Health Canada Santé Canada

GUIDANCE DOCUMENT

Questions and Answers: Plain Language Labelling Regulations

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Health Products and Food Branch

Canada

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

Également disponible en français sous le titre : 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

File name	Guidance Document Questions and Answers: Plain Language Labelling Regulations	**Replaces**	not applicable
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1	not applicable	Initial Issuance of Guidance	2015/06/13

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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.

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 overlabelled 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, prescription products and those administered or obtained through a health professional who file submissions on or after June 13, 2015 will not be required to submit final marketed labels with their market notification.

5 - How will the mock-up requirement work for prescription products and products administered or obtained through a health professional?

(a) **What types of mock-ups does Health Canada wish to receive?**

Health Canada would like to receive mock-ups of the inner and outer label and package, the package insert, and the Product Monograph.

If mock-ups are not included with the submission package, a Screening Deficiency Notice (SDN) will be issued.

(b) **How will this work for Product Monographs and package inserts?**

In the case of submissions for which there is no previously approved Product Monograph (e.g. New Drug Submission (NDS)):
The first language Product Monograph and package inserts are to be submitted at the time of filing. The second language Product Monograph and package insert may be submitted 15 days following acceptance into review. The documents are to comply with whichever version of the guidance and templates apply. The second language documents are to be accompanied the Mock-up Labels and Packages Certification Form (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php) which certifies as to (1) the fidelity of translation, (2) the commitment to update the second language version with any changes made to the Product Monograph and package insert during the review process, and (3) to file the second language version of the final approved Product Monograph and package insert no later than 10

days following the date of the issuance of the Notice of Compliance (NOC), No Objection Letter (NOL) and/or Drug Identification Number (DIN).

When submitting any required second language Product Monographs and package inserts during the submission review period or after approval of the submission (i.e. not at the time of initial submission filing), these should be clearly identified as "Second Language Labels Pre-Approval" or "Second Language Labels Post-Approval". These should be filed alone, with no other materials appended.

In the case of submissions for which there is a previously approved Product Monograph (e.g. all administrative submissions, Supplement to an Abbreviated New Drug Submission (SANDS)):
The Product Monograph and package insert are to be submitted in both official languages at the time of filing. The documents are to comply with whichever version of the guidance and templates apply. The documents are to be accompanied the Mock-up Labels and Packages Certification Form (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php) which certifies as to (1) the fidelity of the translation, (2) the commitment to update the second language version with any changes made to the Product Monograph and package insert during the review process, and (3) to file the second language version of the final approved Product Monograph and package insert no later than 10 days following the date of the issuance of the NOC, NOL and/or DIN.

When submitting any required second language Product Monographs and package inserts after approval of the submission, these should be clearly identified as "Second Language Labels Post-Approval". These should be filed alone, with no other materials appended.

There is no change in the scope of products which require a Product Monograph.

The package insert will be evaluated for legibility.

(c) **For the inner and outer label and package mock-ups, what should be submitted, when should it be submitted, and how will it be handled by Health Canada?**

Time point	**What should be submitted and how it will be handled**
Filing	Bilingual full colour mock-ups of inner and outer labels and colour representations of packages incorporating the proposed text, and placeholders for lot number, expiry date, and DIN. All sides of the package should be visible in the mock-ups, including the cap and ferrule if present. The expiry date placeholder should show the descriptor (e.g. EXP), and the format to be used (e.g. YYYY/MM/DD).

	Where there are no differences other than pill count or volume on the label, submitting the smallest format and citing that the other labels will have identical text, format, layout, color, etc. (with minor differences clearly cited) is acceptable. The inner and outer label and package mock-up should be accompanied by the Mock-up Labels and Packages Certification Form (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php).
First 90 days of review	Design elements will be evaluated in the first 90 days to determine whether they support or impede legibility and comprehension of the label. If any issues are raised, sponsors will be given 30 days to respond. In addition to compliance with existing regulatory requirements pertaining to labelling, the review of the design elements will involve – but is not limited to - an examination of the representation (including font size, type, colour) and placement (including proximity, overlap, and panel location) of key elements of an inner or outer label or package mock-up (as per the Good Label and Package Practices Guide http://www.ismp-canada.org/download/LabellingPackaging/Draft-GoodLabelandPackagePracticesGuide-EN-2015-03.pdf).
Following the review of key design elements	The review of label information will follow the review of key design elements, and will be conducted as per current processes.
Prior to approval	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.
Post-market label changes:	(1) If the change relates to a change in brand name, please refer to the 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). (2) If the change is as a result of a change currently designated as a Level II 90 or 120 day Notifiable Change (NC), follow the current process. (3) If changes are made exclusively to the label design elements: a. These should be filed as S(A)NDS-labelling only if they are

	significant b. These should be filed as Level III safety and efficacy changes if they are not significant.

(d) **What types of post-market changes made exclusively to label design elements should be filed as S(A)NDS-labelling only?**

Please note since these changes are exclusively to label design elements, 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, along with copies of previously approved labels to facilitate timely review.

Some examples include:

- 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

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.

(e) **What types of post-market changes made exclusive to label design elements should be considered Level III Safety and Efficacy Changes?**

Some examples 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.

(f) **What is an acceptable format in which to receive electronic mock-up labels?**

For submissions submitted in Common Technical Document (CTD) or electronic Common Technical Document (eCTD) format, electronic 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.

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

The *Good Label and Package Practices Guide* (http://www.ismp-canada.org/download/LabellingPackaging/Draft-GoodLabelandPackagePracticesGuide-EN-2015-03.pdf) 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. It is currently available online.

The 2014 version of the *Guidance Document: Product Monograph* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_mp_2013-eng.php) is also available online. It provides direction on the content and format of these documents and also references sources of information on plain language labeling.

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 mock-ups and is available online.

7 - How does the mock-up requirement apply to administrative submissions?

Label mock-ups will be required for all submissions including those 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.

To be eligible under the above noted policy, sponsors will continue to be required to 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 be required to 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* http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2014-review-examen_drug-medicament_names-marques/faq-eng.php), 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.

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.

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* (http://www.ismp-canada.org/download/LabellingPackaging/Draft-GoodLabelandPackagePracticesGuide-EN-2015-03.pdf) 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, 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)*