3rd STAKEHOLDERS CONSULTATIONS ON THE DRAFT TREATY FOR THE AFRICAN MEDICINES AGENCY (AMA)

DRAFT CONCEPT NOTE

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12-13 JULY, 2017
1. BACKGROUND

The ‘Luanda Commitment by Ministers of Health on African Medicines Agency: Setting Milestones towards its Establishment’ was adopted at the 1st Meeting of African Ministers of Health Jointly Convened by AUC and WHO in April 2014 as encapsulated in Executive Council Decision EX.CL/DEC.857 (XXVI) of 2015.

The Decision inter alia, requested the AUC and NEPAD Agency with the technical support of the WHO to i) establish a task team with due regard to regional representation and skills required to meet the mandate as noted to facilitate the implementation of the agreed milestones for the establishment of AMA and ii) Define the scope of the medical products that would be covered by the work of the AMA and Work out detailed modalities, institutional framework, legal and financial implications of the establishment of AMA.

The Task Team was duly established in November 2014 and facilitated the drafting of three key documents, namely: i) Legal Framework, ii) Institutional Framework and iii) Business plan for AMA.

The Commission in collaboration with NEPAD Agency with the support of WHO organized a series of consultations to deliberate on these key documents with experts from all AU Member States the first and second of which took place respectively from 20 to 22 February 2017 in Midrand, South Africa and on 20 March 2017 in Addis Ababa, Ethiopia on the margins of the 2nd Session of the African Union Specialised Technical Committee on Health, Population and Drug Control. It is against the above-mentioned background that the 3rd stakeholders’ consultation on the draft legal and institutional frameworks and business plan for the African Medicines Agency (AMA) will be held on 12-14 July, 2017 in Tunis, Tunisia.

2. OBJECTIVES

2.1 General Objective

The general objective of the 3rd stakeholders’ consultation is to provide a platform for AU Member States and RECs to take stock of the progress made in the implementation of the executive council decision on the establishment of AMA.

2.2 Specific Objectives

(i) Deliberate on the draft Treaty for establishment of AMA that emerged from the 2nd Round of consultations held during the 2nd STCHPDC held in Addis Ababa, Ethiopia.

(ii) Agree on a roadmap for next steps

3. EXPECTED OUTPUT

- Revised versions of the (i) Draft Treaty for establishment of AMA with the inputs from the 3rd round of consultations;

- Roadmap for next steps regarding consideration of Draft Treaty on the Establishment of the AMA and implementation of the Recommendations of the 2nd session of the STCHPDC in Addis Ababa including consideration by the ministers of health as a working group of the STCHPDC scheduled to hold on the during the WHO-AFRO Regional Committee meeting in Harare, Zimbabwe.
4. FOLLOW-UP

4.1 Short-Term

   a. Finalize and distribute the draft report of the consultation;
   b. Finalize and distribute revised version of the draft treaty for the establishment of AMA
      based on comments made by the consultation and the agreed Roadmap for next steps;

4.2 Medium-Term

   4.2.1 Implementation of the Roadmap for next steps on establishment of AMA by the Task
          Team members with support from AUC, NEPAD and WHO.
   4.2.2 Translation of final documents in Arabic, French and Portuguese for dissemination to
          Member States.

6. DATES AND VENUE

The 3rd experts’ consultations on the draft Treaty for the establishment of the AMA will take place
at the El Mouradi Hotel in Tunisia, from 12 to 13 July 2017.

7. PARTICIPANTS

The experts invited to attend include:

- One (1) medicines regulator and one (1) legal) from each AU Member State,
- Representatives from the RECs,
- Members of the AMA Task Team,
- WHO, AUC, and NEPAD Agency as secretariat
- Republic of Tunisia.

8. LOGISTICS ON TRAVEL, ACCOMMODATION AND DSA

A separate logistics note with information on travel arrangements, accommodation and DSA will
be shared with all confirmed participants.

9. WORKING LANGUAGE AND FORMAT OF DISCUSSIONS

The meeting will be conducted in Arabic, English and French with simultaneous interpretation.

- Presentations and discussions during all sessions will be in plenary.
- Working groups may be set as deemed necessary by the Chair and co-chairs of sessions.

10. WORKING DOCUMENTS AND OTHER BACKGROUND DOCUMENTS

10.1 The main working documents shall be as follows:

   i) Draft Treaty for the establishment AMA
   ii) Draft Institutional Framework for AMA
   iii) Draft Business Plan for AMA

10.2 Reference documents

   i. Luanda Commitment : Milestones towards the establishment of the AMA
   ii. Executive Council Decision on AMA

All working and background documents will be available on the AU Website in English,
French, Portuguese and Arabic.