

**Confidentiality Arrangement
between the Department of Health of Canada
and
the Swiss Federal Department of Home Affairs**

The Department of Health of Canada (Health Canada) and the Swiss Federal Department of Home Affairs acting through Swissmedic (Swiss Agency for Therapeutic Products), hereinafter referred to as the "Participants",

The Participants understand that the Health Products and Food Branch, the Regulatory Operations and Enforcement Branch, and the Controlled Substances and Cannabis Branch of Health Canada will implement this Arrangement on Health Canada's behalf,

Wishing to enable further increased cooperation as a means to better protect health and facilitate access to safe and high quality health/therapeutic products,

Have come to the following understanding:

1. Purpose:

- (a) This Confidentiality Arrangement (CA) is intended to establish a framework within which the Participants may share specific scientific and technical information and documents ("information") related to ensuring the safety, efficacy and quality of health/therapeutic products for human and veterinary use, authorised, under review or unauthorised in Canada and/or in Switzerland, exclusively for use in the performance of their respective duties with regard to health/therapeutic products, as well as for the protection of public health.
- (b) The Participants will keep confidential any information of a non-public confidential and/or proprietary nature ("non-public information") in accordance with their respective applicable laws and regulations, and as set forth in this CA.
- (c) The Participants understand that "health/therapeutic products" may include, but are not limited to: drugs, radiopharmaceuticals, biologics, natural health products and medical devices.

2. Status:

This CA does not create any legally binding obligation between the Participants.

3. Scope:

The scope of information that may be shared under this CA includes, but is not limited to:

- (a) activities related to the regulation of health/therapeutic 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) activities 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, and policy development to regulate marketed health/therapeutic products; and,
- (c) compliance and enforcement activities such as inspections, compliance verification, recalls, investigations and enforcement measures, policy development and risk assessment.

4. Use of information:

- (a) For the purposes of this CA, the Participants may share, on a need to know basis, non-public information with persons within their respective organisations who are bound by obligations of confidentiality and professional secrecy, as defined in their respective applicable laws and regulations in accordance with the restrictions on use as contained in this CA.

- (b) For Health Canada, "persons within their organisation" includes Health Canada employees, agents, contractors, experts or expert committees who:
- (i) require the information solely for work purposes in respect of this CA;
 - (ii) will only use that information for purposes contemplated by this CA; and
 - (iii) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits those persons to use the information for the purposes of this CA and requires them to protect the confidentiality of the information in accordance with its respective applicable laws and regulations.
- (c) For Swissmedic, "persons within their organisation" includes Swissmedic employees, agents, contractors, experts or expert committees who:
- (i) require the information solely for work purposes in respect of this CA;
 - (ii) will only use that information for purposes contemplated by this CA; and
 - (iii) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency arrangement, confidentiality contract or other document that permits those persons to use the information for the purposes of this CA and requires them to protect the confidentiality of the information in accordance with its respective applicable law.
- (d) The Participants understand that this CA does not affect the possibility for each Participant to limit the scope of the information to be exchanged if its dissemination or exchange undermine specific interests or violate legal obligations, including those imposed by their respective applicable laws and regulations, including in respect of commercial, industrial or professional secrecy, the public interests or the protection of a Participant's interests in the confidentiality of its proceedings. In some cases, exchange of information under this CA may be subject to prior authorisation from third parties concerned, including the person and/or organisation from which the information emanated.

5. Non-public information:

In accordance with the status of the CA (Section 2),

- (a) Swissmedic confirms that they have the authority to protect non-public information, including commercially confidential information provided by Health Canada, and will protect such information as information not to be publicly disclosed in compliance with applicable laws and policies. Swissmedic understands that Health Canada considers it crucial that this non-public information be protected from disclosure to any person not identified in this Arrangement; otherwise, it could endanger the privacy and integrity of individuals, the commercial interests of the entities concerned and/or international relations between the Participants.
- (b) Health Canada confirms that it has the authority to protect non-public information, including confidential information, provided by Swissmedic, and will protect such information as information not to be publicly disclosed in compliance with applicable laws and policies. Health Canada understands that Swissmedic considers it crucial that this non-public information be protected from disclosure to any person not identified in this Arrangement; otherwise, it could endanger the privacy and integrity of individuals, the commercial interests of the entities concerned and/or the international relations between the Participants.

6. Disclosure:

On each occasion where there is a request for disclosure to third parties of information received from a Participant, the Participants may consult each other.

7. Final dispositions:

- (a) This CA will come into effect on the date of the last signature of its English version by the Participants.
- (b) The Participants may amend this CA at any time upon their mutual written consent.

(c) Either Participant may terminate this CA, by giving the other Participant a thirty (30) days written notice of its intent to terminate.

Signed in duplicate at Ottawa, Canada on May 26th, 21, and at Bern, Switzerland, on 16th April 21, in the English and French languages, each being equally valid.

For the Department of Health of Canada

Pierre Sabourin
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

Date

For the Swiss Federal Department of Home Affairs

Dr. Raimund T. Bruhin
Executive Director
Swissmedic

Date