Health Canada Santé Canada

Guidance Document

Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Questions-réponses : Le règlement sur l'étiquetage en langage clair pour les médicaments sur ordonnance

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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Document change log

Version	Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs --- document	**Replaces**	Guidance Document Questions and Answers: Plain Language Labelling Regulations
Date	April 1, 2020 (posted March 23, 2020)	**Date**	June 13, 2015

Version	Location of Change	Change Made	Effective Date
1	not applicable	• Initial Issuance of Guidance	2015/06/13
2	Section 5: Mock-up Requirement Clarification around DIN-As and DIN-Bs	• Removal of Notifiable Change (NC) and post-authorization Division 1 Change (PDC) submissions from the mock-up requirement	2016/02/02
3	Section 5: Mock-up Requirement	• Clarification around the submission of annotated text for Notifiable Changes.	2016/04/12
4	Section 5: Mock-up Requirement	• Reorganization of section on mock-ups • Inclusion of text on recommended font size for labels and package inserts • Addition of requirement to declare font size and style for labels and to provide a rationale, if expected font size is not met • Removal of requirement to submit package inserts for Notifiable Change/Post-authorization Division 1 Change submissions	2016/09/08
5	Appendices	• Addition of guidelines on abbreviated package inserts added as an Appendix	2016/09/08
6	Changes throughout and Section 5	• Revisions to clarify existing content and clarify what types of Plain Language Labelling changes should be submitted for review and what are considered Level III / Post-authorization Division 1 Notification,	2019/08/08

Version	Location of Change	Change Made	Effective Date
		and capture Division 1 submissions within this document.	
7	Changes throughout and Section 5	• Revisions to accommodate change of Notifiable Changes to Supplemental (Abbreviated) New Drug Submissions.	2020/02/15

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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Section 1: Overview

1.1 What is the purpose of this document?

This document provides information for industry on how Health Canada's Health Products and Food Branch interprets and applies the 2014 Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use) for prescription products and those administered or obtained through a health professional. Please note that this includes prescription pharmaceutical drugs, biologic drugs (Schedule D), and radiopharmaceuticals (Schedule C). This document does not address implementation for non-prescription products, which are addressed under the Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs.

Note: the 2014 regulatory amendments are commonly referred to as Plain Language Labelling (PLL) in the Food and Drug Regulations, hereon referred to as the Regulations.

1.2 What are the Regulations and what is their purpose?

The Regulations aim to improve the safe use of drugs by making drug labels and packaging easier to read and understand. The Regulations impose obligations on health product sponsors to:

- provide information in plain language
- assess the name of their health products to avoid confusion
- submit mock-ups of labels and packages for review
- indicate how to report harms on their product's label
- provide information in an easy-to-read format

While these obligations form a coherent set of regulatory obligations, not all of these obligations will apply to all health products and some obligations came into effect at a different date (i.e., non-prescription drugs).

1.3 What products are within the scope of the Regulations?

The Regulations apply to prescription and non-prescription pharmaceutical drugs, biologic drugs, and radiopharmaceuticals. However, there are also specific requirements that only apply to non-prescription drugs that are outlined in the Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs. These Regulations do not apply to medical devices, veterinary drugs, or natural health products.

1.4 When do the Regulations come into force?

The Regulations for prescription pharmaceutical drugs, biologic drugs, and radiopharmaceuticals and those administered or obtained through a health professional, came into force on June 13, 2015.

1.5 Will the Regulations be applied retroactively?

No. New requirements will be applied to submissions received on or after the coming into force dates.

Health Canada expects that over time, labels and packages will be updated to reflect the new requirements as part of the natural cycle of label and package revisions.

Section 2: General Plain Language Requirement

Section A.01.017 of the Regulations: Every label of a drug for human use in dosage form shall meet the following conditions:

(a) the information that is required by these Regulations to appear on the label shall be

(i) prominently displayed on it,

(ii) readily discernible to the purchaser or consumer under the customary conditions of purchase and use, and

(iii) expressed in plain language; and

(b) the format of the label, including the manner in which its text and any graphics are displayed on it, shall not impede comprehension of the information referred to in paragraph (a).

2.1 What is the purpose of the general plain language requirement?

This broad requirement is intended to ensure that information on labels of drugs for human use can be easily understood by the target audience and that the format or presentation of labels does not impede comprehension. It underpins the more specific requirements included in the Regulations.

Section 3: Brand Name Assessment Requirement

Section C.01.014.1 (2) of the Regulations: An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

a) in the case of a drug for human use, an assessment as to whether there is a likelihood that the drug will be mistaken for any of the following products due to a resemblance between the brand name that is proposed to be used in respect of the drug and the brand name, common name or proper name of any of those products:

(i) a drug in respect of which a drug identification number has been assigned,

(ii) a radiopharmaceutical, as defined in section C.03.201, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01, and

(iii) a kit, as defined in section C.03.205, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01.

Section C.08.002(2) of the Regulations: A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

b) in the case of a new drug for human use, an assessment as to whether there is a likelihood that the new drug will be mistaken for any of the following products due to a resemblance between the brand name that is proposed to be used in respect of the new drug and the brand name, common name or proper name of any of those products:

> (i) a drug in respect of which a drug identification number has been assigned,
>
> (ii) a radiopharmaceutical, as defined in section C.03.201, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01, and
>
> (iii) a kit, as defined in section C.03.205, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01.

Section C.08.003(3.1) of the Regulations: A supplement to a submission referred to in subsection (1) shall contain, as the case may be,

c) if the supplement concerns the brand name of a new drug for human use:

> (i) an assessment as to whether there is a likelihood that the new drug will be mistaken for any of the following products due to a resemblance between the brand name that is proposed to be used in respect of the new drug and the brand name, common name or proper name of any of those products:
>
> > (A) a drug in respect of which a drug identification number has been assigned,
> >
> > (B) a radiopharmaceutical, as defined in section C.03.201, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01, and
> >
> > (C) a kit, as defined in section C.03.205, in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01

3.1 What is the purpose of the brand name assessment requirement?

This requirement obliges sponsors to provide Health Canada with evidence that a drug will not be confused with another drug because of similar names.

3.2 How are brand names assessed by Health Canada?

Health Canada conducts a brand name assessment in accordance with the Guidance Document: Review of Drug Brand Name Guidance that outlines how a proposed brand name of the drug is reviewed against the brand name, common name or proper name of other authorized health products, including natural health products.

3.3 What is the meaning of Look-Alike Sound-Alike (LASA) health product names?

Look-alike sound-alike (LASA) health product names refer to names of different health products that are similar when written or spoken. These similarities may cause confusion and result in errors when selecting, prescribing, transcribing, dispensing or administering a health product. The result of product name confusion may be that the patient/consumer takes the wrong product. Such an error may result in harm to a patient by depriving them of the benefit of the correct treatment and/or may subject them, unknowingly, to possible additional risks (including

adverse effects) as a consequence of using the incorrectly selected, dispensed or administered product. Such errors may cause harm, up to and including death.

3.4 Where can we find more information about brand name assessments?

For prescription products and those administered or obtained through a health professional, please refer to:

- Guidance for Industry: Review of Drug Brand Names (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-industry-review-drug-brand-names.html)
- Frequently Asked Questions - Guidance Document for Industry - Review of Drug Brand Names (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/frequently-asked-questions-guidance-document-industry-review-drug-brand-names.html)

Section 4: Contact Information Requirement

Section C.01.004.01 (1) of the Regulations: Every label of a drug for human use in dosage form shall display the following:

> (a) a telephone number, email address, website address, postal address or any other information that enables communication with a contact person in Canada; and
>
> (b) a statement to the effect that any injury to a person's health that is suspected of being associated with the use of the drug may be reported to the contact person.

(2) Subsection (1) does not apply to the labels of a drug that is listed in Schedule C or D to the Act and that is in dosage form.

4.1 What is the purpose of the contact information requirement?

This requirement is intended to ensure that Canadians are given information on drug labels that will allow them to contact someone who is responsible for the product in Canada, if they experience a problem (e.g. adverse reaction, medication error that led to taking the wrong drug or the wrong dose) or have a question or concern.

It is expected that relevant safety information received by the sponsor is reported to Health Canada in a specified time and manner that is in compliance with existing Canadian regulatory obligations.

4.2 To which prescription products does this contact information requirement apply?

This requirement applies to prescription pharmaceutical drugs and those administered or obtained through a health professional.

It does not apply to biologic drugs and radiopharmaceuticals, as per the Regulations listed above.

4.3 In order to comply with this requirement, how many means of contact must be listed?

Sponsors need to provide at least one method of contacting the person in Canada, in both official languages. A toll-free number, email address or website are recommended means of contact. Therefore, providing the contact information by one of these means would be considered sufficient. However, in cases where there is limited spacing on a package label, the sponsor may wish to use their postal address to satisfy both the PLL regulations (C.01.004.01(1)) and existing regulation (C.01.004.1(c)(i)).

For prescription products with a Product Monograph/Prescribing Information, sponsors must comply with the existing and applicable Guidance documents.

4.4 Is there particular wording that is required?

The following wording would be considered sufficient: "For questions or to report problems, please contact…" or "Questions or concerns", followed by the contact information. Where space is limited, the following abbreviated versions of the above "Questions or Concerns" statement can be used: "Concerns / Questions / Problèmes" or "Concerns / Questions / Préoccupations". The name of the contact person does not need to be listed.

4.5 Who can the contact person be?

The sponsor can decide who the contact person will be; however, this person is required to be located in Canada.

4.6 Where does the contact information need to appear?

The contact information should be on the inner and outer labels to ensure that consumers and health care professionals have access to the information even if the packaging has been discarded. In the cases of peel-back labels, the contact should appear on the top layer if space is available to do so. If not, it is acceptable to have the contact information on the bottom layer of a peel-back label.

4.7 Does the current regulatory exemption (C.01.004 (3)) for special containers (e.g. blister packs) and for small containers still apply?

Yes, the exemption still applies.

4.8 Should contact information be added to existing approved labels?

This requirement is not being applied retroactively; therefore, the contact information should be added to labels as part of the natural cycle of label revisions.

Section 5: Mock-up Requirement

Section C.01.014.1.(2) of the Regulations: An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

(m.1) in the case of a drug for human use, mock-ups of every label to be used in connection with the drug — including any package insert and any document

that is provided on request and that sets out supplementary information on the use of the drug — and mock-ups of the drug's packages;

Section C.08.002. (2) of the Regulations: A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(j.1) in the case of a new drug for human use, mock-ups of every label to be used in connection with the new drug — including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug — and mock-ups of the new drug's packages;

Section C.08.003 (3.1) of the Regulations: A supplement to a submission referred to in subsection (1) shall contain, as the case may be,

(a) if, due to a matter specified in subsection (2) — other than the brand name of a new drug for human use — that the supplement concerns, it is necessary to modify a new drug's labels:

(ii) in the case of a new drug for human use, mock-ups of every label to be used in connection with the new drug — including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug — and mock-ups of the new drug's packages; or

(b) if the supplement concerns the brand name of a new drug for human use:

(ii) mock-ups of every label to be used in connection with the new drug — including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug — and mock-ups of the new drug's packages.

5.1 What is the purpose of the mock-up requirement?

This requirement obliges sponsors to provide Health Canada with mock-ups of labels and packages, so that information filed with submissions represents the information that patients/consumers and health professionals will see. These mock-ups will be reviewed by Health Canada.

5.2 How will Health Canada review mock-ups?

What will be reviewed?

In addition to making sure labels comply with existing regulatory requirements on labelling, the review of the design elements as per the Good Label and Package Practices Guide (GLPPG) will focus on (but is not limited to) the following:

- font size
- font type

- colour and
- placement of text and graphics (including proximity, overlap, and panel location) as they relate to the key elements of an inner/outer label or package mock-up

When should a Note to Reviewer be filed?

Note that where sponsors are unable to meet Health Canada Guidance for the design elements of mock ups they should include a rationale or Note to Reviewer in section 1.3.2 of an electronic Common Technical Document (eCTD) format or non-eCTD electronic only format submission. Examples of when this note to reviewer should be filed include:

- When sponsors are unable to meet the minimum recommended font size or type style for mock up labels or package inserts.
- When only a select number of the eight key information elements that should appear on the principal display panel of a label as recommended by the Good Label and Package Practices Guide (and listed in the glossary under key elements of a label) are included. A rationale to support the approach taken which considers the specific product, the environment(s) of use, the regulatory requirements and any labelling limitations including size.
- Where sponsors are unable to meet the requirement to include a placeholder for the lot number and/or expiry date on the mock-ups.
- When an Abbreviated Package Insert has been filed to improve the legibility of the document a rationale to support the format chosen (as described in Appendix A) and/or why recommended sections were removed should be provided.

Timing of the review

In most cases, for submissions with review timelines of 150 days or greater, design elements will be evaluated in the first 90 days of the review (initial label review), to determine whether they support or impede legibility and understanding of the label. The review of product specific/regulatory label information will either follow the review of key design elements or will be carried out at the same time, and will be conducted as per current processes.

For submissions with shorter timelines, the review of the design elements and the regulatory requirements will be reviewed simultaneously.

A final review of the inner and outer labels, including the design elements and label information, will take place before the Notice of Compliance (NOC), or Drug Identification Number (DIN) can be issued in order to address any changes to the content as a result of the review.

Clarification requests

Label reviewers will communicate any concerns to sponsors via clarification requests. When review time permits, sponsors may be given 30 days to respond to a clarification request during the initial label review. Clarification requests will be processed in accordance with the Guidance for Industry: Management of Drug Submissions and Applications.

5.3 When do final mock ups need to be provided?

Final mock-up labels are to be provided during the review process before the issuance of the NOC/DIN. The mock-up labels submitted in response to the last clarification request will be considered the final version for approval.

Note that in connection with the mock-up requirement, the PLL Regulations have repealed the requirement at C.01.014.3 to submit final labels after the drug is available for sale.

5.4 Are DINs required to appear on the final bilingual mock-ups?

No, the actual DIN on the mock-ups is not required; it is acceptable to submit final labels with a placeholder for the DIN, such as "DIN XXXXXXXX".

5.5 What is an acceptable format for listing the expiration date and lot number?

As per the Good Label and Package Practices Guide for Prescription Drugs, the expiration date must be included on both inner and outer labels, using the preferred method as follows: EXP 2020-JA-11. Expiration dates must be presented using sans serif font in minimum size of six (6) points and at least 1.5mm high. It is acceptable to use dashes (-), slashes (/), or spaces to separate the date. Lot numbers must be expressed on both inner and outer labels, preceded by the designation "Lot number", "Lot No.", "Lot", "LOT", or "(L)", per A.01.014 of the Regulations. Clearly separate lot numbers from expiry dates to prevent confusion between these details and to ensure they are not read in combination as a single piece of information.

The expiration date can also be in any of the following acceptable formats listed below, but are not limited to:

- EXP 11-JA-2020
- EXP 11-JAN-2020
- EXP 2020-JA
- EXP 2020-JAN
- EXP JA-2020
- EXP JAN-2020
- EXP 2020-01
- EXP 01-2020
- EXP 01-31-2020 (when only the last day of the corresponding month is used)
- EXP 31-01-2020 (when only the last day of the corresponding month is used)
- EXP 2020-01-31 (when only the last day of the corresponding month is used)

5.6 What is an acceptable format in which to submit electronic mock-up labels?

For submissions submitted in electronic Common Technical Document (eCTD) format or non-eCTD electronic only format, files should be submitted in Portable Document Format (PDF). PDF versions of documents should be generated from electronic source documents and not from scanned material. Sponsors should submit editable labels (i.e. not locked PDF files) which enable reviewers to verify the font type and sizes. If a locked file is provided, sponsors should annotate the labels to indicate the font sizes of the text or provide a summary in a Note to Reviewer.

5.7 What Health Canada guidance documents will help sponsors prepare and file mock ups?

The Good Label and Package Practices Guide for Prescription Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs-profile/guidance-document.html) provides more detailed information about the design of safe health product labels and packages.

The Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html) provides information on the regulatory requirements pertaining to labelling and on the content of labels and packaging.

The Guidance Document: Product Monograph (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/monograph/pm-guid-ld-mp-eng.pdf) provides direction on the content and format of these documents and also references sources of information on plain language labelling.

The Labels and Packages Certification Form for Prescription Drugs (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/form-formulaire-mock-labels-packages-maquettes-etiquettes-emballages-eng.pdf) is required when filing submissions.

The Labelling of Special Containers Policy (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/policy-issues-labelling-special-containers.html) for requirements for special container types.

5.8 What type of mock-ups and documents should sponsors submit for prescription products and products administered or obtained through a health professional?

Sponsors should submit the following:

a) the Labels and Packages Certification Form for Prescription Drugs

b) Mock-ups of the inner and outer labels and packages

c) Mock-ups of the Package Insert (s) and

d) the Product Monograph/Prescribing Information (not in mockup format)

The filing requirements for completing the certification form and for submitting each type of mock-up (including certain exceptions) are listed below and in question 5.9. For Notifiable Change (for Biologic or Radiopharmaceutical drug quality changes), Post-Authorization Division 1 Changes, and submissions processed administratively, which have different requirements, please see question 5.10 below. For more information on when to submit a Labelling Only submission or annual notifications, please see question 5.11.

(a) The Labels and Packages Certification Form for Prescription Drugs

The Labels and Packages Certification Form for Prescription Drugs (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/form-formulaire-mock-labels-packages-maquettes-etiquettes-emballages-eng.pdf) is to be included with the submission at the time of initial filing. A revised form should be provided during the course of the review should the initial certifications require updating.

The form allows the sponsor to outline what types of mock-ups are provided with the submission and to certify to the following:

(1) the fidelity of translation(s) of the required mock-ups;

(2) the commitment to provide the second language Product Monograph/Prescribing Information and/or second language package insert documents within the first 20 days after the submission has been accepted into review;

(3) the commitment to update the second language Product Monograph/Prescribing Information and/or package insert documents with any changes made during the Product Monograph/Prescribing Information review process;

(4) the commitment to file the second language version of the final approved Product Monograph/Prescribing Information and package insert no later than 20 days following the date of the issuance of the:

- Notice of Compliance (NOC),
- No Objection Letter (NOL) and/or
- DIN;

(5) the font size and type style of the mock-up labels*;

(6) the font size and type style of the package insert*; and

(7) the content of the first and second language package inserts.

*Note where sponsors are unable to meet the minimum recommended font size or type style for mock-up labels or package inserts, they should include a rationale or Note to Reviewer in section 1.3.2 of an eCTD format or non-eCTD format.

(b) Inner/Outer Label Mock-ups

Mock-ups of the inner/outer label(s) should be bilingual[1], in full colour, actual size and editable (e.g., PDF). Non-annotated versions of the inner and outer labels should be submitted at the time of filing. Where there are changes to a previously approved label (i.e. for supplements to a/an (abbreviated) new drug submission), annotated labels or a tabular summary of changes in the first official language should be provided in order to facilitate review.

The mock-ups should contain:

- the proposed text and design elements;
- placeholders for the DIN, lot number, and expiry date using an approved format listed in Section 5.5*;

- the dimensions of the labels; and
- any text or designs present on the cap, vial or ferrule, if present

* Note where sponsors are unable to meet the requirement to include a placeholder for the lot number and/or expiry date on the mock-ups, they should include a rationale or Note to Reviewer in section 1.3.2 of an eCTD format or non-eCTD format.

In addition, where the package is in a novel label format as defined by and in accordance with the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (section 2.8), a photograph (or alternative means of visual representation) of the package should also be included upon filing with all sides of the package visible, including the vial, cap and ferrule, if present. A photograph (or alternative means of visual representation) or a drug-free specimen of the drug product, kit or training device may also be requested from the label reviewer through a clarification request, if required during review.

Font size and type:

- As per the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (section 2.3), Health Canada recommends a minimum font size of nine (9) points sans serif type font be used for all inner and outer labels, including any text in a table format. The maximum allowable font size should be used on all labels, as much as the label design permits.
- A font size of no less than six (6) points should be used on inner labels that are either special or small containers as defined in the Labelling of Special Containers Policy and the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (sections 3.6.2 and 3.6.3). For further information on font sizes, sponsors can also refer to the Good Label and Packages Practices Guide for Prescription Drugs (GLPPG).
- The following sans serif fonts considered to be acceptable include, but are not limited to:
    - Helvetica
    - Helvetica LT Standard
    - Helvetica Neue LT Standard
    - Univers, 55 Roman and 65 Bold
    - Frutiger, 55 Roman and 65 Bold
    - Arial MT Standard, Regular and Bold and
    - Arial, and Arial Bold; and Benton Sans, Regular and Bold

Filing Requirements:

- Sponsors are required to submit bilingual inner/outer label mock-ups, at the time of filing. Finalized versions of the inner and outer labels in both official languages must be submitted prior to approval of the submission.
    - For supplemental (abbreviated) new drug submissions where the proposed changes do not impact the package label(s) and, the sponsor has attested to such in the Label and Packages Certification Form for Prescription Drugs, inner and outer label mock-ups are not required to be provided.

- In addition to the example above, this filing requirement does not apply in the following circumstances:
    - Where there are no differences other than pill count or volume on the label, submitting the smallest format and attesting that the other labels will have identical text, format, size, layout, colour, etc. (with all minor differences clearly cited) is acceptable, within reason. For greater clarity of what is covered by this, volume refers to the total volume of the health product in the container and not the expression of strength on the label.
    - For professional samples intended for distribution to patients, provided that the below criteria is met, mock-ups are not required to be submitted. For professional samples where they do not meet the below criteria, sponsors are encouraged to file sample labels to Health Canada at the time of filing. Sponsors should speak to the criteria and the representative commercial product mock-up in a Note to Reviewer citing any minor differences.
        1. The professional sample should be labelled with the same directions required for the safe and effective use as that of the commercial trade package. This includes all regulatory information, directions, warnings and other information that appears on the commercial package including reference to the availability of the Consumer Information (Patient Medication Information) and the Product Monograph/Prescribing Information.
        2. The packaging including specifications, format and label design (layout, colour, font size/style, etc.) should be the same as the commercial package/label with the exception of the additional optional label text as detailed under criteria #3. Minor differences are clearly cited.
        3. The sample may have some wording identifying it as a sample such as "Sample - Not for Sale" or "Sample". The additional text "Sample - Not for Sale" or "Sample" must meet the minimum font size requirements for legibility, be in a Sans Serif font type and must not be superimposed or impede the legibility of the existing text on the labels.

(c) Package Insert Mock-Ups

Sponsors are to submit the first language or bilingual package insert[2] in full colour, actual size with dimensions stated, at the time of filing if:

- a package insert exists for the product; and
- the changes to the labelling proposed within the submission (such as revisions to Parts I or III of the Product Monograph/Prescribing Information) affect the content of the package insert.

Using the Labels and Packages Certification Form for Prescription Drugs, the sponsor should attest that the content of the package insert matches the corresponding content from the Product Monograph/ Prescribing Information. Health Canada label reviewers will assess the package insert for legibility and content, as needed.

For more information on package inserts, refer to the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (section 5.4.2). If a sponsor is considering an abbreviated package insert, refer to Appendix A of this guidance document for recommendations.

Font size and type:

- As per of the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (section 2.3), Health Canada recommends that text be a minimum font size of 10 points sans serif type font in:
    - Consumer information leaflets
    - Patient Medication Information documents, and
    - Package Insert documents.
- Health Canada recommends a minimum of nine (9) points sans serif type font in table text.
- The following sans serif fonts considered to be acceptable include, but are not limited to:
    - Helvetica
    - Helvetica LT Standard
    - Helvetica Neue LT Standard
    - Univers, 55 Roman and 65 Bold
    - Frutiger, 55 Roman and 65 Bold
    - Arial MT Standard, Regular and Bold
    - Arial, and Arial Bold and
    - Benton Sans, Regular and Bold

Filing requirements:

- Sponsors are to submit the first language or bilingual package insert at the time of filing.
- For supplemental (abbreviated) new drug submissions where the proposed content changes do not negatively impact the legibility of the package insert (i.e., no change in font size, type style and/or design layout and dimensions) the sponsor should attest to such in the Labels and Packages Certification Form for Prescription Drugs, and provide package inserts for Health Canada to determine the extent of label review.
- If not provided at the time of filing, the second language package insert is to be submitted up to 20 days following acceptance of the submission into review. When sponsors submit second language documents during the review period; they should identify the documents as ‘Second Language Labels Pre-Approval’ in their cover letter. Health Canada recommends that sponsors file second language documents (Product Monograph/Prescribing Information and package insert) together as one regulatory transaction, when applicable.
- When an Abbreviated Package Insert has been filed, a rationale to support the format chosen (as described in Appendix A) and/or why recommended sections were removed should be provided.
- An annotated MS word version of the package insert or for design changes a tabular summary of changes in the first official language, may be requested in order to facilitate review.

- Before the review of the submission is complete, sponsors will be requested to provide a final package insert that is updated with the content agreed upon during the review.
- Sponsors are to file final second language documents (Product Monograph/Prescribing Information and package insert) no more than 20 days after the receipt of the DIN, or NOC.
- Health Canada recommends that sponsors file final second language documents (Product Monograph/Prescribing Information and package insert) together as one regulatory transaction (when applicable) and identify them as "Second Language Labels Post-Approval" in their cover letter.

(d) Product Monograph/Prescribing Information

The Product Monograph/Prescribing Information is to comply with the version of the Product Monograph guidance and templates that apply at the time of filing. For additional guidance refer to the most recent Product Monograph Guidance. The review of the Product Monograph/Prescribing Information will be conducted as per current Health Canada processes.

Font Size and Type:

- Refer to the Product Monograph Guidance.

Filing Requirements:

- Sponsors are to submit first language Product Monograph/Prescribing Information at the time of filing. If not provided at the time of filing, the second language Product Monograph/Prescribing Information is to be submitted up to 20 days following acceptance of the submission into review.
- When sponsors submit second language documents during the review period; they should identify the documents as "Second Language Labels Pre-Approval" in their cover letter. Health Canada recommends that sponsors file second language documents (Product Monograph/Prescribing Information and package insert) together as one regulatory transaction, when applicable.
- When sponsors submit final second language Product Monograph/Prescribing Information, these should be identified as "Second Language Labels Post-Approval" in their cover letter. Health Canada recommends that sponsors file final second language documents (Product Monograph/Prescribing Information and package insert) together as one regulatory transaction, when applicable. Sponsors are to file these documents no more than 20 days after the receipt of the DIN, or NOC.

5.9 What should be submitted and when for all submission types*?

Please see details about mock-up filing requirements/specific exceptions in 5.8 above. *For Notifiable Change submissions (for Biologic or Radiopharmaceutical drug quality changes), PDC submissions and submissions processed administratively please see question 5.10.

Time point	Inner/Outer labels	Package Inserts	Product Monographs/Prescribing Information	Labels and Packages Certification Form for Prescription Drugs
Filing	• Bilingual mock-ups required • Unilingual mock-up if product to be marketed in on language only	• Bilingual mock-ups preferred • Minimum is first language mock-up	• Bilingual mock-ups preferred • Minimum is first language mock-up	Completed certification form
Up to 20 days after acceptance into review	N/A	Second language mock-up (if not already provided)	Second language document (if not already provided)	N/A
Prior to issuance of NOC, NOL or DIN	Final mock-ups	Final bilingual or first language mock-up	Final first language document	N/A
20 days after issuance of NOC, NOL or DIN	N/A	Final second language mock-up	Final second language document	N/A

5.10 How will the mock-up provision be applied for other submission types?

(a) Notifiable Change -Safety and Efficacy

Effective April 1, 2020, Notifiable Changes will no longer exist for safety and efficacy changes to human drug submissions and instead should be filed as per the Post Notice of Compliance (NOC) Safety and Efficacy Guidance. As such they will be subject to the requirements to submit mock-ups, as applicable, as outlined in 5.8 above.

(b) Notifiable Change submissions or Post-Authorization Division 1 Change submissions (PDCs)

Notifiable Change (NC) (for Biologic or Radiopharmaceutical drug quality changes) refer only to post approval quality changes to Biologic and Radiopharmaceutical Drugs that can be filed as

NCs according to the Post-NOC Quality Changes Guidance Document. Post-Authorization Division 1 Change submissions (PDCs) refer to post approval changes to Division 1 products that can be filed as level II changes (i.e. notifications requiring an assessment).

The Labels and Packages Certification Form for Prescription Drugs should be included with these submission types (see question 5.8a).

i) Inner/Outer Labels

If the labels are impacted by the updates proposed within the submission, non-annotated text versions of the proposed inner/outer label are to be submitted in both official languages at the time of filing.

For NC or PDC submissions, Health Canada will accept annotated written text, in lieu of mock-ups, to reflect proposed changes to the inner/outer labels. If sponsors submit mock-ups in place of annotated text, only the written text will be reviewed. Comments may not be provided on the design elements. Annotated text versions in the first official language should be filed in order to facilitate review.

Sponsors should ensure that any proposed changes to the inner/outer label(s) and package(s) text do(es) not inadvertently result in accompanying design element changes requiring a Level I submission (see question 5.11). Such changes would exceed the scope of a Level II NC /PDC submission.

ii) Package Insert

Sponsors are not required to submit package inserts with NC or PDC submissions.

The content of the Package Insert should be modified to reflect all applicable updates to the Product Monograph/Prescribing Information that are approved as a result of the NC or PDC submission.

The proposed changes should not result in a decrease in font size or a change to font type of the Package Insert text. Such changes would be considered Level I, and therefore exceed the scope of a Level II NC or PDC submission.

iii) Product Monograph/Prescribing Information

For NC or PDC submissions, sponsors are to submit the following at the time of filing:

- Clean (non-annotated) text version of the proposed Product Monograph/Prescribing Information in the first official language
- Annotated version of the proposed Product Monograph/Prescribing Information in the first official language

The second language Product Monograph/Prescribing Information may be submitted up to 20 days following acceptance of the submission into review, if not already provided at filing.

Final second-language copies of the Product Monograph/Prescribing Information will be required no later than 20 days following the date of issuance of the NOL for NCs and PDCs.

For products already approved as per the mock-up requirement, sponsors are expected to continue to maintain the compliance of their labels and package insert with PLL principles (e.g.,

maintaining font size, legibility, colour, layout, format, plain language, etc.), even in the absence of filing a mock-up with their NC or PDC submission. In addition, the content of the package insert should be kept up to date following revisions to the Product Monograph/Prescribing Information that affect the package insert's text.

(c) Administrative Submissions

As per section C.01.014.2 (1)(b) of the Regulations, a DIN identifies the following product characteristics:

- manufacturer
- brand name
- medicinal ingredient(s)
- strength of medicinal ingredient
- pharmaceutical form and
- route of administration

Where any of these product characteristics change or differ, a new DIN is required as per section C.01.014.2 (1) of the Regulations.

As a result, for submissions filed and processed under the administrative pathway (previously the Changes in Manufacturer's Name and/or Product Name policy) the following must be submitted at the time of filing:

- Mock-ups of the bilingual inner/outer labels and packages
- Mock-ups of the first and second language (or bilingual) package inserts
- First and second language Product Monograph/Prescribing Information and
- The Labels and Packages Certification Form for Prescription Drugs

For cross licensed products where an administrative S(A)NDS is being filed for labelling updates to match the licensor, mock-ups of the inner and outer labels and package inserts do not need to be filed if they are not affected by the change. Sponsors are required to attest to this on the Label and Packages Certification Form for Prescription Drugs.

Please refer to the Guidance Document Administrative Processing of Submissions and Applications: Human or Disinfectant Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/administrative-processing-human-disinfectant-drugs-2019/document.html) for the filing requirements for Administrative Submissions.

To be eligible for processing under the administrative pathway, sponsors will certify that all aspects of the product are identical to those previously authorised, including the conditions of manufacture and sale. To meet the purpose of the Regulations, sponsors will also certify that the general layout of their label has remained the same. For example, in the case of a sponsor name change, sponsors will be able to change their label to reflect the trade dress of the new sponsor; however the font and graphic size, as well as the placement of information on the label should be the same as the initial approved label. If sponsors want to change the location or size of graphics or font of their label, they will need to file a Labelling Only submission and pay the related fees.

Additionally, submissions which include a product name change or additional product name where a brand name or LASA name assessment is required will be ineligible for administrative processing. These types of changes should be filed as Labelling Only submissions.

5.11 What changes to the package label mock-ups will require the filing of a labelling only S(A)NDS submission/DINA and what can be filed as a Level III Annual Notification/ Post-authorization Division 1 Notification?

The lists in the table are not exhaustive; they are meant to provide guidance on the types of changes that are considered to be necessary to file as a S(A)NDS Labelling Only / DIN/A Labelling Only or as Level III Annual Notifications or Post-authorization Division 1 Notification. Health Canada encourages sponsors to contact Health Canada should they require further direction on the most appropriate manner to file.

	Division 1: DINA/B Labelling Only submission **Division 8: S(A)NDS Labelling Only submission**	**Division 1: Post-authorization Division 1 Notification** **Division 8: Level III Annual Notification**
Criteria	• Post-market changes made exclusively to label design elements that impact the existing design and layout of the labels. • Content changes, including those to make the text more plain language that do not require supporting data as outlined in the Post-NOC Safety and Efficacy Guidance, the Post-NOC Quality Guidance Document; or the Post Drug Identification Number Changes (PDC) Guidance Documents. • Any change that may be interpreted to reduce the legibility of the label. • Any changes to small or special containers as	Post-market changes to inner/outer labels where the revisions do not negatively impact the legibility and readability of the labels. The revisions should not: • Significantly diminish white space • Create clutter • Change location of existing regulatory information, or • Change content of regulatory text. The revisions should also: • Have a minimal impact on the existing design and layout of the labels, • Meet the minimum font sizes

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
	outlined in Sections 3.6.2 and 3.6.3 of the Labelling of Prescription Drugs for Human Use Guidance Document and the Labelling of Special Containers Policy.	recommended by the Guidance documents (see Question 5.7) and PLL Q&A section 5.8 font size requirements; OR • Where subject to PLL review and exemptions to font sizes were approved, those should be maintained.
Type of Change	**Examples of Changes**	**Examples of Changes**
General label changes (applies to package labels, package inserts, and Product Monograph/Prescribing Information)	• Addition of an electronic link (quick response (QR) code or 2D matrix code, or a website) that leads to drug product information other than approved Health Canada labelling information/Product Monograph. • Addition of a "New/Nouveau" graphic/text to describe a novel or modified formulation to the labels. The inclusion of the term is acceptable for one year of product sale.	• The updating and/or adding of an electronic code (e.g., bar codes, QR codes, technical codes and any other inventory tracking codes) strictly for product traceability purposes (i.e. does not link to drug product information). • Correcting spelling or translation errors. • Increasing the font size to meet the minimum font size outlined in Section 5.8 of this document provided that all other contents, white space, and design elements (layout, font, colour, etc.) are not impacted by this change.

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
		• The removal of the "New/Nouveau" graphic/text from the label to describe a novel or modified formulation that has been marketed for set period of time.
Changes to design	• Reducing overall label dimensions such that the font, graphics, and/or ratio of white space to text are reduced affecting legibility of the label. • Modifications to a font style type other than those noted in Section 5.8, including replacing existing text with condensed, compressed, horizontally scaled, expanded or italicized font styles. • Adding additional design elements, new graphics or symbols. • Changing locations of existing graphics • Increasing the size of company logo/graphics such that the font, graphics, and/or ratio of white space to text are reduced and it affects legibility of the label • Addition or removal of symbols that ensure the	• Increase to overall label dimensions such that there are no other changes to font, graphics, and/or ratio of white space to text and the legibility of the label is not affected. • Changes to non-regulatory label information such as the removal of: ○ Graphics other than symbols required by regulations (i.e., registered trade mark symbols, brand name logo) ○ Company logo and replacement with existing DIN holder's name in text only, or ○ Changes to product trademark symbols ("TM" to

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
	safe use of the product (e.g., Cytotoxic) • Change in the overall layout of the label mock-ups (horizontal to vertical / vertical to horizontal) • Changing the package design, where the package is the immediate container. • Decreasing the font size of the lot number or expiry date • Where the information already appears on the label, the removal of a unilingual side panel and the creation of a bilingual side panel.	"•") or statements. • Change in colour or reduction in the size of a graphic or logo. Not applicable to symbols required by regulations and logos. • Switching panels (e.g. the left and right or top and bottom secondary panels) with no other design or content changes. • Deleting duplicate information from side panels (i.e., brand name, proper or common name, strength (including any text boxes) and company name or logo). • Switching the location of the expiry and lot number from one panel to another panel. • Change in expiry date format, expiry and lot number descriptors to an acceptable format identified in Section 5.5b) of this document. • Change in printing direction for the lot and expiry date information (i.e., horizontal to vertical or vice-versa) provided existing

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
		location, amount of white space and descriptors and expiry date formats are maintained.
Changes to the text	• Applying TallMAN lettering (i.e. capitals) to the labelling materials. • Addition or deletion of text to ensure label adheres to the requirements in the Food and Drug Regulations and in the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use or to comply with changes requested by Health Canada.	• Removal of distributor information on the label, as long as the DIN holder (manufacturer) is in Canada. • Updating of distributor information on the label. • Updating contact information, including the addition of the "Questions or Concerns" statement mentioned in the Contact Information section of this guidance. • Increasing the font size of the last 5 digits of the DIN. • Updating text on the package label(s) to reflect the titles of Health Canada's Consumer Information or Patient Medication Information leaflet to correspond to the titles in the sponsor's approved Product Monograph.

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
		• Removal of a reference on the label to a package insert that never existed. This does not apply to products for which Health Canada has requested the creation of a Package Insert.
Ratio of white space to text	Where the ratio of white space to text is changed by any of the following: • Reducing the size, changing the colour of or changing the order of or positioning of information presented on the principal display panel including product name (proprietary and non-proprietary), warnings, dosage, expression of strength, route of administration, population, and storage (particularly for vaccines)	Where the ratio of white space to text is NOT changed by any of the following changes made: • Change in label dimensions such that the existing design (i.e., font, graphic) is consistent or maintained. • Increasing the dimensions of the label that permit proportional increases in label elements such as the font size such that the smallest font appearing on the label meets the minimum requirements. • Updating the standard of manufacturing When the ratio of white space to text is increased and all other existing text and design elements are maintained.

	Division 1: DINA/B Labelling Only submission Division 8: S(A)NDS Labelling Only submission	Division 1: Post-authorization Division 1 Notification Division 8: Level III Annual Notification
Changes specific to the Package Insert	• Reduction in the dimensions of the package insert that leads to a decrease in font type or a change in font style (i.e., condensed or compressed) • Modifications to a font style type other than those noted in Section 5.8c) including replacing existing text with condensed, compressed, horizontally scaled, expanded or italicized font styles.	• Reduction in the dimensions of the package insert that does not lead to a decrease in font size or a change in font style. The existing text should NOT be replaced with condensed, compressed, horizontally scaled, expanded or italicized font styles. The order of the contents should not be changed. • Increase in the dimensions of the package insert that leads to an increase in font size with the use of a sans serif font that is NOT condensed, compressed, horizontally scaled, expanded or italicized.

5.12 How should a Level III Annual Notification or a Post-authorization Division 1 Notification be filed/submitted?

For Division 8 drugs, notification of a Level III label change should be filed at the time the change is implemented using the Post-Notice of Compliance (NOC) Changes: Notice of Change - Level III Form. For labelling Level III updates, sponsors should choose "other" in the drop down list of the Level III form and use the free text to provide details of the level III change they are making. A copy of the revised annotated labels, Product Monograph/Prescribing Information, and Package Insert should only be submitted with the filing of the next Supplemental submission that necessitates a label change as well. The dates of implementation for these Level III changes should be clearly identified.

For Division 1 drugs, the Post-authorization Division 1 Notification should be submitted to the Office of Submissions and Intellectual Property within 30 days of making the proposed change. A copy of the revised annotated labels, Product Monograph/Prescribing Information, and Package Insert should only be submitted with the filing of the next DIN application or Post-DIN

change that necessitates a label change as well. The dates of implementation for these changes should be clearly identified.

5.13 What should sponsors file for multiple products that are making the same labelling changes?

Sponsors should contact Health Canada for further clarification on how to file changes that affect multiple product submissions.

Section 6: Glossary

Inner label:

"inner label" means the label on or affixed to an immediate container of a drug. (étiquette intérieure)

Key elements of the label (does not include Product Monograph/Prescribing Information):

Eight components of a label identified during the development of the Good Label and Package Practices Guide for Prescription Drugs as being the key pieces of information for the design of safe and clear labels. This does not include all elements required by regulation. These elements include: (1) brand name of health product, (2) non-proprietary name (proper or common name) of a health product, (3) strength with or without total amount per total volume, (4) dosage form, (5) route of administration (other than oral solids, such as tablets, for products available for self-selection), (6) critical warnings, as relevant, (7) population, as relevant (e.g. adult vs. pediatric), (8) storage instructions, as relevant. (éléments principaux de l'étiquette)

Mock-up:

a full-colour, actual-size copy of the labels and a colour representation (e.g., photograph or PDF) of the packages intended to be used for the sale of the drug, including all presentation and design elements, proposed graphics, fonts, colours, dimensions and text (with a place holder for expiry date, DIN, and lot number). (maquette)

Outer label:

"Outer label" means the label on or affixed to the outside of a package of a drug (étiquette extérieure)

Package:

Includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed. This does not include cargo or shipping containers. (emballage)

Package insert:

The package insert for prescribed drug products is usually the prescribing information document equivalent to the Part I, Health Professional Information of the Product Monograph. Sometimes the package insert will consist of the Part I of the Product Monograph, and the Part III (Consumer Information) or Patient Medication Information. (la notice d'accompagnement)

Patient leaflet:

A term that is sometimes used to describe printouts of the PM Part III (Consumer Information) or Patient Medication Information. (dépliant pour le patient)

Plain language:

Plain language is a clear writing style designed to be easy to read and understand by the intended audience. It includes how information is organized and displayed within a space, such as the use of white space, fonts, 'active' instead of 'passive' voice for instructions, design elements, and colour. (langage clair)

Product Monograph/Prescribing Information:

A factual, scientific document on the drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug. (Monographie de produit)

Appendix A: Abbreviated Package Inserts

An abbreviated package insert may be created when a sponsor is not able to fit the complete contents (i.e., sections in their entirety as per the Product Monograph/Prescribing Information of Part I and/or Part III in a package insert at the required minimum required font size to be considered legible. In such cases, the sponsor may prepare an abbreviated package insert that has the minimum sections needed for healthcare professionals to adequately prepare/reconstitute and administer the product. In all cases, Part III of the Product Monograph/Prescribing Information (Patient Medication Information or Consumer Information) cannot be abbreviated.

Sponsors may determine the sections that appear in an abbreviated package insert, however the following criteria should be respected:

a) Abbreviated package inserts should have bolded headings which clearly define their limitations and refer patients and healthcare providers to the complete Product Monograph/ Prescribing Information. For example:

Package Insert for Reconstitution, Administration and Dosage

See Product Monograph for complete product information

OR

Package Insert for Reconstitution, Administration and Dosage

See Prescribing Information for complete product information

OR

Abbreviated Package Insert

See Product Monograph for complete product information

OR

Abbreviated Package Insert

See Prescribing Information for complete product information

b) For prescription drug products: The sections that are covered in an abbreviated package insert (e.g., reconstitution, administration, dosage, storage) should be complete and match exactly the information and order in the Product Monograph/Prescribing Information. Please note that additional sections of the Product Monograph/Prescribing Information may be added as required, based on the drug product. It is recommended that the following sections be included: Dosage and Administration, Overdosage, Storage, Stability and Disposal, Special Handling Instructions, Dosage Forms, Strengths, Composition and Packaging and, if possible, Indications and Contraindications.

c) For biologic drugs and radiopharmaceuticals: The sections that are covered in the abbreviated package insert should include all information related to the conditions of use of a product (e.g., Indications, Contraindications, Warnings and Precautions, Drug

Interactions, Dosage and Administration, Overdosage, Storage and Stability, Special Handling Instructions, etc.)

d) If the product has been issued a Notice of Compliance with conditions, the conditions under which the drug is authorized should be included in a summarized fashion.

e) Regarding the Adverse Reactions section, rather than repeating the information in the Product Monograph/Prescribing Information, a reference to the complete Product Monograph/Prescribing Information is acceptable.

Sponsors are encouraged to contact Health Canada if they require further direction on creating an abbreviated package insert.

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[1] Health Canada strongly recommends that sponsors use bilingual inner/outer labels, however, acknowledges that circumstances may apply when sponsors are unable to do so. In these instances, sponsors should include a rationale along with their submission for Health Canada's review. If not provided at the time of filing, the second language labels are to be submitted up to 20 days following acceptance of the submission into review. When sponsors submit second language documents during the review period; they should identify the documents as 'Second Language Labels Pre-Approval' in their cover letter.

[2] Note that package inserts could also include wallet cards, tear-off pads and hand-outs directed to the patient/consumer and whose content is Part III of the PM.