World Health Organization

AFRICAN UNION
الاتحاد الأفريقي

UNION AFRICAINE
UNIÃO AFRICANA

1st African Ministers of Health meeting jointly convened by the AUC and WHO
1ère réunion des ministres africains de la Santé organisée conjointement par la CUA et l'OMS
1ª reunião dos Ministros Africanos da Saúde organizada conjuntamente pela CUA e a OMS
Luanda, Angola, 14–17/04/2014
الاجتماع الأول لوزراء الصحة في أفريقيا وتشترك في تنظيمه مفوضية الاتحاد الأفريقي ومنظمة الصحة العالمية
لواندا، جمهورية أنغولا
14-17 نيسان/أبريل 2014

AUC/WHO/2014/Doc.2
1 April 2014

Provisional agenda item 4

AFRICAN MEDICINES AGENCY: SETTING MILESTONES TOWARDS ITS ESTABLISHMENT

CONTENTS

BACKGROUND

1. Effective medicines regulation promotes and protects public health. Regulation aims to ensure the quality, safety and efficacy of medical products[1] through the enforcement of legislation, norms and standards. National Medicines Regulatory Authorities (NMRAs) with adequate capacity including a clear legal mandate, quality management systems, human and financial resources, infrastructure and enforcement systems can efficiently play this role of medicines regulation. However, the regulatory systems in many countries are weak, delaying access to quality medical products and resulting in the proliferation of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products.

2. To prevent the circulation and use of SSFFC medical products, the Sixtieth Session of the WHO Regional Committee for Africa, held in Malabo, in 2010, stressed the need to strengthen the capacities of NMRAs and, to that end, recommended the establishment of an African Medicines Agency (AMA).

3. The promotion of sustainable access to quality and affordable medicines and integration of local production into the overall health systems strengthening package have been among the key priorities of African leaders. Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of African Ministers of Health (CAMH3) in April 2007 responded to the AU Assembly decision 55 taken during the Abuja Summit in January 2005 which mandated the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa's Development-NEPAD (AU 2007).

4. The PMPA aims at strengthening the ability of local pharmaceutical manufacturers to produce high quality, affordable essential medicines that will contribute to improved health outcomes and the realization of direct and indirect economic growth. Furthermore, the AU Heads of State and Government at their 19th Ordinary Assembly in July 2012 committed to consolidating efforts for local production and strengthening regulatory oversight in Pillar II of the AU Roadmap on shared responsibility and global solidarity on AIDS, TB and Malaria (ATM) which also underscores the need to accelerate access to affordable and quality-assured medicines and health-related commodities.

5. The roadmap calls for laying the foundation for a single African medicines regulatory agency as stated in the PMPA while strengthening regional medicines regulatory harmonization initiatives. The roadmap also recognizes the coordination mechanism established by the African Union Commission (AUC), the New Partnership for Africa's Development (NEPAD) together with the various Regional Economic Communities (RECs) as platforms that should work together towards achieving convergence of medicines regulation and legislation.

6. Furthermore, the Sixty-third session of the WHO Regional Committee for Africa, held in September 2013, adopted a technical document[2] that emphasized the need for sustainable funding mechanisms to reinforce NMRAs without conflict of interest and for effective implementation of regulatory functions. Member States recommended a stepwise approach in establishing the AMA, involving the RECs and the AUC.

7. Subsequently, the 8th African Vaccine Regulatory Forum (AVAREF), held in Uganda, in October 2013, and the 3rd African Medicines Regulators Conference (AMRC), held in South Africa, in December 2013, discussed and supported the idea of establishing a single AMA. To

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1 Medical products include medicines, vaccines, diagnostics, and medical devices.

2 "Strengthening the capacity for regulation of medical products in the African Region".

that end, the meeting participants called on existing networks and regional platforms to share information and experiences on joint inspections and reviews, harmonization of efforts to develop a model law, guidelines, technical documents and procedures to serve as a basis for establishment of the AMA.

8. Globally, there is only one example of a regional centralized regulatory system, i.e. the European Medicines Agency (EMA).[3] The European Union (EU) harmonization, which began in 1965, started with the creation of Community-wide mechanisms and a clear definition of the mandate of the Community and the mandate of Member States. The whole idea originated from the need to have a common market and was based on the very advanced national systems and supportive legal instruments already in place in Member States. After 30 years of efforts the centralized medicine agency called EMA finally became operational in 1994/1995. All Member States had to accept the body of European Union rights and obligations binding the Member States together within the European Union, commonly known as the *community acquis*, and to implement the regulatory framework for accession to EMA.

9. The EMA is now responsible for scientific evaluation of hundreds of applications for marketing authorization for human and veterinary medicines that fall within the scope of the centralized mechanism. The EMA provides scientific advice for the centralized mechanism, while the European Commission (EC) makes decisions regarding marketing authorization. A representative of each EU Member State participates in the work of the scientific committee that provides scientific advice to the EMA.

10. However, thousands of other medicines that do not fall within this scope are marketed in the European Union either in individual Member States, in accordance with their national authorization procedures, or in multiple Member States through decentralised or mutual-recognition procedures. EMA depends entirely on the services of experts who are full-time employees of the NMRAs in their respective countries and are fully paid by Member States. Functions such as inspection, quality monitoring and safety monitoring are carried out by the NMRAs in the Member States. For their part, NMRAs in Africa assess and register medical products and some Member States have bilateral mutual agreements in this regard.

MEDICINES REGULATORY SYSTEMS IN AFRICA: SITUATION ANALYSIS

11. Between 2002 and 2010, WHO provided support to 26 countries in the African Region to assess their regulatory systems and to draw up and implement institutional development plans.[4] In 2010 and 2011, NEPAD undertook a situation analysis of the status of harmonization of medicines registration in the East African Community (EAC),[5] ECOWAS[6] and SADC subregions respectively. Other assessments and reviews have also been undertaken in the recent past at subregional[7] and regional[8] levels.

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3 www.ema.europa.eu.

4 WHO/EMP/QSM/2010.4, Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports, Geneva, World Health Organization, 2010.

5 AU/NEPAD, Situational analysis study on medicines registration harmonization in Africa. Final report for the East African Community (EAC), 2010.

6 AU/NEPAD, Situational analysis study on medicines registration harmonization in Africa. Final report for the Economic Community of West African States (ECOWAS), 2011.

7 *UEMOA, Etude de faisabilité sur le changement de statut des autorités de réglementation pharmaceutique des Etats membres de l'UEMOA, CHRCP, 2011.*

8 http://www.who.int/medicines/areas/coordination/coordination_assessment/en/; accessed; 21 February 2014.

12. Various study findings by, among others, WHO (2004 and 2010), NEPAD (2010 and 2011), US Food and Drug Administration, (2010) and Management Sciences for Health (2010) show that most African countries are not yet in a position to meet internationally accepted requirements for regulation of medical products. The main findings are that currently only 4% of Member States have moderately developed national regulatory capacity compared with countries of the developed world, while 33% of AU countries have regulatory capacity to carry out most functions to varying degrees and 24% have basic regulatory capacity (i.e. carry out minimum functions).

13. An estimated 39% of AU Member States have limited regulatory capacity to implement all the regulatory functions. The analysis further reveals that most NMRAs have inappropriate organizational structures to implement medical products regulatory functions. In some countries, the entities responsible for coordinating and overseeing the implementation of medical products regulation are units under departments of the ministry of health. Although these entities are expected to be autonomous, full-fledged departments with statutory authority (boards or commissions) to ensure their independence, transparency and accountability in decision-making, the reality is differed in most cases.

14. The analysis of studies shows that the Regional Economic Communities (RECs), namely East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), West African Economic and Monetary Union (UEMOA) and Central African Economic and Monetary Union (CEMAC) are at various stages of economic integration and have policies, laws, regulatory tools and standards for harmonization of medical products regulation. Some of the RECs are also working towards joint dossier reviews and inspection of pharmaceutical manufacturing plants, which is a key factor for building regulatory capacity among participating countries in regional harmonization schemes.

15. For instance, through the African Medicines Regulatory Harmonization (AMRH) initiative, the EAC has developed regionally-agreed technical guidelines for regulation of medicines and is in the process of developing a pharmaceutical policy and bill for the EAC Food and Drug Safety Commission. Other RECs such as SADC and ECOWAS have also hade major milestones in the establishment of their medicines regulation harmonization projects. African countries in the WHO Eastern Mediterranean Region do not cooperate in medicines regulation in the RECs. However, there is convergence of efforts in the Gulf Cooperation Council (GCC) on medicine registration as GCC acts as a pooled procurement entity for its members. Taken together, such efforts form an important foundation for the establishment of the AMA.

ISSUES AND CHALLENGES

16. Despite the capacity building efforts of WHO and partners to strengthen national and sub-regional regulatory systems and promote harmonization, evidence shows that the capacity of countries to regulate medical products is still inadequate in Africa. However, some of the countries have better regulatory systems than others. This disparity in regulatory capacity provides further justification for establishing a continental regulatory system. Moreover, implementation of agreed procedures and processes, coordination of regulatory practices across subregions, priority-setting for products against target diseases, promotion of manufacturing and optimal use of the limited resources available to the NMRAs remain significant challenges. These can be effectively addressed through a regional regulatory system, i.e. the AMA.

RATIONALE FOR ESTABLISHMENT OF THE AMA

17. The AMA is intended to be an organ of the AU, legally mandated by Member States. It will provide a platform for coordination and strengthening of ongoing initiatives to harmonize medicines regulation. It will also serve the purpose of pooling expertise and capacities and strengthening networking for optimal use of the limited resources available. AMA will therefore provide guidance and complement and enhance the efforts of the RECs towards harmonization of medical products regulation. By enhancing the regulatory environment, AMA will contribute to enhancing access to medical products.

OPPORTUNITIES

18. The Global Fund to fight AIDS, TB and Malaria, Global Alliance for Vaccines and Immunization, UN Commission for Life-saving Commodities for maternal, reproductive and child health and the Neglected Tropical Diseases partnership as well as networks of regulators (e.g. AVAREF and AMRC) all represent opportunities to enhance regulatory convergence at the continental level. These initiatives, which aim at enhancing the availability of medical products, require adequate regulatory oversight.

19. African countries recognize the need for a coordination mechanism for the regulation of medical products, and AMA will fulfil that need. The time frame for establishment of AMA should take account of the current opportunities and partnerships to support global health initiatives and will require less investment if established sooner rather than later.

PROPOSAL FOR ESTABLISHMENT OF THE AMA

Vision and mission

20. **Vision:** The vision for establishment of the AMA is to ensure that all Africans have access to affordable medical products for priority diseases/conditions that meet internationally-recognized standards of quality, safety and efficacy.

21. **Mission:** The mission of the AMA at the continental level is to coordinate national and subregional medicines regulatory systems, carry out regulatory oversight of selected medical products and promote cooperation, harmonization and mutual recognition of regulatory decisions.

Guiding principles

22. The guiding principles of the AMA will be as follows**:**

(a) **Good governance and stewardship:** AMA will observe practices of good governance in creating an enabling environment for sustained regulatory systems, partnership and coordination of activities in an integrated manner.

(b) **Competency**: AMA will fulfil its functions by deploying and maintaining the best competencies available.

(c) **Ownership**: Member States will have primary ownership of AMA to ensure that the financial, human, infrastructural and other resources are adequate for performing its functions.

(d) **Transparency and accountability in decision-making:** The AMA will make its decisions independently, based on current scientific evidence, professional ethics and integrity. The detailed evidence of its decision-making process and the justification for

its decisions will be fully respected. The AMA will be accountable to Member States of the African Union.

(e) **Confidentiality:** The AMA will adhere to the principles of confidentiality in all its operations.

(f) **Commitment to sound quality management:** In all its functions the AMA will adhere to international standards of quality management and create the conditions for continuous improvement of its regulatory practices and those of NMRAs of Member States of the African Union.

(g) **Partnerships and collaboration:** The AMA will build and strengthen partnerships and promote collaboration and information sharing with all relevant stakeholders.

(h) **Support for innovation:** The AMA will support innovations that will enhance access to new medical products in order to address the public health priorities of Africa.

Functions of the AMA

23. The AMA will have a coordination and stewardship function for the regulatory activities of the Member States. Among the core regulatory functions, the AMA will perform the following:

(a) **Marketing authorization:** The AMA will be responsible for evaluation and decision-making with regard to selected medical products for treatment of priority diseases/conditions as determined by the African Union.

(b) **Inspection:** The AMA will undertake coordination and share information on a regular basis in regard to all products that it has authorized for marketing.

(c) **Market surveillance:** The AMA will coordinate the collection and sharing of information on all medical products including SSFFC medical products.

(d) **Safety monitoring:** The AMA will be responsible for making regulatory decisions concerning products selected for treatment of priority diseases/conditions as determined by Member States, based on available safety information. In addition, the AMA will collect and store information on the quality and safety of medical products and share them with all its Member States and even globally. It will also establish collaboration with global and regional centres in the area of safety monitoring.

(e) **Oversight of clinical trials:** The AMA will coordinate joint reviews of applications for conduct of clinical trials.

(f) **Quality control:** The AMA will coordinate and network quality control laboratory services for national and subregional regulatory authorities.

Expert committees

24. The AMA will have a small critical mass of competent staff to facilitate the work of experts and expert committees. To ensure that NMRAs retain their human resources, the AMA will rely on the contributions of NMRA experts for the evaluation of applications for marketing authorization. Through their participation in the work of these expert committees and regulatory evaluation, the NMRAs will enrich their capacities to perform their mandated functions more effectively.

Governance of the AMA

25. The AMA will be established by the African Union Summit of Heads of State and Government. It will be governed in accordance with the rules and procedures of the African Union. The resources of the AMA will be provided by the AU in accordance with its relevant practices and procedures.

ACTIONS REQUIRED: MILESTONES AND CORRESPONDING TIMELINES

26. The milestones with corresponding timelines in the establishment of the AMA are summarily presented in the table below.

Milestone	Timeline
Adoption of proposal for the establishment of the AMA by the AU Conference of African Ministers of Health	2014
Establishment of Task Team/Project Unit for operationalization of the objectives of the AMA by Ministers of Health	2014
Decision/endorsement in principle by the AU Summit of Heads of State and Government	2015
Designation of host institution/country	2016
Approval of the governing body of the AMA	2017
Appointment of staff and allocation of resources	2017
Launch of the AMA	2018

FINANCIAL IMPLICATIONS

27. The primary source of funding of the AMA will be the Member States of the AU. In addition, Member States of AU will provide contribution in kind by dedicating part of the time of their NMRAs staff to the work of the AMA. Funding may also be sought from financial institutions and development partners. As an independent regulatory authority, its funding should not put it in any situation likely to undermine its decision-making processes. An estimated total of US$ 100 000 000 will be required to fund the AMA for the first five years. This amount covers staff cost (US$ 10 000 000), equipment/infrastructure (US$ 65 000 000), and operational budget (US$ 25 000 000) for the establishment and operation of the AMA.

ROLES AND RESPONSIBILITIES

Member States

28. Member States of the African Union will have the following roles and responsibilities:

(a) Delegate to the AMA some of the regulatory functions for selected medical products in accordance with the agreement establishing the AMA.

(b) Allocate adequate resources for the operationalization of the AMA.

(c) Mobilize additional resources for the AMA.

(d) Designate a host country/institution and appoint the staff of the AMA.

(e) Commit themselves (through a Memorandum of Understanding) to the decisions of the AMA.

African Union Commission

29. The roles and responsibilities of the AUC will be as follows:

(a) Ensure the availability of technical, legal, managerial and administrative procedures for the establishment of the AMA.

(b) Develop criteria for the selection of a host country of the AMA.

World Health Organization

30. WHO will provide technical support to the AMA and to subregional and national medicines regulatory authorities.

WAY FORWARD

31. The first African Ministers of Health meeting jointly convened by the AUC and WHO is invited to review and adopt this proposal and provide policy guidance for the establishment of the AMA.