CONFIDENTIALITY ARRANGEMENT BETWEEN
THE DEPARTMENT OF HEALTH OF CANADA AND
THE BRAZILIAN HEALTH REGULATORY AGENCY OF BRAZIL
CONCERNING THE SHARING OF NON-PUBLIC INFORMATION

The Department of Health of Canada (Health Canada) and the Brazilian Health Regulatory Agency of Brazil (ANVISA), hereinafter referred to as the "Participants",

WISHING to increase cooperation as a means to protect and promote health and facilitate access to safe and high-quality health products and food;

HAVE COME to the following understanding:

1. **Definitions**

(a) For the purpose of this Confidentiality Arrangement ("Arrangement"):

(i) **"Health products"** means health products for human use including, but not limited to, drugs, radiopharmaceuticals, biologics, active pharmaceutical ingredients (APIs), and medical devices, but excluding human blood, cells, plasma, tissues, and organs.

(ii) **"Non-public information"** means confidential information of one Participant or of a third party cooperating with that Participant.

2. **Purpose**

The purpose of this Arrangement is to establish a framework within which the Participants may share non-public information, including specific scientific and technical information and data, related to the safety, efficacy, quality, supply and availability of health products for human use and the safety and quality of food.

3. **Scope**

(a) The Participants understand that the scope of information that they might share under this Arrangement includes, but is not limited to, activities related to:

(i) the review, regulation, and investigation of health products for safety, efficacy and quality, such as: licensing; clinical trials or investigational testing; labelling; laboratory activities; the development of policies and guidance; and health products that are unauthorized or under review;

(ii) scientific and technical expertise, including that related to product regulation, research and studies, laboratory activities, and investigations of health products for safety, efficacy and quality, such as: licensing; clinical trials or investigational testing; product labelling; laboratory activities; and the development of policies and guidance;

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

(iv) compliance and enforcement such as: inspections; compliance verification; recalls; investigations and enforcement measures; policy development; and risk assessment;

(v) food safety and quality, such as, but not limited to: evidence-based food standards, regulations and guidelines; safety assessments of food ingredients, food additives, food processes, final food products and food packaging materials; food labelling; and risk analysis (assessment, management and communication) to prevent, detect and respond to food safety incidents;

(vi) identification, tracking, and mitigation of actual and potential shortages of health products; and

(vii) any other non-public information the Participants may jointly decide upon.

4. Confidentiality and Use of Information

(a) The Participants will use the non-public information shared under this Arrangement exclusively for the performance of their respective duties with regard to health products and food, as well as for the protection and promotion of public health ("Intended Use").

(b) The Participants may share, on a need-to-know basis and solely for the Intended Use, non-public information with persons within their respective organisations 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 Arrangement.

(c) The Participants understand that this Arrangement does not affect their respective possibility to limit the scope of the non-public information to be shared under this Arrangement, if its dissemination or exchange undermine specific interests or violate legal obligations.

5. Protection of Non-Public Information

The Participants understand that they each have the authority to treat non-public information provided to their officials or representatives in confidence, under their applicable laws and regulations, and will protect such information from public disclosure.

6. Disclosure

(a) On each occasion when there is a request for disclosure to third parties of non-public information received from one of the Participants, the Participants will consult with each other.

(b) The receiving Participant will not publicly disclose non-public information from the disclosing Participant to a third party without the prior written consent of the disclosing Participant.

(c) The Participants will promptly inform each other of:

(i) any change to their laws, regulations and/or internal policies, that may influence their ability to fulfill their confidentiality commitment as set forth in this Arrangement;

(ii) any organizational changes (including name changes) that may influence their ability to fulfill their confidentiality commitment as set forth in this Arrangement; and

(iii) any effort made by judicial or legislative mandate to obtain non-public information received by the other Participant.

7. Differences in Interpretation and Application

The Participants will attempt to resolve any difference in the interpretation or application of this Arrangement amicably through discussions.

8. Status

This Arrangement is not legally binding.

9. Final Dispositions

(a) This Arrangement will come into effect on the date of its last signature by the Participants.

(b) The Participants may amend this Arrangement at any time upon their mutual written consent.

(c) Either Participant may terminate this Arrangement by giving a thirty (30) day written notice to the other Participant.

(d) The Participants understand that, in the case of termination of this Arrangement, the dispositions on confidentiality and the use of the non-public information contained in this Arrangement will continue to be applied for the information that was shared under this Arrangement.

Signed in duplicate at Ottawa, this 22nd day of April, 2024, and at Brasília, this 29 day of April, 2024, in the English, French and Portuguese languages, each version being equally valid.

For the Department of Health of Canada

Linsey Hollett Apr 22/24
Date

Linsey Hollett
Assistant Deputy Minister
Regulatory Operations and Enforcement Branch
Health Canada

For the Brazilian Health Regulatory Agency of Brazil

Apr. 29th 2024
Date

Antonio Barra Torres
Director President
Brazilian Health Regulatory Agency (Anvisa)
Brazil