



**CONFIDENTIALITY ARRANGEMENT BETWEEN
THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA
AND THE DEPARTMENT OF HEALTH OF CANADA**

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS) and the Department of Health of Canada (Health Canada), hereinafter referred to as the “Participants”,

WISHING to enable further increased 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:

For the purpose of this Confidentiality Arrangement (the “Arrangement”):

- (i) **“non-public information”** means confidential information of one Participant or of a third party cooperating with that Participant;
- (ii) **“health products”** covers, health products for human use including, but not limited to, drugs, radiopharmaceuticals, biologics, active pharmaceutical ingredients (APIs), and medical devices; and
- (iii) **“food”** includes, but is not limited to, any article manufactured, sold or represented for use as food or drink for human consumption, chewing gum, and any ingredient that may be mixed with food for any purpose.

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, related to the safety, efficacy, quality, supply and availability of health products, the safety and nutritional quality of food, and public health nutrition.

3. Scope:

The Participants understand that the scope of information related to health products and food that they might share under this Arrangement includes, but is not limited to:

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

- (ii) scientific and technical expertise related to regulation, research and studies, laboratory activities and investigations of health products for safety, efficacy and quality;
- (iii) pharmacovigilance and compliance monitoring such as 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;
- (iv) compliance and enforcement for health products such as inspections, compliance verification, recalls, investigations and enforcement measures, policy development and risk assessment;
- (v) the safety and nutritional quality of food such as evidence-based food standards, policies, regulations and guidelines, safety assessments of select food ingredients, food processes, final food products, food labelling, food packaging materials, and health risk assessments pertaining to the safety of foods to support the management of food safety incidents;
- (vi) public health nutrition such as dietary guidance;
- (vii) identification, tracking, and mitigation of actual and potential shortages of health products; and
- (viii) 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 (the “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. “Persons within their organisation” include employees, agents, contractors, experts or expert committees who:
 - (i) require the information solely for work purposes in respect of this Arrangement;
 - (ii) will only use that information for purposes contemplated by this Arrangement; and
 - (iii) 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 Arrangement and requires them to protect the confidentiality of the information in accordance with the applicable law of each Participant.
- (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 undermines specific interests or violates legal obligations.

5. Protection of Non-Public Information:

The Participants understand that they have the authority to protect non-public information provided to persons within their respective organizations 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 any change to their laws and regulations, if any, and/or internal policies, that may influence their ability to fulfill their confidentiality commitment as set forth in this Arrangement.
- (d) The Participants will promptly inform each other of any organizational changes (including name changes) that may influence their ability to fulfill their confidentiality commitment as set forth in this Arrangement.
- (e) The Participants will promptly inform each other of any effort made by judicial or legislative mandate to obtain non-public information received from the other Participant. If such judicial or legislative mandate orders disclosure of provided non-public information, the receiving Participant will take all appropriate measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

7. Differences in Interpretation and Application

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

8. Status

- (a) This Arrangement is not legally binding.
- (b) This Arrangement will be carried out in accordance with the respective laws and regulations of the two countries and subject to the availability of appropriated funds and human resources of the Participants.

9. Financing

Each Participant will bear its own costs arising from this Arrangement, unless otherwise jointly decided by the Participants.

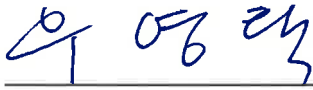
10. Final Dispositions

- (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.

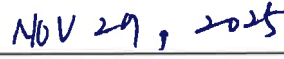
- (c) Either Participant may terminate this Arrangement, by giving thirty (30) days written notice to the other Participant.
- (d) The Participants understand that, in the case of termination of this Arrangement, they will continue to protect non-public information already shared under this Arrangement from unconsented disclosure and use it in accordance with this Arrangement.

Signed in duplicate at Canada, on 20th day of November, 2025, and at Republic of Korea, on 27th day of November, 2025, in the English, French and Korean languages, each version being equally valid.

For the Ministry of Food and Drug Safety of the Republic of Korea:

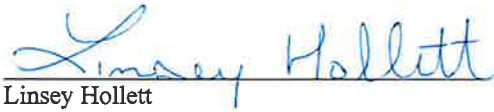


WOO, Young Taek
Director General for Planning & Coordination
Ministry of Food and Drug Safety



Date

For the Department of Health of Canada:



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



Date