



## **SECOND IGAD REGIONAL MEDICINE REGULATORY AUTHORITIES CONFERENCE ON REGULATORY COLLABORATION AND HARMONIZATION**

April 26 – 27, 2016, Khartoum, Sudan

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### **Khartoum Declaration**

We, the representatives of IGAD Member States (from Djibouti, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda); the IGAD Secretariat, the African Union Commission (AUC), NEPAD, World Bank, WHO, UNFPA, and other partner agencies, having attended the Second IGAD Conference on Regulatory Collaboration and Harmonization held in Khartoum, Sudan on April 26 – 27, 2016

**Deeply concerned** by the widespread and unregulated circulation, within our countries, of Sub-standard, Spurious, Falsely labeled, Falsified, and Counterfeit (SSFFCs) medical products.

**Aware of** the negative consequences of SSFFCs on health and development of 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; and inadequate resources.

**Recognizing** the benefits of regional collaboration and harmonization in the regulation of medical products; **Desirous** of sharing best practices and application of the lessons learnt in other Regional Economic Communities (RECs) and member states of the African Union.

**Informed by** the African Union Pharmaceutical Manufacturing Plan for Africa (PMPA), the African Medicines Regulatory Harmonization Initiative and the ongoing effort of the AU to establish the African Medicines Agency (AMA).

**Recalling** the Declaration of the First IGAD Scientific Conference on Health held in Addis Ababa, Ethiopia, in December 2014, particularly its emphasis on health systems strengthening and the need for enhancing regional regulatory mechanisms and cross-border collaboration in the fight against illicit trafficking of medical products.

**Encouraged** by recent global dialogues on the post-2015 sustainable development agenda including the Third International Conference on Financing for Development and the Addis Ababa Action Agenda adopted in the Conference (July 13-16, 2015) as well as the High-

Level Ministerial Conference of African Ministers of Health and Finance on Investing in Human Resources for Health (HRH) in Africa, held in Addis Ababa, Ethiopia between July 17-18, 2015.

**Recalling** the Call for Action of the First IGAD Regional Medicines Regulatory Authorities Conference on Regulatory Collaboration and Harmonization, August 2015, in Addis Ababa, which declared establishment of the **IGAD Regional Medicines Regulatory Collaboration and Harmonization Program**.

**Recalling** the various commitments made by the IGAD committee of Ministers of Health to the development of the health sector through strengthening the health systems, harmonization of regional interventions and promoting medicines regulatory systems.

Encouraged by the progress made since the First IGAD Conference especially the Joint IGAD – WHO Statement issued on November 5, 2015 in Djibouti and requested IGAD to expedite the process of implementation of the next steps.

**We therefore, strongly recommend the following:**

1. Strengthen **national** medicines regulatory authorities capacity and support the authorities with inadequate regulatory system
2. Strengthen the partnerships among IGAD Member States and other development partners on the regional medicines regulation and harmonization
3. Conduct a rapid assessments for the NMRAs following regionally adapted WHO guidelines with focus on the cross border pharmaceutical regulatory issues; the assessment should be finalized and ready for member state validation in the coming six months
4. Member States and IGAD Secretariat with the support of WHO and other partners to develop a summary project proposal for funding to be submitted to interested donors within the coming six months
5. Recommend for the Ministerial committee to endorse;
  - a. The proposed Term of Reference (ToR) of IGAD Steering Committee composed of Heads of NMRAs and/or related Sectoral Directorates (and chief pharmacists) of Member States
  - b. The proposed Term of References (ToRs) of the expert Regional Technical Working Group of Experts from IGAD Member States with well-defined, realistic objectives, advising and reporting to the Steering Committee
  - c. The proposed well-functioning unit within the IGAD Health and Social Development Department that is responsible for planning, coordination and facilitating the implementation of the IGAD Regional Medicines Collaboration and Harmonization Program

6. Establish a sustainable financing mechanism for the IGAD Regional Medicines Regulatory Harmonization program
7. Build the capacity of IGAD Secretariat and its Member States to ensure effective coordination and implementation of the program
8. Establish an integrated information management system that links all authorities and enables joint activities as well as develop a website for information sharing and exchange
9. Initiate a phased approach for harmonization of medicines regulation based on the priorities identified in the IGAD Member States
10. Support the development of an overarching regional pharmaceutical policy and the adoption of modern legislative frameworks based on the AU Model Law.

**We call upon IGAD** to lead the implementation of these recommendations and the establishment of the regional medicines regulatory collaboration and harmonization program.

**We urge our collaborating and development partners**, including the AUC, NEPAD, RECs, World Bank, WHO, UNFPA, USAID, USP, the pharmaceutical industries, and other stakeholders to provide all-rounded support for the effective functioning of the proposed IGAD regional medicines regulatory collaboration and harmonization program.

**We noted** the willingness and the request from the Government of the Sudan to host the **IGAD regional Medicines Regulatory Collaboration and Harmonization Program**.

Finally, we call upon our IGAD Ministers of Health to endorse and support this Declaration when they convene in their next regular session.

***Done on April 27, 2016 in Khartoum, Sudan***