

Memorandum of Understanding
Between
The Brazilian Health Regulatory Agency of the Federative Republic of Brazil
And
The Department of Health of the Government of the Hong Kong Special
Administrative Region of the People's Republic of China

The Brazilian Health Regulatory Agency (hereinafter referred to as "ANVISA") of the Federative Republic of Brazil and the Department of Health ("DH") of the Government of the Hong Kong Special Administrative Region of the People's Republic of China, hereinafter individually referred to as the "Participant" and jointly referred to as the "Participants",

CONSIDERING the role of international cooperation on the work of health regulatory authorities;

INTENDING to establish a framework for bilateral cooperation and the exchange of information in the areas of common interest within the respective fields of competence of the Participants including pharmaceutical ingredients, drugs, biological products, traditional medicinal products, medical devices, private healthcare facilities and tobacco control;

DESIRING to strengthen their communication to facilitate and promote access to safe, effective and quality regulated products and health services within their jurisdictions;

Have reached the following understanding:

Paragraph I : Scope

1. This Memorandum of Understanding ("MoU") applies to information exchange to the extent jointly decided by the Participants and it covers the whole regulatory activities of both Participants, acknowledging that the Participants may have respective jurisdictions over specific products, for which they may have different definitions. Communication between the Participants will be intended to facilitate the exchange of information about the regulation of products and services, including: policies, guidelines, standards, laboratory testing, pre-market assessment, post-market vigilance, compliance, good manufacturing practices and assessment of clinical trials.
2. Both Participants will encourage cooperation for the purpose stated in Paragraph I.1 above on the basis of mutual benefit, and to the extent appropriate and/or permitted by their respective laws and regulations. The cooperation includes, but is not limited to, the following activities:

- a) participation of experts in meetings, scientific conferences, workshops and seminars, as decided by the Participants;
- b) collaboration in training courses, seminars and workshops; and
- c) joint projects.

Paragraph II : General Provisions

1. This MoU does not constitute a treaty or an international agreement, nor does it create any obligations under international law between the Participants.
2. This MoU is not intended to create any legally binding obligations, including to share confidential information between the Participants, and does not restrict the Participants' powers granted by the laws and regulations in their respective jurisdictions to fulfill their respective responsibilities.
3. Any cooperation initiative arising from this MoU will be jointly decided by the Participants and formalized through a mutually decided work plan. Such initiatives will be carried out in accordance with the applicable laws and regulations of the respective jurisdictions and will be subject to the availability of the necessary funds and personnel of the Participants.
4. The following items are excluded from the scope of this MoU and will not be exchanged in any case:
 - a) Personal data, such as medical files;
 - b) Any information subject to an obligation of confidentiality, the disclosure of which constitutes a Participant's breach of contractual obligations or undertakings to a third party.
5. Save for what is provided for in Paragraph III, this MoU does not grant any other rights to the receiving Participant towards the information shared under its scope, whether such information is confidential or not.
6. Nothing in this MoU will be construed as creating a joint venture, partnership, agency, or fiduciary relationship between the Participants.
7. The Participants will inform each other, without delay, of any changes in the laws, regulations, policies or procedures of their respective jurisdictions which may affect their capacity to implement the provisions of this MoU.

Paragraph III : Information exchange

1. The Participants will exchange the relevant information and documents necessary for the implementation of this MoU, without prejudice to their own laws, regulations, and procedures,

and any restrictions or provisions that either Participant may require to ensure the confidentiality of information and documents, in compliance with personal data protection regulation.

2. The Participants will handle the information exchanged under this MoU with due protection, refraining from making unauthorized or improper use of such information, in accordance with the applicable legal provisions, laws, regulations, and procedures of their respective jurisdictions.
3. The commitment to protect the information exchanged under this MoU will not prevent the Participants from using that information to carry out the tasks entrusted to them provided that such information is protected.
4. The Participants may use information exchanged under this MoU as a basis for their regulatory decisions.
5. The Participants decide to convene bilateral meetings to address technical and operational issues regarding the information exchange under this MoU, whenever considered necessary by one of the Participants and through mutual consent. Such meetings can be face to face, alongside an international forum, or through video/teleconference.

Paragraph IV : Confidentiality

1. For the purpose of this MoU, "Confidential Information" means information submitted and listed as confidential by the disclosing Participant, as well as any information that is protected from disclosure under the applicable laws and regulations of the disclosing Participant.
2. For the purpose of subparagraph 1, each Participant will treat documents, information, and any other data exchanged, received, or supplied for the implementation of this MoU as information submitted and listed as confidential by the disclosing Participant, unless otherwise jointly decided in writing by the Participants.
3. The receiving Participant of Confidential Information will not disclose such Confidential Information to any third party without the prior written consent of the disclosing Participant.
4. Each Participant will inform the other Participant of any legislative measure or judicial decision that may give third parties access to Confidential Information exchanged between them. If any such measure or decision requires the disclosure of Confidential Information provided by the disclosing Participant, the receiving Participant will, to the extent permitted by law and practicable, notify the disclosing Participant in advance of such disclosure. This notification will be made in a timely manner so as to enable the disclosing Participant to contest the disclosure or to decide on the timing and content of the information to be disclosed.

5. The Participants understand that, in the case of the expiration or termination of this MoU, Confidential Information already shared under this MoU will continue to be protected from unauthorized disclosure and will only be used in accordance with the provisions of this MoU.

Paragraph V : Limits on confidentiality and restricted use

1. Paragraphs III and IV do not apply to information for which the receiving Participant can clearly indicate and provide concrete evidence to the disclosing Participant that:
 - a) the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the disclosing Participant (as verified by written reports or other acceptable evidence); or
 - b) the information was already in the public domain or publicly known at the time of the disclosure by the disclosing Participant; or
 - c) the information came into the public domain or was brought to public attention in the absence of any fault of the receiving Participant; or
 - d) the information was made available to the receiving Participant by a third party without breach of any legal confidentiality commitment; or
 - e) the information is the result of activities carried out independently by or on behalf of the receiving Participant without having access to the information of the disclosing Participant.
2. Confidential Information may be disclosed to employees and advisors of the receiving Participant who are engaged in performing this MoU and who are bound to protect the confidentiality of such information.

Paragraph VI : Contact Points

The liaison officers responsible for the administration of this MoU are:

- a) For ANVISA, the Head of International Affairs Office (rel@anvisa.gov.br).
- b) For DH, Head, Strategic Initiatives and Regulatory Compliance Office (icmc_cmpr@dh.gov.hk).

Paragraph VII : Financial arrangements

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MoU.

Paragraph VIII : Dispute Resolution

Any disputes arising from the interpretation and/or implementation of this MoU will be collaboratively resolved between the Participants.

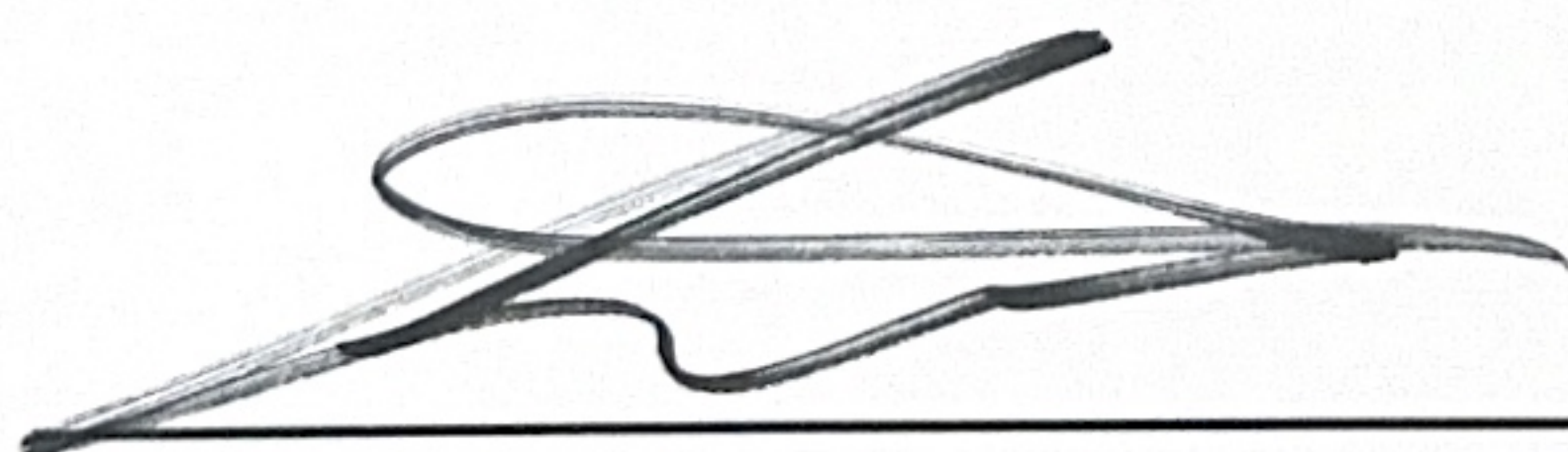
Paragraph IX : Entry into effect, duration, renewal and amendment

1. This MoU will become effective on the date of signature by both Participants.
2. This MoU is valid for five (5) years after signature and will be automatically renewed for five (5) more years, unless either Participant notifies the liaison officer of the other Participant assigned in Paragraph VI of its decision not to renew the MoU.
3. Any amendment to this MoU will be made under mutual written consent of the Participants and the amendments will come into effect on such date as may be jointly decided by the Participants.
4. This MoU may be terminated at any time by either Participant upon thirty (30) days of prior written notice to the liaison officer of the other Participant assigned in Paragraph VI.

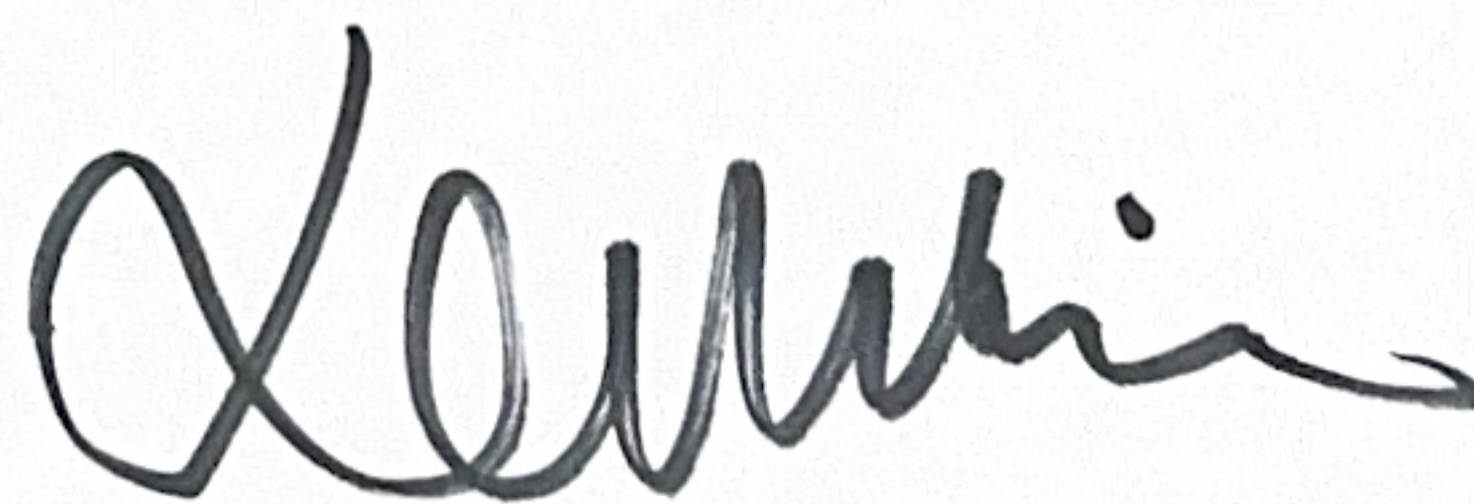
Signed on **September 23, 2026**, with two original copies in the Portuguese and English languages, both texts being equally authentic. In the event of divergence in the interpretation of this MoU, the English text will prevail.

For the Brazilian Health Regulatory Agency of the
Federative Republic of Brazil

For the Department of Health of the Government
of the Hong Kong Special Administrative Region of
the People's Republic of China



Leandro Pinheiro Safatle
Director-President



Dr. Lam Man Kin, Ronald
Director of Health