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GUIDANCE DOCUMENT

Questions and Answers:

Plain Language Labelling Regulations

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Health Products and Food Branch

Canada 

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>The Health Products and Food Branch (HPFB)'s mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:</p> <ul style="list-style-type: none"> • 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. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre : Ligne directrice : Questions-réponses : le règlement sur l'étiquetage en langage clair

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles 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.

DOCUMENT REVISION HISTORY

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Version	Location of Change	Change Made	Effective Date
1	not applicable	Initial Issuance of Guidance	2015/06/13
2	Section 2: 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 2: Mock-up Requirement	Clarification around the submission of annotated text for Notifiable Changes.	2016/04/12
4	Section 2: Mock-up Requirement	<ul style="list-style-type: none"> • 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

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Section 1: Overview

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, and radiopharmaceuticals. **This document does not address implementation for non-prescription products.**

Note: these will be referred to as the *Regulations* throughout the document.

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 new obligations on health products 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; and
- 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 come into effect at a later date than others.

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 specific requirements that only apply to subsets of these products. For example, the facts table requirement only applies to non-prescription drugs. These *Regulations* do not apply to medical devices, veterinary drugs, or natural health products.

4 - When do the *Regulations* come into force?

The *Regulations* take effect at two different times:

- 1) For prescription products and those administered or obtained through a health professional, the *Regulations* apply as of June 13, 2015.
- 2) For non-prescription products, the *Regulations* apply as of June 13, 2017.

5 - Will the *Regulations* be applied retroactively?

No. New requirements will be applied to submissions received on or after the coming into force dates. They will not be applied retroactively and they will not be applied to submissions in the queue.

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: Information on Specific Requirements

General Plain Language Requirement

A.01.017 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).
-

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*.

2 - To which products does this requirement apply?

This requirement applies to prescription and non-prescription pharmaceutical drugs, biologic drugs, and radiopharmaceuticals.

3 - When does this requirement apply?

For prescription products and those administered or obtained through a health professional, the requirement applies as of June 13, 2015.

Brand Name Assessment Requirement

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

(o) 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.

C.08.002(2) 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:

(o) 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.

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

(b) 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
-

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.

2 - To which products does this requirement apply?

This requirement applies to prescription and non-prescription pharmaceutical drugs, biologic drugs, and radiopharmaceuticals.

3 - When does the requirement apply?

For prescription products and those administered or obtained through a health professional, the requirement applies as of June 13, 2015.

4 - Why are we concerned with Look-Alike Sound-Alike (LASA) names?

Look-alike sound-alike (LASA) drug product names refer to names of different drug products that are similar when written or spoken. These similarities may cause confusion and result in errors when self-selecting, prescribing, transcribing, dispensing or administering a drug product. The end 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 mistakenly selected product. Such errors may cause harm, up to and including death.

5 - 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 (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2014-review-examen_drug-medicament_names-marques/index-eng.php)

Frequently Asked Questions - Guidance Document for Industry - Review of Drug Brand Names (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2014-review-examen_drug-medicament_names-marques/faq-eng.php)

Contact Information Requirement

C.01.004.01 (1) 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.
-

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 [for example (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 the information will be gathered and reported in a manner that is in compliance with existing Canadian regulations and requirements.

2 - To which products does this requirement apply?

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

It does not apply to biologic drugs and radiopharmaceuticals.

3 - When does the requirement apply?

For pharmaceutical prescription products and those administered or obtained through a health professional, the requirement applies as of June 13, 2015.

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

Sponsors need to provide, in both official languages, at least one method of contacting the person in Canada. Therefore, providing the information by just one of these means (e.g., toll-free number, email address, website) would be considered sufficient. A toll-free number, email address or website are the recommended means of contact. 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 regulation (C.01.004.01(1)) and existing regulation (C.01.004.1(c)(i)).

For prescription products with a Product Monograph (PM), sponsors must comply with the existing and applicable PM guidance documents.

5 - 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. The name of the contact person does not need to be listed.

6 - Who can the contact person be?

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

7 - 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 case of prescription products, the contact information should be located - if possible - on a section of the inner and outer label and package which is not likely to be overlabeled with the prescription label dispensed at the pharmacy.

8 - 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.

9 - Should contact information be added to existing approved labels?

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

Mock-up Requirement

C.01.014.1.(2) 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;

C.08.002. (2) 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;

C.08.003 (3.1) 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.

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 consumers and health professionals will see. These mock-ups will be reviewed by Health Canada.

2 - To which products does this requirement apply?

This requirement applies to prescription and non-prescription pharmaceutical drugs, biologic drugs, and radiopharmaceuticals.

3 - When does the requirement apply?

For prescription products and those administered or obtained through a health professional, the requirement applies as of June 13, 2015.

4 - Is the requirement to submit mock-ups retroactive?

No. This requirement will not be applied retroactively. Mock-ups will be required for submissions that are filed on or after the applicable coming into force date. Mock-ups will not be required for submissions in queue.

In connection with the mock-up requirement, the *Regulations* repeal the requirement at C.01.014.3 to submit final labels after the drug is available for sale. Therefore, sponsors who file submissions for prescription products, and those administered or obtained through a health professional, on or after June 13, 2015 will not be required to submit final marketed labels with their market notification, as labels will need to be reviewed and finalized prior to approval. Sponsors are asked not to send in final marketed labels with their market notification.

5- How will Health Canada review mock-ups?

In addition to making sure labels comply with existing regulatory requirements on labelling, the review of the design elements will focus on (but is not limited to) the following:

- font size
- font type;
- colour; and
- placement (including proximity, overlap, and panel location)

as they relate to the key elements of an inner/outer label or package mock-up. For more information on the key elements and good label design, please see *the Good Label and Package Practices Guide for Prescription Drugs* on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-rx/index-eng.php).

In most cases, design elements will be evaluated in the first 90 days of the review to determine whether they support or impede legibility and understanding of the label. Label reviewers will communicate any concerns to sponsors via clarification requests. When review time permits, sponsors will be given 30 days to respond to clarification requests and include revised mock-ups when necessary. For submissions with shorter review times, sponsors will have shorter time periods to respond to clarification requests. The review of label information will follow the review of key design elements, and will be conducted as per current processes.

Upon Health Canada request, finalized versions of the inner and outer labels in both official languages must be submitted. 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), DIN or DIN Application Approval Letter can be issued.

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. A locked file impedes reviewers from making annotations to the labels.

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

For NDS and SNDS submission types, sponsors should submit the following:

- Mock-ups of the inner and outer labels and packages;
- Mock-ups of the Package Insert (s);
- the Product Monograph; and
- the Mock-up Labels and Packages Certification Form (see (d)).

For information on submission types with different requirements (Notifiable Change, Post-Authorization Division 1 Change, and submissions processed administratively), please see question 8. For more information on Labelling Only submissions, please see question 8, section (c).

(a) Inner/Outer Label Mock-ups

Sponsors are to submit inner/outer label mock-ups at the time of filing.

Mock-ups of the inner/outer label should be representative of the package. They should be bilingual¹, full colour and actual size. They should contain:

- the proposed text
- placeholders for lot number, expiry date, and DIN including the descriptor (e.g., EXP) and the format to be used (e.g., YYYY/MM/DD).
- the dimensions of the labels.

All sides of the package should be visible in the mock-ups, including the cap and ferrule, if present.

Annotated versions in the first official language may be requested in order to facilitate review.

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.

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 15 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 and package insert) together as one regulatory transaction, when applicable.

As per section 2.3 of the *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.php), Health Canada recommends a minimum font size of nine points for inner and outer labels, including any text in a table format. All labelling should be in Sans Serif type font.

A point size of no less than 6 should be used for inner labels that may be subject to the *Labelling of Special Containers Policy* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/lab_eti_con_pol-eng.php) and sections 3.6.2 and 3.6.3 of the *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use* relating to labelling for small containers and special containers (e.g., multiple-dose packs, single-dose packs such as blister packs).

Sponsors should include the font size and style of inner/outer label text in the *Mock-up Labels and Packages Certification Form* (see section (d) below). When Health Canada label reviewers know the font size and type style of labels at the beginning of a review, they are able to review labels more efficiently. Sponsors should include a rationale or Note to Reviewer when they are unable to meet the minimum recommended font size or type style. The rationale or Note to Reviewer should be placed in section 1.3.2 of a CTD submission.

(b) Package Insert Mock-Ups

Sponsors are to submit the first language or bilingual package insert² at the time of filing if:

- a) a package insert exists for the product and
- b) the changes to the labelling proposed within the submission (such as revisions to Part III of the PM) affect the content of the package insert.

If the mock-up of a package insert is not included at the time of filing, the sponsor should confirm that either the product does not have a package insert or that the submission does not impact the package insert, as applicable.

If not provided at the time of filing, the second language package insert is to be submitted up to 15 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 and package insert) together as one regulatory transaction, when applicable.

An annotated version in the first official language may be requested in order to facilitate review.

As per section 2.3 of the *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*), Health Canada recommends that text be a minimum font size of ten points in:

- Consumer information leaflets;

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

- Patient medication information documents; and
- Package insert documents.

Health Canada recommends a font size of nine points for text in table format. All labelling should be in Sans Serif type font.

Sponsors should include the font size and type style of package inserts in the *Mock-up Labels and Packages Certification Form* (see section (d) below). Sponsors should include a rationale or Note to Reviewer if they are unable to meet the minimum recommended font size or type style. The rationale or Note to Reviewer should be placed in section 1.3.2 of a CTD submission.

The sponsor should also attest in the *Mock-up Labels and Packages Certification Form* that the content of the package insert matches the content of the Product Monograph. Health Canada label reviewers will assess the package insert for legibility, and content as needed.

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

When sponsors submit final second language package inserts, 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 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, DIN Approval Letter or NOC.

(c) Product Monograph

Sponsors are to submit first language Product Monographs (PM) at the time of filing. The PM is to comply with the version of the Product Monograph guidance and templates that apply at the time of filing. For additional guidance on Product Monographs, please see the Product Monograph Guidance (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_mp_2013-eng.php).

If not provided at the time of filing, the second language PM is to be submitted up to 15 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 (PM and package insert) together as one regulatory transaction, when applicable.

The review of the PM will be conducted as per current Health Canada processes.

When sponsors submit final second language PMs, these should be identified as "Second Language Labels Post-Approval" in their cover letter. Health Canada recommends that sponsors file final second language documents (PM 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, DIN Approval Letter or NOC.

(d) The Mock-up Labels and Packages Certification Form

The *Mock-up Labels and Packages Certification Form* (<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php>) is to be included with the submission at the time of initial filing.

The form certifies:

- (1) the fidelity of translation(s);
- (2) the commitment to provide the second language PM and/or second language package insert documents within the first 15 days after the submission has been accepted into review;
- (3) the commitment to update the second language PM and/or package insert documents with any changes made during the PM review process;
- (4) the commitment to file the second language version of the final approved PM 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 or DIN Approval Letter;
- (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.

(e) What should be submitted and when for NDS and SNDS?

***For NC/PDC submissions and submissions processed administratively, please see question 8.**

Time point	Inner/Outer labels	Package Inserts	Product Monographs	Mock-up Labels and Packages Certification Form
Filing	<ul style="list-style-type: none"> • Bilingual mock-ups required • Unilingual mock-up if product to be marketed in one language only 	<ul style="list-style-type: none"> • Bilingual mock-ups preferred • Minimum is first language mock-up 	<ul style="list-style-type: none"> • Both official languages preferred • Minimum is first language document 	Completed certification form
Up to 15 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

8 - How will the mock-up provision be applied for other submission types?**(a) Notifiable Change (NC) submissions or Post-Authorization Division 1 Change submissions (PDCs)**

The Mock-up Labels and Packages Certification Form should be included with the submission (see question 7, section (d)).

i) Inner/Outer Labels

If the labels are impacted by the updates proposed within the submission, clean (non-annotated) text versions of the proposed inner/outer label are to be submitted in the first official language at the time of filing. Second language labels may be submitted up to 15 days following acceptance of the submission into review, if not already provided at filing.

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, the written text will be reviewed. Comments may not be provided on the design elements. Annotated text versions in the first official language may be requested in order to facilitate review.

Sponsors should ensure that any proposed changes to the inner/outer label and package text do not inadvertently result in accompanying design element changes requiring a Level I submission (see question 8, section c). 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

Sponsors are to submit the following at the time of filing:

- Clean (non-annotated) text version of the proposed PM in the first official language
- Annotated version of the proposed PM in the first official language

The second language PM may be submitted up to 15 days following acceptance of the submission into review, if not already provided at filing.

Final second-language copies of the PM 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 PM that affect the package insert's text.

(b) Administrative Submissions

For submissions processed administratively filed under the *Change to Product and/or Manufacturer Name* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/chang_name_nom_pol-eng.php) policy, the following must be submitted at the time of filing:

- First and second language (or bilingual) inner/outer labels and packages;
- First and second language (or bilingual) package inserts;
- First and second language PMs; and
- the Mock-up Labels and Packages Certification Form.

To be eligible under the above noted policy, 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, for product name changes which fit the criteria for a Brand Name Assessment (as set out in the *Frequently Asked Questions - Guidance Document for Industry - Review of Drug Brand Names*), the sponsor will be required to submit evidence of this assessment and the submission will be ineligible for administrative processing. These types of changes should be filed as Labelling Only submissions.

(c) SNDS and SANDS Labelling only submissions

Post-market changes made exclusively to label design elements should be filed as S(A)NDS-labelling only submissions. The label text information should remain the same as in the previously approved label. Sponsors are encouraged to file mock-ups of labels which indicate the font size and type style, along with copies of previously approved labels to facilitate timely review.

Some examples of when S(A)NDS labelling only submissions should be filed include, but are not limited, to:

- Adding new graphics or symbols (other than symbols required by regulations) or changing locations of graphics within the inner or outer label (e.g., addition of a symbol that relates to the type of packaging being used).
- Changing the size or colour of text or background in connection with product name (proprietary and non-proprietary), warnings, dosage, expression of strength, route of administration, population, and storage (particularly for vaccines).
- Reordering text on the label necessary for the safe and effective use of the product
 - moving label information to different panels;
 - changing the order 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).
- Reducing overall label size
- Changing the package design, where the package is the immediate container.
- Increasing the size of company logo/graphics
- In response to a Health Canada-issued advisement letter specifically soliciting a labelling-only SNDS

This list is not exhaustive; it is meant to provide guidance on the types of changes which will require submissions for review. Health Canada encourages sponsors to contact Health Canada should they require further direction on the most appropriate manner to file.

(d) Level III Safety and Efficacy Changes

Some changes to inner/outer labels can be filed as Level III Safety and Efficacy changes. A Level III changes form (http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_pn_leviii_form_ac_sa_niviii-eng.pdf) should be filed at the time the changes are made. Sponsors are not required to file the inner/outer labels at this time.

Any Level III changes that have been implemented should be clearly marked as such, and annotated in the affected documents with the filing of the next submission to Health Canada.

Some examples of these include:

- Updating bar codes and technical codes;
- Removing graphics;
- Removing non-regulatory label information;
- Changing colour of graphics where there is no text overlay or changing colour of company logo;
- Correcting spelling errors;
- Updating contact information on the label.

This list is not exhaustive; it is meant to provide guidance on the types of changes that are considered to be Level III. Health Canada encourages sponsors to contact Health Canada should they require further direction on the most appropriate manner to file.

9 - What Health Canada guidance documents will help sponsors prepare mock ups?

The *Good Label and Package Practices Guide for Prescription Drugs* (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-rx/index-eng.php) will provide more detailed information about the design of safe health product labels and packages.

The *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.php) provides information on the regulatory requirements pertaining to labelling and on the content of labels and packaging.

The *Guidance Document: Product Monograph* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_mp_2013-eng.php) provides direction on the content and format of these documents and also references sources of information on plain language labelling.

The *Mock-up Labels and Packages Certification Form* (<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php>) is required when filing submissions.

Facts Table Requirement

C.01.004.02 (1) In addition to the requirements of section C.01.004, the outer label of a drug for human use in dosage form shall display, either one bilingual table, placed on any panel, that contains only the following information in both English and French or one table in English and one table in French, each of which is placed on any panel, that contains only the following information:

- (a) adequate directions for use of the drug;
 - (b) a quantitative list of the drug's medicinal ingredients by their proper names or, if they have no proper names, by their common names;
 - (c) the drug's non-medicinal ingredients listed in alphabetical order or in descending order of predominance by their proportion in the drug, preceded by words that clearly distinguish them from the medicinal ingredients; and
 - (d) the information referred to in subsection C.01.004.01(1).
-

1 - To which products does this specific requirement apply?

This requirement applies to non-prescription pharmaceutical drugs only.

It does not apply to biologic drugs and radiopharmaceuticals, prescription pharmaceuticals, non-prescription drug products administered or obtained only through health professionals, hard surface disinfectants, and products submitted as extraordinary use new drugs.

The requirement applies as of June 13, 2017. For more information on the Drug Facts Table, please see section 2.4.4 of the *Good Label and Package Practices Guide for Non-prescription drugs and Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-non/index-eng.php#a2.4.4).

Section 3: 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): Eight components of a label identified during the development of the *Good Label and Package Practices Guide for Prescription Drugs* (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-rx/index-eng.php) 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. paediatric), (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. (*dépliant 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: 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

As per section 5.4.2 of the *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*, a package insert is considered to be the professional material equivalent to Part I of the PM, or equivalent to the Prescribing Information document, and is intended to assist the healthcare provider in the proper use of the product. This is not to be confused with the consumer information or patient medication information document which must be provided as an insert or handed to the patient at the time of dispensing.

In order to improve legibility of a product's package insert, sponsors may wish to create an abbreviated package insert. An abbreviated package insert may be created when a sponsor is not able to fit the complete contents (sections in their entirety as per the PM) of Part I and III in a package insert at the required minimum font size requirements to be considered legible and readable. 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.

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 or Prescribing Information. For example:

Package Insert For Reconstitution, Administration and Dosage
See Product Monograph (Prescribing Information) for complete product information

or

Abbreviated Package Insert
See Product Monograph (Prescribing Information) for complete product information

b) 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 or Prescribing Information. Please note that additional sections of the Product Monograph may be added as required, based on the drug product.

c) 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, a reference to the complete Product Monograph may be acceptable.

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