AMA entered into Force on 5 November 2021 (Announcement)

Multilingual links to the AMA Treaty:

- The AMA Treaty in English
- The AMA Treaty in Arabic
- The AMA Treaty in French
- The AMA Treaty in Portuguese



Related

Breaking: Majority of African Countries Have Now Signed African Medicines Agency Treaty, Enabling Better Access to Newer, Safer Medicines

AMA Countdown

05/11/2021

African Medicines Agency Will Come into Being on 5 November – after 15th African Country Ratifies & Deposits AMA Treaty

AMA Countdown

06/10/2021

AMA Treaty Article 6 – AMA Function

ARTICLE 6
FUNCTIONS

The AMA shall perform the following functions:

(a) Coordinate and strengthen ongoing initiatives to harmonize medical products regulation and enhance the competence of GMP inspectors to do so;

(b) Coordinate the collection, management, storage and sharing of information on all medical products including SF medical products, with all its States Parties and globally;

(c) coordinate joint reviews of applications for the conducting of clinical trials and Provide technical support in quality control of drugs at the request of Member States which do not have the structures to carry out these examination/controls/checks;

(d) Promote the adoption and harmonization of medical products regulatory policies and standards, as well as scientific guidelines, and coordinate existing regulatory harmonization efforts in the RECs and RHOs;

(e) Designate, promote, strengthen, coordinate and monitor RCOREs with a view to developing the capacity of medical products regulatory professionals;

(f) Coordinate and collaborate, where required and on a regular basis, the inspection of drug manufacturing sites, including the regulatory oversight and safety monitoring of medical products, as determined by State Parties and/or the AMA, and make reports available to States Parties;

(g) Promote cooperation, partnership and recognition of regulatory decisions, in support of regional structures and NMRAs, that takes into account

mobilization of financial and technical resources to ensure sustainability of the AMA;

(h) Convene, in collaboration with the WHO, the AMRC and other bodies, meetings related to medical products regulation in Africa;

(i) Provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics in the event of a public health emergency on the continent with cross border or regional implications where new medical products are to be deployed for investigation and clinical trials;

(j) Examine, discuss and/or express regulatory guidance on any regulatory matter within its mandate, either on its own initiative or at the request of the African Union, RECs, or States Parties;

(k) Provide guidance on regulation of traditional medical products;

(l) Provide advice on the marketing authorization application process for the priority drugs described by the States Parties or on the products proposed by the pharmaceutical laboratories;

(m) Monitor the medicines market through the collection of samples in every State Party to ensure the quality of selected drugs, have them analysed and provide the results to States Parties and other interested parties, who will thus have reliable information on the quality of the drugs circulating in their countries and, where necessary, will take appropriate measures;

(n) Develop systems to monitor, evaluate and assess the comprehensiveness of national medical products regulatory systems with the view to recommend measures that will improve efficiency and effectiveness;

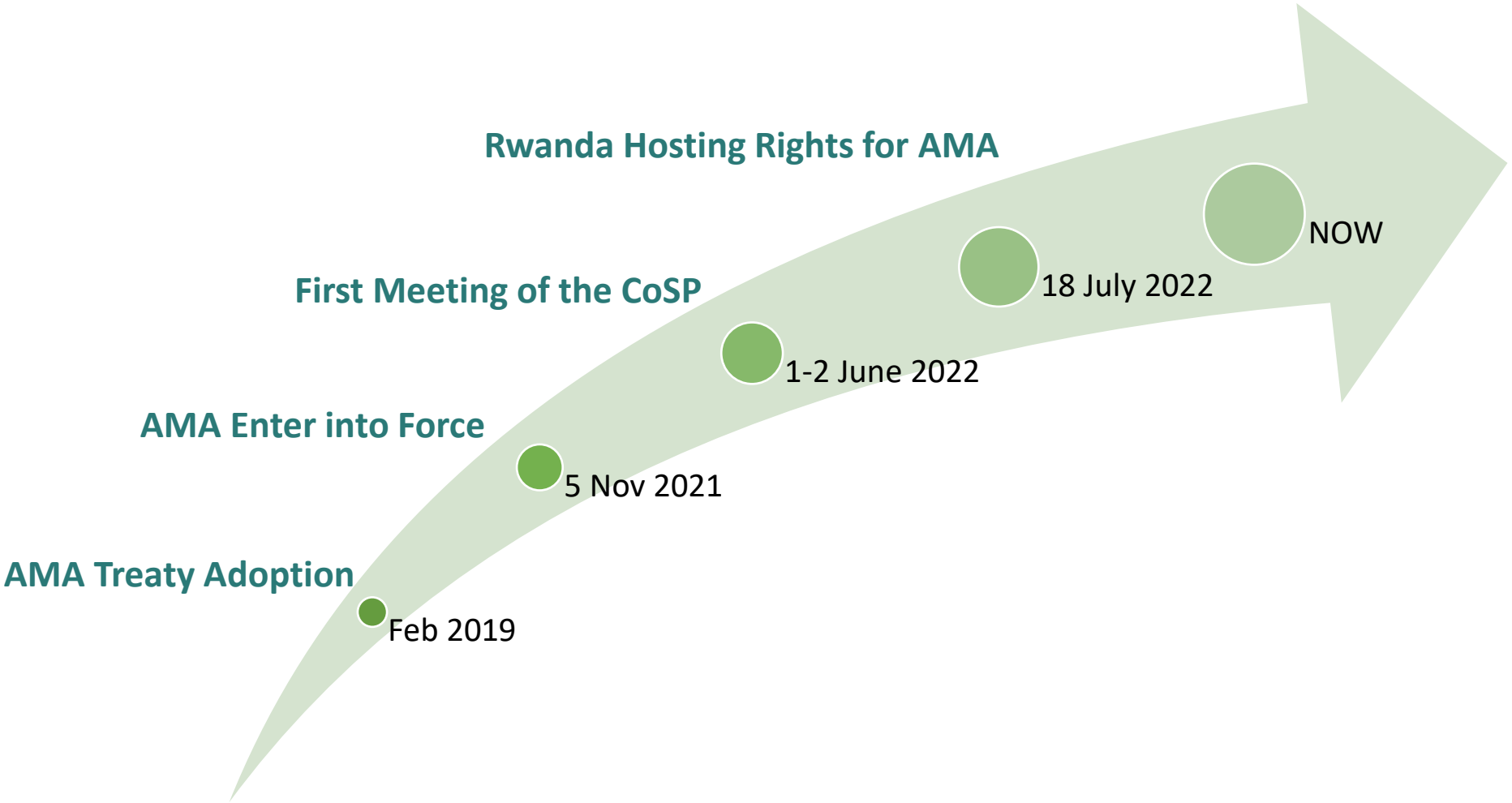
(o) Evaluate and decide on selected medical products, including complex molecules, for treatment of priority diseases/conditions as determined by the African Union, and WHO;

(p) Provide technical assistance and resources, where possible, on regulatory matters to States Parties that seek assistance and pool expertise and capacities to strengthen networking for optimal use of the limited resources available;

(q) coordinate access to and network the services available in quality control laboratory services within national and regional regulatory authorities; and

(r) Promote and advocate for the adoption of the AU Model Law on medical products regulation in States Parties and RECs to facilitate regulatory and legal reforms at continental, regional and national levels.

AMA Progress



AMA | African Medicines Agency

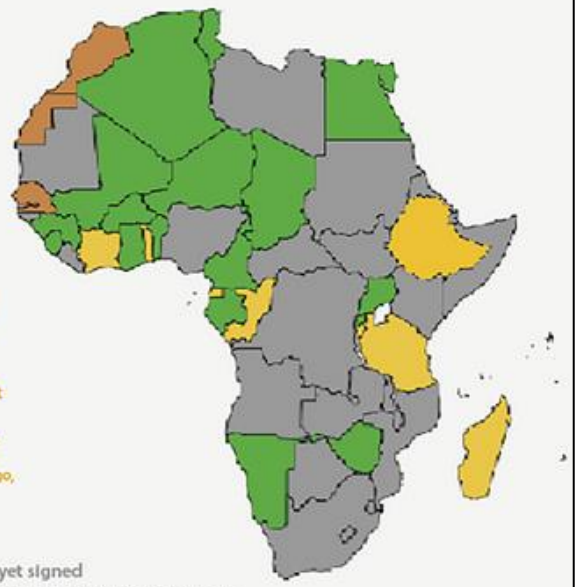
African Medicines Agency Countdown
status of support

31 countries have supported the AMA treaty

19 countries have ratified and deposited the treaty

19 Member States ratified and deposited

Algeria, Benin, Burkina Faso, Cameroon, Chad, Egypt, Gabon, Ghana, Guinea, Mali, Mauritius, Namibia, Niger, Rwanda, Seychelles, Sierra Leone, Tunisia, Uganda, Zimbabwe



3 Member States ratified but NOT deposited

Morocco, Saharawi Arab Democratic Republic, Senegal

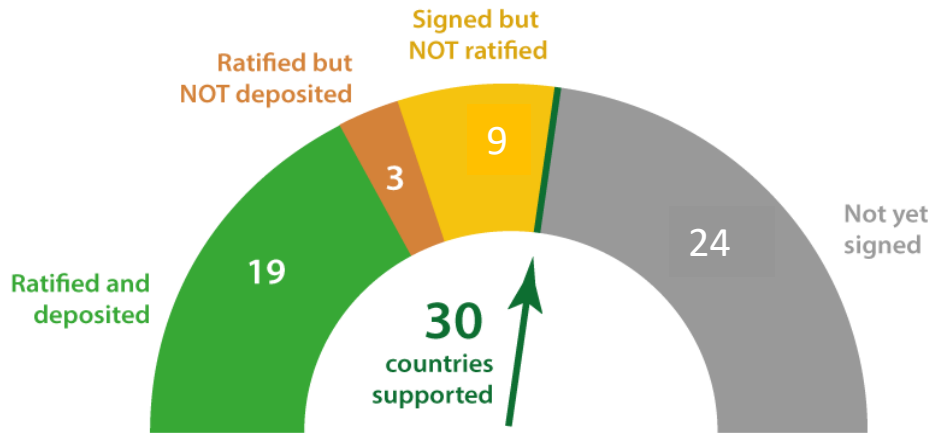
9 Member States signed but NOT ratified

Burundi, Comoros, Cote d'Ivoire, Equatorial Guinea, Madagascar, Republic of Congo, Tanzania, Togo, Ethiopia

24 Member States have NOT yet signed

Angola, Botswana, Cape Verde, Central African Republic, Democratic Republic of Congo, Djibouti, Eritrea, Eswatini, Gambia, Guinea-Bissau, Kenya, Lesotho, Liberia, Libya, Malawi, Mauritania, Mozambique, Nigeria, South Sudan, Sao Tome and Principe, Somalia, South Africa, Sudan, Zambia

African Medicines Agency Countdown
status of support



Algeria, Benin, Burkina Faso, Cameroon, Chad, Egypt, Gabon, Ghana, Guinea, Mali, Mauritius, Namibia, Niger, Rwanda, Seychelles, Sierra Leone, Tunisia, Uganda, Zimbabwe

Morocco, Saharawi Arab Democratic Republic, Senegal

Burundi, Comoros, Cote d'Ivoire, Equatorial Guinea, Madagascar, Republic of Congo, Tanzania, Togo

Angola, Botswana, Cape Verde, Central African Republic, Democratic Republic of Congo, Djibouti, Eritrea, Eswatini, Ethiopia, Gambia, Guinea-Bissau, Kenya, Lesotho, Liberia, Libya, Malawi, Mauritania, Mozambique, Nigeria, South Sudan, Sao Tome and Principe, Somalia, South Africa, Sudan, Zambia

Health Policy Watch

Sources: African Union infographics - https://au.int/en/documents/20211105/infographics-treaty-establishment-african-medicines-agency, updated by AU Comms - https://twitter.com/Dottienjagi/status/1468217802439995396. States "supporting" refers to countries that have signed treaty and/or ratified the treaty. (Two states, Burkina Faso and Namibia ratified and deposited the treaty without ever signing it formally).

IFPMA Engagement on AMA

AMA

Advocacy

- Monitor ratification process
- Continue advocacy activities
- Support the operationalisation of AMA based on the draft AMA workplan

AMATA

- Collaborate with AMATA Membership and its Working Group

Local Production

- PAVM
- EU/AU dialog


African Medicines Agency Has Key Role as Continent Pushes Local Vaccine Production

Medicines & Vaccines 07/12/2021 • Kerry Cullinan

Share this:

Dr Michel Sidibe, WHO's Mariangela Simao and representatives from African medicine national regulatory authorities

AMA Draft Workplan – IFPMA Areas of Interest and Support

Activity 1 – Continue to push for ratification. At least 10 additional countries ratify AMA treaty by Dec 2022

Activity 5 – First meeting of the Conference of State Parties

Activity 6 – Y1 and Y2-5 workplan to support AMA (support and expertise)

Activity 8 – Industry fees and procedures

Activity 9 – Socialize framework with AMRH/AMA Stakeholders

Activity 10 – Cooperate with NMRAs and RECs set up AMA and local procedures

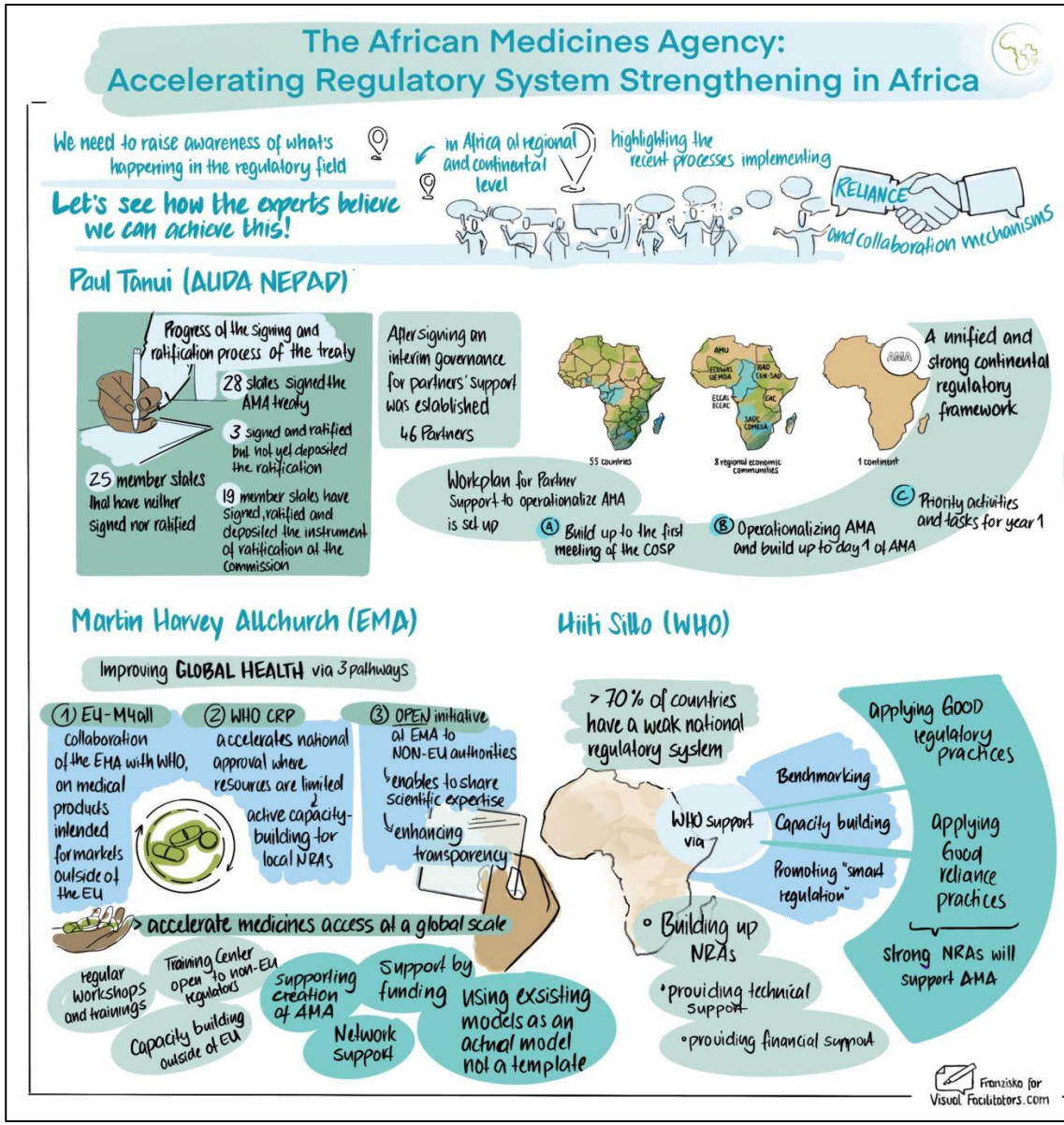
Activities 12 and 15 – AMA communication plan and timelines

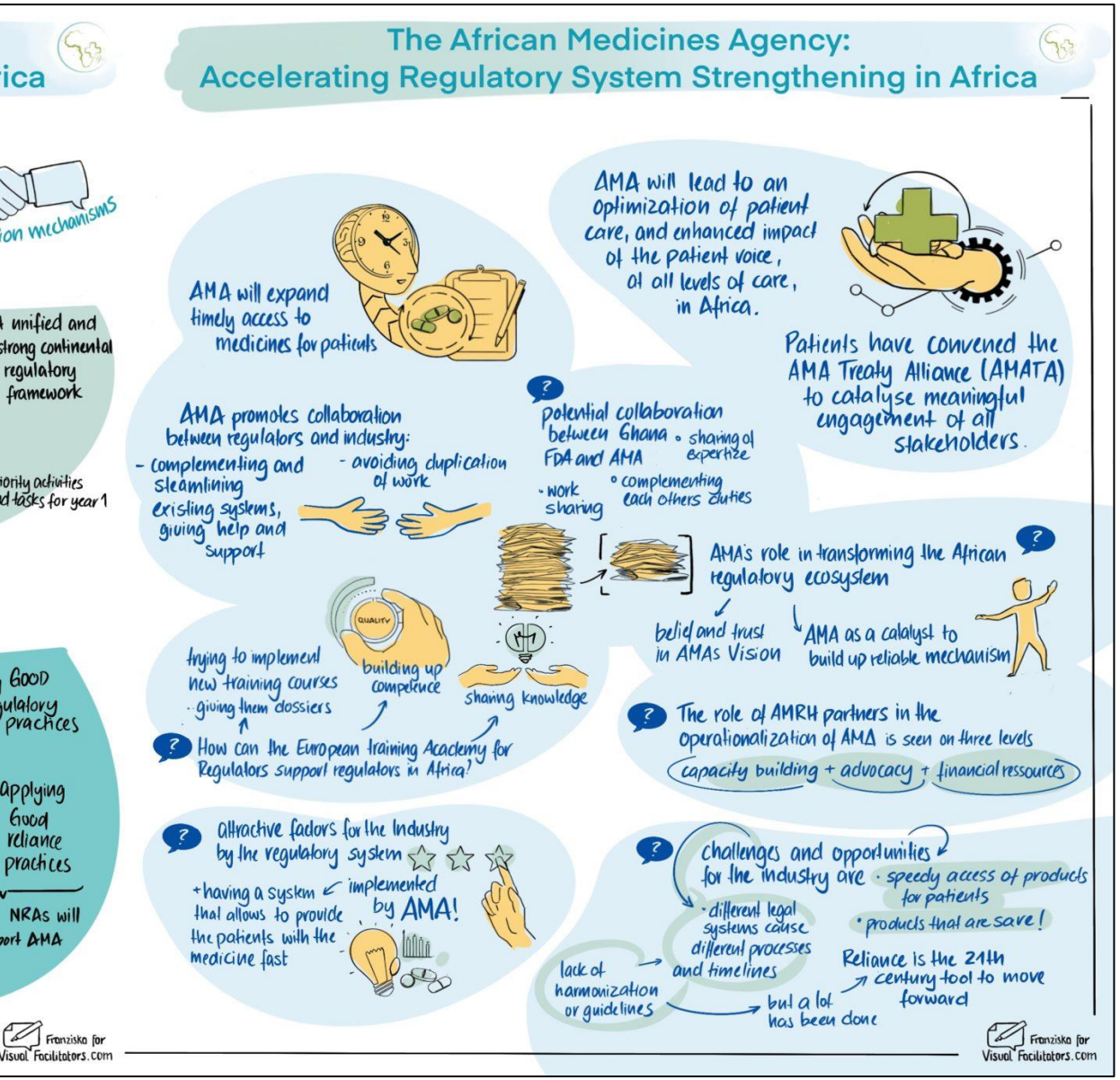
Activity 14 – Create knowledge and product database and website

Activity 16 – Mapping of experts across the continent

IFPMA

AFRICA Track – DIA Europe 2022





AMATA

African Medicines Agency
Treaty Alliance

www.iapo.org.uk/amata

African Medicines Agency Treaty Alliance (AMATA) Launch

AMATA is a multi-stakeholder alliance of non state actors, set up to advocate for the rapid ratification and implementation of the AMA Treaty and for meaningful engagement with patients and other relevant parties, in all aspects of the Agency framework and development.
AMATA is an initiative led by the International Alliance of Patients' Organisation (IAPO) with operational support from IFPMA.

Officially launched on 22 June 2021 at AMA High Level Trilingual Virtual Event co-organised by IFPMA – LEEM – IAPO and convened by Michel Sidibe, AU Special Envoy for AMA.

Steering Committee has diverse representation from patient and civil society organisations; health NGOs; industry associations; academic networks and youth groups.24

International Alliance of Patients' Organizations
A global voice for patients

alliance (K)

PATH

amref health africa

IFPMA

International Pharmaceutical Students' Federation

SpeakUpAfrica.

Association of African Universitie
Association des universités africaines

AMATA – Progress

First Steering Committee 14 July 2021

- Core Group of Founding Members
- Terms of Reference
- Growth Strategies
- Toolbox

Introduction of AMATA to Relevant Stakeholders

- Youth Shaping the Future of Africa (15 July 2021)
- AMA Treaty Regulatory Convergence and Reliance (21 July 2021)
- Outreach to various stakeholders, including, but not limited to, WMA, FIP, IHF, WONCA, Pandemic Action network, GSCF, Fight the Fake Alliance, Africa Siter Trade Associations, Local producers, and more.

International Alliance of Patients' Organizations
A global voice for patients

alliance (K)

PATH

amref health africa

IFPMA

International Pharmaceutical Students' Federation

SpeakUpAfrica.

Association of African Universitie
Association des universités africaines

AMATA
African Medicines Agency Treaty Alliance

Joint Statement by founding members of AMA Treaty Alliance (AMATA) to welcome the African Medicines Agency coming into force

November 5, 2021 --We, as founding members of AMATA, representing patients, academia, civil society, and industry, welcome the official ratification of the AMA Treaty, which has enabled the African Medicines Agency to effectively enter into force today.

We now call on the African Union to build on the current momentum gained with the legal deposition of instrument of ratification of the Treaty by the minimum required 15 AU Member States, to prepare for the practical implementation of the Agency, ensuring the following critical elements:

The African Medicines Agency Governing Board to recognise patients as key partners in the management structures and development of the Agency.

A solid governance structure is put in place and a seamless transition from the AMRH to the AMA is ensured.

Robust regulatory infrastructures continue to be strengthened in all African Union Member States and at regional level.

A Secretariat is formed, and its location is decided without undue delay.

The African Medicines Agency is equipped with adequate human resource capacity to operationalise its mandate.

The African Medicines Agency Governing Board to set up a framework of engagement with non-state actors and to draw upon all available expertise from academia, research bodies, private sector and community and patient groups to provide technical guidance on specific areas.

A sustainable funding model is implemented to ensure short and long term stability of the Agency at the time of its inception.

We congratulate the 15 Member States of the African Union that completed the process of ratification and invite all remaining AU Member States to follow in their footsteps.

COVID-19 has demonstrated that health security will only be achieved through concerted efforts and cross-border collaboration.

We thus call on all AU Heads of State to seize this historic opportunity to have one regulatory affairs oversight across the Continent to enhance national, regional and continental regulation of medical products and oversee rapid and effective market authorization of safe, quality, effective and accessible medical products, for the good of all African people.

International Alliance of Patients' Organizations — A global voice for patients
IFPMA
alliance (K)
amref health africa
University of the Witwatersrand, Johannesburg
PATH
SpeakUpAfrica.
Association of African Universities — North Africa Regional Office — AAU - NARO — المقر الإقليمي لاتحاد الجامعات الإفريقية لشمال إفريقيا
International Pharmaceutical Students' Federation

AMATA Steering Committee

AMATA — African Medicines Agency Treaty Alliance

Kawaldip Sehmi
CEO, International Alliance of Patients' Organisations

Catherine Karakezi
Technical Advisor, NCD Alliance Kenya

Catherine Kanari
Head of UHC Amref Health Innovations , Amref Health Africa

Greg Perry
Assistant-Director General, IFPMA

Precious Matsoso
Former Director General Ministry of Health South Africa and Director of the Health Regulatory Science Platform University of the Witwatersrand, South Africa

Johnpaul Omollo
Policy and Advocacy officer, PATH

Yacine Djibo
Founder and Executive Director, Speak Up Africa

Prof. Amany El-Sharif
Director of AAU North Africa Regional Office (NARO), Al-Azhar University, Egypt

Yaw Asamoah Mfoafo
Chairperson of IPSF African Regional International Pharmaceutical Students' Federation

AMATA
African Medicines Agency
Treaty Alliance

AMATA welcomes the decision for Rwanda to host headquarters of African Medicines Agency

July 19, 2022 –The founding members of the African Medicines Agency Treaty Alliance (AMATA), an alliance representing African patients, academia, civil society, and industry, welcome the decision by the AU Executive Council to nominate Rwanda as the country that will host the African Medicines Agency (AMA) headquarters and Secretariat. We congratulate Rwanda on this milestone.

This a historic moment to bring all stakeholders together and co-create an African Medicines Agency that will truly enhance the capacity of State Parties and AU recognized Regional Economic Communities (RECs) to regulate medical products to improve access to quality, safe and efficacious medical products on the continent.

During the early stages of COVID-19 vaccine authorisation, it was clear that Africa needed a body like AMA to co-ordinate and support State Parties and Regional Economic Communities to quickly assess and licence these vaccines in a coherent and consistent manner. AMATA welcomes AMA as a measure for pandemic preparedness too.

We all know that finding a building is different from making it a home. Let us build this new AMA family home together. We now call upon the remaining family of African Union Member States who have yet to ratify and deposit their AMA Treaty instruments to do so urgently so that we can now build on the current momentum gained with this major milestone.

We now call upon the AU to ensure that:

We have an unanimously ratified Treaty Instrument- all 54 Member States must ratify and deposit to make us one AMA Pan-African Medicines Regulatory Family

Sufficient finances and budgets are established and firmed up quickly for this new Agency

Ensure that the AMA Governing Board is quickly recruited and appointed and mandated to ensure that the AMA is equipped with adequate human resource capacity to operationalise as mandated.

Will continue to build up and strengthen robust national regulatory infrastructures in all African Union Member States Regional Economic Communities

The AMA Board must set up a framework of engagement with non-state actors and to draw upon all available expertise from African academia, research bodies, industry and private sector and community and patient groups to provide technical guidance on specific areas.

Reach out to international development agencies, partners such as the European Union and the international banks to establish a sustainable funding model and implemented to ensure short- and long-term stability of the Agency.

The African Medicines Agency Governing Board to recognise patients as key partners in the management structures and development of the Agency and its NSA engagement frameworks. Like the Patient and Consumer Working Party (PCWP) at the European Medicines Agency and the Patient Engagement Collaborative (PEC) at FDA USA, a Pan-African Patients Working Party needs to be set up.

The founding members of the African Medicines Agency Treaty Alliance (AMATA), an alliance representing African patients, academia, civil society, and industry

Progress within South Africa

Support from SAHPRA, DSI, and the ICTS DG Cluster Forum

2021

Cabinet Memo was presented at ICTS DG Cluster Forum

5 May 2022

Treaty ready to be presented to Cabinet process

July2022

International Law Advisors are providing guidance

NOW

Target to be Signed

Before AU Summit (November 2022)

Thereafter to be Ratified and Instrument of Ratification to be submitted to the AU

SAHPRA - South African Health Products Regulatory Authority; DSI - Department of Science and Innovation;
ICTS DG Cluster Forum - mainly consist of a number of Departments, including DIRCO, DTIC, Science and Technology

Concluding Remarks

- Importance of strong regulatory system in place, at national, regional and continental level (link with WHO GBT and ML3).
- Use of reliance, collaboration and work-sharing to accelerate access to medicinal products to patients.
- Encourage greater harmonisation and convergence of regulatory requirements.
- Lessons learnt from the pandemic, development of regulatory agilities that can become the new normal.
- AMA has the unique opportunity to become one of the most efficient and modern regulatory systems in the world.
- Patients are waiting.


THANK
YOU