



PEACE, PROSPERITY AND
REGIONAL INTEGRATION

EXPERT MEETING RECOMMENDATIONS

First IGAD Committee Meeting on Information Management System and Medicines Assessment and Registration.

April 18 – 28, 2017, Entebbe, Uganda

WE, expert representatives from National Medicines Regulatory Authorities (NMRAs) of IGAD Member States (Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda); the IGAD Secretariat, World Bank and WHO, having attended the **First IGAD Committee Meeting on Information Management System and Medicines Assessment and Registration** held in April 18 – 28, 2017, Entebbe, Uganda.

DEEPLY CONCERNED by the widespread and unregulated circulation, within our countries, of Sub-standard and Counterfeit Medicines in the region and weak regulatory systems in some member states;

AWARE of the public health threat of Sub-standard and Counterfeit Medicines to our societies, particularly those in the rural, pastoralist and cross-border mobile populations largely owing to the weak regulatory systems, limited capacity; limited health workforce, inadequate resources and lack of collaboration between IGAD-NMRAs that will mitigate the impact of Sub-standard and Counterfeit Medicines;

RECOGNIZING the benefits of regional collaboration and harmonization in the regulation of Medicines in line with the commitment of IGAD and all its member states to meet Universal health coverage and Sustainable Development Goals (SDGs) **Goals 3 and 9**;

INFORMED by the African Union Pharmaceutical Manufacturing Plan for Africa (PMPA) and the African Medicines Regulatory Harmonization Initiative that are in line with African Union's Agenda 2063;

RECALLING the Khartoum Declaration and Addis Ababa call of Action, particularly its emphasis on health systems strengthening and regulatory collaborative harmonization, which declared establishment of **IGAD Regional Medicines Regulatory Harmonization (IGAD-MRH) Program**;

ENCOURAGED by the progress made by IGAD with regard to IGAD-MRH program;

REQUESTED IGAD to expedite the process of implementation of the next steps for the IGAD-MRH program;

WE, therefore, strongly recommend the following:

1. That the regulatory capacity of **National Medicines Regulatory Authorities (NMRAs)** should be strengthened and supported especially the member states with relatively under-developed regulatory system;
2. That the partnerships and cooperation among IGAD Member States, IGAD Secretariat, WHO, NEPAD, World Bank and other partners concerned with medicines regulatory harmonization should be strengthened;
3. That there should be close consultation and communication between IGAD, WHO, NEPAD, World Bank and other partners during resource mobilization and planning for activities of IGAD-MRH program.
4. The Steering committee to endorse;
 - a. The proposed Term of References (ToRs) of the Experts Committee of Information Management System and Medicines Assessment and Registration from IGAD Member States (**attached Annex I**);
 - b. The proposed Governance structure of the IGAD-MRH program (**attached Annex II**);
 - c. That all IGAD-NMRAs share non-confidential public information of medicines registered in member states for purpose of monitoring sub-standard and counterfeit medicines in the region and assist other member states to make informed decision in the provision of market authorization information;
 - d. That IGAD develop a Technical Cooperation Framework Agreement that provides framework of cooperation and sharing of confidential information with the view of enhancing collaboration among IGAD-NMRAs;
 - e. The development of a mechanism for continuous update of the web portal developed by the expert committee on IMS;
 - f. The expansion of the IGAD-MIS to an IGAD Health Information Management Systems (HIMS) for all health activities in IGAD;

- g. That WHO conduct pilot joint assessment of the common applications submitted to NMRAs as a proof of concept activity for IGAD-MRH program and support capacity building for all member states especially Djibouti, South Sudan and Somalia.
 - h. That NMRAs should develop mechanism for accelerating the registration of quality, safe, effective and affordable medicine and vaccines used for management of communicable and non-communicable diseases especially products recommended by IGAD Medicine Assessment and Registration Committee, those prequalified by WHO and registered by Stringent Regulatory Authorities.
5. That IGAD establishes a regulatory pool of experts based on defined criteria to assist member states develop regulatory systems.
 6. That IGAD establishes a twining arrangement to share regulatory experience, skills and exchange of experts among IGAD-NMRA's in order to enhance the capacity of the member states with the weak regulatory systems.
 7. That WHO should continue supporting technical activities of IGAD-MRH program.
 8. That IGAD will work closely with member states and partners to mobilize resources for IGAD-MRH program to support initial activities based on the priorities identified in IGAD Member States;
 9. That IGAD will work closely with member states and partners to develop a fundable regional proposal and regional strategic plan for IGAD – MRH program.
 10. That IGAD support the development of an overarching regional pharmaceutical policy and the adoption of modern legislative frameworks based on the AU Model Law for all member states.

We request the Steering Committee and IGAD Secretariat to lead the implementation of these recommendations and the establishment of the regional medicines regulatory harmonization program.

We request our collaborating and development partners, and other stakeholders to provide support for the effective functioning of the proposed IGAD regional medicines regulatory harmonization program.

We note the planned first steering committee of the **IGAD Medicines Regulatory Harmonization Program** meeting to be held as from 2nd – 7th July 2017.

Done on April 28, 2017 in Entebbe, Uganda

**The
Federal
Democratic
Republic of
Ethiopia**

**The
Republic of
Kenya**

**The
Federal
Republic of
Somalia**

**The
Republic of
South
Sudan**

**The
Republic of
Sudan**

**The
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Signature

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Date

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