JOINT IGAD - WHO STATEMENT ON THE ESTABLISHMENT OF THE IGAD MEDICINES REGULATORY COLLABORATION AND HARMONIZATION PROGRAMME

5th November 2015, Djibouti, Republic of Djibouti

Preamble

High-level delegates and representatives of the Intergovernmental Authority on Development, hereafter referred to as “IGAD” Secretariat, the Ministry of Health of Djibouti and the World Health Organization, hereafter referred to as “WHO” from the WHO Headquarters, the Africa Regional Office, the Eastern Mediterranean Regional Office and the Djibouti Country Office met on the 5th of November, 2015. The joint IGAD-WHO meeting discussed their commitments to the implementation of the recommendations of the “Addis Ababa Call for Action” that was an outcome of the 1st IGAD conference on medicine regulatory harmonization held from 3rd to 5th August, 2015 in Addis Ababa, Ethiopia.

IGAD is one of the eight Regional Economic Communities (RECs) of the African Union (AU). Among IGAD’s mandate is to contribute and supplement the development agenda of its Member States in advancing the quality of life of their populations through the promotion and facilitation of common social policies in the areas of health, education and employment, social protection and young people. To realize this particular mandate, IGAD supports the development and harmonization of common strategies and policies to strengthen health systems including regulatory systems, that contribute to improved access to medical products and other health technologies of assured quality, safety and efficacy.
WHO is a specialized agency of the United Nations (UN) with a constitutional mandate of ensuring the attainment of the highest standard of health, which is one of the fundamental human rights. In this context, WHO supports Member States in promoting quality health services including access to safe, effective, quality assured medical products and other health technologies. To realize this broad mandate, WHO works closely with its Member States, RECs and collaborating and development partners in strengthening regulatory systems.

WHO and IGAD envisioned that Members States have regulatory systems that ensure all medical products and other health technologies meet internationally recognized standards of quality, safety and efficacy.

Acknowledging that access to quality medical products and other health technologies is one of the major challenges affecting the healthcare delivery systems in the IGAD region, impeded by ineffective regulatory systems and inappropriate procurement policies;

Greatly alarmed by the widespread and unregulated circulation within the countries of Substandard, Spurious, Falsified, Falsely labeled and Counterfeit (SSFFC) medical products;

Recognizing the negative consequences that SSFFC medical products have on health and development of the societies, particularly those in rural, pastoralist and cross-border mobile populations;

Informed by the World Health Assembly Resolution 67.20 on regulatory systems strengthening, the African Union Pharmaceutical Manufacturing Plan for Africa and its implementation framework and the ongoing efforts of the AU to establish the African Medicines Agency (AMA);

Aware of the African Medicines Regulatory Harmonization (AMRH) initiative implemented in different RECs on the continent;

Recalling the 1st IGAD Scientific Conference on Health and the “Addis Ababa Call for Action” of the 1st IGAD Regional Medicines Regulatory Authorities Conference, both held in Addis Ababa, Ethiopia, December 2014 and August 2015 respectively;

Desirous of sharing best practices and lessons learned from other RECs, harmonization initiatives and Member States of the African Union;
Recalling the various commitments made by the IGAD Ministerial Committee on Health to the development of the health sector through strengthening the health systems, harmonization of regional interventions and promoting medicines regulatory systems;

Recognizing the role of the IGAD Secretariat and WHO to support the implementation of the recommendations of the “Addis Ababa Call for Action” and the establishment of the regional medicines regulatory mechanism;

IGAD commits to the following actions:

1. Establish the IGAD Regional Medicines Regulatory Collaboration and Harmonization Programme as a mechanism to foster harmonization and coordination to:
   a) Conduct medicines regulatory system situational assessments in each member state,
   b) Develop a mechanism to implement an agreed common technical document for registration of medicines in the IGAD Member States,
   c) Implement a common information management system for medicines registration in the IGAD Member States through their respective National Medicines Regulatory Agencies (NMRAs) linked to the IGAD Secretariat,
   d) Implement a quality management system in each of the NMRAs in the IGAD Member States,
   e) Build regional and national capacities to implement medicines registration harmonization in the IGAD region,
   f) Create an IGAD platform for information sharing on the harmonized medicines registration system to key stakeholders at national and regional levels,
   g) Develop and implement a structure for mutual recognition based on a regional legal framework endorsed and enforced within,
   h) Facilitate the creation of regional centres of excellence in various field of medicines regulation, and
   i) Facilitate an exchange program to fill gap on shortage of experts in the region;

2. Strengthen existing NMRAs and create new ones in countries where they do not exist;

3. Create a unit within the IGAD Secretariat to lead and coordinate the Regional Medicines Harmonization Program and network with similar programs and partners; and
4. WHO within the context of this initiative, to provide technical support to IGAD, including assistance in resource mobilization for the development and implementation of the IGAD Medicines Regulatory Collaboration and Harmonization Programme;

**We also urge other development partners**, including the UN Fund for Population Activities (UNFPA), the United States Agency for International Development (USAID), the World Bank, the Bill and Melinda Gates Foundation (BMGF) and other stakeholders, including the medical products industry, to provide all-rounded support for the establishment and support and effective functioning of the Regional Medicines Regulatory Programme for the IGAD region and beyond. We also urge development partners to adopt a coordinated approach to support according to a single, established plan and their defined roles and responsibilities.

**Next Steps:**

1. IGAD Secretariat to report on commitments made by the IGAD Ministers of Health to the Addis Ababa “Call for Action”.

2. IGAD in collaboration with WHO to conduct a comprehensive situational analysis of national medicines regulatory systems of IGAD Member States.

3. IGAD to organize the 2\(^{nd}\) IGAD Regional Medicines Regulatory Authorities Conference to be held in Khartoum, Sudan in the early second quarter of 2016.

4. IGAD with the support of WHO and other partners to develop a summary project proposal for funding to be submitted to interested donors.