

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE GOVERNMENT OF THE REPUBLIC OF BOTSWANA

AND

THE GOVERNMENT OF THE REPUBLIC OF INDIA

ON PHARMACOPOEIAL COOPERATION

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PREAMBLE

The Government of the Republic of Botswana, represented by the Ministry of Health through the Botswana Medicines and Regulatory Authority, and the Government of the Republic of India, represented by the Ministry of Health and Family Welfare through the Indian Pharmacopoeia Commission, (hereinafter jointly referred to as the "Participants" and separately as a "Participant");

DESIRING to promote mutual understanding and strengthen the friendly ties between their two countries;

CONSIDERING the mutual benefit that the Participants can draw by cooperating on pharmacopoeial standards;

COMMITTED to developing cooperation in areas of pharmacopoeial standards;

RECOGNIZING the importance of developing close cooperation and exchange of information in the field of regulation of medicines in accordance with their respective laws and regulations;

HAVE REACHED THE FOLLOWING UNDERSTANDING:

PARAGRAPH 1 **DEFINITIONS**

In this Memorandum of Understanding, unless the context otherwise indicates:

- (a) "IP" means Indian Pharmacopoeia;
- (b) "IPC" means the Indian Pharmacopoeia Commission;
- (c) "IPRS" means Indian Pharmacopoeia Reference Standards; and
- (d) "MoU" means this Memorandum of Understanding together with any annexures hereto.

PARAGRAPH 2
OBJECTIVE

The objective of this MoU is to promote and develop cooperation and exchange of information in the field of regulation of medicines between the Participants in the field of pharmacopoeia, on the basis of equality and mutual benefit.

PARAGRAPH 3
AREAS OF COOPERATION

The Participants endeavour to:

- 3.1 recognize IP as a book of standards for medicines that were manufactured using the IP along with other officially recognized pharmacopoeias in Botswana;
- 3.2 recognize the Certificate of Analysis issued by Indian manufacturers per IP;
- 3.3 obtain IPRS and impurity standards from IPC at reasonably low cost to be used during the quality control analysis;
- 3.4 have an enhanced scope for development of generic medicines and contributing to availability of affordable medicines in Botswana;
- 3.5 promote an understanding of pharmacopoeia in regulatory framework, requirements and processes;
- 3.6 facilitate the exchange of information and documentation relating to the development of monographs of IP;
- 3.7 enhance the ability of regulatory authorities in the provision of their services relating to or in connection with public health, to meet the needs of their respective population; and
- 3.8 explore opportunities for technical cooperation in areas of mutual benefit in the development of monographs and future technologies.

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PARAGRAPH 4
COMPETENT AUTHORITIES

The Competent Authorities responsible for the implementation of this MoU will be:

- (a) for the Republic of Botswana, the Ministry of Health (Botswana Medicines and Regulatory Authority); and
- (b) for the Republic of India, the Ministry of Health and Family Welfare (Indian Pharmacopoeia Commission).

PARAGRAPH 5
FINANCIAL ARRANGEMENTS

- 5.1 Each Participant will bear its own expenses connected with activities under this MoU.
- 5.2 Unless the Participants agree otherwise, all costs for the attendance of the respective delegations of the Participants at consultations and meetings, including international travel, accommodation and subsistence, will be borne by the sending Participant.
- 5.3 The Participants will, with regard to specific joint activities undertaken in terms of this MoU, agree on their respective financial obligations in executing such activities.

PARAGRAPH 6
CONFIDENTIALITY

- 6.1 Neither Participant shall disclose, release nor transmit in any way documents, information and data in their possession received from the other Participant under this MoU to a third party without first obtaining written consent of the other Participant.
- 6.2 Press releases or media statements relating to this MoU or any collaboration activities thereunder shall be provided to the other Participant for comment and approval prior to release. An official title for the collaboration to be used by both Participants shall be agreed upon jointly.
- 6.3 The confidentiality undertaking in this Paragraph shall not apply:
 - (a) to information which is in the public domain; or

- (b) if a Participant is required to disclose such information to satisfy any order of a competent court; or
 - (c) if a Participant is required to disclose the information under any law or regulation applicable from time to time; or
 - (d) if the information is reasonably required for a Participant to enforce its rights under this MoU; or
 - (e) if a Participant is reasonably required to comply with its international obligations.
- 6.4 The obligations set out in this Paragraph shall survive the completion, expiration or termination of this MoU.

PARAGRAPH 7
INTELLECTUAL PROPERTY RIGHTS

- 7.1 The Participants undertake to acknowledge and respect each other's intellectual property rights.
- 7.2 Each Participant is the copyright owner of its respective pharmacopoeia and shall retain all intellectual property in the items published.
- 7.3 This MoU does not transfer any ownership of the intellectual property possessed by the respective Participants.
- 7.4 All intellectual property rights developed or created by a Participant pursuant to this MoU shall be owned by that Participant.
- 7.5 All intellectual property rights owned by a Participant prior to this MoU shall remain the sole property of that Participant.
- 7.6 Neither Participant will acquire any rights, title or interest of any kind in any intellectual property of the other Participant, unless agreed otherwise in writing by both Participants.
- 7.7 All intellectual property rights in respect of any research, products and/or services developed jointly by both Participants pursuant to this MoU, shall upon creation be jointly owned by the Participants. For the avoidance of doubt and without limitation, the intellectual property rights acquired under this Paragraph shall be mutually agreed to in writing by the Participants upon creation.

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- 7.8 Each Participant shall have unlimited ownership with respect to such intellectual property rights referred to under Paragraph 7.7 and without limiting the scope of any such rights, each Participant shall be entitled to use, reproduce, adapt, modify, publish, communicate, licence and transfer such intellectual property upon written consent of the other, which consent shall not be unreasonably withheld.
- 7.9 Where consent for the exercise of rights under this Paragraph has been given, any matters in relation to such exercise shall be agreed to by both Participants in a separate agreement.
- 7.10 For the avoidance of doubt, except where expressly stated to the contrary, the provisions of this Paragraph shall not affect the ownership of intellectual property rights in research, products and/or items that existed prior to the date of the coming into effect of this MoU.
- 7.11 The provisions of this Paragraph shall survive the completion, expiration or termination of this MoU.

PARAGRAPH 8

COMPLIANCE WITH NATIONAL AND INTERNATIONAL LAW

- 8.1 The Participants will ensure that the persons delegated under this MoU will comply with the national laws and regulations of the country where they perform their duties or any other activities under this MoU.
- 8.2 Nothing in this MoU will affect the Participants' obligations under the national laws of either Participant or obligations under the existing international treaties or obligations arising from regional or international organisations of which they are members.

PARAGRAPH 9

COMING INTO EFFECT, DURATION AND RENEWAL

- 9.1 This MoU will come into effect on the date of signature thereof by the authorised representatives of the Participants.
- 9.2 This MoU will remain in effect for a period of five (5) years and thereafter be automatically renewed for further periods of five (5)

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years at a time unless earlier terminated by either Participant by giving three (3) months' written notice in advance through diplomatic channels, of its intention to terminate it.

PARAGRAPH 10
RESOLUTION OF DISPUTES

- 10.1 Any dispute between the Participants arising out of the interpretation or implementation of this MoU shall be settled amicably through negotiations or consultations between the Participants through established diplomatic channels and shall not be referred to any national or international tribunal or third party for settlement.
- 10.2 In the event disputes relating to the interpretation or implementation of Paragraphs 6 (Confidentiality); 7 (Intellectual Property Rights); 10 (Resolution of Disputes) and 11(Termination), have not been settled through negotiations or consultations between the Participants, such disputes shall be settled through any mechanism that the Participants may agree upon in writing.
- 10.3 It is specifically agreed that all dispute resolution proceedings shall be held in the English language.
- 10.4 The Participants agree that any dispute resolution proceedings hereunder shall be conducted on a confidential basis, and shall be subject to the provisions set out in Paragraph 6 of this MoU.

PARAGRAPH 11
TERMINATION

- 11.1 This MoU shall remain in effect until terminated by mutual consent or by one of the Participants giving the other prior written notice of not less than three (3) months, of its intention to terminate this MoU.
- 11.2 Unless otherwise agreed to by the Participants, each Participant shall on the termination of this MoU forthwith hand over any documentation or other material belonging to the other Participant, which may have been used during the period of this MoU. This shall not affect those that are related to the outstanding activities or arrangements which shall be returned upon completion thereof.
- 11.3 The termination of this MoU by one of the Participants shall not affect any projects or agreements between the Participants,

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established in terms of this MoU that will still be in operation at the time of such termination. Such projects or agreements will continue until they have been completed within a period agreed to by the Participants.

PARAGRAPH 12
LEGAL EFFECT

- 12.1 This MoU is not legally binding and does not constitute a binding commitment of either Participant.
- 12.2 Notwithstanding the provisions of Paragraph 12 (1), the provisions of Paragraphs 6 (Confidentiality); 7 (Intellectual Property Rights); 10 (Resolution of Disputes); and 11 (Termination), shall be binding, and shall constitute enforceable obligations of the Participants.
- 12.3 The foregoing represents the understanding reached between the Participants on matters referred to in this MoU.

IN WITNESS WHEREOF, the undersigned, being duly authorized thereto by their respective Governments, have signed this MoU in two original copies in the English language, both texts being equally authentic.

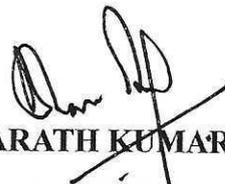
DONE at Gaborone on this 12th day of the month of November in the year 2025.

**FOR AND ON BEHALF OF
THE GOVERNMENT OF THE
REPUBLIC OF BOTSWANA**

**FOR AND ON BEHALF OF THE
GOVERNMENT OF THE REPUBLIC
OF INDIA**



DR. STEPHEN MODISE
MINISTER OF HEALTH



BHARATH KUMAR KUTHATI
**HIGH COMMISSIONER OF INDIA
TO BOTSWANA**