MEMORANDUM OF UNDERSTANDING

BETWEEN

THE GOVERNMENT OF THE REPUBLIC OF RWANDA

AND

THE GOVERNMENT OF THE UNITED REPUBLIC OF TANZANIA

ON

COOPERATION IN THE REGULATION OF MEDICAL PRODUCTS

PREAMBLE

The Government of the Republic of Rwanda, through the RWANDA FOOD AND DRUGS AUTHORITY hereinafter referred to as "RWANDA FDA" - a public institution established by the Law No. 003/2018 of 09/02/2018 to regulate Food and Drugs in Rwanda on one hand;

AND

The Government of the United Republic of Tanzania through TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY hereinafter referred to as "TMDA" - a regulatory authority established under Section 4(1) of the Tanzania Medicines and Medical Devices Act, Cap 219 to regulate medicines, medical devices and diagnostics in the United Republic of Tanzania on the other hand.

WHEREAS Parties wish to establish collaborative mechanism on harmonization in areas of product registration, good manufacturing practices inspection, clinical trials control, post-marketing surveillance, quality control, research and trainings and information sharing;

WHEREAS, in accomplishment of the responsibilities assigned to them, one Party may need services offered by the other Party in respect of each Party's mandate and capabilities; and

NOW THEREFORE THE PARTIES WISH TO RECORD IN WRITING THIS MEMORANDUM OF UNDERSTANDING IN RESPECT OF THE ABOVE AND MATTERS ANCILLARY THERETO.

ARTICLE 1
PURPOSE OF THE MOU

The purpose of this MoU is to establish the cooperation for harmonization on regulatory requirements between Rwanda FDA and TMDA, hereinafter referred to as "Parties" in the following areas:

1. Product Registration;
2. Good Manufacturing Practices Inspection;
3. Quality audits;

4. Good Clinical Practices Inspection;
5. Clinical Trials Control;
6. Post-Marketing Surveillance;
7. Quality Control Laboratory Testing;
8. Research and Trainings;
9. Information sharing; and
10. Other regulatory functions as may be deemed necessary by either Party.

ARTICLE 2
SCOPE OF THIS MOU

This MoU covers all products regulated by both Parties including human and veterinary medicines, herbal medicines, medical devices, diagnostics, biological products including vaccines and tobacco products.

ARTICLE 3
MUTUAL RECOGNITION

Each Party will recognize as its own the regulatory functions as provided in Article 1 of this MoU performed by the other to meet the goals and objectives of the MoU:

3.1 Product Registration

i. Each Party will recognize and use as technical input the data submitted before registration of products by the other Party;

ii. The registration of a product by either Party will be evidenced by a certificate of registration and/or registration mark issued by the other Party; and

iii. Both Parties commit to suspend the manufacture, importation and exportation, sale, distribution and storage of any product that does not comply with quality, safety and efficacy requirements to be traded in markets of either Party.

3.2 Good Manufacturing Practices Inspection and Quality Audits

i. Each Party will share the Good Manufacturing Practices (GMP) inspection reports for medicines manufacturing facilities before deciding on the outcome of an inspection

ii. The GMP inspection conducted will be evidenced by a certificate (GMP Certificate) issued by the other Party.

iii. Each Party will share data on quality audits conducted at medical devices and diagnostics manufacturing facilities to very conformity to ISO requirements.

iv. The quality audit reports will be evidenced by a certificate issued by the other Party.

3.3. Clinical Trials Control

i. Each Party will share information on the protocol and other data related to clinical trials to be conducted in each Party's investigator site(s);

ii. The results of the clinical trials conducted on the territory of either Party will be shared on by the other Party;

iii. In case of changes or inconsistencies in clinical trial results, the investigator or sponsor will review its results and perform further studies basing on the information provided by the other Party; and

iv. During conduct of clinical trials, both Parties may conduct good clinical practice (GCP) inspection and share reports.

3.4 Post-Marketing Surveillance

i. Each Party will share information on post marketing surveillance (PMS) results from either Party;

ii. Each Party will share information on product recalls after confirming their quality defects to include batch numbers, quantities, labels, address of manufacturers and any other details that may permit identification of products in each Party's market; and

iii. Each Party may seize and confiscate condemned products after thorough investigation depending on each jurisdictional legislative framework.

3.5 Quality Control Laboratory

i. Each Party agree to establish quality control laboratories that will ensure compliance to standards;

ii. Each Party will share laboratory test results once requested to allow for regulatory decision making;

iii. Each Party will work on the accreditation of the quality control laboratories to allow for more reliable results to be obtained; and

iv. Each Party may conduct further testing of products for self-assurance in case of disputed results or not.

3.6 Research, Trainings and Sharing experts

i. Both Parties agree to regularly share research findings and conduct joint research whenever possible and necessary;

ii. Each Party may organize trainings on regulatory matters which may take place at any of the Party's territory or conducted using online platforms; and

iii. Both parties may share or exchange their experts for mentorship, coaching and capacity building of either parties' staff.

3.7 Information sharing

i. Both Parties agree to share information being accurate or suspicious concerning the quality, safety and efficacy of regulated products under the mandate of either Party;

ii. Parties agree to follow-up and analyse the information shared including the outcome of the analysis; and

iii. Both Parties agree to share information on new regulatory requirements including laws, regulations and guidelines to facilitate compliance and protection of public health.

ARTICLE 4
REGULATORY SERVICE FEES AND CHARGES

Regulatory service fees and charges on regulatory functions such as registration, import and export control, clinical trial authorization and others will continue to be paid in accordance with the existing legislative requirements.

ARTICLE 5
AMENDMENTS

Either Party is free to propose amendments which come into effect following mutual agreement of the Parties.

ARTICLE 6
DISPUTE RESOLUTION

The Parties to this MoU undertake to do everything in their powers to amicably reach a mutual settlement of any conflicts that may arise in respect to the interpretation or implementation of this MoU.

ARTICLE 7
DURATION AND TERMINATION

1. This MoU commences on the date of signature and will continue until terminated by either Party and will endure a period of five (5) years subject to renewal upon agreement between Parties.

2. The terminating Party will give a notice of sixty (60) days to the other Party before implementing the decision.

ARTICLE 8
CONFIDENTIALITY

Each Party will keep confidential all information received from the other Party (directly or indirectly) in relation to that Party, any aspect of its business, provided that Confidential Information will not include information which:

i. is or becomes available to the general public through no act of the receiving Party in breach of this Article,

ii. is received by the receiving Party from a third Party in circumstances where the receiving Party is not aware that such third Party is breaching a duty of confidentiality,

iii. was independently developed by the receiving Party without reference to or use of the Confidential Information received from the other Party, or

iv. is required to be disclosed by the receiving Party pursuant to the operation of applicable laws, order of a court or other judicial or arbitral body or the direction or request of any governmental authority or body or as may be required to comply with audit requirements (but only to the extent of such disclosure).

ARTICLE 9
NOTICES

All notices required under this MOU will be written in English and delivered by registered mail to the herein mentioned addresses:

Tanzania Medicine and Medical Devices Authority
P.O. Box 77150, Or P.O.Box 77150
Dar es Salaam Kisasa B Area
TANZANIA DODOMA
info@tmda.go.tz

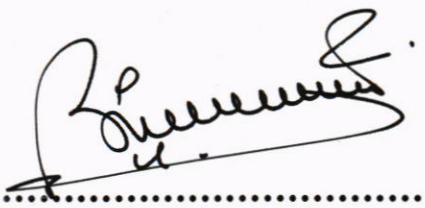
Rwanda Food and Drugs Authority
P.O Box: 1948 Kigali-Rwanda
info@rwandafda.gov.rw
Nyarutarama Plaza, Rwanda KG 9 Avenue, Kigali

ARTICLE 10
FINAL PROVISION

Any area that may not be covered by this MoU but provided by either Party will be provided in the spirit of this MoU through a written agreement signed by both Parties.

IN WITNESS WHEREOF, the undersigned being authorized by their respective governments, have signed this MoU in two (2) original copies in English language, both texts being equally authentic.

For the Government of the Republic of Rwanda.



.....

DR. VINCENT BIRUTA

Minister for Foreign Affairs and International Cooperation of the Republic of Rwanda

For the Government of the United Republic of Tanzania.

.....

Hon. AMB. LIBERATA MULAMULA (MP)

Minister for Foreign Affairs and East African Cooperation of the United Republic of Tanzania