



MEMORANDUM OF UNDERSTANDING (MOU)

BETWEEN

THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

a juristic person established in terms of section 2 of the Medicines and related Substances Act (Act No. 101 of 1965) ("The Act"), as amended, herein represented by **Dr Boitumelo Semete- Makokotlela**, in her capacity as the Chief Executive Officer who warrants that is authorised to do so

(herein after referred to "SAHPRA")

AND

THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE

a statutory body established in terms of Section 3 of the Medicines and Allied Substances Control Act (Chapter 15:03), herein represented by **Mr Richard Rukwata**, in his capacity as the Director-General and duly authorized to do so

(herein after referred to "MCAZ")

ON COOPERATION IN THE REGULATORY FUNCTIONS OF MEDICAL PRODUCTS

Two handwritten signatures in blue ink are located at the bottom right of the page. The first signature is a large, stylized 'P' or 'B' shape, and the second is a smaller, more complex scribble.

PREAMBLE

WHEREAS SAHPRA, is responsible for the regulation of health products intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides; and the conduct of clinical trials.

AND WHEREAS The Medicines Control Authority of Zimbabwe is responsible for the registration and regulation of medicines intended for human and animal use, the licensing of manufacturers, wholesalers and distributors of medicines and the conduct of clinical trials.

AND WHEREAS SAHPRA may in terms of section 2B (2) (a and b) of the Act liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, **exchange information with and receive information from any such authority** or institution in respect of—

- (i) matters of common interest; or
- (ii) a specific investigation; and
- (b) enter MOUs to co-operate with any regulatory authority in order to achieve the objects of this Act.

AND WHEREAS SAHPRA and MCAZ intend to establish and maintain a co-operative relationship for the provision of mutual assistance collaborative study on registration of antiretrovirals in South Africa.



NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1 INTERPRETATION

In this Agreement, unless the context otherwise indicates—

- 1.1 The headings of the clauses of this Agreement are inserted for reference purposes only and shall not govern or affect the interpretation thereof;
- 1.2 Any annexures to this Agreement form an integral part hereof and words and expressions defined in this agreement shall bear, unless the context otherwise requires, the same meaning in such annexures;
- 1.3 Unless the context clearly indicated a contrary intention, words importing the singular shall include the plural and *vice versa*;
- 1.4 Reference to any one gender shall include the other gender and any reference to a natural person shall include a legal person and *vice versa*;
- 1.5 Where the day on or by which anything is to be done is not a business day, it shall be done on or by the first business day thereafter; and

Where any number of days is prescribed in this Agreement, these shall be reckoned as working days exclusively of the first, but inclusive of the last day, unless the last day falls on a weekend or on a public holiday, in which case the last day shall be the next succeeding day which is not a weekend or a public holiday.

2 DEFINITIONS

In this Agreement, unless clearly inconsistent with or otherwise indicated by the context:

- 2.1 **“Act”** means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1998), as amended.
- 2.2 **“Agreement”** means this Memorandum of Understanding set out in this document and the Annexure/s attached hereto;



2.3 **“Confidential Information”** means information disclosed by the Disclosing Party that (a) relates to the Disclosing Party’s past, present or future research, development, business activities, products, services and technical knowledge and (b) either has been identified in writing as confidential or is of such a nature (or has been disclosed in such a way) that it should be obvious to the Receiving Party that it is claimed as confidential. (As used herein, the Party disclosing Confidential Information is referred to as the “Disclosing Party” and the Party receiving the Confidential Information is referred to as the “Recipient”);

2.4 **“Effective date”** means the date of signature of the last Party to sign this Agreement;

2.5 **“Parties”** means SAHPRA, and MCAZ respectively and **“Party”** shall have a corresponding meaning;

3. COMMENCEMENT AND TERMINATION

3.1 This MOU will come into effect on the date signed by the last Party.

3.2 This MOU will remain in effect for five (5) years and will thereafter be renewed automatically for successive (5) year periods, unless one of the Parties informs its intention to terminate it in writing through diplomatic channels to the other Party. In this case, the MOU will be considered as terminated six (6) months after the said notification.

3.3 This MOU may be terminated by either Party, by giving 6 months written notice to the Other Party.

3.4 The termination of this MOU will not affect any ongoing programs and projects under this MOU, unless the Parties agree otherwise.

4. RELATIONSHIP BETWEEN THE PARTIES

4.1 Neither Party shall present itself as the representative or agent of the other Party for any business, legal or any other reason, nor shall it have the power of authority to commit the other Party, unless it receives the other Party’s prior written consent.



- 4.2 Nothing in this Agreement shall be interpreted as establishing a partnership or joint venture between the Parties and the Parties shall both act as independent contractors.
- 4.3 Each Party agrees that it shall not use the name and/or logo of the other Party in any advertising or publicity material, nor make any form of representation or statement in relation to the Project conducted under the terms of this Agreement which would constitute an expressed or implied endorsement by that Party of any commercial products or service, and that it shall not authorize others to do so without having obtained prior written authorisation from that Party.
- 4.4 This Agreement is entered into on the basis of co-operation, mutual respect, in the spirit of goodwill and does not in any way affect the independence of the Parties in terms of their respective enabling legislation.

OBJECTIVE

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 based on equality and mutual benefit.

5. AREAS OF COOPERATION

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

- 5.1 Medicines
- 5.2 Track and trace, authentication control application;
- 5.3 Detection of substandard and falsified medicines;
- 5.4 Nanotechnology;
- 5.5 Biotechnology for medicines;
- 5.6 Vaccine production;
- 5.7 Active Pharmaceutical Ingredients (API) Production;
- 5.8 Complementary medicines and health supplements; and
- 5.9 Any other areas agreed by "the Parties".

6. FORMS OF COOPERATION

The cooperation between the Parties will take the following forms:



- 6.1 Exchange and sharing information, best practices, and knowledge in the field of standards and regulations;
- 6.2 High official and technical visit related to familiarization of regulatory processes of both Parties;
- 6.3 Support capacity building through the exchange of personnel, sharing of knowledge and experience, and education and training programs;
- 6.4 Exchange of information on the status of Good Manufacturing Practice (GMP) inspection results as may be requested by one of “the Parties”;
- 6.5 Provide mutual understanding of each Party’s laws, regulation and procedures relating to the implementation of medicines and medical products safety measures.
- 6.6 Participation in international events organized by either Party;
- 6.7 Any other form of cooperation as mutually decided upon in writing by “the Parties”.

7. FINANCIAL RESOURCES

- 7.1 Each Party will bear its own expenses related to any activities conducted under this MOU.
- 7.2 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.

8. 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.

9. JOINT COMMITTEE AND ITS CONFORMATION

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” (SAHPRA and the MCAZ); The “Joint Committee” functions include:

- i. Monitor and facilitate the implementation of this MOU considering the compliance with the regulations, commitment and the pharmaceutical policies of “the Parties”;



10. CONFIDENTIALITY

- 10.1 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.
- 10.2 Each Party will make every reasonable effort to prevent:
- i. The public release of confidential information that has been shared for the purposes set out in this MOU; and
 - ii. the release of information for purposes not set out in this MOU.

11. BREACH AND TERMINATION

- 11.1 Should either Party ("**the Defaulting Party**") fail to fulfil any of the material obligations undertaken by it and fail to remedy the breach within a period of 30 (thirty) calendar days after receiving written notification from the other ("**the Aggrieved Party**"), demanding that the breach be rectified, the Non-Transgressing Party shall be entitled, without further notice, to cancel this Agreement, without prejudice to any claim which the Non-Transgressing Party might have for damages, breach of contract or otherwise.
- 11.2 Any termination of this Agreement shall not absolve the Parties from the obligation to observe the confidentiality measures and other restraints as set out herein.
- 11.3 The provisions relating to Intellectual Property shall survive any termination or expiry of this Agreement in perpetuity.
- 11.4 In the event of a breach by the SAHPRA of any of the terms and conditions of this Agreement, and in the event that the SAHPRA fails to remedy such breach within 30 (thirty) working days after receiving written notice from MCAZ to do so, MCAZ shall be entitled without prejudice to any other right it might have, to exercise all or any number of the following rights:
- 11.4.1 to terminate the agreement with the SAHPRA; and/or
 - 11.4.2 claim specific performance.



- 11.5 In the event of any breach by MCAZ of the terms and conditions of this Agreement, and in the event of MCAZ remaining in default after 30 (thirty) working days written notice calling for rectification of the breach, SAHPRA shall be entitled to:
- 11.6 Enforce strict compliance with the terms and conditions of the Agreement; or
- 11.7 To cancel the Agreement:
- 11.7.1 In the event of the Agreement being terminated for whatever reason, both parties will be entitled to payment for the programmes for which they had not yet been paid.
- 11.7.2 If, owing to circumstances beyond the control of the parties it becomes impossible for a party fulfil any of its obligations in terms of this Agreement, a party, upon receipt of a written request from the other party shall consider granting that party the necessary permission to defer such performance for such period as may be required under the circumstances.
- 11.7.3 The party, from whom the request is directed, reserves the right to terminate this Agreement or temporarily defer this programme, or any part thereof, should it decide not to proceed with the programme. That party may terminate the agreement by giving the other party a ten (10) days' notice of its intention to terminate.

12. DISPUTE RESOLUTION

- 12.1 Any dispute between the Parties in regard to:
- i. the interpretation of;
 - ii. the effect of;
 - iii. the termination of;
 - iv. the Parties' respective rights and obligations under;
 - v. a breach of; or
 - vi. any matter arising out of;
 - vii. this Agreement shall be decided in accordance with the dispute resolution mechanism set out in this clause 12 hereunder.



- 12.2 Any Party that is of the view that a dispute of the nature referred to in clause 12.1 has arisen shall give written notice thereof to the other Party concerned, provided that such notice shall clearly identify the dispute and provide full particularity thereof, and the Parties shall thereafter take immediate steps to attempt to resolve the dispute.
- 12.3 If the Parties cannot agree on a resolution of the dispute within twenty (20) Business Days of receipt of the notice referred to in clause 12.2, then the dispute shall be referred to the Chief Executive Officers of the Parties (collectively the **CEOs**) or their respective nominees for resolution.
- 12.4 If the CEOs cannot resolve the dispute within twenty (20) Business Days of the dispute having been referred to them, then the subject matter of the dispute may be referred within a further period of twenty (20) Business Days to arbitration in accordance with this clause 12.
- 12.5 Any dispute arising from or in connection with this Agreement must be finally resolved in accordance with the Rules of the Arbitration Foundation of Southern Africa (**AFSA**) by an arbitrator appointed jointly by the Parties or failing such joint appointment, appointed by AFSA.
- 12.6 The arbitration will be held in **Pretoria**.

13. ***DOMICILIUM CITANDI ET EXECUTANDI AND NOTICES***

- 13.1 Any Notice, instruction or request required or permitted to be given or made under this agreement shall be in writing. Such legal notice, instruction or request shall be deemed to be duly given or made when it shall have been delivered by hand, mail or facsimile at the *domicilium citandi et executandi* of the party concerned as specified below. Any facsimile notice must be followed up by the original document. Mailed notices will be regarded as having been delivered seven days after dispatch by registered mail. or other documents or communications of whatever nature, the following addresses are provided by the Parties for purposes of this Agreement:



For SAHPRA: **Attention: Dr Boitumelo Semete-Makokotlela**
South African Health Products Regulatory Authority
Loftus Park, Building A,
402 Kirkness Street,
Arcadia, Pretoria 0007
Tel: 012 501 0412
Email: CEOOffice@sahpra.org.za

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

14. GENERAL TERMS AND CONDITIONS

- 14.1 No failure or delay on the part of either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege preclude any other or further exercise thereof, or the exercise of any other right, power or privilege. The rights and remedies herein expressly provided are cumulative and not exclusive of any rights or remedies which the Parties would otherwise have.
- 14.2 No indulgence, leniency or extension of time which either Party ('the Grantor') may grant or show to the other Party shall in any way prejudice the Grantor or preclude the Grantor from exercising any of its rights in the future.
- 14.3 If any clause or term of this Agreement should be invalid, unenforceable or illegal, then the remaining terms and provisions of this Agreement shall be deemed to be severable there from and shall continue in full force and effect unless such invalidity, unenforceability or illegality goes to the root of this Agreement.
- 14.4 Each Party shall pay its own costs relating to the drafting, negotiation and execution of this Agreement.



15. INTERPRETATION OF AGREEMENT

The law of the Republic of South Africa shall govern the interpretation of the Agreement.

16. ENTIRE AGREEMENT

a. The parties confirm:

- i. That this document and its Annexures constitute the whole agreement between the parties;
- ii. That no other terms apart from those contained herein were stipulated; and
- iii. That no other suggestions, guarantees and motives apart from those contained herein have been made by either the parties themselves or on their behalf.

17. VARIATION

No amendment, alteration, addition or suspension of any provision of the Agreement shall be of any force, unless reduced to writing and signed by both Parties.

18. WAIVER

No waiver of any right in terms of the Agreement shall be binding for any purpose unless expressed in writing and signed by the Party concerned and such waiver shall be effective only in the specific instance and for the purpose given. No failure or delay on the part of either Party in exercising any right precludes any other or further exercise thereof or the exercise of any other right.

19. CESSION

A Party may not cede any right or obligation in terms of the Agreement to another person without the other Party's written consent.

20. SEVERABILITY

If any provision of the Agreement is or becomes invalid or unenforceable, such provision shall be severable and be regarded as *pro non scripto* and the remainder of the Agreement shall be regarded as valid and binding unless materially affected.

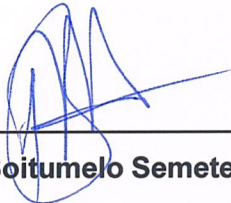


the Agreement shall be regarded as valid and binding unless materially affected.

21. TERMINATION

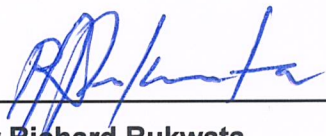
Any of the Parties may terminate this Agreement by giving 30 days written notice to the other party. The termination of this Agreement shall not affect any contribution which had already been made by the parties prior to the date of termination of this Agreement.

THUS DONE AND SIGNED by Dr B Semete Makokotela at
Cairo on the 6th day of December 2023



Dr Boitumelo Semete-Makokotela
The Chief Executive Officer of SAHPRA

THUS DONE AND SIGNED by Richard T. Rukwata at
CAIRO on the 6th day of DECEMBER 2023



Mr Richard Rukwata
The Director-General MCAZ