Agência Nacional de Vigilância Sanitária

SAHPRA South African Health Products Regulatory Authority

Memorandum of Understanding between the Brazilian Health Regulatory Agency (ANVISA) and the South African Health Products Regulatory Authority (SAHPRA) concerning the sharing of confidential information

The Brazilian Health Regulatory Agency (hereinafter referred as ANVISA) and the South African Health Products Regulatory Authority (hereinafter referred as SAHPRA), hereinafter referred to as the "Participants",

Wishing to enable further increase cooperation as a means to protect and promote health and facilitate access to safe and high-quality health products,

NOW THEREFORE THE PARTICIPANTS HEREBY AGREE AS FOLLOWS:

1. Purpose:

The purpose of this Memorandum of Understanding (MoU) is to establish a framework within which the Participants may share non-publicly available information, such as specific scientific and technical information, related to the safety, efficacy, quality, supply, and availability of health products for human use. The Participants understand that health products include, but are not limited to, drugs, radiopharmaceuticals, biologics, natural health products and medical devices.

2. Scope:

I. The scope of information that might be shared under this Memorandum of Understanding("the MoU") includes, but is not limited to:

(a) related to the regulation and investigation of health products for safety, efficacy and quality, such as licensing, authorization of clinical trials or investigational testing, product labelling, and the development of policies and guidance;

(b) related to pharmacovigilance and compliance monitoring such as, but not limited to the collection, monitoring and analysis of adverse reactions, complaints or incident data as well as benefit-risk assessments, advertising regulatory requirements, research and policy development to regulate marketed health products;

(c) of compliance and enforcement activities such as inspections, compliance verification, recalls, investigations and enforcement measures, policy development and risk assessment;

(d) related to identification, tracking, and mitigation of actual and potential shortages of health products.

(e) access to assessment reports and any other reports pertaining to review of health products.

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(f) education and training, and capacity building in regulatory sciences.

(g) the exchange of information and sharing of documentation to enhance regulatory processes and decision-making practices.

(h) access to confidential information pertaining to medicines, medical devices and IVDs.

(i) sharing regulatory best practices

II. The following items are excluded from the scope of this MoU and will not be exchanged in any case:

(a) Personal information or related to the privacy of an individual, such as medical files;

(b) Confidential information shared by a third party within the framework of any confidentiality agreement.

III. This MoU does not grant any rights to the receiving Participant towards the information shared under its scope.

3. <u>Use of Information:</u>

I. The Participant will use the non-publicly available information shared under this MoU exclusively for the performance of their respective duties with regard to health products, as well as for the protection and promotion of public health (the "Permitted Use").

II. The Participants may share, on a need-to-know basis and solely for the Permitted Use, non-publicly available information with persons employed or contracted within respective organizations who are bound by obligations of confidentiality and are required to respect restrictions on use, which are no less restrictive than those set forth in this MoU.

III. The Participants understand and agree that this MoU does not affect their respective possibility to limit the scope of the confidential information to be shared under this MoU if its dissemination or exchange undermine specific interests or violate legal obligations of the disclosing Participant, including those imposed by their respective applicable laws and regulations, and internal policies, including in respect of commercial, industrial or professional secrecy, the public interests or the protection of the disclosing Participants' interests in the confidentiality of its proceedings.

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4. **Confidentiality of the information shared:**

I. For the purpose of this MoU, "Confidential Information" means information disclosed by a Participant (disclosing Participant):

(a) that is not publicly available,

(b) in respect of which a Participant or third party has taken reasonable measures to ensure that it remains not publicly available, is communicated to others in confidence, and is treated consistently in a confidential manner by the Participant providing the information,

(c) that is protected by Brazilian or South African laws and regulations.

II. The Participants confirm that they have the authority to protect the confidential information received under this MoU.

III. The Participants will protect the non-publicly available information shared under this MoU in accordance with their respective applicable laws and regulations, and/or internal policies, and as set forth in this MoU.

IV. The Participants will take all necessary measures to:

(a) ensure that confidential information exchanged under this MoU will not be disclosed, circulated, or commented upon in any way by their personnel, exercising professional discretion and of duty of confidentiality.

(b) prevent the disclosure or use of confidential information by external organizations and their staff who have been appointed by the receiving Participant to have access to confidential information transmitted within the framework of this MoU.

5. **Disclosure:**

I. Should a Participant receives a request for disclosure to third parties of non-public information received from the other Participant, the Participants shall consult each other and agree on the disclosure of such non-public information.

II. In the event, the Participants agree that such non-public information can be disclosed to a third party, the Participant receiving such a request from the third party shall ensure that the third party also signs a non-disclosure undertaking and also keeps confidential, any non-publicly available information shared in accordance with their respective applicable laws and regulations, and/or internal policies.

III. The Participants will promptly inform each other of any changes to their respective laws and regulations and internal policies that might influence the ability to fulfill their confidentiality commitment as set forth in this MoU

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6. Limits on Confidentiality:

The principles of confidentiality mentioned above 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.

7. Differences in interpretation and implementation:

Any differences, controversies or disputes arising from the interpretation and/or implementation of this MoU shall be resolved amicably through consultations between the Participants, for which the English text of this MoU shall be treated as the authentic text.

8. Status:

This MoU is not intended to create any legally binding obligations to share confidential information between the Participants and it does not restrict the Participants' powers granted by the laws and regulations in their respective countries to fulfill their respective responsibilities.

9. Financial Agreement:

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

10. Final Dispositions:

I. This MoU will come into effect on the date of its signature by the Participants.

II. The Participants may amend this MoU at any time upon their mutual written consent.

III. This MoU is valid for five (5) years and may be renewed for five (5) more years, unless either Participant formally notify the other Participant of its decision not to renew by giving a thirty (30) day written notice to the other Participant.

IV. Either Participant may terminate this MoU by giving a thirty (30) day written notice to the other Participant. The Participants understand that, notwithstanding such termination, the dispositions on confidentiality and the restrictions on use contained in this MoU shall survive the termination.

Signed in duplicate in Brasília, on November 08, 2022, in two original copies in English and Portuguese, both being equally valid.

Dr Antonio Barra Torres
Director President
For the Brazilian Health Regulatory Agency - ANVISA

Dr Boitumelo Semete- Makokotlela
Chief Executive Officer
South African Health Products Regulatory Authority - SAHPRA