COOPERATION FRAMEWORK AGREEMENT FOR EAC PARTNER STATES NATIONAL MEDICINES REGULATORY AUTHORITIES

FINAL

APRIL 2018

Preamble

The attainment of this Cooperation Framework between Partner States National Medicines Regulatory Authorities (NMRAs) of the Republic of Burundi, Republic of Uganda, Republic of Kenya, Republic of Rwanda and United Republic of Tanzania, including Tanzania (Mainland) and Tanzania (Zanzibar) (hereinafter collectively referred to as "NMRAs" or "EAC NMRAs" or singularly as "NMRA"); is premised on the successful implementation of EAC medicines regulatory harmonized guidelines and technical requirements which are anchored on Article 118 of Chapter 21 of the EAC Treaty establishing East African Community.

RECOGNISING the objectives of the EAC Common Market Protocol, Article 2 (4) which are to allow free movement of goods, persons, and services within the EAC Community;

COGNISANT that there is no NMRA that can do everything on its own without interactions, cooperation and exchange of information with other regulatory authorities to protect their citizens and promote public health; and taking into account the progress made under the East Africa Community Medicines Regulatory Harmonization Project in Good Manufacturing Practices (GMP), Marketing Authorizations, Quality Management Systems, Information Management Systems, Clinical Trials and Pharmacovigilance;

NOTING that Chapter 21, Article 118 (d), and (e) on Health of the Treaty requires Partner States to harmonise drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the community and exchange information on health issues in order to achieve quality health within the Community;

RECOGNISING the objectives of EAC Customs Union, which are to eliminate tariff, non-tariff and technical barriers to trade; harmonise and mutually recognize standards and implement a common trade policy for the Community;

NOTING that Article 47 of the EAC Common Market Protocol mandates Partner States to approximate their national laws and to harmonize their policies and systems, for purposes of implementing the Common Market Protocol.

DESIRING for a Cooperation Framework (hereinafter referred to as "CFW") on regulatory decisions as well as promoting the flow of relevant information and exchanging expertise, experiences and best practices suited to specific needs of each EAC NMRA;

RECOGNISING the right of each EAC NMRA to regulate the pharmaceutical sector within its territory;

NOTING that the collaborative procedures shall be voluntary

HAVE AGREED on the following:

Article 1: Interpretation

In this Cooperation Framework Agreement, unless the context otherwise indicates:

"Cooperation Framework Agreement" is a written agreement between EAC partner states NMRAs to provide a guide for technical collaboration in the regulation of medicines and health technologies.

"**domestic regulations"** means laws, by-laws, regulations, rules, orders of respective EAC Partner States as well as directives, guidelines and standards, relating to regulatory decisions, issued by the respective National Medicines Regulatory Authority ;

"EAC" means the East African Community Partner States

"health technologies" refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.

"medicines" means any medications, drugs, substances used to diagnose, treat, cure or prevent diseases and promote health.

"**mutual recognition"** means the reciprocal adoption or acceptance of regulatory decisions or outcomes made by other NMRAs as valid.

" **NMRA**" means the EAC Partner State National Medicines Regulatory Authority;;

"**recognition**" means acceptance by an NMRA of compliance with its requirements of a regulatory decision or outcome by another NMRA as valid.

"**regulatory decisions**" means the outcomes of the activities covered under pharmaceutical or medicine laws or equivalent in the respective Partner States,

"regional technical officers" means properly qualified and competent staff of the NMRAs who has skills and knowledge in relation to medicines registration, inspections/audits and other regulatory functions;

"**standards**" means a standard document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

"**technical cooperation"** means collaboration between EAC partner states NMRAs

Article 2: Objectives

2.1 The overall objective of this Cooperation Framework Agreement is to provide a guide for technical cooperation among EAC Partner States NMRAs to improve efficiency and effectiveness in the regulation of medicines and health technologies.

2.2 The specific objectives of this framework are:

a) Enhancing cooperation and collaboration in the regulation of medicines and health technologies among EAC NMRAs;

b) Enhance capacities through technical information exchange and work sharing among NMRAs
c) Promote reliance and convergence on regulatory decisions with respect to regulation of medicines and health technologies among EAC -NMRAs ;
d) Facilitate the exchange of information about the regulation of medicines and health technologies by each EAC NMRAs including: Polices, practices, standards, pre-market assessments, post market vigilance, market compliance, regulation of manufacturers, regulation of clinical trials and requirements for the regulation of medicines and health technologies to promote and protect health
e) to enhance the ability of the EAC NMRAs, in the provision of their services relating to or in connection with public health, to meet the needs of their respective population.

Article 3: Principles of the Cooperation Framework Agreement

This Cooperation Framework represents the understanding reached by the EAC NMRAs, in particular that each EAC NMRA has jurisdiction over regulation of medicines and health technologies in its territory.

In achieving the above objectives, EAC NMRAs shall be guided by the following principles:

3.1 Respecting and conforming to the Domestic Regulations of the participating EAC NMRAs without lowering the standards and requirements in each EAC Partner States;

3.3 Observance of Objectivity, mutual respect, transparency, fairness and reciprocity in implementing this Cooperation Framework.

Article 4: Scope of the Cooperation Framework Agreement

The scope of the Cooperation Framework Agreement shall cover regulatory areas on the following:
4.1 Marketing authorizations or product evaluation and registrations of medicines and health technologies
4.2 Good manufacturing practice (GMP) inspections
4.3 Good clinical practice (GCP), Good laboratory practice (GLP) inspections and good clinical laboratory practice
4.4 Medicines and health technologies regulatory Information and work sharing
4.5 Pharmacovigilance/haemovigilance and Post Marketing Surveillance activities
4.6 Regulation of Clinical Trials
4.7 Quality Management System
4.8 Integrated Information Management System
4.9 Medicines and health technologies waste management
4.10 Regulatory enforcement activities

Article 5: Legislations and Regulatory Systems

5.1 The Cooperation Framework Agreement will be based on recognized systems, standards, and practices.

5.2. Each NMRA shall have in their policies, laws and / or regulations, governing the pharmaceutical sector as applicable provisions for granting marketing authorisation,

licensing of premises, inspections of manufacturing sites and clinical trial sites as provided for under Article 4 of this agreement.

5.3 The EAC Partner States undertake to establish functional regulatory systems for processing and decision making that are supported by an appropriate legal framework, clear written procedures, and mechanism for making decisions that complying with good regulatory practice requirements meeting the minimum Community and International standards

5.4 The EAC Partner States undertake to adopt the agreed common technical standards, where applicable, or the national standards should approximate or be equivalent to the agreed common technical standards. Where appropriate, use of global standards where regional standards are unavailable shall be followed.

5.5 The Partner States undertake to ensure that the technical staff have the minimum requisite qualifications for the specific regulatory function responsibilities.

Article 6: Responsibilities of NMRAs

6.1 The Partner States hereby agree to implement Article 4 and that each NMRA shall undertake to;

a) participate in joint activities in different regulatory areas;
b) cooperate in information and work sharing on marketing authorization and GMP ;
c) make decisions on the outcomes of the joint activities within twenty one (21) days following the endorsement by the Heads of NMRAs Forum;
d) publicize regional assessment pathway for the product classes that are included in the EAC Expression of Interest on NMRA's website;
e) Conduct Post marketing surveillance of products on the market and share information, including updating the reports where necessary, used as basis for making a decision to support granting of recognition/ approval by other NMRAs;
f) Setting and/or maintaining, where applicable, the approximate regulatory systems, the agreed common standards and competences of technical staff;
g) Exchanging information regarding Domestic Regulations, practices and developments on regulatory systems in the EAC NMRAs with the view to harmonise the practice in accordance with regional and/or international standards;
h) Appoint and designate regional technical officers to spearhead the implementation of joint regulatory activities at national level and
i) Any other related regulated areas that NMRAs shall agree upon from time to time

Article 7: Finances

7.1 EAC Partner States NMRAs shall develop fee structures and guidelines for the EAC joint medicinal product registration procedures , EAC joint GMP Inspections and other regulatory functions as may arise from time to time;

7.2 EAC Partner States NMRAs shall establish mechanisms for collecting and sharing fees in regard to jointly carried out regulatory activities as stipulated in 7.1;

Article 8: Cooperation Framework Agreement Procedures

8.1 EAC Partner States NMRAs shall develop procedures for appropriate implementation of the provisions of this cooperation framework agreement

8.2 EAC Partner States NMRAs shall develop procedures to create conducive environment for growth of the EAC Regional Pharmaceutical Industry

Article 9: Confidentiality under the Cooperation Framework Agreement

9.1 EAC Partner States NMRA irrevocably undertake to protect all the information shared and shall only use it for the intended purposes by the respective NMRAs. It is mutually agreed that all information shared is confidential.

9.2 Without prejudice to Article 8.1, EAC Partner States NMRAs shall agree on information that will be public and non-confidential.

Article 10: Amendments

10.1 This Cooperation Framework Agreement may be amended at the written request of any EAC Partner State.

10.2 Without prejudice to Article 9.1, any EAC Partner State may enter into Mutual Recognition Agreement(s) with another EAC Partner State(s) if the two Partner States are ready to enter such Agreement.

10.3 Mutual Recognition Agreements between the two or more EAC Partner States shall only be entered upon meeting the EAC set criteria.

Article 11 : Dispute Settlement

11.1 EAC Partner State shall at all times endeavour to agree on the interpretation and application of this Cooperation Framework Agreement and shall make every attempt through communication, dialogue, consultation and cooperation to arrive at a mutually satisfactory resolution of any matter that might affect the implementation of this Cooperation Framework Agreement.

11.2 Without prejudice to Article 10.1, the EAC dispute settlement Procedures shall be applicable to this agreement.

Article 12: Entry into force

The EAC Cooperation Framework Agreement shall enter into force upon signature by the EAC Partner States

Article 13: Termination

This Cooperation Framework Agreement shall be obsolete once the Mutual Recognition Agreement for EAC Partner States' NMRAs come into force.

Signed on this ……Day of ……by the EAC Sectoral Council of Ministers of Health

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Hon. Sarah Opendi.	**Hon. GASHUMBA Diane**	**Hon. Dr. Josiane Nijimbere**	**Hon. Dr. Cleopa Mailu**	**Hon. Dr. Riek Gai Kok**	**Hon. Ummy Ally Mwalimu**
Minister of Health	**Minister of Health**	**Minister of Health**	**Cabinet Secretary**	**Minister of Health**	**Minister of Health**
Ministry of Health	**Ministry of Health**	**Ministry of Public Health & Fight Against Aids**	**Ministry of Health**	**Ministry of Health**	**Ministry of Health, Community Development, Gender, Elderly and Children**
REPUBLIC OF UGANDA	**REPUBLIC OF RWANDA**	**REPUBLIC OF BURUNDI**	**REPUBLIC OF KENYA**	**REPUBLIC OF SOUTH SUDAN**	**THE UNITED REPUBLIC OF TANZANIA**