The African Medicines Agency

MOVING TOWARDS REGULATORY HARMONIZATION IN AFRICA

Introduction

- African continent is home of 55 countries
- Major importer of medicines for domestic use across the continent
- Access to medicines of good quality, appropriately used and affordable is one of the major health challenges of the region
- Characterised by weak regulations on medicines in most countries due to

-limited regulatory capacity- e.g. resulting in unregulated medicines markets, posing serious risks for individual and public health.

-**local production capacity-** limited pharmaceutical production capacity, most depended mainly on imports

-**supply chain integrity-** diverse distribution chain, with some types of unauthorized outlets suggesting the presence of an informal market

-contradictions between the interests of public health and those of the transnational pharmaceutical industry (**complex politically**)

National Medicines Regulatory Authorities

- 54 NMRAs in Africa –variable organizational set-up and functionality (some are located within Ministries of Health and others are semi-autonomous)
- Most NMRAs incapable of performing the core functions expected.
- Only 7% of African countries have moderately developed capacity with more than 90% having minimal or no capacity (WHO)
- The absence of functional NMRAs in any country

(i) exposes the population to potentially unsafe medical products of variable quality and effectiveness;

(ii) facilitates the proliferation of substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products; and

(iii) prevents rational use of medical products, all of which are detrimental to public health and patient safety

Towards medicines regulatory harmonisation

- **2007** launched the Africa Medicines Harmonisation Initiative
- **2009**, African Ministers of Health –working towards a continental wide regulatory framework
- **2014 -Guidance for the establishment of the African Medicines Agency (AMA) in Luanda Angola,** 1st African Ministers of Health meeting. AUC, NEPAD Agency and WHO- joint secretariat established for AMA (define the scope of activities, institutional framework, legal and financial implications)
- **2015 Executive Council decision endorsed the establishment of AMA**- a single medicines regulatory agency in Africa in the context of the African Medicines Regulatory Harmonisation (AMRH) Programme which is part of implementation of AU Pharmaceutical Manufacturing Plan for Africa (PMPA) Framework
- **2016 AU Assembly Decision (26th Ordinary Session) Adopted the AU Model Law on Medicines Regulation** as a legal instrument to guide AU Member states

Process of African Medicines Agency

- **In 2017, draft AMA treaty** at the 67th session of WHO Afro (Zimbabwe)-more time to review

- May 2018, African health ministers of 55-countries **adopted a treaty to establish the African Medicines Agency**, (71st World Health Assembly)

- **February 2019**: African Union Heads of State and Government adopted the treaty for the establishment of the African Medicine Agency (AMA) during their 32nd Ordinary Session of the Assembly, Addis Ababa, Ethiopia.

- **In 2019** the WB invited expressions of interest in a consultancy for the strategy and business plan of the African Medicines Agency.

African Medicines Agency (AMA)

- **A Specialized Agency of the AU** to assist Member States of the African Union to improve their capacities to regulate medical products

Purpose of the AMA

- to ensure the coordination and strengthening of continental initiatives to harmonize medical products regulation, provide guidance, complement and enhance the efforts of the African Union-recognised RECs and Member States, and contribute to improving access to medical products on the continent

- Ultimate goal of establishing AMA is to have very strong national regulatory systems, with excellent technical backup at regional and continental levels in Africa

Scope OF AMA activities

- Serve as a catalyst for stronger regulatory oversight

1. Promotion of policy, legal and regulatory reforms in AU Member States;
2. Development of technical guidelines;
3. Assessment of regulatory systems;
4. Strengthening capacity of national regulatory agencies (training, meetings, databases and exchange);
5. Resource mobilization;
6. Designation and resourcing of regional centres of regulatory excellence (RCOREs); and
7. Promotion of international cooperation and partnerships.

AMA

- AMA will be established ***once the Treaty is ratified by fifteen African Union Member States***

- Once ratified, the new African Medicines Agency (AMA) will support the varying regulatory capacities of its member states and will help set-up a comprehensive, regional system of regulatory supervision that serves to harmonize regulations across national boundaries, make efficient use of its limited resources, and deepen its capacity building.

- It is a vital step that will help improve timely access to effective, quality therapies, and vaccines for all patients, in every corner of Africa.

AU Model law on Medical Products regulation

- AU Model Law was adopted by AU member states in 2016

Purpose

- To facilitate regional harmonization initiatives by MS operating on the same rules, requirements and standards for regulation of medical products and technologies across the continent.

AU Model law

- A legislative framework that is aimed at directing AU member states and Regional Economic Communities in the harmonisation of regulatory systems
- 14 countries thus far have domesticated the model law to some degree in their respective countries.
- Acts as a tool in mitigation of Sub-standard and Falsified (SF) medical products in Africa which remains a major challenge, hence why the domestication of the model law by African governments is pivotal.

Model laws deals with

- **Marketing health technologies**: All medical products must be registered and have valid authorization to be marketed and promoted. Applications for this authorization will be reviewed by the NRA.
- **Licensing**: Only with a licence from the NRA may a person or company manufacture or distribute health technologies.
- **Quality and safety of health technologies:** The NRA will be responsible for monitoring and analysing adverse effects of registered health technologies and clinical trials, as well as the recall and withdrawal of substandard products. The NRA will conduct quality and safety inspections of health technologies and manufacturing facilities, and a National Quality Control Laboratory will be established for research, training and the analysis of medical products.
- **Clinical trials:** To conduct a clinical trial with human participants, the trial must be cleared by a National Ethics Committee or Institutional Review Board and authorized by the NRA.
- **Appeals procedures:** authority overseeing the NRA (e.g. the Moh) will establish an Administrative Appeals Committee to hear cases lodged against the NRA.

AU Model law on Medical Products

Benefits

- It will help AU member states to fill the legislative gaps that hinder effective regulation of medical products and prevent harmonization of these regulations at the regional level.
- Facilitates the use of a regulatory generic framework across the African regions
- Strengthens national laws on medical product regulation
- Encourages independent national regulatory authorities
- AU states have ability to adapt their national regulatory laws to align with AU model law.
- By 2020 its expected that a minimum of 25 AU Member states will be using some form of the Model law in their national law

Policy, Legal and Regulatory Reforms-Scope of AMA

- In its operations, the AMA will therefore:

a) **Continuously revise the model law** taking into account emerging public health issues; technological advances in the regulation of medical products and health technologies.

b) **Promote the use of the model law** to develop new medicines legislations in countries where such legislation do not exist or are out-dated.

c) **Advocate the use of the model law** at continental, regional and country levels to the highest decision makers in health, justice, trade and human rights.

d) **Support the development of accompanying regulations** in countries to facilitate the implementation of legislation.

e) **Advocate the use of these legal instruments** by Legislative Assemblies and Parliaments of Member States and Regional Economic Communities (RECs)

Benefits of AMA

- Promoting local manufacturing (and lower prices)
- Preventing substandard and falsified medicines
- Controlling unethical marketing of medicines
- Promoting supply chain integrity

Potential Risks

Keeping big PHARMA out!

- Presents a more central opportunity to be compromised by issues of conflict of interest especially influence of big pharma on policies and decisions (agency adopting regulatory policies promoted by Big Pharma)
- Issues of barriers to competition- AMA can be used to grant data market exclusivities –which obstructs availability of generic drugs
- Used to enforce or create Intellectual Property Rights in medicines
- Level of standards set and enforced by AMA – caution in lowering acceptable standards
- Limited inclusive process of civil society engagement in the AMA process e.g. similar to African Regional Intellectual Property Organization (ARIPO)

To consider

- Keeping big PHARMA out of medicines regulation
- Advocate for ratification of AMA
- Domestication of AU Model law
- Representation of independent CS in AMA-to increase transparency
- AMA autonomous and funded by MS to avoid vested interests

Towards **Regulatory Harmonization**

55 **COUNTRIES**

8 **REGIONS**

1 **CONTINENT**

Questions

1. Are there international/ regional days that we can utilize for an advocacy engagement?

2. Are there AMA and AU meetings that we can participate and set up targeted advocacy?

3. How many countries have adopted AU Model Law? Can we do a scorecard with key advocacy message on that and disseminate?

4. Are there opportunists for face to face advocacy with AMA?

5. The AMA does not have adequate resources to exert its influence? What can we do about that?