Health Canada Santé Canada

September 28, 2012

Notice

Our file number: 12-116582-662

Revisions to the Draft Guidance Document: The Use of Foreign Reviews by Health Canada* and *revisions to the Use of Foreign Reviews pilot project

The purpose of the *Draft Guidance Document: The Use of Foreign Reviews by Health Canada* is to provide guidance to market authorization holders on how Health Canada uses foreign reviews, and how they can help facilitate this use. All final decisions on the market authorization of health products will be made by Health Canada.

Since October 2011, Health Canada has implemented the pilot project on the Use of Foreign Reviews and this pilot will continue to March 31, 2013.

The Therapeutic Products Directorate (TPD) has also recently launched the *Generic Drugs Foreign Review Pilot*. It should be noted that the Generic Drugs Foreign Review Pilot falls under and is consistent with the objectives of the larger *Use of Foreign Reviews by Health Canada* initiative.

Throughout the pilot phase, Health Canada has received internal and external comments and suggestions for consideration to improve the project. The following are the changes that Health Canada will be implementing for the *Use of Foreign Reviews by Health Canada* project and pilot.

To increase the ease of obtaining the 'Foreign Review Attestation Template', Health Canada has posted the forms on its website. The 'Foreign Review Attestation Template' for generic drugs can be found at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/for_rev-exam_etr/foreign_rev_sdq_exam_etra_dtq-eng.php. The 'Foreign Review Attestation Template' for all other health products can be found at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/for_rev-exam_etr/foreign_rev_attest_exam_etra-eng.php. Information on the 'Foreign Review Attestation Template' is also provided in the *Draft Guidance Document: The Use of Foreign Reviews by Health Canada*.

For the purposes of this pilot, it should be noted that under the *Draft Guidance Document: The Use of Foreign Reviews by Health Canada,* Section 2.4.2.3, "Market Authorization Holder's Attestation", will no longer be applicable during the pilot. A 'Foreign Review Attestation Template' will only be required when a foreign review is provided.

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For assistance on where to file the foreign review and 'Foreign Review Attestation Template', please refer to sub heading, 2.4.2.2 in the *Draft Guidance Document: The Use of Foreign Reviews by Health Canada* for suggested locations.

It should be noted that Module 1.2.7, of the *Guidance Document: Preparation of Drug Regulatory Activities in the Common Technical Document (CTD) Format,* is where sponsors should provide international information on the product such as the application status of the product in another jurisdiction. The *Guidance Document: Preparation of Drug Regulatory Activities in the Common Technical Document (CTD) Format* can be found at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/ctd_prep_nds-eng.php.

To assist Health Canada in identifying international information in submission files, we would request sponsors to specify in the cover letter of the submission whether a foreign review is included and if included, identify which foreign regulatory authority produced the review, and where the foreign review and 'Foreign Review Attestation Template' are located in the submission. If a foreign review is not included with the submission, we would request that the sponsor provide additional international information in the cover letter, such as, whether or not a similar submission was submitted to another foreign regulator and if yes, which regulatory authority is conducting the review, and the status of the review.

Health Canada understands that at times it may be difficult to receive a review from a foreign authority and as such, Health Canada will accept to receive foreign reviews directly from the foreign authority at the request of the sponsor. The sponsor is responsible to contact the foreign regulator to request that the foreign review be sent directly to Health Canada.

The scope of the pilot for the Use of Foreign Reviews has been revised to include the following data packages:

- New Drug Submissions (drugs);
- Abbreviated New Drug Submissions (drugs);
- Supplement to a New Drug Submissions (drugs);
- Supplement to an Abbreviated New Drug Submissions (drugs);
- Drug Identification Number Applications (drugs);
- Class III and IV Licence Applications (medical devices);
- Class III and IV Licence Amendment Applications (medical devices);

Notifiable Changes (drugs), Risk Management Plans (drugs), Periodic Safety Update Reports and evidence provided to confirm the continued safety and effectiveness of a marketed product (drugs and medical devices) are also included.

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Market authorization holders are encouraged to submit foreign reviews for these types of data packages concerning human and veterinary biologics[1], disinfectants, radiopharmaceuticals and pharmaceuticals, and medical devices.

The development of this draft guidance document is the result of a thorough survey of existing Canadian legislation, regulations, guidance documents, policies and current practices within Health Canada.

In order to test the principles and practices described here during the pilot phase, this guidance document will not be finalized until fiscal year 2013-2014. Therefore, comments may be submitted until March 31, 2013.

Comments should be provided to Health Canada, preferably in electronic format. All comments will be considered in the finalization of the draft guidance.

Comments should be directed to:

Use of Foreign Regulatory Information Steering Committee
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Health Canada
Graham Spry Building 2004A
250 Lanark Avenue
Ottawa, Ontario
K1A 0K9

Facsimile: (613) 954-9981
E-mail: UFRI_URRE@hc-sc.gc.ca

[1] Except veterinary vaccines, as stipulated in the *Health of Animals Act*

Health Canada Santé Canada

DRAFT GUIDANCE DOCUMENT

The Use of Foreign Reviews by Health Canada

This guidance document is being distributed for comment purposes only.

Published by authority of the
Minister of Health

Draft Date	2012/09/11

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related to health 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 : *Ébauche de la ligne directrice : L'utilisation des examens étrangers par Santé Canada*

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's 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.

TABLE OF CONTENTS

1. INTRODUCTION

Health Canada strives to take into consideration the efforts, experience, and expertise of its peer regulatory agencies through many collaborative activities. These include participation in multi-national groups like the International Conference on Harmonisation (ICH), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH), and the Global Harmonization Task Force (GHTF), as well as through the development of bilateral arrangements such as Memoranda of Understanding and confidentiality arrangements.

This guidance is intended to inform industry of the procedures to follow when including a foreign review in applications, submissions, and other data packages such as Periodic Safety Update Reports (hereafter collectively referred to as data packages) filed with Health Canada.

It also provides clarification to sponsors and applicants (hereafter collectively referred to as market authorization holders) on the way in which the Therapeutic Products Directorate (TPD), the Biologics and Genetic Therapies Directorate (BGTD), the Marketed Health Products Directorate (MHPD), and the Veterinary Drugs Directorate (VDD) will use foreign reviews in the regulatory review of health products for marketing authorization.

1.1 Policy Objectives

Health Canada is now implementing the necessary framework to make optimal and more consistent use of foreign reviews in the regulatory review of health products in Canada in order to:

- enhance the quality of Health Canada regulatory assessments; and
- assist Health Canada in meeting performance targets for regulatory assessments while maintaining;
- the integrity of Health Canada's regulatory review process; and
- Canadians' timely access to safe, efficacious and high quality health products.

1.2 Scope and Application

The principles and practices outlined in this document apply to human and veterinary biologics[2], disinfectants, radiopharmaceuticals and pharmaceuticals (hereafter collectively referred to as drugs), and medical devices. The following data packages are included within the scope:

- New Drug Submissions (drugs);
- Abbreviated New Drug Submissions (drugs);

[1] Except veterinary vaccines, as stipulated in the *Health of Animals Act*

- Supplement to a New Drug Submissions (drugs);
- Supplement to a Abbreviated New Drug Submissions (drugs);
- Drug Identification Number Applications (drugs);
- Class III and IV Licence Applications (medical devices);
- Class III and IV Licence Amendment Applications (medical devices);
- Notifiable Changes (drugs);
- Risk Management Plans (drugs); and
- Periodic Safety Update Reports (drugs).

The BGTD, Therapeutic TPD, MHPD, and VDD are the directorates involved.

Foreign reviews from regulatory authorities in the United States of America [Food and Drug Administration (FDA) and Environmental Protection Agency (EPA)] and from the European Union's centralized procedure [European Medicines Agency (EMA)] should be provided. The use of foreign reviews from other regulatory authorities may also be considered [for example (e.g.) Switzerland's Swissmedic; Australia's Therapeutic Goods Administration (TGA); and Singapore's Health Sciences Authority (HSA)].

Canadian data packages shall contain all the information and material normally submitted, regardless of the existence of foreign review(s) in the data package.

Health Canada has published numerous guidance documents and policies to assist market authorization holders in the preparation and filing of drug and medical device data packages, for example, the *Guidance on the Management of Drug Submissions* and the *Guidance on Post-Notice of Compliance (NOC) Changes: Safety and Efficacy*, among others. Market authorization holders should refer regularly to the Health Canada website for applicable guidance documents.

1.3 Background

The use of foreign reviews in Health Canada is not new. Over the past 20 years, a series of studies have recommended greater use of foreign review reports. During this period, foreign regulatory information has been considered and used inconsistently on an ad hoc basis. Health Canada is now formalizing the practice in areas that already use foreign reviews, extending the practice to areas that currently do not, and standardizing the practice across the Health Products and Food Branch.

2. GUIDANCE FOR IMPLEMENTATION

2.1 Guiding Principles

Health Canada will adhere to the following guiding principles when using foreign reviews:

a. Although the use of foreign reviews may enhance timely access to high quality health products, it is essential that benefit-risk assessments of health products be made within the context of the Canadian health care system. **Final regulatory decisions on the granting or removal of marketing authorization of health products for Canadians must be made by Health Canada.**

b. The *Food and Drug Regulations* and the *Medical Devices Regulations* do not prevent Health Canada from using, where appropriate, foreign reviews to perform part of the evaluation or to inform Health Canada's decision-making. However, Health Canada cannot grant (or refuse to grant) marketing authorization based solely on the existence of a foreign review and its corresponding regulatory decision.

c. The use of foreign reviews may be applicable, to variable degrees, to the regulatory review of health products covered under the scope of this initiative and when available, will be considered when determining the review strategy. However, a market authorization holder cannot be required to file a foreign review, nor can Health Canada unilaterally decide to delay the Canadian review until a foreign review is available.

d. The extent to which a foreign review may be used to inform Health Canada's regulatory decision on a health product will be guided by Health Canada's estimation of the benefits and risks/limitations of using a foreign review (or components thereof) to inform the Canadian regulatory decision making process.

2.2 Operating Principles

Health Canada will adhere to the following operating principles when using foreign reviews:

a. In all cases, it is review management's responsibility to decide on the appropriate method for using a foreign review, in accordance with Health Canada standard operating procedures.

b. Due to the variety of products regulated by Health Canada, different review areas [that is (i.e.) Directorates, Bureaus, Divisions] will focus on different regulatory authorities, products, data package types, and review disciplines in order to optimize their use of foreign reviews.

c. Wherever possible, the foreign review(s) should be provided by the market authorization holder when the data package is filed with Health Canada or during the screening phase (i.e. prior to assigning the data package to a reviewer).

d. If the foreign review is not available from the market authorization holder, Health Canada may request it directly from the foreign regulator.

e. If the foreign review(s) is/are provided directly to Health Canada by the market authorization holder, the market authorization holder should confirm in writing that the review(s) provided is/are complete and unaltered.

f. The market authorization holder should confirm in writing that the documentation filed in the data package is identical to that on which the foreign marketing review and authorization decision was based. If it is not identical, all differences should be clearly indicated.

g. In all cases, the Canadian product labeling (e.g. Product Monograph, package insert) will be reviewed by Health Canada to ensure it meets Canadian requirements, in accordance with the *Food and Drug Regulations* and the *Medical Devices Regulations*, applying Health Canada standard operating procedures and current practices.

h. As with other information filed in data packages, foreign reviews provided with the data packages will be subject to the same protection regarding confidential business information and Access to Information requests.

2.3 Methods for the Use of Foreign Reviews

The extent to which Health Canada uses foreign reviews will vary. Health Canada will apply four methods to the use of foreign reviews. Each method may be used for the review of the entire data package (except labeling) or for (a) component(s) of the data package. Different methods may be used for different components of a data package.

The four methods are:

Method 1
The Canadian regulatory decision (on the entire data package or component thereof) is based on a critical assessment of the foreign review.

Method 2
The Canadian review is based on a critical assessment of the foreign review, referring to the data filed in Canada as necessary. The Canadian regulatory decision (on the entire data package or component thereof) is based on the Canadian review.

Method 3
The Canadian review is based on a critical assessment of the Canadian data package, with the foreign review as an added reference. The Canadian regulatory decision (on the entire data package or component thereof) is based on the Canadian review.

Method 4
The Canadian review is based on a critical assessment of the Canadian data package. The foreign review is not referenced, because it does not address Canadian regulatory requirements or is otherwise not relevant. The Canadian regulatory decision (on the entire data package or component thereof) is based on the Canadian review.

Some of the factors which may inform the choice of method selected could include the degree of similarity between the foreign and Canadian regulatory frameworks, the degree of similarity between the product reviewed and the product proposed for the Canadian market, existence of any Canadian-specific considerations for the proposed product (e.g. disease prevalence, clinical practices, reference products) and the level of detail of the foreign review.

2.4 Filing a Foreign Review with Health Canada

2.4.1 Foreign Review Components

See Appendix II for a list of the documentation that could form a foreign review from specific regulatory authorities. The list is not exhaustive and additional documentation could be included from the authorities listed, and foreign reviews from additional authorities could be provided.

2.4.2 Filing the Foreign Review

Full Canadian data packages, in accordance with the *Food and Drug Regulations*, *Medical Devices Regulations* and related Health Canada guidance documents, are still required. Submission of a foreign review is in addition to, and should accompany, components of the full Canadian data package currently required by Health Canada. The foreign data package should not be sent to Health Canada in addition to the Health Canada data package.

Foreign reviews should be provided in either French or English. If the original language of the foreign review is not French or English, it may be provided translated to French or English. In this case it should be accompanied by an attestation of the accuracy and validity of the translation and a copy of the original foreign review in the original language.

Foreign reviews from both positive and negative outcomes should be provided.

2.4.2.1 Timing

Market authorization holders are strongly encouraged to continue to file data packages in a timely fashion, regardless of whether a foreign review has been completed or is in the process of being completed. Health Canada will not delay review until a foreign review is available.

Market authorization holders are requested to include copies (preferably searchable, electronic copies) of all available EMA, United States EPA, and United States FDA reviews in the data package, at time of filing. Reviews from other foreign regulators may also be provided and considered for use by Health Canada.

If a foreign review only becomes available after the data package has been filed in Canada, the market authorization holder may still provide it to Health Canada. However, depending on when the foreign review is received, it is possible that it will not assist the Canadian review and therefore may not be used or considered.

For human biologics, radiopharmaceuticals, and pharmaceuticals, it should be noted that the *Guidance on Management of Drug Submissions* indicates that foreign reviews should be submitted within 120 days of receipt of the original submission filing.

For all products, copies of the actual correspondence between the market authorization holder and other regulatory authorities may be submitted at any time.

2.4.2.2 Location

The following table provides the suggested locations of the foreign review within the Canadian data package:

Data Package	**Location of Attestation and Foreign Review**
Human Drugs: • New Drug Submissions; • Abbreviated New Drug Submissions; • Supplement to a New Drug Submissions; • Supplement to a Abbreviated New Drug Submissions; • Notifiable Changes.	Module 1, Section 1.2.7: International Registration Status.

Human Drugs: • Risk Management Plans (filed directly with the Marketed Health Products Directorate, outside of one of the above submissions).	Listing in Table of Contents and Appendix to the data package.
Human Drugs: • Drug Identification Number Applications.	Module 1, Section 1.2.7: International Registration Status if applicable, or Listing in Table of Contents and Appendix to the data package.
Veterinary Drugs: • New Drug Submissions; • Abbreviated New Drug Submissions; • Supplemental New Drug Submissions; • Supplemental Abbreviated New Drug Submissions.	Part I: Foreign Registration Information.
Veterinary Drugs: • Drug Identification Number Applications; • Notifiable Changes.	Listing in Table of Contents and Appendix to the data package.
All Drugs: • Periodic Safety Update Reports.	Listing in Table of Contents and Appendix to the data package.
Medical Devices: • Class III and IV Licence Applications; • Class III and IV Licence Amendment Applications.	Listing in Table of Contents and Appendix to the data package.

2.4.2.3 Market Authorization Holder's Attestation

Regardless of the existence of foreign review(s), market authorization holders should provide a signed attestation (see Appendix III) with all data packages described in the scope of this guidance. Whether a foreign review is provided with the data package or not, the attestation provides useful information on the registration status of the product in other countries. If a signed attestation has not been provided when the data package is filed, Health Canada will request a copy from the market authorization holder.

2.4.2.4 Additional Foreign Information

If available, the authorized labeling used in the European Union and the United States should also be provided, in either English or French, preferably in electronic format only. Labeling from other jurisdictions may also be provided (in English or French) and considered for use by Health Canada.

For human and veterinary biologics[3], radiopharmaceuticals and pharmaceuticals, it should be noted that the *Guidance on Post-Notice of Compliance (NOC) Changes: Safety and Efficacy* indicates that the following should be provided in support of changes to drugs authorized for marketing:

- copies of the most recent labels authorized in other major regulatory jurisdiction(s), and correspondence or communications with the foreign regulator(s) (Levels I and II);
- wording of any related instructions or communications (translated into English or French if necessary) to Health Care Professionals that may have been or is currently required in other major regulatory jurisdictions or a statement confirming that such instructions or communications have not been required by other authorities (Level II).

[2] Except veterinary vaccines, as stipulated in the *Health of Animals Act.*

APPENDICES

I. GLOSSARY

Data Package
For the purposes of this document: a formal submission or application to a regulatory authority in order to obtain a regulatory decision or to maintain regulatory status for a health product. In Canada, data as per the *Food and Drug Regulations* or *Medical Devices Regulations*, or other information filed for review by Health Canada (e.g. Notifiable Changes, Risk Management Plans filed independently of a submission, Periodic Safety Update Reports).

Data Package Component
For the purposes of this document: a portion of the scientific safety, efficacy, and quality data provided (e.g. chemistry and manufacturing data, toxicology study data, etc.).

Drugs
For the purposes of this document: human and veterinary biologics[4], disinfectants, radiopharmaceuticals and pharmaceuticals.

EMA
European Medicines Agency is a decentralised body of the European Union (EU), located in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (centralised procedure). Under the centralised procedure, companies submit a single marketing-authorisation application to the Agency. Once granted by the European Commission, a centralised (or 'Community') marketing authorisation is valid in all EU and European Economic Area-European Free Trade Association (EEA-EFTA) states (Iceland, Liechtenstein and Norway).

Foreign Reviews (also referred to as foreign review reports)
Scientific safety, efficacy, and quality reports prepared by foreign regulatory authorities, upon which foreign regulatory decisions on health products are based. Includes initial scientific assessments, regulatory correspondence with the sponsor/applicant, follow-up assessments, and the final decision (e.g. positive, negative, conditional). Includes, where applicable, risk management plans and on-site evaluation reports (or equivalent). Does not include the data package filed with the foreign regulatory authority.

[3] Except veterinary vaccines, as stipulated in the *Health of Animals Act.*

Labeling
For the purposes of this document: package labels and all other related documentation provided to health care professionals and consumers (e.g. Canadian Instructions for Use, Summary of Product Characteristics in the European Union, Product Information Leaflet in the United States, etc.).

Market authorization holder
For the purposes of this document: a person or company who files a submission, application, or other information for review by Health Canada, in order to obtain a regulatory decision or to maintain regulatory status (includes sponsors and applicants).

Regulatory Framework
Health product scientific safety, efficacy, and quality requirements from Acts and Regulations, as well as instructions in other documents which describe how to comply with governing Acts and Regulations (e.g. guidance documents, policies, etc.).

United States EPA
The United States Environmental Protection Agency licenses or registers pesticides (including disinfectants which are regulated as drugs in Canada) for use in strict accordance with label directions, based on review of scientific studies on the pesticide to determine that it will not pose unreasonable risks to human health or the environment.

United States FDA
The Food and Drugs Administration is an agency within the United States Department of Health and Human Services. The FDA is responsible for protecting public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, the nation's food supply, cosmetics, dietary supplements, and products that give off radiation.

II. LIST OF FOREIGN REVIEW COMPONENTS

(The table is not comprehensive with respect to regulatory authorities.)

Regulatory Authority	Documentation
European Medicines Agency (Human and Veterinary Drugs)	• Day 70 (Veterinary) or 80 (Human) Quality, Non-Clinical, Clinical, and Overview Assessment Reports; • Day 120 List of Questions; • Day 150 Quality, Non-Clinical, Clinical, and Overview Assessment Reports; • Day 160 (Veterinary) or 180 (Human) Joint Assessment Report; • Day 180 List of Outstanding Issues; • Final Assessment Report; • Summaries of meetings with the European Medicines Agency and/or Assessors; • Committee for Medicinal Products for Veterinary Use (CVMP) or Committee for Medicinal Products for Human Use (CHMP) Summary of Opinion; • CVMP Assessment (Veterinary Drugs); • Questions from the Regulator to the Market Authorization Holder; • Letter of Undertaking; • European Commission Decision; • Risk Management Plan Review(s); • Post Marketing Review(s).
United States Environmental Protection Agency (Disinfectants)	To be determined.
United States Food and Drug Administration (Human Pharmaceuticals)	• Medical Review(s); • Chemistry Review(s); • Pharmacology Review(s); • Statistical Review(s); • Clinical Pharmacology Biopharmaceutics Review(s); • Risk Assessment and Risk Mitigation Review(s); • Administrative Document(s) and Correspondence; • Cross Discipline Team Leader Review; • Office Director Memo; • Summaries of meetings with the United States Food and Drug Administration;

	• Summary Review; • Complete Response Letter; • Approval Letter; • Post Marketing Reviews.
United States Food and Drug Administration (Human Biologics)	• Discipline Review Memo(s) (e.g. clinical, chemistry and manufacturing, statistical, etc.); • Management Memos; • Summaries of meetings with the United States Food and Drug Administration; • Summary Basis of Regulatory Actions; • Complete Response Letter; • Approval Letter; • Other letters (Proprietary Name Review, pediatric, etc.); • Post Marketing Reviews.
United States Food and Drug Administration (Medical Devices)	• Engineering (all disciplines) Review; • Software Review; • Biocompatibility Review; • Sterilization/Shelf Life Review; • Toxicology Review; • Magnetic Resonance Imaging (MRI) Compatibility Review; • Consulting Reviews; • Labeling Review; • Manufacturing Review and Correspondence; • Bioresearch Monitoring Review and Correspondence; • Advisory Panel Information; • Advisory Panel Member Review; • Deficiency Letters; • Post Approval Study Review; • Cross United States Food and Drug Administration Center Reviews (for Combination Products).
United States Food and Drug Administration (Veterinary Drugs)	• Technical Section Reviews (e.g. Human Food Safety, Target Animal Safety, etc.); • Approved Labeling; • Approved “Freedom of Information Summary”; • Questions from the Regulator to the Market Authorization Holder; • Post Marketing Review(s).

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III. SAMPLE COMPLETED FOREIGN REVIEW ATTESTATION TEMPLATE

A **blank Foreign Review Attestation template** is available in Portable Document Format (PDF) on the Health Canada website. If there is difficulty in downloading the **blank Foreign Review Attestation template**, please contact the Use of Foreign Regulatory Information Steering Committee at UFRI_URRE@hc-sc.gc.ca. A sample completed template is provided here for reference.

Foreign Review Attestation

Complete parts 1, 2, and 7 for all products and parts 3, 4, 5, and 6 as applicable. Delete parts that are not applicable.

Part 1 - Canadian Product Information

Brand or Proprietary or Product Name (should be the same as the brand name on the product label): XYZ™	
Market Authorization Holder Name: ABC Inc.	
Application / Submission / Data Package Type: New Drug Submission	Filing Date: March 1, 2011

Part 2 - Foreign Product Information

European Medicines Agency European Product Name: XYZ™ Date of Filing: January 1, 2009	1. Data package filed? X Yes ☐ No 2. Regulatory decision issued? X Yes ☐ No 3. Review provided? If yes, go to part 3 X electronic X paper ☐ none 4. Is / Are indication(s) for use filed with the foreign regulator identical to that requested in Canada? X Yes ☐ No ☐ Not applicable
Environmental Protection Agency American Product Name: Not applicable Date of Filing: Not applicable	1. Data package filed? ☐ Yes X No 2. Regulatory decision issued? ☐ Yes X No 3. Review provided? If yes, go to part 4 ☐ electronic ☐ paper X none 4. Is / Are indication(s) for use filed with the foreign regulator identical to that requested in Canada? ☐ Yes ☐ No X Not applicable

Food and Drugs Administration American Product Name: LMN™ Date of Filing: March 2, 2011	1. Data package filed? X Yes ☐ No 2. Regulatory decision issued? ☐ Yes X No 3. Review provided? If yes, go to part 5 ☐ electronic ☐ paper X none 4. Is / Are indication(s) for use filed with the foreign regulator identical to that requested in Canada? X Yes ☐ No ☐ Not applicable
Other (specify): TGA, Australia Other Product Name (specify): LMN™ Date of Filing: March 1, 2011	1. Data package filed? X Yes ☐ No 2. Regulatory decision issued? ☐ Yes X No 3. Review provided? If yes, go to part 6 ☐ electronic ☐ paper X none 4. Is / Are indication(s) for use filed with the foreign regulator identical to that requested in Canada? X Yes ☐ No ☐ Not applicable

Part 3 - European Medicines Agency (EMA) Review (Human and Veterinary Drugs)
EMA documents provided (see Appendix I of Guidance Document on The Use of Foreign Reviews by the Health Products and Food Branch): Day 80 Quality, Non-Clinical, Clinical, and Overview Assessment Reports Day 120 List of Questions Day 150 Quality, Non-Clinical, Clinical, and Overview Assessment Reports Day 180 Joint Assessment Report Day 180 List of Outstanding Issues Final Assessment Report Risk Management Plan Review Committee for Medicinal Products for Human Use (CHMP) Summary of Opinion
Differences between EMA and Health Canada data packages: Quality: Same except capsule markings, which use the same ink. Non-Clinical: Identical. Clinical: One additional study provided in Health Canada data package, CCV-42.

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Part 7 - Signed Attestation		
I, the undersigned, certify that 1. the information and material included in this attestation is accurate and complete; 2. the foreign review(s) provided is (are) the complete and unaltered review(s) provided to us by the foreign regulator; 3. all differences between the data packages filed with Health Canada and the foreign regulator(s) (upon which the foreign review(s) and marketing authorization decision(s) was (were) based) have been identified.		
Name of Authorized Signing Official: Jane Doe	Signature:	Date: March 1, 2011
Title, Company: Vice-President, Medicines ABC Inc.	Email Address: jane.doe@ABC.com	Telephone Number: 555-867-5309

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