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SECOND SESSION OF THE SPECIALISED TECHNICAL COMMITTEE ON HEALTH, POPULATION AND DRUG CONTROL (STC-HPDC-2)
ADDIS ABABA, ETHIOPIA
20-24 MARCH 2017

Theme: "Youth, Health and Development: Overcoming the Challenges towards Harnessing the Demographic Dividend"

STATUS REPORT ON IMPLEMENTATION OF THE MILESTONES TOWARDS THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)

STATUS REPORT ON IMPLEMENTATION OF THE MILESTONES TOWARDS THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY

2ND MEETING OF THE SPECIALISED TECHNICAL COMMITTEE ON HEALTH, POPULATION AND DRUG CONTROL

ADDIS ABABA, ETHIOPIA, 20-24 MARCH 2017

1. BACKGROUND

Most African Union Member States continue to suffer not only the inadequate supply of medical products but also the consequences of weak regulatory systems unable to curtail the circulation of substandard counterfeit medical products and health technologies. These products pose risk to public health, harm patients and undermine confidence in healthcare delivery systems.

The 55th Decision of the African Union (AU) {Assembly /AU/Dec. 55(IV)} of January 2005 requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD Framework to enhance local capacities to produce quality assured essential medicines including through boosting research and development and taking full advantage of the flexibilities within the Trade and Related Intellectual Property Rights (TRIPS). In 2012, the PMPA Business Plan was endorsed by the 19th AU Assembly {Assembly AU/Dec.442 (XIX)} in January and the AU Roadmap on Shared Responsibility and Global Solidarity on AIDS, TB and Malaria in July. The business plan as a package of technical solutions to the challenges confronting the local pharmaceutical industry and the AU Roadmap on shared responsibility and global solidarity as a mechanism to speed up the continent's efforts to end the HIV, TB and Malaria scourge, necessitate a conducive medicines regulatory and legislative environment. Therefore the latter two Assembly Decisions stressed the need and expressed Africa's leaders' commitment to accelerate and strengthen regional medicines regulatory harmonization initiatives that lay the foundation for a single African regulatory agency.

To pursue implementation of the above decisions, the First African Ministers of Health meeting jointly convened by the AUC and WHO held in Luanda, Angola, from 16 to 17 April 2014 endorsed milestones towards the establishment of the African Medicines Agency (AMA); and committed to prioritize investment for regulatory capacity development; to pursue the efforts towards convergence and harmonization of medical products regulation in Regional Economic Communities (RECs) and to allocate adequate resources for the agency. They also requested the AUC, NEPAD Agency and WHO to establish a task team that would facilitate the implementation of the following milestones towards the establishment of the AMA by 2018:

Milestones and corresponding timelines as agreed in Luanda	
Adoption of proposal to establish AMA by the African Ministers of Health	2014
Establishment of a task team to facilitate the operationalization of the AMA milestones by African Ministers of Health	2014
Decision/Endorsement in principle by the Assembly of Heads of State and Governments	2015
Designation of Host Country/Institution	2016
Approval of the Governing Body of the AMA	2017
Appointment of staff and Allocation of Resources	2017
Launch of AMA	2018

This status report highlights the objectives of AMA, key achievements since 2014 to date, and opportunities for accelerating progress in the implementation of the milestones towards the establishment of the AMA. Finally it proposes a roadmap for the next steps and for consideration by the 2nd meeting of the AU Specialized Technical Committee on Health, Population & Drug Control (STCHPDC).

2. THE OBJECTIVES OF AMA

The AMA is intended to be an AU Specialized Agency, legally mandated by Member States; to coordinate on-going regulatory systems strengthening and harmonization efforts of the Regional Economic Communities (RECs), Regional Health Organization (RHOs) and Member States; provide guidance, complement and enhance collaboration; and contribute to improving patient's access to quality, safe and efficacious medical products and health technologies on the continent.

The **Vision** for establishment of AMA is to ensure that both locally produced and imported medical products for priority diseases/conditions in Africa are affordable and meet internationally recognized standards of quality, safety and efficacy.

The **Mission** of AMA at the continental level is to coordinate national and regional medicines regulatory systems, carry out regulatory oversight of selected medical products and to promote co-operation, harmonization and mutual recognition of regulatory decisions.

The AMA will not supplant national regulatory authorities' efforts but will complement and continue to harness existing regulatory systems strengthening and harmonization efforts as opportunities to enhance regulatory convergence on the continent. They include the African Medicines Regulatory Harmonization Initiative; African Vaccines Regulatory Experts Forum (AVAREF); the Pan African Harmonization Working Party on Medical Devices and In-Vitro Diagnostics (PAHWP), Network of Official Medicines Control Laboratories–Africa (NOMCoL-Africa); Biennial African Medicines Regulators Conference (AMRC); and Biennial Scientific Conference on Medicines Regulation in Africa.

3. ACHIEVEMENTS

Progress has been made in the implementation of the Luanda commitment which expressed Member States' political will to:

i. Increase and prioritize investment for regulatory capacity development;
ii. Pursue the efforts towards convergence and harmonization of medical products regulation in RECs and
iii. Allocate adequate resources for AMA.

and requested:

i. *AUC, NEPAD and WHO to establish a Task Team that would facilitate the implementation of the agreed milestones with due regard to regional representation and skills required to meet the mandate as noted.*
ii. *AUC to seek support from Heads of State and Government for the institutional and financial implications of AMA;*

3.1 *…Increase and prioritize investment for regulatory capacity development*

In Luanda, Member States committed to increase and prioritize investment for regulatory capacity development. A number of Member States' continue to participate in the activities of the eleven (11) Regional Centers of Regulatory Excellence established under the African Medicines Regulatory Harmonization programme and operating across the continent. This indicates their commitment and investments in this field.[1]

Established in 2014 and expected to be evaluated in 2018, the RCOREs provide:

- Academic and technical training on regulatory science applicable to different regulatory functions[2] and managerial aspects;
- Skills enhancement through hands-on training, twinning and exchange;
- Practical training through placement in the pharmaceutical industry and
- Execution of operational research to pilot-test innovations and interventions to inform best practices for scale–up to other National Medicines Regulatory Authorities.

In the same manner, Member States are also expected to support the African Medicines Regulatory Professionals Fellowship Programme established to nurture and develop technical and managerial competencies to ensure effective medicines regulation in Africa.

3.2…*Pursue the efforts towards convergence and harmonization of medical products regulation in RECs*

In the context of implementation of the 24th Ordinary Session of the NEPAD Heads of State and Government Orientation Committee of January 2015 Decision {Assembly/AU/Dec.563(XXIV) Para 11} as part of implementation of the African Medicines Regulatory Harmonization programme, member states through the AUC, and their respective RECs and RHOs mobilized human, financial and material resources and continental expertise to deal with the Ebola Virus Disease(EVD) Outbreak. In addition, NEPAD Agency facilitated the establishment of regional Expert Working Groups (EWGs) on Clinical Trials Oversight in East African Community (EAC) and the Economic Community of West African States (ECOWAS).

[1]Countries hosting one or two RCOREs include: Uganda, Zimbabwe, Nigeria, Kenya, Ghana

[2] Regulatory functions covered under current RCOREs include: Clinical Trial Oversight, Licensing of manufacture, import, export, distribution and inspection and surveillance of manufacturers, dispensers of medicine; medicines registration and evaluation, quality assurance/quality control and clinical trials oversight; Training in core regulatory functions, Pharmacovigilance, Medicines evaluation and Registration; Registration and evaluation and clinical trials oversight

3.3…*Allocate adequate resources for AMA*

As the milestones for establishment of the AMA progress, Member States continue to demonstrate commitment including the nominating experts on various technical teams and experts groups e.g. Experts have been drawn from across the continent to boost the human resource required to design, elaborate the legal and institutional framework as well as the business plan for AMA. Continued contribution of human, infrastructure and financial resources is expected from Member States to support the operations of AMA once established in 2018 and beyond.

3.4 AUC, NEPAD Agency and WHO *establish a Task Team that would facilitate the implementation of the agreed milestones with due regard to regional representation and skills required to meet the mandate as noted*

Led by the AUC, in November 2014 the terms of reference and members of the Task Team to facilitate implementation of the milestones towards AMA were drafted and appointed respectively. AMA Task Team provides the necessary guidance and advises on the modalities for the operationalization AMA. It convened its first meeting that deliberated its terms of reference, endorsed the AUC-NEPAD-WHO as its joint secretariat, and adopted a 4-year action plan ending in 2018 with the launch of AMA.

In April 2015, the 1st meeting of the AU specialized technical committee on health population and drug control (STCHPDC-1) endorsed the AMA Task team's report which included an update on the implementation of the 26th ordinary session Executive Council decision EX.CL/Dec.857 (XXVI) that requested

…the Commission, the NEPAD Planning and Coordinating Agency and WHO in collaboration with other stakeholders to

i) Define the scope of the medical products that would be covered by the work of the AMA
ii) Work out detailed modalities, institutional framework, legal and financial implications of the establishment of AMA.

The AMA Task Team has since undertaken to support the development of and convened three times to review the legal and institutional frameworks as well as a draft business plan for AMA.

In February 20-22, 2017; stakeholders' consultation on the three key AMA documents was conducted during which experts from across the continent and regional economic communities deliberated and provided inputs. The consultation attended by over 100 experts from 29 member states culminated in the revision of the legal, institutional frameworks and business plan for AMA which are attached to this report for consideration and adoption by the 2nd meeting of the STCHPDC.

3.5…*AUC to seek support from Heads of State and Government for the institutional and financial implications of AMA*

In 2015, AUC submitted to the 26th ordinary session of the Executive the report of the 1st meeting of African Ministers of Health jointly organized by the AUC and WHO composed of seven commitments one of which was the 'Luanda commitment on the establishment of the AMA. The executive council adopted Ex.Cl/Dec.897 (XXVI) on the 1st African Ministers of Health Meeting jointly convened by the AUC and WHO (Doc. Ex.Cl/872(XXVI).

The Executive Council Decision (Ex.Cl/Dec.897 (XXVI):

RECOGNIZED *the need to strengthen the capacity for regulation of medical products in Africa and the harmonization of medicines regulatory systems, as a foundation for the establishment of a single medicines agency in Africa within the context of the African Medicines Regulatory Harmonization Programme, which is part of the framework of the pharmaceutical manufacturing plan for Africa (PMPA).*

ENDORSED *the milestones towards the establishment of the African Medicines Agency (AMA) and*

REQUESTED *the Commission, the NEPAD Planning and Coordinating Agency and WHO in collaboration with other stakeholders to*

iii) Define the scope of the medical products that would be covered by the work of the AMA

iv) Work out detailed modalities, institutional framework, legal and financial implications of the establishment of AMA.

Additionally, AUC submitted for the adoption by the Assembly of Heads of State and Governments, the AU model Law on Medical Products regulation. The Assembly reaffirmed their commitment to domesticating the model law to enhance effective regulation at the national level, bridge the gaps and inconsistencies in legislation and allow for harmonization and mutual recognition at the regional level. This would contribute to building stronger regulatory systems that will support the fight against the proliferation of substandard medical products on the continent which poses a major public health threat.

4. OPPORTUNITIES

Member States, RECs and RHOs have manifested commitment to support related AU programs such as the PMPA, AMRH, and AU Model Law for medical products regulation, and other existing AU initiatives. This commitment to create a robust medicines regulatory environment to support pharmaceutical sector development on the continent.

5. PROPOSED ROADMAP FOR NEXT STEPS

The matrix below shows proposed actions to fast track implementation of the milestones for establishment of AMA which as part of this report will be submitted for consideration and adoption by the 2nd meeting of the STCHPDC.

Milestones and corresponding timelines	
Consideration of the status report on implementation of milestones towards establishment of AMA and Report of Member States' Consultations on the Legal and Institutional Frameworks and Business plan of the AMA milestones by African Ministers of Health at special session of the STCHPDC	March 2017
Consideration of the legal framework and the Agreement for establishment of AMA by the STC on Legal and Justice Affairs	May 2017
Decision/Endorsement by the Assembly of Heads of State and Governments(Launch of AMA)	January 2018
Approval of the Governing Body of the AMA	July 2018
Designation of Host Country/Institution	July 2018