



# Guidance Document

## Data Protection under C.08.004.1 of the Food and Drug Regulations

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## Document change log

Date	Change	Location (section, paragraph)	Nature of and/or Reason for Change
2021/04/08	Updated in accordance with the new Health Products and Food Branch organizational structure	Throughout	Change in Health Products and Food Branch organizational structure.
2017/05/16	Clarification following judicial considerations and reflecting current practices	All	The updates to the Guidance Document are being made to clarify the interpretation of “innovative drug” following the judicial considerations of the data protection provisions and to reflect current administrative practices.
2011/10/11	Clarification to section 2.1	2.1	The clarifications to the Guidance Document are being made in light of recent inquiries in respect to the interpretation of the definition of “innovative drug” for veterinary drugs and for human drugs under subsection C.08.004.1(1) of the Food and Drug Regulations.
2010/03/08	Change to scope of Data Protection	2.1 & 3.1	Updated to reflect the administration of the data protection provisions in light of the finalized Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs).

## 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 scientific 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 guidance, 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 guidances.

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# 1. Introduction

## 1.1 Policy objectives

The determination of what is an innovative drug eligible for data protection in accordance with subsection C.08.004.1(1) of the Food and Drug Regulations is to be made with a view to the purpose articulated in subsection C.08.004.1(2), which is stated as follows:

The purpose of this section is to implement Article 1711 of the North American Free Trade Agreement, as defined in the definition Agreement in subsection 2(1) of the North American Free Trade Agreement Implementation Act, and paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the Agreement Establishing the World Trade Organization, as defined in the definition Agreement in subsection 2(1) of the World Trade Organization Agreement Implementation Act.

Furthermore, Canada's obligations under the North American Free Trade Agreement and the Agreement on Trade-Related Aspects of Intellectual Property Rights require the granting of protection for undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical product which utilizes a new chemical entity, the origination of which involved considerable effort.

## 1.2 Policy statements

Section C.08.004.1 of the Food and Drug Regulations is intended to provide the manufacturer of an innovative drug with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. The introduction of this market exclusivity will provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada. An additional six-month extension will be applied if an innovator includes clinical trials which were designed and conducted with the purpose of increasing knowledge about the use of the drug in pediatric populations. Extending market exclusivity in this manner will encourage pediatric research and improve drug information regarding pediatric usage for health professionals, thus providing health benefits to children.

## 1.3 Scope and application

This guidance document provides information regarding the administration of section C.08.004.1 of the Food and Drug Regulations which came into force on October 5, 2006 by the Office of Patented Medicines and Liaison (OPML) within the Office of Submissions and Intellectual Property, Resource Management and Operations Directorate (RMO), Health Canada. It is applicable only to those drugs that receive a Notice of Compliance (NOC) on or after June 17, 2006 and includes pharmaceutical, biological and radiopharmaceutical drugs that receive NOCs, including relevant products for veterinary use.<sup>1</sup>

## 1.4 Background

In 1995, Health Canada amended the Food and Drug Regulations to provide a regulatory framework for abbreviated new drug submissions (ANDSs). Included in the 1995 amendments was a data protection provision that was triggered upon the examination of any information filed by an innovative manufacturer to obtain approval for its drug, to support the review of a

subsequent-entry drug product. Where the Minister relied on the innovator's information, Health Canada would not issue an NOC for the subsequent-entry drug product until five years after the issuance of the NOC to the innovator. In those cases where this would result in a delay in the issuance of the NOC, the Regulatory Impact Analysis Statement (RIAS) stated that Health Canada would give the subsequent-entry manufacturer the option of supplying additional information to support its submission without relying on the innovator's information.

In most cases, Health Canada does not consult the information in the innovator's drug submission and, therefore, does not rely directly on the innovator's information. Therefore in the view of Health Canada, the provision did not allow for an indirect reliance on the innovator's information. The Minister's interpretation was upheld in a Court challenge of the provision where it was held that to trigger the five-year period of data protection required a direct reliance on the innovator's drug submission.

Under the October 5, 2006 data protection provisions, companies introducing a drug containing a new chemical entity (i.e. an "innovative drug") are entitled to an eight-year period of market exclusivity. In addition, a subsequent-entry manufacturer is prevented from filing a submission for a copy of that innovative drug for the first six years of the eight-year period.

The data protection period may be extended a further six months if, within the first five years of the eight-year period, the results of pediatric clinical trials, designed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations, are also submitted and found acceptable. Extending the period of data protection in this manner is intended to encourage the submission of pediatric research results to provide health benefits to children.

## 2. Innovative drugs

### 2.1 Scope of data protection

The data protection provisions in section C.08.004.1 of the Food and Drug Regulations provide an eight-year period of market exclusivity for innovative drugs.

Section C.08.004.1 of the Food and Drug Regulations defines an "innovative drug" as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Under the definition of an innovative drug, drugs that contain medicinal ingredients that have been previously approved in Canada, including drugs that have previously received an NOC, a Natural Product Number (NPN) and/or a Drug Identification Number (DIN), will not be afforded protection. An extension of the period is not available for drugs that are issued an NOC for a new indication, dosage form or other changes made through a supplement to a new drug submission (SNDs) with the exception of SNDs containing pediatric clinical trial data. See section 2.8 of this document for more information.

Consistent with the policy intent underlying the data protection amendments of 2006 and the decision in *Bayer Inc. v. Canada (Attorney General)*, 84 C.P.R. (3d) 129, aff'd 87 C.P.R. (3d) 293, leave to appeal to SCC refused, [1999] S.C.C.A. No. 386, when interpreting the definition of

“innovative drug”, the prior approval of a medicinal ingredient in a drug for veterinary use does not preclude the granting of data protection to a drug for human use containing the identical medicinal ingredient or a variation thereof. Conversely, the prior approval of a medicinal ingredient in a drug for human use does not preclude the granting of data protection to a drug for veterinary use containing the identical medicinal ingredient or a variation thereof.

Approval for a biosimilar, as set out in Health Canada’s Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs (Biosimilar Guidance), is sought by filing a new drug submission (NDS) in which the sponsor seeks to reduce the clinical and non-clinical study requirements by demonstrating similarity to a previously approved reference biologic drug. As such, a biosimilar will not be considered to be an “innovative drug”.

## 2.2 Eligibility of drugs for data protection

Jurisprudence has confirmed, in light of the purpose statement in subsection C.08.004.1(2) of the Food and Drug Regulations, that there are two requirements in the analysis of data protection eligibility. The first is a determination of whether or not the medicinal ingredient under consideration is a new chemical entity. The second is whether or not the generation of the data that supports the approval of the medicinal ingredient under consideration required considerable effort.

### 2.2.1 New chemical entity

The concept of “new chemical entity” has been incorporated into the Food and Drug Regulations through the definition of “innovative drug”. As noted above, an innovative drug is a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

#### **Identification of the medicinal ingredient**

The medicinal ingredient is identified using the pharmaceutical information in the sponsor’s drug submission (e.g. Product Monograph) including the proper name, the chemical name, the molecular formula, the molecular mass, the structural formula and, where appropriate, the amino acid sequence. This information is then used to identify synonyms for the medicinal ingredient using a number of publicly available chemical databases. For more information on drugs containing more than one medicinal ingredient, please see section 2.3 of this document.

Once the medicinal ingredient has been identified, it is necessary to determine whether or not it has been previously approved in a drug by the Minister.

#### **Previous approval**

The analysis of whether or not the medicinal ingredient has been previously approved involves a search of Health Canada’s databases to look for previous approvals of the very medicinal ingredient that is present in the drug under consideration. All known names and synonyms of the medicinal ingredient are input as search criteria into the various databases.

If the medicinal ingredient has been previously approved, the drug cannot be considered an “innovative drug”.



If the medicinal ingredient has not been previously approved, it is necessary to determine whether or not it is a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

### **Variations**

The following types of variations are excluded from the consideration of what is an “innovative drug”: salts, esters, enantiomers, solvates and polymorphs. Reference will be made to standard internationally recognized resources, e.g. International Union of Pure and Applied Chemistry (IUPAC) Compendium of Chemical Terminology, when considering these terms.

### **Arguable variations**

Molecules with arguable variations have a molecular structure that is similar to a previously approved medicinal ingredient, but that is not a variation enumerated in the definition of “innovative drug”.

The RMOD must identify whether or not the medicinal ingredient in the drug under consideration is a variation of a previously approved medicinal ingredient.

This is done by comparing the structure of the medicinal ingredient under consideration with previously approved medicinal ingredients that have similar structures. The group of previously approved medicinal ingredients is identified using the mechanism of action of the medicinal ingredient under consideration and the therapeutic class of drugs to which it belongs.

Once the group of previously approved medicinal ingredients with possible structural similarities has been identified, side-by-side comparisons are performed to look at the structures of the medicinal ingredient under consideration and the previously approved medicinal ingredients. Differences due to salt appendages or ester appendages are identified at this point. While the synthetic pathway used to produce a salt or ester variation can aid in the analysis, it is not in itself determinative. There is a concern that, if the test for a variation depends on the synthetic pathway, it may be possible to design and utilize a different route of synthesis in order to circumvent the regulatory intent of protecting new chemical entities.

Enantiomers, solvates and polymorphs are typically identified by comparing the name of the medicinal ingredient under consideration with the names of the previously approved medicinal ingredients.

If an arguable variation is identified, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data.

#### **2.2.2 Considerable effort**

Once it has been established that the drug contains a medicinal ingredient not previously approved in a drug by the Minister and that the medicinal ingredient is not a variation of a previously approved medicinal ingredient, it is necessary to assess the nature and extent of the data contained in the drug submission to ensure that approval is being sought on the basis of new and significant data (i.e. the product of considerable effort). This determination is also performed where a drug is found to contain a medicinal ingredient that is an arguable variation. New and significant data is characterized as that which provides the evidence to determine the safety, efficacy, properties, and conditions of use of the drug (e.g. pivotal clinical trials). However, drugs approved on the basis of literature references (e.g. articles published in peer-

reviewed journals, study reports of trials not conducted or sponsored by the submission applicant, books, consensus guidelines from professional bodies, etc.) and/or market experience (e.g. information concerning the product's safety profile from domestic and/or foreign markets, details of adverse reactions from foreign authorities, etc.) would not be considered eligible for data protection.

### 2.2.3 Conclusion

If a drug contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph, and approval is sought on the basis of data, the origination of which involved considerable effort, the drug will be considered eligible for data protection.

## 2.3 Product-line extensions and drugs containing the same medicinal ingredient as an innovative drug

In some cases a drug may contain one or more medicinal ingredient(s) that is/are the same as the medicinal ingredient(s) found in an innovative drug for which a data protection period is still in effect. Consistent with the intent of section C.08.004.1 to protect new chemical entities, these drugs will benefit from the same period of data protection as the innovative drug. The brand name of the drug(s) benefitting from the same period of protection as the innovative drug will be included on the Register of Innovative Drugs. In order to benefit from the data protection term, there must be a relationship to the innovative drug. This does not apply to subsequent-entry drugs which are typically considered "generic".

Combinations of previously approved medicinal ingredients are not eligible for data protection. The following scenarios are provided as examples:

Drug 'A' is an innovative drug that qualifies for an eight-year period of data protection ending January 1, 2022.

Drug 'B' is an innovative drug that qualifies for an eight-year period of data protection ending June 1, 2023.

Drugs 'C' and 'D' were each previously approved in Canada.

#### Example 1:

A new drug that includes the medicinal ingredients found in Drug 'A' and in Drug 'C' in combination is approved before the expiry of the original period of data protection for Drug 'A'. Data protection for Drug 'A' will also protect the combination until the expiry of the original data protection period for Drug 'A' on January 1, 2022.

#### Example 2:

A new combination drug containing the medicinal ingredients found in Drugs 'C' and 'D' is approved. However, it is not eligible for data protection.

#### Example 3:

A new combination drug containing the medicinal ingredient found in Drugs 'A' and 'B' will benefit from the terms of data protection for Drugs 'A' and 'B'. In this example, protection would extend to the expiry of the data protection period for Drug 'B' on June

1, 2023. The brand name of the new combination drug will be included on the Register of Innovative Drugs under the listing for both Drugs 'A' and 'B'.

Example 4:

Drug 'E' containing the same medicinal ingredient found in Drug 'A' is approved, manufactured by the same company as Drug 'A'. Drug 'E' will benefit from the same period of data protection as Drug 'A', but is not eligible for its own period of data protection.

Example 5:

Drug 'F' is a combination drug containing the same medicinal ingredient as Drug 'B' in combination with another previously approved medicinal ingredient. The drug submission for Drug 'F' cross-references data from the Drug 'B' submission, however Drug 'F' is manufactured by a different brand-name company than Drug 'B'. As there is a relationship between the two drugs, Drug 'F' will benefit from the same period of data protection as Drug 'B'.

## 2.4 Process

A manufacturer that believes that its drug qualifies as an innovative drug may submit any supporting information in module 1.2.4.2 - Data Protection Information, in accordance with the electronic Common Technical Document (eCTD) format or the non-eCTD electronic-only format. Please consult the Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format, Frequently Asked Questions - Common Electronic Submissions Gateway, the CESG Health Canada Reference Guide, and the Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format for more information.

The RMOD will prepare a preliminary assessment while the submission is under review to determine if the drug qualifies for data protection. The manufacturer will be notified of the assessment in writing. The result of the assessment will also be entered into the Drug Submission Tracking System. Manufacturers may access information about their own submission via the Drug Submission Tracking System - Industry Access. Where a dispute arises, a manufacturer will have the opportunity to provide representations in writing. In order to facilitate and ensure proper processing, representations must be submitted in eCTD or non-eCTD electronic-only format, as appropriate. The RMOD will consider the representations before a further assessment is made. Prior to the issuance of the NOC, only a preliminary acceptance can be given as the drug in question must remain the first to be approved with the specific medicinal ingredient. Should there be two manufacturers with products containing the same medicinal ingredient, only the first drug issued an NOC could qualify for the protection. Manufacturers are encouraged to consult the Submissions Under Review List to determine whether or not another submission for a particular medicinal ingredient is under review.

## 2.5 Requirement for marketing in Canada

As per subsection C.08.004.1(5) of the Food and Drug Regulations, protection for an innovative drug is only available where the innovative drug has received an NOC and is marketed in Canada. Where the drug is withdrawn by the innovative drug manufacturer from the market,

no protection will be offered. This is to prevent the situation where the marketed version of an innovative drug is withdrawn from the Canadian market by the innovative drug manufacturer, but no equivalent generic drug is allowed on the Canadian market until the data protection period has expired. The inactivation of a DIN in accordance with paragraph C.01.014.6(1)(a) will be accepted as an indication that the drug is no longer being marketed in Canada. The marketing status of the DIN will be confirmed by consulting the Drug Product Database. It is recognized that a drug may not be notified as per section C.01.014.3 of the Food and Drug Regulations immediately following the issuance of the NOC. Where there is insufficient evidence as to the marketing status of the drug, the innovative drug manufacturer will be contacted to confirm the status of the drug.

In the case of a DIN newly-issued due to a change in the manufacturer, data protection will continue to be provided for what remains of the period as long as the new product is marketed by the new manufacturer.

An innovative drug that is re-introduced to the market will receive protection from any subsequent entry submissions for the remainder of the original data protection term. However, if a manufacturer files a subsequent entry submission when the innovative drug is not marketed, the submission will proceed and be issued an NOC even if the innovative drug is later marketed and the period of protection is restored. If the manufacturer of the subsequent entry drug seeks approval on the basis of additional direct or indirect comparisons to the innovative drug, e.g. introduces new information, after the innovative drug is marketed, the data protection period will apply.

Drugs that benefit from the same period of data protection as an innovative drug (section 2.3 of this document) will only be protected while the innovative drug is marketed.

## 2.6 Register of Innovative Drugs

A Register of Innovative Drugs will be maintained in accordance with subsection C.08.004.1(9) of the Food and Drug Regulations. The Register of Innovative Drugs is intended to provide a measure of transparency.

The Register of Innovative Drugs, updated on a weekly basis, is posted on the Health Canada website at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs.html>.

Innovative drugs are added to the Register of Innovative Drugs after the issuance of the NOC. When an NOC issues for an administrative submission to change the manufacturer's name of an innovative drug, the RMOD will update the Register of Innovative Drugs with the new manufacturer name. If manufacturers have concerns over the listing of the innovative drug or the information provided on the Register of Innovative Drugs, please notify the RMOD.

## 2.7 Period of protection

The data protection period is eight years from the date of issuance of the first NOC for the innovative drug. Where the drug has qualified for a six-month pediatric extension, the period is extended to eight years and six months. See section 2.8 of this document for information on the six-month pediatric extension.

Within the protection period, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug will be prevented from filing its drug submission for the first six years of the eight-year period.

## 2.8 Pediatric extension

In addition to the eight-year period of data protection, an additional six-month pediatric extension will be applied if an innovative drug manufacturer includes, in its NDS, or any SNDS filed within the first five years of the eight-year data protection period, results of clinical trials which were designed and conducted for the purpose of increasing knowledge about the use of the drug in pediatric populations and which will lead to a health benefit for children. To qualify, the drug must be an innovative drug and be eligible for the eight-year period of data protection.

### **Submission of clinical trial data**

The threshold requirement provided in paragraph C.08.004.1(4)(a) of the Food and Drug Regulations is that the innovator must provide the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first NDS for the innovative drug or in any SNDS that is filed within five years after the issuance of the first NOC for that innovative drug.

“Clinical trial” is defined in Division 5 of the Food and Drug Regulations as “an investigation in respect of the drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug”. For the purposes of the six-month pediatric extension, the clinical trials must have been conducted in at least one of the three groups set out in the definition of “pediatric populations” in subsection C.08.004.1(1).

### **Designed and conducted to increase knowledge that provides a health benefit**

The next requirement, provided in paragraph C.08.004.1(4)(b) of the Food and Drug Regulations, is whether the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.

This design and conduct requirement can be broken into two elements:

- 1) Knowledge
- 2) Health benefit

### **Knowledge**

The extension of data protection for submitting the results of pediatric studies is intended to encourage sponsors to submit clinical trial data pertaining to the use of the drug in pediatric populations in order to maximize the information available for the benefit of children.

The study hypothesis, objectives, design and conduct will be used to determine if the clinical trial was developed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations.

In addition, studies must result in increased knowledge about the behaviour of the drug in pediatric populations in order to assist health professionals, parents, caregivers, and patients in making informed choices about drug therapy. In such cases, the knowledge is considered to be of the type that, once made available, can provide a health benefit to pediatric patients.

The knowledge requirement for the six-month pediatric extension does not contemplate knowledge that can only be used for the purpose of designing a future study.

### **Health benefit**

Provided that the knowledge requirement is met, a determination will be made as to whether or not that knowledge is available to provide a health benefit. At minimum, the knowledge must be available to the public, e.g. through the approved labelling or Product Monograph. It is not necessary that the published information leads to a pediatric indication. Where the clinical studies demonstrate that the drug should not be used in pediatric populations, the addition of contraindications and/or other warning statements in the labelling of the drug may be sufficient to warrant granting of the six-month pediatric extension. The nature of information needed to satisfy the requirement will be assessed on a case-by-case basis.

#### **2.8.1 Process**

The cover letter accompanying a submission should indicate when a manufacturer believes that its submission is eligible for the six-month pediatric extension. Supporting information may be placed in module 1.2.4.2 - Data Protection Information of the submission.

When an NDS for a drug that is eligible for data protection includes pediatric data, or when an SNDS that contains pediatric data for an innovative drug is filed, the RMOD will enter the document "Dataprotect Pediatr Check" in the Drug Submission Tracking System. Manufacturers may access information about their own submission via the Drug Submission Tracking System - Industry Access. A letter will not be sent to the manufacturer at the time of filing the submission to acknowledge the consideration of the six-month pediatric extension.

The determination of whether the drug is eligible for the six-month pediatric extension will be made following the review of the submission. If the determination is made that the drug is eligible for the six-month pediatric extension, the Register of Innovative Drugs will be updated accordingly. If the determination is made that the drug is not eligible for the six-month pediatric extension, a preliminary decision letter will be sent to the manufacturer and the manufacturer will be provided with an opportunity to make representations. If, after consideration of the representations received, the RMOD remains of the position that the drug is not eligible for the six-month pediatric extension, the manufacturer will be informed in writing. If the determination is to extend the data protection period by six months, the Register of Innovative Drugs will be updated accordingly.

In accordance with paragraph C.08.004.1(4)(b) of the Food and Drug Regulations, the Minister is required to make a determination whether the drug is eligible for the six-month pediatric extension before the end of six years after the day on which the first NOC was issued for the innovative drug.

Where the pediatric data is submitted by way of an SNDS, the review of the SNDS may not be complete within the six-year period, for example, if a Notice of Non-Compliance is issued for

the submission. In such cases, the RMOD will be required to assess the information available at that time to determine whether the drug is eligible for the six-month pediatric extension. If the RMOD determines preliminarily that the innovative drug is eligible for the six-month pediatric extension, the Register of Innovative Drugs will be updated to reflect the extension before the completion of the drug submission review in order to provide a measure of transparency for subsequent entry manufacturers. However, the RMOD will verify whether the submission has received an NOC by the end of the eight-year period of data protection to ensure that the health benefit requirement has been met. If the submission has not received an NOC, the eligibility for the six-month pediatric extension will be re-evaluated, and if the requirements of paragraph C.08.004.1(4)(b) have not been met, the six-month pediatric extension will be removed from the Register of Innovative Drugs.

### 3. Submissions comparing to innovative drugs

#### 3.1 Prevention from filing

In accordance with paragraph C.08.004.1(3)(a) of the Food and Drug Regulations, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug may not file a submission for six years from the date of issuance of the first NOC for the innovative drug. This language is intended to capture ANDSs and supplements to an abbreviated new drug submission (SANDSs), where the innovative drug is the Canadian Reference Product.

However, this paragraph is also intended to include NDSs and SNDSs seeking an NOC for a drug on the basis of a comparison to an innovative drug, including biosimilar drug submissions and submissions relying on third-party data.

A biosimilar must be subsequent to a biologic drug that is approved in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies. If the Canadian drug is an innovative drug, comparative submissions are considered to contain a comparison between the biosimilar and the innovative drug. These submissions will not be accepted for filing within the six-year period from the date of issuance of the NOC for the innovative drug.

NDSs which are based on independent clinical trials and not on a comparison to an innovative drug are not captured by subsection C.08.004.1(3). In addition, submissions that do not result in a subsequent entry version of the innovative drug are not captured by this subsection. For example, a submission for a drug indicated for use in combination with an innovative drug will not be prevented from filing.

#### 3.2 Prevention from approval

In accordance with paragraph C.08.004.1(3)(b) of the Food and Drug Regulations, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug will not be issued an NOC before the end of the period of eight years after the day on which the first NOC was issued for the innovative drug. The period will be lengthened to eight years and six months where the innovative drug qualifies for the six-month pediatric extension. Once the examination of the submission is complete, the manufacturer will be notified and an

invoice for the review of the submission will be issued, where applicable. The submission will be placed on Intellectual Property (IP) Hold as of that date. If the innovative drug is also listed on the Patent Register, upon expiration of the data protection period the submission will remain on IP Hold until the requirements of the Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) are met.

### 3.3 Consent to file a submission

In accordance with subsection C.08.004.1(6) of the Food and Drug Regulations, an innovative drug manufacturer may consent to the filing of a submission during the six-year no-filing period. A letter of consent to file the submission within the data protection period signed by the innovative drug manufacturer must be submitted with the submission.

### 3.4 Consent to the issuance of a Notice of Compliance

An innovative drug manufacturer may consent to the issuance of an NOC during the data protection period, per subsection C.08.004.1(8) of the Food and Drug Regulations. A letter of consent signed by the innovative drug manufacturer may be submitted with the submission of the authorized manufacturer or provided at a later time in eCTD or non-eCTD electronic-only format, as appropriate. The innovative drug manufacturer may provide consent to both the filing of a submission and the issuance of the NOC in the same letter.

### 3.5 Exemption under Canada's Access to Medicines Regime

An exemption from the six-year no-filing period has been created to allow a manufacturer to file a submission under Canada's Access to Medicines Regime under subsection C.08.004.1(7) of the Food and Drug Regulations.

Canada's Access to Medicines Regime provides a framework within which eligible countries can import less expensive generic versions of patented drugs and medical devices. Notwithstanding that a manufacturer may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, Health Canada will not grant an NOC providing Canadian market authorization unless the requirements for both data protection under section C.08.004.1 of the Food and Drug Regulations and the PM(NOC) Regulations have been met.

The introduction of the six-year no-filing period requires an exception to allow for the filing of drug submissions within the framework of Canada's Access to Medicines Regime. As a result, subsection C.08.004.1(7) provides an exemption where an application is filed pursuant to section C.07.003 of the Food and Drug Regulations.

Where second person submissions are filed within the six-year period, the date of filing for the purpose of the PM(NOC) Regulations is deemed to be six years after the date of issuance of the first person's NOC. Please see Health Canada's Guidance Document: Patented Medicines (Notice of Compliance) Regulations for details.

### 3.6 Process

When it appears that the filing of a submission is prevented, the manufacturer will be provided with a written preliminary decision and an opportunity to make representations in response. If, following consideration of the representations, the RMOD remains of the view that the submission cannot be filed, the manufacturer will be notified and the submission will not be



processed further. In order to facilitate and ensure proper processing, representations or other information must be submitted in eCTD or non-eCTD electronic-only format, as appropriate. Please consult the Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format, the Frequently Asked Questions - Common Electronic Submissions Gateway, the CESG Health Canada Reference Guide, and the Guidance Document: Preparation of Drug Regulatory Activities in the “Non-eCTD Electronic-Only” Format for more information.

## 4. Inquiries

Inquiries regarding a particular listing on the Register of Innovative Drugs should be sent to the RMOD at the address below.

The RMOD will endeavour to respond to inquiries by providing, whenever possible, information that is in the public domain. Confidential submission information, however, will not be provided.

As discussed in section 2 in this document, a drug is eligible for data protection if it meets the definition of an innovative drug. Data protection for the innovative drug applies only where an innovative drug has received an NOC and is marketed in Canada.

Letters challenging the innovative drug’s status will be provided to the manufacturer of the innovative drug. Therefore, inquiries cannot be accepted if marked ‘confidential’. In order to ensure a transparent process, the RMOD will provide its response to the inquiry to both the inquirer and the innovative drug manufacturer, with an opportunity to make representations prior to a final decision.

All inquiries, including on electronic media, should be sent to the OPML within the Office of Submissions and Intellectual Property (<https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/resource-management-operations-directorate.html#a4>).

## Appendices

### Appendix 1 - Acronyms

ANDS	Abbreviated New Drug Submission
CAMR	Canada's Access to Medicines Regime
DIN	Drug Identification Number
HPFB	Health Products and Food Branch
NAFTA	North American Free Trade Agreement
NDS	New Drug Submission
OPML	Office of Patented Medicines and Liaison
RMOD	Resource Management and Operations Directorate
SANDS	Supplement to an Abbreviated New Drug Submission
SNDS	Supplement to a New Drug Submission
TRIPS	Trade Related Aspects of Intellectual Property Rights Agreement
WTO	World Trade Organization

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<sup>1</sup> Veterinary products that fall under the *Health of Animals Act* S.C. 1990, c.21 are not within the scope of this Guidance.