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DRAFT CONCEPT NOTE

1ST STAKEHOLDERS CONSULTATIONS ON THE DRAFT LEGAL & INSTITUTIONAL FRAMEWORKS AND BUSINESS PLAN FOR THE AFRICAN MEDICINES AGENCY (AMA)

20-22 FEBRUARY, 2017, MIDRAND, SOUTH AFRICA

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 is therefore organizing a series of consultations to deliberate on these key documents with experts from all AU Member States, the first of which is scheduled to commence from 20 to 22 February 2017 in Midrand, South Africa.

OBJECTIVES

The main objectives of the consultations are to:

- i) Provide a platform for all Member States and regional economic communities (RECs) to take stock of the progress made so far in the implementation of the executive council decision on the establishment of AMA;
- ii) Deliberate on the draft legal, institutional framework as well as AMA business plan as prepared by the AMA Task Team; and
- iii) Agree on a roadmap for next series of consultations.

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.

EXPECTED OUTPUT

- Revised versions of the i) legal framework, ii) institutional framework and iii) business plan for AMA
- Roadmap for next steps regarding subsequent consultations on the three documents.

DATE AND VENUE

The consultations will be conducted in Midrand, from 20 to 22nd February 2017. The venue of the meeting will be communicated once confirmed.

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.

WORKING LANGUAGE AND FORMAT OF DISCUSSIONS

The consultations meeting will be conducted both in plenary sessions.

The working languages will be English and French.

WORKING DOCUMENTS AND OTHER BACKGROUND DOCUMENTS

The **main working documents** shall be as follows:

- i) Draft Legal Framework for AMA
- ii) Draft Institutional Framework for AMA
- iii) Draft Business Plan for AMA

Other 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.