Side Event on Clinical Trials Oversight on Ebola Therapies and Vaccines and other Neglected Tropical Diseases; 19 July, 2015, Malabo, Equatorial Guinea

CONCEPT NOTE

Background:

As part of the African Union Support to Ebola Outbreak in West Africa (ASEOWA), NEPAD Agency undertook to use the African Medicines Regulatory Harmonization (AMRH) Initiative as a platform for strengthening African capacity for clinical trials oversight on drugs and vaccines as part of implementation of the Pharmaceutical manufacturing Plan for Africa (PMPA). This is supported by the AU Assembly January 2015 decision (AU/Dec.19 (XXIV) which recognises the contributions of the AMRH Initiative in regulatory capacity development in Africa and **directed** the NEPAD Agency and African Union Commission in collaboration with the World Health Organization (WHO) to support the acceleration of the evaluation of promising treatment options and vaccine candidates against EVD through the AMRH Initiative.

Subsequently, regional Expert Working Groups (EWGs) on Clinical Trials Oversight are to be established in the East African Community (EAC) and the Economic Community of West Africa States (ECOWAS) regions. The EWGs shall be responsible for developing and facilitating implementation of regionally harmonised regulatory tools and standards for clinical trials oversight and joint assessment of clinical trial application dossiers. In addition,the designated Regional Centres of Regulatory Excellence (RCOREs) in Clinical Trials Oversight will serve as a resource for training members of National Ethics Committees (NECs)and national medicines regulatory agencies (NMRAs) in Africa on ethics and regulatory requirements and oversight. Currently, three centres have been designated as partnerships in clinical trial oversight, they include; i) the Direction General de la Pharmacie du Medicament et des Laboratoires and University of Ouagadougou in Burkina Faso; the Medicines Control Authority of Zimbabwe (MCAZ) in partnership with the National research Council of Zimbabwe; and the Food & Drugs Authority (FDA) Ghana in partnership with University of Kumasi.

Joint reviews of applications for EVD therapies and vaccines have been conducted in EAC Partner States involving Burundi, Kenya, Rwanda, Tanzania Mainland, Tanzania Zanzibar and Uganda NMRAs and some West African countries within the Framework of the African Vaccines Regulators Forum (AVAREF). All these efforts are aimed to serve as pathfinder for scaling up ethics review, regulatory and clinical trials oversight capacity to cover the current and future public health threats.

It is important to note that, while these efforts are being made, countries have been facing challenges in expediting the approval of clinical trials based on decisions made by the advanced regulatory authorities in the West such as the European Medicines Agency (EMA) and the United States Food and Drug Administration (US-FDA). We have also witnessed campaigns against Ebola vaccines clinical trials in Ghana which presents the Food and Drug Authority of Ghana with a challenge in terms of facilitating the approval process. There is therefore need for concerted efforts in building capacities and increasing advocacy on the importance of clinical trials and also to ensure that NMRAs are properly equipped to handle such circumstances based of the needed scientific rigor and evidence.

A side meeting is therefore being convened on the **19th July, 2015** to bring together experts to debate on how African countries will be able to manage similar situations in the future. The meeting will provide technical guidance that informs the International Conference on Africa's Fight Against Ebola "Africa helping Africans in the Ebola Recovery and Reconstruction" which will be held from 20 – 21 July 2015 in the Malabo, Equatorial Guinea.

Main Objectives of the side-event

To mobilise the African NMRAs and NECs to come up with strategies that will assist the African Union Member States in facilitating clinical development and oversight of new therapies and vaccines for prevention and treatment of diseases that disproportionately affect the African populations.

Specific Objectives:

a. Mobilize NMRAs, NEC, RCOREs on Clinical Trials Oversight and private sector in support and strengthening actions against the Ebola epidemic as well as the preparedness and response to all emerging and re-emerging health threats in Africa;
b. Reinforce the link between health research and intervention actions to better coordinate the response against Ebola and other major emerging endemic diseases in Africa;
c. To share experiences in the joint review of EVD therapies and vaccines, the lessons learned and commit to assisting the Ebola-affected countries in their efforts to strengthen health systems as well as in the management of future applications for new therapies and vaccines for public health outbreaks on the continent.
d. Capitalize on the experiences from the current EVD and come up with lessons learned and best practices for a more effective fight against Ebola and other major endemic diseases, as well as preparedness and the response against future outbreaks.
e. Develop advocacy strategies to support resource mobilization, public awareness and preventive measures for post Ebola recovery and reconstruction of Ebola affected countries and the continent.

Expected outputs of the side event:

To inform the main Ebola conference on how the African Union will address future public health threats with a focus on the following areas:

a. Agreed strategies on joint review of EVD therapies, vaccines and technologies based on the lessons learned
b. Agreed strategies for strengthening regulatory capacity and ethics review as part of health systems strengthening as well as in the management of future applications for new therapies, vaccines and technologies for public health outbreaks and neglected tropical diseases affecting the continent.
c. Agreed advocacy strategy for clinical trials on new therapies for prevention and treatment of epidemics and neglected tropical diseases affecting Africa.
d. Agreed strategies for resource mobilization to support research and development, and regulation of clinical trials and safety surveillance programmes.

Participants:

The conference will bring together Heads of NMRAs and members of NECs from 6 EAC and ECOWAS regions; representatives of EAC, ECOWAS-WAHO, RCOREs on clinical trial oversight, the regional associations of pharmaceutical industry, the European and

Developing Countries Clinical Trials Partnership (EDCTP), World Health Organization (WHO), European Medicines Agency (EMA) and the United States Food and Drug Administration (US-FDA).

Meeting Structure and Organization:

The meeting is co-organised by NEPAD Agency and AUC.

Morning:

Session I: Opening Plenary Session at Technical Level: Affected countries will present their experiences on clinical trials oversight and Ethical Clearance

Session III: Regulatory Oversight and Systems Strengthening WHO, NEPAD Agency, AUC, ECOWAS-WAHO, EAC

Afternoon:

Session IV: Plenary: EDCTP, RCOREs and African Private sector perspective

Additional information could be obtained from:

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