MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN

ZAMBIA MEDICINES REGULATORY AUTHORITY

AND

THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE

ON

COOPERATION IN THE REGULATORY FUNCTIONS OF MEDICAL PRODUCTS

THIS MEMORANDUM OF UNDERSTANDING (hereinafter referred to as "MOU") is made the.....day of.....2024 **BETWEEN** ZAMBIA MEDICINES REGULATORY AUTHORITY ("ZAMRA") established under the Medicines and Allied Substances Act No. 3 of 2013 ('the Act") and having its head office at Plot No. 2350/M off Kenneth Kaunda International Airport Road, Lusaka of the one part **AND** the MEDICINES CONTROL AUTHORITY OF ZIMBABWE (hereinafter referred to as "MCAZ") established under the Medicines and Allied Substances Control Act, Chapter 15.03 and having its head office at plot no. 106 Baines Avenue, Harare, Zimbabwe of the other part, hereinafter jointly referred to as the "Parties" and in the singular as "Party".

1.0 OBJECTIVES OF THE MOU

The Parties will promote and develop cooperation in the field of medical products regulatory functions within the respective jurisdiction by cooperating in the manner set out in this MOU on the basis of equality and mutual benefit.

2.0 AREAS OF COOPERATION

The Parties will cooperate in the field of supplying and regulatory functions related to:

2.1 medical devices;
2.2 track and trace, authentication control application;
2.3 detection of substandard and falsified medicines;
2.4 nanotechnology;
2.5 biotechnology for medicines;
2.6 vaccine production;
2.7 active Pharmaceutical Ingredients (API) Production; and
2.8 any other areas agreed by "the Parties".

3.0 FORMS OF COOPERATION

The cooperation between "the Parties" will take the following forms:

3.1 Support and facilitate private sectors and activities of participants;
3.2 Exchange and sharing information, best practices, and knowledge in the field of standards and regulations;
3.3 High official and technical visit related to familiarization of regulatory processes of both Parties;

3.4 Support capacity building through the exchange of personnel, sharing of knowledge and experience, and education and training programs;

3.5 Exchange of information on the status of Good Manufacturing Practice (GMP) inspection results as well as on professional and bioequivalent center inspection results as may be requested by one of "the Parties";

3.6 Facilitate the investment of "the Parties" companies in each Party;

3.7 "The Parties" will promote the implementation of issuing electronic certification and other technologies to facilitate trade;

3.8 Provide mutual understanding of each Party's laws, regulation and procedures relating to the implementation of medical products safety measures;

3.9 Participation in international events organized by either Party;

3.10 Mutual cooperation in common areas at multilateral fora; and

3.11 Any other form of cooperation as mutually decided upon in writing by "the Parties".

4.0 COMMENCEMENT AND DURATION

4.1 This MOU will come into effect on the date its signed by the Parties.

4.2 This MOU will remain in effect for the period of five (5) years and may thereafter be renewed for a further period of Five (5) years, unless one of the Parties informs its intention to terminate it in writing through diplomatic channels to the other Party.

5.0 FINANCIAL RESOURCES

5.1 Each Party will bear its own expenses related to any activities conducted under this MOU.

5.2 When deemed necessary and by mutual agreement, "the Parties" may invite funds from any third party such as UN, WHO, etc. to support the activities under this MOU.

6.0 INTELLECTUAL PROPERTY RIGHTS

The Parties declare that any intellectual property arising from the implementation of this MOU will be jointly owned and its utilization will be subject to a separate arrangement between the Parties.

7.0 RESEARCH MATERIAL TRANSFER AGREEMENT

In case the transfer of research materials is required for collaboration activities to be carried out within this MOU, such materials may be transferred in accordance with the prevailing laws and regulations in force in the countries of "the Parties" through a separate Material Transfer Agreement concluded between "the Parties" or between enterprises, institutions and economic agents from the two countries subject to the approval by "the Parties".

Note: The access and utilization of Genetic Resources and Associated Traditional Knowledge in the implementation of the cooperative activities under this MOU will be further regulated in the specific arrangement on a case by case project basis to be decided by the Parties prior to the commencement of related project activities.

8.0 JOINT COMMITTEE AND ITS CONFORMATION

In order to achieve the defined objective of this MOU "the Parties" decided to establish a "Joint Committee" which will be chaired by the Head of any of the competent bodies of "the Parties" (ZAMRA and the MCAZ); The "Joint Committee" functions include:

8.1 Monitor and facilitate the implementation of this MOU considering the compliance with the regulations, commitment and the pharmaceutical policies of "the Parties"; and

8.2 Submit a follow-up report, twice a year in the fields of understandings made, to the High-Level Joint Economic Commission between the Republic of Zambia and the Republic of Zimbabwe.

9.0 CONTACT POINTS FOR THE IMPLEMENTATION

The Parties will appoint contact points as authorized representatives of "the Parties", which are responsible for the communication of organizing the implementation of the MOU:

For: The Zambia Medicines Regulatory Authority:
The Director General

Zambia Medicines Regulatory Authority
Plot No. 2350/M
P. O Box 31890
Off Kenneth Kaunda International Airport Road
Lusaka, Zambia

Cell: +260-211 432350
Email: pharmacy@zamra.co.zm

For: The Medicines Control Authority of Zimbabwe:
No. 106 Baines Avenue, Harare
Phone number: +263-772145192
Email address: mcaz@mcaz.co.zw

10.0 EXCHANGE OF DATA/INFORMATION

The Authority and the Port Health may, under certain circumstances, share each other's available data and information in order to bring the provisions of this MoU into full effect; provided such a process is reasonable, will not compromise the respective independence of the two parties and does not contravene the Data Protection Act, No.3 of 2021 and any other piece of legislation.

11.0 CONFIDENTIALITY

11.1 Each Party understands that the information exchanged between them may include confidential information that is not in the public domain in the country of the Party providing the information. "The Parties" note that it is essential that confidential information emanating from one Party be treated as such by the other Party.

11.2 Each Party will make every reasonable effort to ensure that:

i. All communications and all information whether written, visual or oral and all other material supplied to or obtained by either Party in the course of or as a result of the discharge of their obligations under this MoU will not be disclosed by themselves, their Subcontractors, agents or otherwise to any third party or published without prior written consent of the other Party.

ii. A party who receives confidential information from another under this MoU must use it except for the purpose of exercising its rights or performing its obligations under this MoU.

iii. A party who has received confidential information from another under this MoU must, on the request the party, immediately deliver to that party all documents or other materials containing or referring to that information which are in its possession, power or control of persons who have received confidential information from it under the terms of this MoU.

11.3 The obligation to observe confidentiality will subsist notwithstanding the termination of the MoU.

12.0 DISPUTE RESOLUTION

12.1 This MOU is not intended to create legal relations, any rights and obligations under international law.

12.2 Any dispute between "the Parties" arising out of the implementation, application, or interpretation of this MOU will be settled amicably through consultation or negotiations between "the Parties" through diplomatic channels.

13.0 AMENDMENTS

This MOU may be amended only by mutual written agreement of the Parties through diplomatic channels. Such amendments will constitute an integral part of this MOU and will come into effect on the date of its signature by the Parties.

All amendments of this MoU shall be subject to the approval of relevant authorities.

14.0 TERMINATION

This MOU may be terminated by either Party at any time for any reason by giving written notice of at least **Six (6) months** in advance to the other Party. In such event, all obligations and pending responsibilities will be finalized prior to the effective date of termination. However, termination of this MOU will not affect any ongoing programs and projects under this MOU, unless the Parties agree otherwise.

15.0 SURVIVAL

The termination or expiration of this MOU for any reasons will not release either party from any liabilities or obligations set forth in the MOU which remain to be performed or by their nature would be intended to be applicable following any such termination or expiration.

16.0 NON- WAIVER

A delay or failure by either party to exercise or enforce any right under this MOU will not constitute a waiver of that or any other right nor will it prevent the subsequent exercise of such right remedy.

17.0 ILLEGALITY

If any provision of this MOU becomes unlawful or invalid under any applicable law, the legality and validity of the remaining provisions will not be affected.

18.0 SEVERABILITY

If any provision or condition of the MoU is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability will not affect the validity or enforceability of any other provision of the MoU.

19.0 ASSIGNMENT

Neither Party will assign the whole or part of the MoU or any benefit or any interest under the MoU.

20.0 FORCE MAJEURE

If at any time during the subsistence of this MoU or any renewal thereof either Party informs the other about the onset of reasons beyond its control, where they are unable to carry out the work in terms hereof and/or the property or building in which it is situated is destroyed or damaged by fire, tempest, earthquake, accident, act of God, war. Flood, etc. i.e. Force Majeure, so that the work at the terms of this MoU cannot be reasonably fulfilled, the same will not be treated as breach of this MoU. Either party will have the option to put an end to this MoU forthwith, if such Force Majeure events continue for more than fourteen (14) days, however, the affected

Party will have the obligation to communicate the cessation of the Force Majeure event should it end before 14 days.

21.0 LEGAL RELATIONSHIP

Nothing in this MOU will be construed as creating any legal relationships between the Parties. This MOU is a statement of intent to foster genuine and mutually beneficial collaboration.

22.0 CONFORMITY

The implementation of this MoU will be in accordance with the laws and regulations applicable in Zambia. The provisions of this MoU will be without prejudice to any other treaties or agreements to which both sides are parties.

IN WITNESS WHEREOF the Parties or their duly authorized representatives have set their hands the day and year first before written.

Signed by the **DIRECTOR-GENERAL**)
for and on behalf of Zambia Medicines Regulatory Authority)

In the presence of
Name: MOSES LUPIYA
Signature:
Address: P.O Box 31893 LUSAKA
Occupation: DIRECTOR LEGAL/BOARD SECRETARY

Signed by the **DIRECTOR-GENERAL**)
for and on behalf of Medicines Control Authority of Zimbabwe)
In the presence of
Name:
Signature:
Address:
Occupation: