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**PROGRESS REPORT ON THE ESTABLISHMENT OF THE
AFRICAN MEDICINES AGENCY**

Information Document

CONTENTS

	Paragraphs
BACKGROUND	1–4
PROGRESS MADE.....	5–8
NEXT STEPS	9–10

BACKGROUND

1. In 2010, the Sixtieth session of the Regional Committee for Africa, having considered the report of the task force on substandard, spurious, falsely-labelled, falsified or counterfeit (SSFFC) medical products,¹ recommended the creation of an African Medicines Agency (AMA). As a supranational regulatory authority, AMA will curtail SSFFC medical products in line with Resolutions WHA65.19² and WHA67.20.³ AMA will coordinate national and subregional regulatory systems, promote regulatory standardization and harmonization of the processes, as well as collect, store and share information on the quality and safety of medical products.
2. Following a recommendation of the Sixty-third session of the Regional Committee for Africa and a declaration of the Nineteenth African Union (AU) Summit,⁴ a roadmap for the establishment of AMA was developed in 2014 as part of the framework for the Pharmaceutical Manufacturing Plan for Africa (PMPA). The roadmap sets key milestones for establishing AMA in five years. These are: the establishment of a task team to coordinate efforts; the endorsement of AMA by AU organs; approval of the governing body; designation of the host country; allocation of resources; and launching of AMA by 2018.
3. The existing networks of regulators and initiatives for harmonization and cooperation among countries have created an enabling environment for the establishment of AMA. In addition, the African Medicines Regulation Harmonization Initiative and the African Vaccine Regulatory Forum have laid the foundation for AMA.
4. This report summarizes the progress made since the First Meeting of African Ministers of Health jointly organized by the African Union Commission (AUC) and WHO in Luanda, Angola, in April 2014 and provides the next steps towards the operationalization of AMA.

PROGRESS MADE

5. **Endorsement of the proposal and commitment to the establishment of AMA by African ministers of health during their first meeting in Luanda in 2014.** The AMA concept was developed by WHO and the AUC and endorsed by African ministers of health.⁵ They reinforced the mandate of AMA which is to coordinate regulatory oversight of medical products for priority diseases at continental level and to promote cooperation among countries as well as harmonization of the regulation of medical products. The ministers of health also adopted key milestones and committed themselves to allocating adequate resources for the establishment of AMA.⁶ They declared the need to prioritize investments in national capacity-building as regards regulation of medicines, convergence and harmonization within the regional economic communities (RECs).

¹ For the purpose of this report medical products include medicines, vaccines, diagnostics and medical devices.

² Resolution WHA65.19, Substandard/spurious/falsely-labelled/falsified/counterfeit medical products. *In Sixty fifth World Health Assembly, Geneva, 21–26 May 2012. Resolutions, decisions and annexes.* Geneva, World Health Organization, (WHA65/2012/REC/1; http://apps.who.int/gb/or/e/e_wha65r1.html. Accessed on 6 March 2015).

³ Resolution WHA67.20, Regulatory system strengthening for medical products. *In Sixty-seventh World Health Assembly, Geneva, 19–24 May 2014. Resolutions, decisions and annexes.* Geneva, World Health Organization, (WHA67/2014/REC/1; http://apps.who.int/gb/or/e/e_wha67r1.html. Accessed on 6 March 2015).

⁴ AU/Decl.2 (XIX), Declaration on the report of AIDS Watch Africa (AWA) endorsing African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, Tuberculosis and Malaria Response in Africa, Assembly of the Union, Nineteenth Ordinary Session, 15-16 July 2012, Addis Ababa, Ethiopia.

⁵ WHO/AUC, African Medicines Agency: setting milestones towards its establishment, adopted by First African Ministers of Health meeting jointly convened by the AUC and WHO, Luanda, Angola, 14-17 April, 2014 (Document AUC/WHO/2014/Doc.2).

⁶ WHO/AUC, Commitment on the Establishment of the African Medicines Agency: Setting milestones towards its establishment, adopted by First African Ministers of Health meeting jointly convened by the AUC and WHO, Luanda, Angola, 14-17 April, 2014.

6. **Establishment of a joint coordination platform by AUC and WHO to facilitate the establishment of the AMA.** WHO and the AUC established a Task Team as the platform for coordinating all efforts geared towards the establishment of AMA. The First Task Team meeting, held in Addis Ababa in 2014, adopted a four-year action plan (2015–2018). Furthermore, the Regional Working Group on SSFFC medical products established by WHO in 2012 met in 2014 and adopted its four-year action plan (2014–2017). As part of the efforts geared towards establishing AMA, the Working Group will contribute to AMA's intelligence through the collection, storage and sharing of information on trends as well as strategies to combat SSFFC medical products. The AUC, WHO and New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency serve as a Joint Secretariat for the Task Team.

7. **Preparation for the endorsement of AMA by the Summit of AU Heads of State and Government scheduled to take place in 2018.** The Task Team developed a legal and institutional framework for AMA and a business plan for its operationalization. AMA will be anchored on strong institutional capacity, an effective legislative framework and a clear accountability framework. The business plan emphasizes a sustainable funding mechanism and adequate human resources, including a critical mass of staff and expert committees utilizing experts from national medicines regulatory authorities (NMRAs) to fulfil AMA's mandate.

8. **Challenges.** Despite the progress made, sharing regulatory responsibilities between the AMA, NMRAs, subregional medicines regulatory authorities (MRAs) and other stakeholders remains a challenge. Furthermore, stakeholder awareness is undermined by the lack of a communication strategy that enables AMA to elicit buy-ins. Inadequate financial resources also compromise the implementation of the Task Team action plan and the AMA business plan. This is aggravated by the risk of diversion of available resources towards regulatory activities in countries while pre-service and in-service training of regulatory personnel remains inadequate.

NEXT STEPS

9. It is anticipated that the following steps will accelerate the process of establishing AMA:
- (a) development of an advocacy and communication strategy by the Task Team to facilitate consultations with stakeholders;
 - (b) mobilization of resources by WHO and AUC to support implementation of the Task Team action plan and AMA business plan;
 - (c) endorsement of the legal and institutional framework of the AMA and approval of governing body by the AU with a mechanism to share regulatory responsibilities between AMA, subregional MRAs, NMRAs and other stakeholders;
 - (d) designation of a host country for AMA offices by the AU;
 - (e) allocation of resources for AMA activities and recruitment of staff by the AU;
 - (f) launching of AMA in 2018.
10. The Regional Committee is invited to take note of the progress report and to endorse the proposed next steps for the establishment of AMA.