Health Canada Santé Canada

DRAFT GUIDANCE DOCUMENT

Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the *Food and Drugs Act*

This guidance document is being distributed for comment purposes only.

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : *l'Ébauche de la ligne directrice : Communication de renseignements commerciaux confidentiels aux termes de l'alinéa 21.1(3)c) de la Loi sur les aliments et drogues*

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1 INTRODUCTION

Confidential business information (CBI) may be included in a variety of regulatory documents that Health Canada requires companies to provide regarding the safety, efficacy and quality of therapeutic products. In certain situations, where publicly available information is not sufficient, access to information that may contain CBI can assist the work of health researchers and practitioners, contributing to improved patient safety and better health outcomes for Canadians.

This draft guidance document describes how Health Canada applies the authority to disclose CBI under paragraph 21.1(3)(c) of the *Food and Drugs Act*. This provision gives the Minister of Health discretionary authority to disclose CBI to eligible persons for the purpose of protecting or promoting human health or the safety of the public.

This draft guidance document does not apply to other authorities in the *Food and Drugs Act*, which permit Health Canada to disclose CBI when the Minister believes that a product may present a serious risk of injury to human health, to other governments, and persons from whom the Minister seeks advice. Information on these authorities can be found in, Amendments to the *Food and Drugs Act* 2014 -- Guide to New Authorities (http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php).

About this draft guidance document

Guidance documents are meant to assist individuals and organizations to comply with Health Canada's policies and its governing statutes and regulations. They also serve to assist Health Canada staff to implement its mandates in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles, considerations and requirements described in this document may be acceptable provided they comply with relevant laws. Discussion with the relevant program area in advance is encouraged to determine whether an alternative approach meets applicable statutory or regulatory requirements.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance document, in order to allow the Health Canada to adequately assess whether or not to disclose CBI related to a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

2 PARAGRAPH 21.1(3)(C) OF THE *FOOD AND DRUGS ACT*

21.1(3) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to

(a) a government;
(b) a person from whom the Minister seeks advice; or
(c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Under paragraph 21.1(3)(c), the Minister of Health has discretionary authority to disclose CBI to an individual or corporation who carries out functions relating to the protection or promotion of human health or the safety of the public for the purpose of protecting or promoting human health or the safety of the public. This discretionary authority was added to the *Food and Drugs Act* by the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) and came into force in November 2014.

The disclosure authority in paragraph 21.1(3)(c) complements other changes introduced to strengthen Health Canada's capacity to respond quickly to health risks and to promote greater confidence in the oversight of therapeutic products by increasing transparency. These changes are summarized in a separate guidance document, Amendments to the *Food and Drugs Act*: Guide to New Authorities (http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php).

Vanessa's Law also added a definition of CBI to the *Food and Drugs Act*. This definition codifies common law principles and is consistent with other domestic law. It sets out three conditions that must be met in order for information to be considered CBI.

> "'confidential business information", in respect of a person to whose business or affairs the information relates, means - subject to the regulations - business information:
> (a) that is not publicly available,
> (b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and
> (c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

The *Food and Drugs Act* defines "therapeutic product" to mean "a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*.

The authority to disclose CBI under paragraph 21.1(3)(c) therefore applies to CBI related to therapeutic products, including prescription and non-prescription drugs, vaccines, blood and blood products, radiopharmaceuticals, donor semen for assisted conception, gene and cell therapies, tissues and organs, and medical devices. It does not apply to CBI related to natural health products.

Vanessa's Law also provides regulation making powers to specify what information obtained under the *Food and Drugs Act* in relation to a therapeutic product authorization is not or ceases

to be CBI, and to authorize disclosure of this information. Supporting regulations may be developed at a later date with input from internal and external stakeholders.

3. PRINCIPLES AND CONSIDERATIONS FOR HEALTH CANADA'S EXERCISE OF THE AUTHORITY UNDER PARAGRAPH 21.1(3)(C) OF THE *FOOD AND DRUGS ACT*

Health Canada's application of this authority is guided by principles of administrative law which require that powers be exercised fairly, reasonably and in accordance with the powers duly conferred on the body exercising them.

The following principles and considerations, consistent with the broad administrative law principles noted above, provide additional guidance on the exercise of the discretion under paragraph 21.1(3)(c).

3.1 Principles

i. Health Canada will be judicious in its exercise of this authority. The requirements of paragraph 21.1(3)(c) are broadly defined to permit the Minister to act in a variety of circumstances. In addition to considering whether or not the requirements of the Act would be fulfilled, a decision on whether to disclose CBI under this authority should consider all relevant factors both for and against exercising the discretion to disclose in the particular circumstances.

ii. Consistent with the objectives of the *Protecting Canadians from Unsafe Drugs Act*, information disclosed under this authority should contribute to improving the health of Canadians. Requests for disclosure under this authority should clearly define how the purpose relates to this objective and include a formal plan to use the information to advance knowledge, including making results publicly available.

iii. Use of this authority should be necessary to achieve the purpose for which the information is requested. A decision on whether or not to disclose CBI will include consideration of whether or not all other possible sources of the information, including from the originator of the information, have been exhausted. Only information that is directly related to the purpose set out in the request should be considered for disclosure.

iv. Information disclosed under this authority should be kept confidential and used only for non-commercial purposes. Prior to disclosure, Health Canada requires that potential recipients of CBI sign a legally binding agreement to maintain confidentiality, except as permitted by specific exclusions. Requesters are also required to confirm that the information will not be used for commercial purposes, and to report any activities that could result in a conflict of interest. These requirements are not intended to prevent publication of the results of analyses of the disclosed information.

v. Health Canada will maintain the integrity of its regulatory function. It will consider the consequences of disclosure on its capacity to evaluate and regulate therapeutic products based on science and the interests of the health of Canadians. A significant factor is the stage of the regulatory decision process at the time that disclosure is being considered.

3.2. Considerations - Persons to whom Confidential Business Information (CBI) may be disclosed

Health Canada's decision regarding disclosure of CBI includes an assessment of whether the person to whom the CBI would be disclosed fulfills the Act's requirement that they be a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Where disclosure of CBI has been requested by an individual, Health Canada expects that the principal requester would have qualifications in a health profession and demonstrated expertise in the subject of the request.

Where disclosure of CBI has been requested by a corporation, Health Canada expects that its corporate mandate, as described in its articles of incorporation or other documentation, would include purposes relevant to the protection or promotion of human health or the safety of the public and the health or safety issue that is the subject of the request. In addition, it is expected that the designated representative of the corporation identified in the request would have qualifications in a health profession and demonstrated expertise in the topic of the research.

An assessment of the qualifications of a requester may include other considerations, including:

- Relevance of the requester’s qualifications to the purpose of the proposed disclosure. Requesters should have the necessary expertise to lead the proposed project. Projects requiring specialized technical expertise may involve collaborators, who should be identified at the request stage where possible.
- Record of contribution to improving the health and/or safety of Canadians in an area relevant to the subject of the request. Publications and research projects related to health and safety issues other than the subject of the request may be taken into account in assessing a request.
- Record of disseminating information to advance scientific knowledge for non-commercial purposes. Where the requester is a corporation, its legal status (for-profit, not-for-profit) may be considered in assessing the risk of a conflict of interest.

3.3 Considerations - Purpose of disclosure

Health Canada's decision regarding disclosure of CBI will also include an assessment of whether the disclosure would fulfill the Act's requirement that the "purpose of the disclosure is related to the protection or promotion of human health or the safety of the public."

Public exposure to a therapeutic product is generally required in order for CBI related to the product to be used for protecting or promoting human health or the safety of the public. Consequently, Health Canada expects that requests for disclosure will relate to CBI obtained in the course of its regulatory activities to evaluate and monitor the safety, efficacy and quality of therapeutic products for use in Canada.

Health Canada may also consider the following to assess the purpose of disclosure.

- Demonstrated relevance of the proposed project to the purpose of protecting or promoting human health or the safety of the public. Evidence should be provided regarding the health and safety issue to which the request relates, and requests should explain how the disclosed information would be used to advance efforts in this area.
- The severity of the health or safety issue to which the request relates, or the vulnerability of the affected population. The feasibility of the proposed use of the CBI. A project summary should outline how its objectives will be accomplished with the available expertise and resources.
- The anticipated impact of the proposed use of the CBI on the health and safety of Canadians.

- The type of information requested may include:
  - CBI that relates to a therapeutic product that has been authorized for sale in Canada.
  - CBI related to an amendment of a market authorization to obtain approval for new uses or indications for a product already authorized for sale, or authorization for changes that may affect the safety, efficacy or quality of an authorized product. CBI in such submissions or applications may add to the body of knowledge regarding the safety, efficacy and quality of a product to which Canadians are exposed. Consideration should be given to the consequences of disclosure for the integrity of Health Canada's regulatory function, particularly for information related to amendments to market authorization (for example, supplemental submissions) that are in review, cancelled, withdrawn, or rejected.
  - Interim clinical study results related to a therapeutic product authorized for sale in Canada provided the disclosure does not jeopardize the completion of the study or the integrity of Health Canada's regulatory function. The personal information of all study participants will be protected as described in section 4. Consideration of requests related to interim study results will involve an assessment on whether the benefits of a disclosure outweigh any risks associated with the creation of study bias that may jeopardize the completion of an ongoing study.
  - Other information obtained by Health Canada for post-market surveillance purposes, for example , information obtained from the market authorization holder indicating a potential but not established new risk, information obtained pursuant to a risk management plan (RMP) through a periodic safety update report (PSUR), information that was provided by a market authorization holder used to conduct a signal assessment or other safety review or to issue a risk communication.
  - Other information obtained by Health Canada for compliance and enforcement purposes, e.g., information that is obtained during the course of an inspection.

4. PROTECTION OF PERSONAL INFORMATION AND RESPECTING PARTICIPANTS' INFORMED CONSENT

All personal information contained within the records considered for disclosure will be redacted according to the *Privacy Act* and other applicable laws.

When disclosing information related to clinical trials Health Canada will respect the participants' consent for data sharing, when that information is available.

5. PROTECTION AGAINST COMMERCIAL USE

Health Canada will exercise this authority taking into account the importance of protecting CBI against commercial use. Requesters are required to confirm that the project for which they request disclosure of CBI is for a non-commercial purpose. Health Canada also requires requesters to complete a Conflict of Interest declaration. Health Canada reviews the information provided in the declaration to determine whether or not to disclose CBI to a requester whose financial interests, employment and other affiliations could conflict with their commitment to use the CBI exclusively for non-commercial purposes that supports the protection or promotion of human health or the safety of the public.

6. MAINTAINING CONFIDENTIALITY OF DISCLOSED INFORMATION

Health Canada requires requesters to sign a legally binding Confidentiality Agreement to maintain the confidentiality of disclosed information. Among other things, this Agreement provides that the disclosed information can be used only for the purposes of the proposed project and must be kept confidential using appropriate safeguards. The Confidentiality Agreement also prohibits reproduction of disclosed information. The Agreement provides exclusions to the confidentiality obligations, such as for information that is in the public domain, received from another source or for information that the originator has consented to be released. The requester is free to publish results of the analysis as long as the confidentiality of the disclosed information is maintained.

7. PROCESS TO REVIEW REQUESTS FOR DISCLOSURE

Health Canada's decision is based on a rigorous evaluation and a review process that is fair, reasonable and takes into account all relevant factors. The review process is overseen by a committee of senior Health Canada officials mandated to recommend a decision based on relevant technical and scientific expertise. The Review Committee's recommendation is considered by a senior Health Canada official, not involved in the review process, who has been designated to exercise the Minister's authority to disclose CBI under the *Food and Drugs Act* (section 21.1(3)(c)).

Key steps in the process are outlined below.

1. **Screening**: Requests are reviewed to ensure that they are complete, including proof of qualifications, corporate mandate, and a project description that includes a specific purpose for seeking access to CBI. Incomplete requests will be returned to the requester.

2. **Assessment**: Complete requests are referred to a Review Committee for assessment. The Committee will assess whether or not the request meets the requirements of the Act, taking into account the requester's qualifications, corporate mandate (where relevant) and the proposed project. Where a request does not meet the requirements of the Act, the Committee will recommend that it be denied. Where a request meets the requirements of the Act, the Committee will proceed to the next step in the review process.

3. **Record search**: For requests that meet the requirements of the Act, Health Canada will conduct a search of its records. The search will identify records that include information described in the request and that are directly related to the project described in the request. If the records do not contain CBI, the requester will be notified and provided an opportunity to obtain the information from the appropriate Health Canada office or Access to Information and Privacy division.

4. **Communication with requester**: If CBI is included in records relating to an assessed request, the requester will be notified and, where large volumes of records have been identified, may be consulted to refine their request. At this stage the requester will be asked to complete a Conflict of Interest Declaration and to sign a Confidentiality Agreement. The signing of a Confidentiality Agreement by the requester at this point in the process does not mean that information will be disclosed. Further information may also be required in order to complete Health Canada's review of the request.

5. **Recommendation**: Once the requester has provided a completed Conflict of Interest Declaration, signed Confidentiality Agreement and any other required information, the Review Committee will prepare a recommendation regarding whether to disclose records containing CBI identified in the record search. The recommendation will include the assessment that a request meets the requirements of the Act and an assessment of whether or not the designated decision maker should exercise the Minister’s authority to disclose CBI, based on the principles and considerations in section 3 of this guidance document and other factors relevant to the particular request. Some records relevant to a particular request may contain other protected information, such as personal information or information obtained in confidence from another regulator. This information will be redacted from any records that are recommended for disclosure.

6. **Decision**: The Review Committee recommendation is considered by a senior Health Canada official designated to exercise the Minister's authority to disclose CBI under the *Food and Drugs Act* (paragraph 21.1(3)(c)). When the decision is to disclose CBI, Health Canada will give effect to the Confidentiality Agreement.

7. **Notification to requester**: Health Canada will notify the requester of its decision. When the decision is to disclose CBI, arrangements will be made to ensure secure transmission of the information to the recipient. When the decision is to refuse to disclose CBI, the requester will be notified with an explanation for the decision.

8. **Notification to originator**: Health Canada does not notify the originator of the CBI when it is considering a request for disclosure. As a voluntary practice, Health Canada may notify the originator following disclosure of CBI.

9. **Notification of the public**: Information regarding the request, including a description of the project and the terms and conditions of the Confidentiality Agreement, may be made public.

8. REQUIREMENTS FOR PERSONS REQUESTING DISCLOSURE OF CONFIDENTIAL BUSINESS INFORMATION UNDER PARAGRAPH 21.1(3)(C)

Health Canada expects that decisions regarding disclosure of CBI under paragraph 21.1(3)(c) will normally be in response to a request from an individual or corporation. For this purpose, Health Canada provides a request form that should be completed by requesters. All requests should include the following information:

- Personal and contact information for the principal requester.
- Professional information for the principal requester, including professional qualifications, employment and relevant research experience.
- Names and positions of project collaborators.
- A description of the information requested, including the therapeutic product and regulatory functions to which the information relates. Requesters are encouraged to consult Health Canada's on-line databases of regulatory information and other resources in order to specify their requests as much as possible.
- Indication that the requester has exhausted other sources of the information requested, including from the originator of the information.
- A project summary that clearly indicates the purpose of the proposed disclosure and how it relates to the protection or promotion of human health or the safety of the public.
- Confirmation that the requested information will not be used for commercial purposes.

If a request is incomplete, a requester may be asked to provide missing information. Where Health Canada's assessment finds that the request meets the requirements of the Act, a requester will be asked to provide additional information required to prepare a recommendation regarding disclosure. This will include:

- A completed Conflict of Interest Declaration that provides information required by Health Canada to assess whether or not the requester's financial interests and other affiliations may conflict with their use of the requested information.
- A signed Confidentiality Agreement with Health Canada that would take effect only if and when Health Canada decides to disclose CBI to the requester.
- A dissemination plan to make the results of the project publicly available.

9. FINDINGS GENERATED FROM DISCLOSED INFORMATION

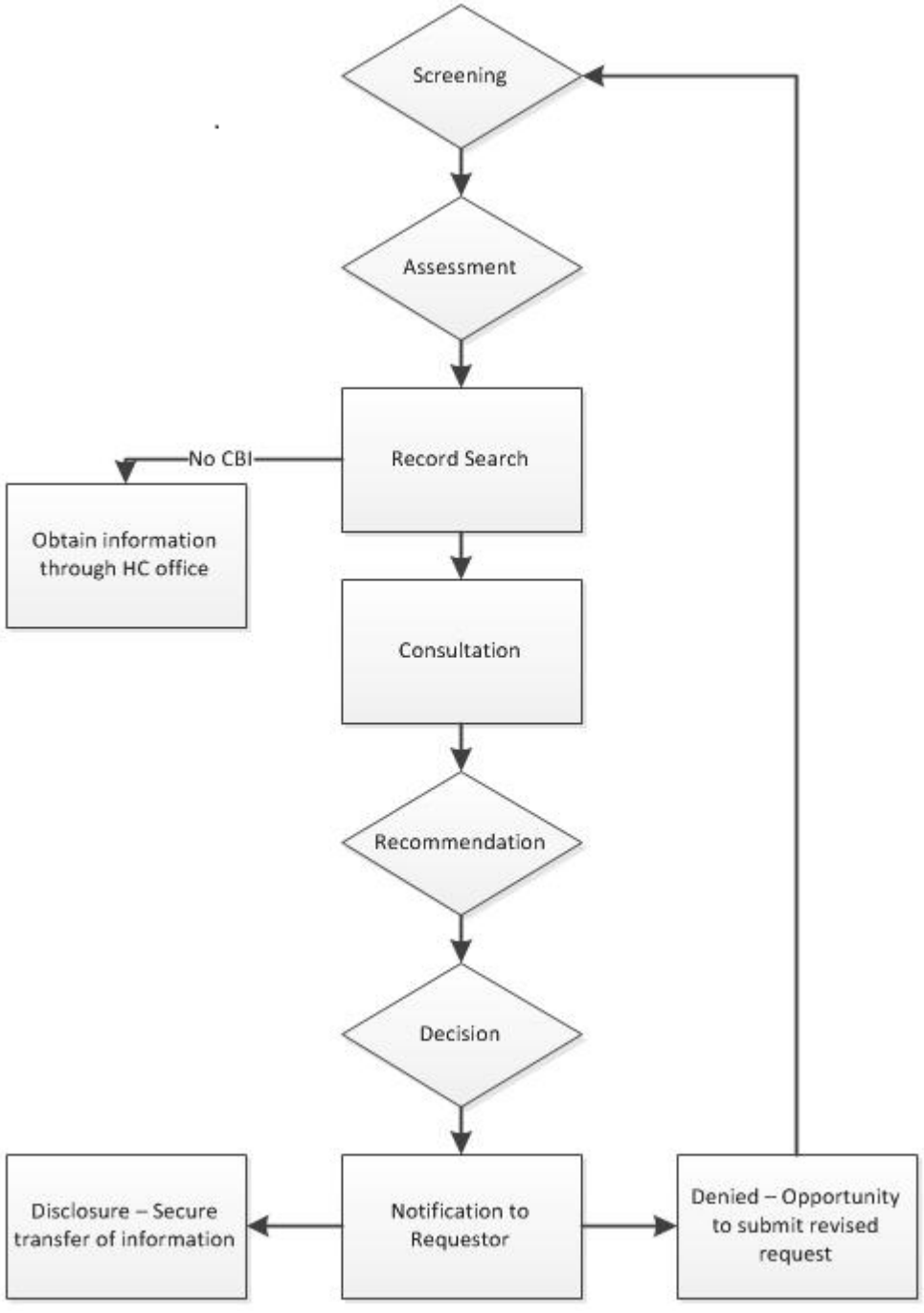
Recipients of disclosed information are expected to make the findings of their undertakings with the disclosed information publicly available when the findings provide additional knowledge about the therapeutic product under study. If the recipient of disclosed information has made a determination that the safety, efficacy or quality of a product(s) is changed as a result of the evaluation of the CBI then the results should be submitted to Health Canada. Information regarding therapeutic products authorized for the Canadian market should be sent to MHPD-stakeholders_intervenants-DPSC@hc-sc.gc.ca. Health Canada considers and assesses on a regular basis a multitude of sources when deciding the priority of a potential signal. This includes literature, decisions made in a foreign jurisdiction, as well as information provided by a recipient of CBI, which could lead to the prioritization of a signal for a safety review.

As always, Health Canada will take the necessary actions to safeguard the health and safety of Canadians should the benefit, harm and uncertainty profile of a product(s) be determined changed. Manuscripts should be copied to Health Canada upon submission for publication.

10. FORMS AND ADDITIONAL INFORMATION

- Review process flow chart
- Tools to assist requesters
- Confidentiality Agreement template
- Conflict of Interest Declaration form

Review process flow chart



Tools for Finding Regulatory Information

- Health Canada publishes information of interest to Canadians on its regulatory decisions, inspections, compliance and enforcement activities. The information you want may be available publicly on Health Canada's website or databases.

- Drug Product Database (includes access to Product Monographs) (http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp)

- Drug and Health Product Register (https://hpr-rps.hres.ca/hpr-rps/templates/search-recherche-eng.php)

- Drug and Health Product Review and Approval (includes Regulatory Decision Summaries, Summary Basis of Decisions, Notice of Compliance for approved drugs, and list of submissions under review for new active substances) (http://healthycanadians.gc.ca/drugs-products-medicaments-produits/authorizing-manufacturing-autorisation-fabrication/review-approvals-evaluation-approbations/index-eng.php)

- Canadian Vigilance Adverse Reaction Online (http://webprod3.hc-sc.gc.ca/arquery-rechercheei/index-eng.jsp)

- Clinical Trial Search (http://ctdb-bdec.hc-sc.gc.ca/ctdb-bdec/index-eng.jsp)

- Patent Register (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/patregbrev/index-eng.php)

- Advisories, Warnings and Recalls (http://www.hc-sc.gc.ca/dhp-mps/advisories-avis/index-eng.php)

- Drug and Health Product Inspections (http://healthycanadians.gc.ca/apps/inspections/index-en.html)

- Safety Reviews (includes Summary Safety Reviews and a list of safety reviews started since October 2015) (http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/index-eng.php)

If the information you are seeking is not available publicly and contains CBI, you may be able to obtain it on request from Health Canada. The following categories of regulatory information may include CBI that is relevant to a health or safety issue:

Clinical studies	Drug Submissions	Post-market surveillance	Compliance and enforcement
• Clinical trial protocols • Clinical study reports • Patient level data	• Safety summaries • Efficacy summaries • Non-clinical safety studies	• Drug Safety reviews • Adverse event signal assessments	• Inspection reports • Notices of violation • Letters of non - compliance

- A request for disclosure of CBI should be as specific as possible. Consult the Health Canada web site to learn more about the types of records that may be requested. Useful links include:
- How drugs are reviewed in Canada (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php)
- Notice of Compliance Database (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/noc-acc/index-eng.php)
- Glossary of Health Canada terms (http://www.hc-sc.gc.ca/dhp-mps/homologation-licensing/gloss/index-eng.php)
- Guidance document: Preparation of drug regulatory activities in the Common Technical Document format (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/ctd_prep_nds-eng.php#a35)

Additional information for requestors

There are other authorities in the *Food and Drugs Act* that Health Canada to disclose CBI when there is a risk of serious injury to human health, and for Health Canada to disclose CBI to other government agencies, including regulatory counterparts and members of advisory bodies.

- Serious risk of injury to human health (section 21.1(2))
- To a government (section 21.1(3)(a)
- To a person from whom the Minister seeks advice (section 21.1(3)(b))

For more information on the implementation of the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) - (in force November 6, 2014) please refer to the following guide:

- Amendments to the *Food and Drugs Act* 2014 -- Guide to New Authorities (http://hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php)

Templates

Forms to be completed only following identification of requested records:

- Conflict of Interest Declaration for Individuals
- Standard Confidentiality Agreement

Other sources of clinical trial-related information

Clinical trial information is available through the following registries and databases:

- US - Clinicaltrials.gov
- European Clinical Trials Database (Eudra CT) (https://eudract.ema.europa.eu/)
- World Health Organization - International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/)
- Yale University Open Data Access (YODA) (http://yoda.yale.edu/)

Direct requests for clinical trial data can be made to the following drug companies through the Clinical Study Data Requests website (https://www.clinicalstudydatarequest.com/Study-Sponsors-Info.aspx).

- Astellas
- Astra Zeneca
- Bayer
- Boehringer Ingelheim
- Eisai
- GSK
- Janssen Clinical Trial Data
- Lilly
- Novartis
- Roche
- Sanofi
- Takeda
- UCB
- ViiV Healthcare

575 **Access to Confidential Business Information for Health and Safety Purposes form**

1. Personal and Professional Information NB: Please list all applicants and collaborators associated with the request	
Name (Principal applicant)	**Professional Title & Employer**
Requester ☐ individual ☐ corporation	**Name of corporation (if applicable)**
Professional Qualifications	
Street Address	
City	**Prov./Territory**
Postal Code	**Country**
Primary Phone Number	**Alternative Phone Number**
Email	
2. Information requested	
Have you consulted all available sources of information prior to submitting this request? ☐ yes ☐ no	
□ Name of the health product(s) to which the information relates:	
□ Regulatory functions to which the information relates: ☐ clinical trials	

☐ market authorization

☐ post-market surveillance

☐ compliance and enforcement

☐ other:

☐ Please briefly describe the information that you are seeking from Health Canada:

3. Project summary

Please attach a summary of the project for which you are seeking the information (maximum 1,000 words). Include headings that respond to the following questions:

- What are the perceived health and/or safety issues associated with the therapeutic product?
- What is the proposed objective of your project?
- How do you propose to carry out your project?
- How will the proposed project accomplish the stated objective?
- How will the project results be disseminated?

In addition to the summary, you may attach publications or other documents related to your project.

☐ Project summary attached

- Does your project have a commercial purpose? ☐ Yes ☐ No

☐ Supporting publications, other documents attached (please list below)

Preferred language for receiving future communications:

☐ French or ☐ English

Please acknowledge that the information provided in this form is accurate and complete, and that you agree to its use for the purpose of reviewing your request.

☐ I agree

☐ I do not agree

PRIVACY NOTICE: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to process requests for confidential business information (CBI) authorized

under paragraph 21.1(3)(c) of the *Food and Drugs Act.*

Purpose of collection: Your personal information is used to determine whether requested CBI may be disclosed to you. This information will be reviewed by a committee of senior Health Canada officials who will assess whether you qualify under the Act as "a person who carries out functions relating to the protection or promotion of human health or the safety of the public."

Other uses or disclosures: Health Canada may notify the public and/or the originator of the requested information of your request for CBI. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

Refusal to provide the information: Failure to provide the requested information will prevent the assessment of your qualifications under paragraph 21.1(3)(c) and will consequently prevent the processing of your request.

For more information: This personal information collection will be described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank (to come).

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-954-9165 or privacy-vie.privee@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Signature	Date

Instructions

1. Personal and Professional Information: Provide all information relevant to your request. Health Canada has discretionary authority under the *Food and Drugs Act* to disclose CBI to individuals and organizations. To be eligible, the applicant (individual or corporation) must carry out functions relating to the protection or promotion of human health or the safety of the public. In this section, please list all collaborators who require access to the requested information in order to carry out the proposed project.

2. Information Requested: Describe the information that you are requesting as specifically as you can, including the product(s) (common and/or brand names) and the regulatory function(s) to which the information relates. Please consult the resources listed under Tools of the guidance document to help identify the information required. Health Canada's authority under paragraph 21.1(3)(c) of the *Food and Drugs Act* to disclose CBI applies to regulatory information related to therapeutic products, including prescription and non-prescription drugs, vaccines, blood and blood products, donor semen for assisted conception, gene and cell therapies, tissues and organs, and medical devices. It does not apply to natural health products.

3. Project summary: Describe the research project or other activity for which you are seeking access to CBI, including how the purpose for obtaining access to the CBI is related to the protection or promotion of human health or the safety of the public. Health Canada's authority under the Food and Drugs Act to disclose CBI to individuals or corporations can be used only for a purpose related to the protection or promotion of human health or the safety of the public. Health Canada will not disclose CBI for commercial uses.

Conflict of Interest Declaration

Information Sheet
How to complete the Conflict of Interest Declaration for Disclosure of Information
Please read this information sheet before you complete the declaration form.

This Information Sheet will assist you in completing the *Conflict of Interest Declaration for Disclosure of Information*.

What to declare?

Each individual is responsible for the declaration of his/her interests, and the interests of their spouse/partner, and/or dependent child. When completing Question 1, you are only required to indicate the company name, and the type of interest, such as stocks, shares, or bonds etc. In order to maintain privacy, do not identify the individual who owns the interest, nor the financial amounts.

Changing circumstances of affiliations and interests

If there is a change in the circumstances reported on the Affiliations and Interest Declaration Form during your Project you must promptly report such changes to the Secretariat.

How will the information in my declaration be used?

Health Canada will review your completed declaration form with a view to ensuring that there is no conflict of interest with respect to the information requested for the purpose of carrying out the proposed project related to the protection or promotion of human health or the safety of the public.

Protection of personal information

Once completed, your personal information in the *Conflict of Interest Declaration for Disclosure of Information* is protected in accordance with the *Privacy Act*.

Before you mail your completed declaration

Before you send this application form to the Secretariat, please make sure that you have completed, signed and dated your declaration.

Conflict of Interest Declaration for Disclosure of Information

To be completed by individuals requesting disclosure of information for the purposes of a project that relates to the protection or promotion of human health or safety of the public.

Prefix
Mr. Mrs. Ms.
Miss
First Name Last Name
Home Address (No., Street, Apt., P.O. Box, R.R)
City Prov./Territory
Postal Code
Country
Mailing Address □ Same as above Or (No., Street, Apt., P.O. Box, R.R)
City Prov./Territory
Postal Code Country
Daytime Phone Number
Evening Phone Number
Preferred language for receiving future communications: French □ *or* English □

Direct Financial Interests

Q 1) Do you, your spouse/partner, and/or dependent minor child have any **direct financial interests** with the regulated industry that are of relevance to the subject of the information request including current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares, or bonds?
□ Yes
□ No

If yes, please list the company name, and the type of interest. In order to maintain privacy, household members do not need to be identified.

Response:

Indirect financial interests

Q 2) Within the past five years, have you received from the regulated industry **payment for work done or being done, or financial support**, of relevance to the subject of the information request? Include past employment, contracts or consulting, research support, personal education grants, contributions, fellowships, sponsorships, and honoraria for teaching, speaking, or writing engagements.

Note: if you are currently employed by the regulated industry and have declared this under Q1), do not include any of the above from your present employer.

□ Yes
□ No

If yes, please list the approximate value. When was the work performed? What was your role? Who provided the support? When did the support cease?

Response:

Q 3) Within the past five years, have you received **materials, discounted products, gifts, or other benefits**, or attended conferences or meetings where all or part of the **travel and accommodation costs** were provided by the regulated industry, of relevance to the subject of the information request.

Note: if you are currently employed by the regulated industry and have declared this under Q1), do not include any of the above from your present employer.

□ Yes
□ No

If yes, please provide the dates and details, including who provided the support and the approximate value.

Response:

Q 4) Within the past three years, have any of the organizations where you are currently employed or where you participate in internal decision making (that is, as a board member, or as an executive or non-executive director) **received grants or other funding from the regulated industry**, of relevance to the subject of the information request?

□ Yes
□ No

If yes, please provide the dates and details, including who provided the support, and the amounts.

Response:

Intellectual interests

Q 5) Within the past five years, have you provided any **formal advice or opinion** to industry, a Canadian federal, provincial, or municipal government, a foreign government, or a nongovernment organization, on a matter of relevance to the subject of the information request?

Include expert testimony or acting as witness (full or part time), participation on an advisory body, etc.

□ Yes
□ No

If yes, please provide the dates and details and note if you volunteered your services or were paid.

Response:

Q 6) Have you ever made **public a statement (including speeches, lobbying, etc.) or publicly stated a point of view** (including in scientific papers, articles, journals, or other publications or on Web sites) on issues of relevance to the subject of the information request?

□ Yes
□ No

If yes, please list by date, title, and publication

Response:

Q 7) Do you currently have **any professional or volunteer affiliations** (such as membership of professional/scientific societies, trade associations, lobbying, public interest or advocacy groups, etc.) who may have an interest in the subject of the information request?

□ Yes
□ No

If yes, please describe.

Response:

Other affiliations and interests

Q 8) Do you have any other affiliations and interests or potential circumstances that might give a well-informed member of the public reasonable apprehension or grounds for concern that access to the information for which you have requested disclosure could place you in a conflict of interest?

□ Yes
□ No

If yes, please describe.

Response:

Section C – Your Declaration

I _____ (**name)** have reviewed my affiliations and interests as they relate to the matters itemized in this disclosure form, and I hereby certify that I have disclosed all relevant information. Except as otherwise disclosed in this form, I declare that I have no additional relevant affiliations and interests to report.

I understand that it is my responsibility to report to the Secretariat any material change in circumstances in my affiliations and interests as soon as it is known to me.

_____

Name of individual requesting disclosure of information
Signature Date YY / MM / DD

Please return your completed form to:

Health Products and Food Branch
250 Lanark Avenue, Room 452
Ottawa, ON K1A 0K9

FOR OFFICE USE ONLY
Direct Financial Interest
□ **YES**
□ **NO**

Signature:
Date: / /
YY MM DD

Comments:

CONFIDENTIALITY AGREEMENT TEMPLATE

BETWEEN:

HER MAJESTY THE QUEEN IN RIGHT OF CANADA,
as represented by the Minister of Health ("**Health Canada**")

- and -

XYZ

WHEREAS:

A. XYZ wishes to obtain information from Health Canada for the purposes of the Project;
B. Health Canada is willing to disclose relevant information to XYZ exclusively for the purposes of the Project;
C. The purpose of the disclosure is related to the protection or promotion of human health or the safety of the public;
D. XYZ is a person who carries out functions relating to the protection or promotion of human health or the safety of the public;
E. Health Canada wishes to preserve the confidentiality of the information it is willing to disclose to XYZ;
F. The information that Health Canada is willing to disclose includes Confidential Business Information, which may be disclosed pursuant to paragraph 21.1(3)(c) of the *Food and Drugs Act* (R.S.C., 1985, c. F-27);
G. The Parties wish to set out in this Agreement the terms and conditions under which Health Canada is disclosing information to XYZ for the purposes of the Project;

NOW THEREFORE IN CONSIDERATION of the mutual terms and conditions, the Parties agree as follows:

1. PREAMBLE

The preamble forms an integral part of this Agreement.

2. DEFINITIONS

a) "**Agreement**" means this agreement between Health Canada and XYZ respecting the information disclosed by Health Canada to XYZ for the purposes of the Project.

b) "**Confidential Business Information**" means, information that may be captured under the definition of Confidential Business Information in section 2 of the *Food and Drugs Act* which provides:

"confidential business information", in respect of a person to whose business or affairs the information relates, means - subject to the regulations - business information

(a) that is not publicly available,

(b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and

(c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors;

d) "**Disclosed Information**" means any information, including, data, or any part or portion thereof, that has been provided by Health Canada to XYZ under this Agreement, that is listed in Annex B, for the purposes of the Project and includes Confidential Business Information;

e) "**Party**" means either Health Canada or XYZ individually, and "**Parties**" means both Health Canada and XYZ collectively.

f) "**Project**" means a non-commercial undertaking that relates to the protection and promotion of human health or the safety of the public as described more specifically in Annex A to this Agreement.

3. CONFIDENTIALITY

a) Obligation of Confidentiality - Disclosed Information provided to XYZ under this Agreement shall:

i. be held in confidence by the XYZ ;
ii. be used by XYZ exclusively for the purposes of the Project;
iii. be safeguarded by XYZ by maintaining appropriate physical and technological safeguards to limit the risk of theft, loss, unauthorized access, copying, use, disclosure or disposal of the Disclosed Information;
iv. not be reproduced in whole or in part in any document, paper, manuscript, etc. that XYZ intends to publish or otherwise make public.
v. not be disclosed to third parties.

b) No Waiver of Privilege - XYZ acknowledges that Health Canada and/or the third party who provided the Disclosed Information to Health Canada does not intend to waive any rights, title or privilege that either may have in respect of any of the Disclosed Information.

c) Duty of Confidentiality - Nothing in this Agreement derogates, displaces or otherwise diminishes the common law or equitable duty of confidentiality applicable to XYZ concerning the Disclosed Information.

d) Confidentiality Exclusions - The obligations imposed by Article 3 (Confidentiality) do not apply to information which:

i. In the Public Domain - is now or hereafter becomes, through no act or failure to act on the part of XYZ, generally known or available to the public;
ii. Already Known to XYZ - was already in the possession of XYZ at the time of disclosure;
iii. Disclosed by a Third Party - becomes available from a third party who has a lawful and legitimate right to disclose the information to others;
iv. Independently Developed - was independently developed by XYZ without any of the Disclosed Information being reviewed or accessed by the XYZ;
v. Required to be Disclosed Pursuant to law, including, on the basis of a Judicial or Administrative Order – the disclosure of which was required by law or pursuant to a compulsory order under a judicial process or under a compulsory regulatory requirement. XYZ shall provide written notice of any such disclosures to Health Canada, as soon as reasonably possible;
vi. Consent has been Obtained - where the originator of the Disclosed Information, whether it be Health Canada or a third party, agrees in writing that it can be disclosed.

4. RESEARCH AND PUBLICATIONS

a) XYZ shall provide Health Canada with a copy of any draft manuscript which was developed using the Disclosed Information at least 15 business days prior to submitting it for publication or otherwise disseminating it in order for Health Canada to verify that the Disclosed Information was used for the purpose of the Project.
b) If XYZ references Health Canada in any publication, XYZ shall include a statement in the publication that the analysis, conclusions, opinions and/or statements expressed therein are those of the author and are not necessarily those of Health Canada.

5. DESTRUCTION OF DISCLOSED INFORMATION

a) XYZ shall destroy in a secure manner the Disclosed Information, as well as any copies or extracts, including electronic files, after completion of the Project or upon termination of this Agreement and shall provide notification of destruction in writing to Health Canada.

6. INTELLECTUAL PROPERTY

This Agreement does not grant or transfer any rights to XYZ respecting the intellectual property associated with the Disclosed Information. XYZ further understands that

a) by obtaining the Disclosed Information, XYZ is not obtaining an implied license to that Disclosed Information; and
b) the use of the Disclosed Information shall be limited to the purpose of the Project as further detailed in this Agreement.

7. EFFECTIVE DATE

This Agreement shall come into force and effect on the date of last signature (the "Effective Date").

8. INDEMNIFICATION

XYZ shall, at his own cost, indemnify and save harmless Health Canada from and against all claims, demands, losses, damages, costs (including the complete costs of defending any legal action by a third party), actions, suits or other proceedings, all in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or omissions whatsoever of XYZ (whether by reason of negligence or otherwise) in the breach by XYZ of the provisions of the Agreement.

9. TERMINATION AND EQUITABLE REMEDIES

a) Termination - Health Canada may terminate this Agreement immediately at any time by providing a written notice to XYZ.
b) Provisions that Survive Termination - Notwithstanding the termination or expiration of this Agreement, all obligations of the Parties, which expressly or by their nature survive termination or expiration, shall continue in full force and effect subsequent to and notwithstanding such termination or expiration, until they are satisfied or by their nature expire, including without limitation, Confidentiality (Article 3), Intellectual Property (Article 6) and Indemnification (Article 8).
c) Should XYZ breach the provisions of this Agreement, Health Canada shall be entitled to equitable relief, in addition to all other remedies available to the Parties at law or in equity. The Parties agree that an award of damages may not be an effective remedy in the event of a breach of this Agreement.

10. MISCELLANEOUS

a) Entire Agreement - This Agreement, and its Annexes, constitutes the entire agreement between the Parties pertaining to the subject-matter hereof and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, of the Parties pertaining to such subject-matter. There are no warranties, representations or other agreements between the Parties in connection with the subject matter hereof, except those specifically set out herein. The execution of this Agreement has not been induced by, nor do any of the Parties rely upon or regard as material, any representations not included in this Agreement.
b) Amendment - No amendment to this Agreement shall be effective unless agreed to in writing and signed by the Parties.
c) Waiver - No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision (whether or not similar) nor shall such waiver constitute a continuing waiver unless otherwise expressly provided.
d) No Representations or Warranties – Any use of the Disclosed Information shall be at the sole risk and expense of XYZ. Any Disclosed Information provided to XYZ by Health Canada is

provided on an "as is" basis without any warranty or guarantee or representation of any kind whatsoever.

e) Successors - This Agreement shall enure to the benefit of, and be binding upon, the Parties and their respective heirs, executors, administrators and permitted successors and assigns.

f) Relationship - The Parties expressly disclaim any intention to create a partnership, joint venture or joint enterprise.

g) Forum Conveniens and Applicable Laws - This Agreement shall be governed by and interpreted under the laws in force in XXXX, without regard to any choice of law rules. The courts of XXXX shall have exclusive jurisdiction over all matters arising in relation to this Agreement and each Party hereby submits to the jurisdiction of the courts of XXXX.

h) Assignment - This Agreement is personal to the Parties and cannot be assigned by a Party, in whole or in part, or any interest, right or obligations hereunder.

i) Breach - XYZ shall notify Health Canada immediately upon becoming aware of any breach or suspected breach of the provisions of this Agreement. XYZ shall advise Health Canada of all steps taken to correct any such breach.

11. NOTICES

a) Contact Individuals, Addresses and Numbers - unless otherwise notified, the representative of the Parties for the purpose of the Agreement shall be:

For HEALTH CANADA: [Insert name, address]
Telephone: [Insert telephone number]
Facsimile: [Insert facsimile number]
Email: [Insert email address]

For XYZ: [Insert name, address]
Telephone: [Insert telephone number]
Facsimile: [Insert facsimile number]
Email: [Insert email address]

b) Mode of Service - Any notices or other communications required or permitted under this Agreement shall be in writing and shall be either

i. personally delivered;
ii. sent by courier;
iii. sent by registered mail, postage prepaid;
iv. sent by facsimile; or
v. sent by email;

to the addresses and persons cited above. Any Party may change the names of the intended recipient and addresses by written notice.

c) Confirmation of Service - Any notice or communication

i. given by personal delivery shall be deemed to have been received on the date of delivery;
ii. given by courier or registered mail shall be deemed to have been received on the date of signature on the delivery slip;
iii. given by facsimile shall be deemed to have been received on the date of the facsimile transmission sheet;
iv. given by email shall be deemed to have been received when the Internet "postmaster" states receipt of the electronic message.

d) This Agreement may be executed in counterpart.

12. EXECUTION / SIGNATURES

IN WITNESS WHEREOF this Agreement has been executed by the Parties.

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

By:

_____ _____
[Name of official] Date
[Title]

XYZ:
By:

_____ _____
[Name] Date
[Title]

ANNEX A - Project Description

ANNEX B - Disclosed Information Provided by Health Canada to XYZ for the Purpose of the Project