



## EAST AFRICAN COMMUNITY

# Ministerial Communiqué

### Advocacy and Support for the Harmonization and Strengthening of Medicines Regulation in the East African Community Partner States and the African Continent

*African Medicines Regulatory Harmonization (AMRH) Donors' Roundtable  
EAC HQs, Arusha, Tanzania*

*Friday, 17 October 2014*

The East African Community (EAC) Secretariat in collaboration with the Africa Union (AU) - New Partnership for Africa's Development Agency (NEPAD Agency) and the African Medicines Regulatory Harmonization (AMRH) Partners held a one-day Donors' Roundtable meeting at the East African Community Headquarters in Arusha, Tanzania on Friday, 17<sup>th</sup> October, 2014.

The Donors' Roundtable was attended by Ministers of Health, Ministers of Finance, EAC Affairs, Senior Government Officials, Heads of Partner State's National Medicines Regulatory Authorities. Members of the EAC Partner States Parliamentary Health Committees, East African Legislative Assembly were also in attendance. In addition, the meeting was attended by representatives from the Bill and Melinda Gates Foundation (BMGF), the U.K Department for International Development, the World Bank, the World Health Organization, European and Developing Countries Clinical Trials Partnership, African Union Commission, the New Partnership for Africa's Development Agency, the Pan African Parliament, Southern African Development Community (SADC), the West African Health Organisation (WAHO) and the Economic Community Of West African States (ECOWAS).

The purpose of the Donors' Roundtable was to:-

- a) Give an overview of the overall AMRH initiative, its vision and underlying implementation plan;
- b) Showcase the exciting progress made to date in the EAC;
- c) Present the plans to consolidate the progress in the EAC and, as a next step, to expand the initiative to other product streams and regulatory functions in the EAC and to other Regional Economic Communities in Africa; - next wave to cover SADC and ECOWAS;

- d) Expand the donor funding base for AMRH in order to consolidate the EAC progress and drive the expansion of the initiative.

**WHEREAS** the EAC Partner States having regard to the interests of and their desire to promote social, economic and overall wellbeing of the people of East Africa resolved to co-operate in the area of health as per the provisions of Article 118 of the Treaty for the Establishment of the East African Community through, among others, harmonization of drug registration procedures in order to achieve quality health of the people within the Community.

**NOTING** that the EAC Treaty obliges the Partner States to cooperate in relation to health, the EAC Council of Ministers agreed and decided to establish and implement the “**East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme**” in support of the process of harmonizing the regulation of the manufacture, import, trade, sale and export of all medicines and health supplies within the region through the legal mandate of the existing National Medicines Regulatory Authorities (NMRAs) in each of the Partner States.

**RECOGNIZING** that the Partner States desirous of addressing issues related to the strengthening of regional cooperation on the regulation of medicines have agreed to have a harmonized and functioning medicines regulation system within the East Africa Community in accordance with national and internationally recognized policies and standards.

**FURTHER RECOGNIZING** that the 29<sup>th</sup> Ordinary Meeting of the EAC Council of Ministers that was held at the EAC Headquarters in Arusha, Tanzania had considered and adopted the final EAC regional harmonized guidelines, standards and requirements for Medicines Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management System (QMS) for National Medicines Regulatory Authorities and recommended the same to the EAC Partner States’ for implementation at national level in each Partner State as per Report Ref: (EAC/CM29/Decision 036) of 20<sup>th</sup> September 2014.

**NOW THEREFORE the Ministers considered and recommend to:**

**1) The East African Community Partner States:-**

- a) Urge all EAC Partner States to progressively strengthen and establish mechanisms for sustainable financing, institutional and infrastructure development and human resources capacity building for National Medicines Regulatory Authorities (NMRAs);
- b) Urge the Republic of Burundi to enact the law for the establishment of “**L’Autorite Burundaise des Régulation des Médicaments et des Aliments (ABREMA)**”;

- c) Urge the Republic of Kenya to enact a law for the establishment of **"Kenya Food and Drug Authority (KFDA)"**;
- d) Urge the Republic of Uganda to enact a law for the establishment of **"Uganda Food and Drug Authority (UFDA)"**;
- e) Urge the Republic of Rwanda to operationalize the Law on the establishment of the **"Rwanda Food and Medicines Authority (RFMA)"**;
- f) Support the designated **"Regional Centres of Regulatory Excellence (RCOREs)"** in the EAC region in order to build capacity in the region and the continent;
- g) Support the establishment of the proposed **"East African Community Medicines and Food Safety Commission (EACMFSC)"**;
- h) Support the establishment of the proposed **"African Medicines Agency (AMA)"**;
- i) Share experiences and offer capacity building technical exchanges, twinning, trainings among themselves and also with other African countries and beyond;
- j) Commit to implementation of Phase II of the EAC Medicines Regulatory Harmonization Programme; and
- k) Commit to the implementation of the following priority activities namely;
  - (i) Development of Harmonized EAC Pharmaceutical Policy, Legal, Regulatory Frameworks and the Bill for Establishment of the East African Community Medicines and Food Safety Commission (EACMFSC);
  - (ii) Strengthening Pharmacovigilance and Post Market Surveillance;
  - (iii) Strengthening regulation of medical devices and diagnostics; and
  - (iv) Strengthening of clinical trials and the regulation of biotherapeutic products.

## 2) The East African Community Secretariat to:-

- a) Coordinate implementation of Phase II of the **"East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme"** in accordance with the approved objectives and timelines;
- b) Coordinate and facilitate the establishment of the proposed **"East African Community Medicines and Food Safety Commission (EACMFSC)"**;

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- c) Coordinate resource mobilization for harmonization and strengthening of regulation of other product streams as well as regulatory functions; and
- d) Coordinate the implementation of the priority activities towards Policy, Legal, Institutional and capacity building initiative for further strengthening medicines regulation in the EAC region.

**3) The Pan African Parliament (PAP), the East African Legislative Assembly (EALA) and the National Parliaments of the East African Community Partner States to:-**

- a) Advocate and support harmonization and strengthening of Medicines Regulation in the East African Community Partner States and the African Continent;
- b) Advocate for all EAC Partner States to progressively strengthen and establish mechanisms for sustainable financing, institutional and infrastructure development and human resources capacity building for National Medicines Regulatory Authorities (NMRAs);
- c) Advocate for the Republics of Burundi, Rwanda, Kenya and Uganda to establish Food and Medicines Regulatory Authorities;
- d) Advocate for the establishment of the proposed "**East African Community Medicines and Food Safety Commission (EACMFSC)**";
- e) Advocate for adoption of the African Union (AU) Model Law on medical products regulation to successfully move towards harmonization;
- f) Advocate for the establishment of the proposed "**African Medicines Agency (AMA)**";
- g) Advocate for sharing of experiences and capacity building technical exchanges, twinning, trainings among the EAC Partner States, with other African countries and beyond; and
- h) Advocate for the mobilization of technical and financial assistance in support of the implementation of the following priority activities towards Policy, Legal, Institutional and capacity building initiative for further strengthening medicines regulation in the EAC region.

**4) Development Partners and the International Community to:-**

- a) Continue support and provide technical and financial support for implementation of Phase 2 of the "**East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme**" in accordance with the approved objectives and timelines;
- b) Provide technical and financial support for implementation of the following priority activities towards Policy, Legal, Institutional and



capacity building initiative for further strengthening medicines regulation in the EAC region.

- c) Ensure coordinated approach to resource mobilization.
- d) Work with countries to strengthen and establish mechanisms for sustainable financing, institutional and infrastructure development and human resources capacity building for National Medicines Regulatory Authorities (NMRAs) in the East African Community Partner States and the African Continent as a whole.

In conclusion, the Ministers re-affirmed their commitment to Medicines Regulatory Affairs and expressed their satisfaction in the way the meeting was organized and thanked the EAC Partner States, the EAC Secretariat, the AU-NEPAD Agency and the various international collaborating development partners and stakeholders for their participation and support.

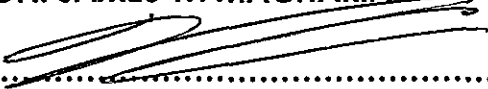
**DONE** at Arusha, Tanzania on the 17th day of October, in the year Two Thousand and Fourteen.

**HON. NZEYIMANA LE'ONTINE**



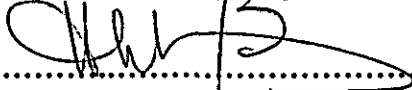
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MINISTER TO THE OFFICE OF THE PRESIDENT RESPONSIBLE FOR EAC AFFAIRS  
REPUBLIC OF BURUNDI

**HON. JAMES W. MACHARIA**



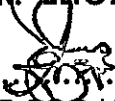
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CABINET SECRETARY FOR HEALTH  
REPUBLIC OF KENYA

**HON. DR. AGNES BINAGWAHO**



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MINISTER FOR HEALTH  
REPUBLIC OF RWANDA

**HON. DR. ELIODA TUMWESIGYE**



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MINISTER FOR HEALTH  
REPUBLIC OF UGANDA

**HON. DR. SEIF SELEMAN RASHID (MP),**



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MINISTER FOR HEALTH AND SOCIAL WELFARE  
UNITED REPUBLIC OF TANZANIA