Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

May 31, 2017

Notice to Stakeholders

The intention of Plain Language Labelling (PLL) Regulations is to improve the safe use of prescription and non-prescription drugs by making labels easier to read and understand. PLL regulations impose new obligations on sponsors of non-prescription drugs, including the requirement to include a Canadian Drug Facts Table (CDFT) on the outer labels of products.

This notice outlines the implementation approach to have all non-prescription drug labels in compliance with the requirement for a CDFT. Stakeholder feedback has been considered in finalising specifications for the facts table and the implementation approach.

Submissions

Health Canada will require that for non-prescription drugs, any new Drug Identification Number (DIN) applications or (Supplemental) New Drug Submissions submitted on and after June 13, 2017 to be in compliance with the PLL Regulatory requirement which includes the presence of the CDFT on the product labels. This applies to new products, or marketed products with a substantive enough label change that the issuance of a new Drug Identification Number (DIN) or Notice of Compliance (NOC) is required. For details on the requirements related to submission filing, please consult *Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs and Contact Lens Disinfectants*.

Marketed Products

All non-prescription drug products must be in full compliance at the retail level by June 30, 2021.
Marketed products coming into compliance are not required to file a submission solely for the purpose of complying with PLL, provided there are no substantive label text changes (i.e., label changes that would require a new DIN or NOC) and that labels follow the standard CDFT format. Marketed Category IV monograph products as well as mouthwash and toothpaste, are not required to file a submission solely for the purpose of complying with PLL, provided there are no substantive label text changes (i.e., label changes that would require a new DIN) and that labels follow the "Category IV CDFT flexibilities." If there are substantive changes that would require a new DIN or NOC, a submission would need to be filed.

Compliance

As of June 30, 2021, regulated parties are expected to be in full compliance with the Drug Facts Table requirement at the retail level, and Health Canada will begin activity to verify compliance. As always, Health Canada retains the authority to take action at any point to assess and mitigate a potential risk to health and safety.

Preamble

The utmost care has been taken to ensure the accuracy of information presented in this guide. The guide reflects the information available during its development and is meant to provide initial considerations when preparing the content and design of labels and packages. It is anticipated that new research on various topics addressed in this guide will become available in the future, and revisions may be warranted to integrate such new information.

This document should be read in conjunction with the relevant sections of other applicable Health Canada regulations, guidance documents, and policies.

Organization of the Guide

The guide is divided into three parts:

Part 1 presents the objective, introduction, and scope. It also provides an overview of the process used in developing the guide.

Part 2 addresses the specific components applicable to the design of labels and packages from a safety perspective. The section for each component presents background information followed by recommendations.

Part 3 provides information on the design specifications and permitted flexibilities for the Canadian Drug Facts Table for Non-prescription Drugs.

The appendices contain supplementary information to the guide as follows:

Appendix 1: Glossary
Appendix 2: Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging
Appendix 3: Product-Use Process Maps
Appendix 4: Acknowledgements

All parts of the guide and its sections should be considered together (i.e., no topic is to be considered in isolation).

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1 Overview of the Guide

1.1 Objective

The objective of the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products is to provide direction to sponsors, manufacturers and license holders (to be referred to as 'sponsors' within this guide) in designing safe and clear labels and packages.

It is essential that all labelling and packaging regulatory requirements be met.

The recommendations provided in this guide will aid sponsors in the organization of (a) information required by the regulations, and (b) other complementary information important to the proper identification, selection, and use of the products. The information is presented to support the design and development of labels and packages that are clear, effective, and minimize the risk of errors causing harm.

1.2 Introduction

The label and package are the first points of interaction between a health product and a consumer or healthcare professional. The user may be a consumer selecting a bottle of pain medication or a blister pack of allergy medication, or a naturopathic doctor selecting a product from a dispensary. The label and package communicate key information about the safe and proper use of health products and are important aids in product identification, selection and use. For consumers, this is even more critical, as they help inform decisions when there is limited interaction with a healthcare professional. The ability to perform product identification, selection and administration safely is dependent on the user being able to read and understand the information on the label.

Through the Plain Language Labelling (PLL) Initiative, new *Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)*[1] have been introduced with the intention of improving the safe use of drugs by making drug labels easier to read and understand. These amendments include a requirement for a standard table format for outer labels of non-prescription drugs, the addition of contact information on the label and the submission of label and package mock-ups. The content presented in this guide will provide information that supports the objectives of the Plain Language Labelling Initiative.

Note: While natural health products (NHPs) are not covered under the PLL regulations, the guide offers guidance to NHP sponsors in the design of safe and clear labels and packages. If a sponsor wishes to use a facts table, refer to Part 3, section 3.7, "Product Facts table for natural health products".

1.3 Scope

This guide focuses on the inner and outer labels and packages for non-prescription drugs, natural health products, and contact lens disinfectants. Any of these may be referred to as a "product" or "health product" in the context of this guide. The content presented provides information that supports the design of safe and clear labels and packages.

This guide is **not** applicable to:
- prescription pharmaceuticals
- biologics and radiopharmaceuticals
- drugs that are permitted to be sold without a prescription but that are obtained or administered only under the direction of a healthcare professional (e.g., exempted codeine preparations per the *Narcotic Control Regulations* 36(1),[2] nitroglycerin, insulin, injectable epinephrine for anti-allergic purposes)
- disinfectants with the exception of contact lens disinfectants
- active pharmaceutical ingredients
- drug products used in clinical trials
- drug products for veterinary use, and
- cosmetics

The guide complies with the *Food and Drugs Act*, *Food and Drug Regulations*[3] and the *Natural Health Products Regulations*[4]. It is essential that all regulatory requirements are met in the design of a label and package. The guide complements Health Canada's Guidance Document: Labelling of Pharmaceutical Drugs for Human Use[5] and the Labelling Guidance Document for Natural Health Products[6].

Aspects of product labelling that are not covered include the naming of health products, user-applied labels, product monographs, package inserts (e.g., prescribing information, consumer leaflets).

Note: If a Drug Facts table is required by regulations, the specifications outlined for the table must be followed. (Refer to Part 3, "Drug Facts Table for Non-prescription Drugs" for more information.) Other recommendations in this guide are provided for inner labels and for products not requiring a Drug Facts table.

1.4 Content contributing to guide development

A large volume of information has been published providing direction to optimize the design and content of health product labels and packages to support safe use. This body of knowledge, along with additional research and consultation on the topic, has been reviewed and adapted to produce this guide and is inclusive of the following:
- Applicable Canadian regulations, standards, policies, and guidelines
- Health Canada risk communications applicable to inner and outer labels and packages
- Package and label changes and relevant learning from published reports of safety incidents with labels and packages identified as a contributing factor
- Aggregate analysis of error reports voluntarily submitted to the Institute for Safe Medication Practices Canada (ISMP Canada) in which sponsor's labels or packages were explicitly identified as a concern or a contributing factor[7,8]
- Consideration of human factors issues and principles (refer to Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging")
- Applicable international regulations, standards, policies, and guidelines
- Concepts applied to labelling and packaging of health products by safety organizations (e.g., the United Kingdom's National Patient Safety Agency, now part of the National Health Service)
- Engagement of an international, multidisciplinary expert advisory panel and other relevant stakeholders and experts (refer to Appendix 4, "Acknowledgements")

Note: Although some published information may be related to prescription drugs, lessons learned can provide important and valuable information and concepts that can be applicable to preventing confusion or errors involving all health products, e.g., look-alike labels and packaging.

2 Designing Labels and Packages for Safety

2.1 Introduction

Part 2 of this guide presents information on current good practices in the design and layout of a health product label, the information contained on the label, and the design or choice of package. The topics and principles cover various contributing factors in reported medication incidents and issues identified by environmental scans of sponsors and users.

Although the various topics are presented separately within Part 2, they must be considered together to achieve a balance between standardization and differentiation (e.g., within a sponsor's product line). Standardization of product labels and choice of packages can reduce errors by reinforcing the pattern recognition on which humans rely when processing information.[9] However, the more label or package characteristics that products have in common (e.g., type style, size and colour of type, size and shape of container or package, layout of information), the more likely that products will look alike. The cumulative effect of individual label and package characteristics can result in look-alike issues that make it difficult for users to distinguish one product from another. The potential for look-alike issues should be considered during the design phase of a product's labelling and packaging. Similarly, changes to existing product labels and packages should strike a balance to prevent introduction of new look-alike issues. Achieving a balance between standardization and differentiation is particularly important to prevent (or resolve) look-alike issues for a sponsor's higher-risk products.

In addition to all the topics discussed in the guide, sponsors are strongly encouraged to consider human factors aspects of product selection, use and handling, as well as consumer use studies in accordance with a risk based approach (refer to Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging") in the design of labels and packages.

2.2 Planning the design of labels and packages

When designing product labels and packages, sponsors are strongly encouraged to undertake a number of steps. The following is an overview of the steps that sponsors can incorporate into existing product development:

- Consider the design of health product labelling and packaging as early as possible in the development process.
  - Development of the package should begin early. Factors influencing the choice of a package should go beyond maintenance of stability, ease of manufacturing, or marketing considerations. The package design will also affect the size of both inner and outer labels.
  - For products gaining approval in Canada, the sponsor may already have experience in other markets. Carefully review complaint and incident data to determine if changes are needed for the planned label or package of the health product for the Canadian market.
- Identify the users of the product and their environments of use.
  - Designing a label and package for safe use requires keeping the users and the environments of use at top of mind throughout product development.
  - At a minimum, review the questions in Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging", to identify the users and environments of use. These questions are intended to elicit a wide range of considerations, and their answers can provide opportunities to understand factors important to safe design.

- Product-use process maps can be helpful when human factors-based user testing is planned, in that such maps will help in identifying the scope of use and the primary users. (Refer to Appendix 3, "Product-Use Process Maps" for an example.)
- Consider other products that might be used simultaneously with the product of interest as products are rarely used in isolation.
- Consider consumer use studies. A variety of consumer use studies and other methods have been applied to the design and redesign of labels (refer to Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging").
- Prepare mock-ups of the label and package, including the outer packaging. Mock-ups can have multiple uses (e.g., consumer use studies, focus groups, submission for approval where required by regulations).
- Use a continuous improvement approach. Review complaint and incident data to identify challenges and unanticipated label or package problems early in the design process and following marketing. Manufacturers should monitor trends and implement risk-mitigation measures to improve labels and packages. Gathering information throughout the product life-cycle is a proactive approach and can assist with package and label design.

2.3 Design and layout

2.3.1 Type style and size

Background
Illegibility of printed information is a contributing factor in health product errors.[8,10] Interactions between or changes to typographic elements on a label (e.g., type style, size, spacing, use of bold or italic, colour, contrast) can affect both legibility and comprehension.[11] Label information must be legible to users in the real-world environments or situations in which products will be used.

Recommendations
For the purpose of the Drug Facts table, sponsors are required to use the type style, size and formatting as specified in Part 3, "Drug Facts Table for Non-prescription Drugs".

The following recommendations do not apply to trademarks, copyrighted text, and logos.

Type style (Typeface)

- When choosing a type style, consider that different styles of the same point size do not appear the same in size.[11]

Calibri	9 point
Arial	9 point
Arial Black	**9 point**
Univers	9 point
Verdana	9 point

- Use of a sans serif type style (e.g., Helvetica, Univers), that is not compressed, expanded, or decorative is preferred for key information.[12] A sans serif type style has no decorative extensions, is crisper and cleaner, and typically appears larger than a serif style of the same point size.[13] Compressed or condensed fonts may be more difficult to read, even with a larger point size.[11]

- Choose a type style with adequate spacing between letters (to enhance legibility) and between words (to enhance readability).[11] Narrow letter and word spacing can cause apparent merging of words, whereas extremely wide spacing can be disruptive to the reader.[11] Adequate spacing can also reduce possible illegibility if ink were to bleed.
- Avoid using all capital letters[11,12,14,15] (exceptions: brand names, headings, and warnings that are brief may be fully capitalized). (Refer to section 2.4.3, "Warnings".) The use of all capital letters reduces legibility and adversely affects readability to a greater extent than any other factor. Lowercase characters have more variation (e.g., letter shapes) in their features, which results in better legibility.[11]
- Avoid the use of italic type except to emphasize a particular portion of text.[11]
- For the Drug Facts table, please note the specific requirements for type style as listed in Part 3, "Drug Facts Table for Non-prescription Drugs".

Type size
- Use a type size that can be read easily by a variety of users (e.g., elderly people, those with visual impairment) in environments where products will be used (e.g., in a room with low lighting). The following examples show one type style in various point sizes to illustrate that small changes in point size can affect readability:

  this is Verdana 4.5 point
  this is Verdana 6 point
  this is Verdana 8 point
  this is Verdana 9 point
  this is Verdana 10 point
  this is Verdana 12 point

- The largest type size possible is recommended. However, a point size less than 6 should not be used for key information, [12,16] including that on the inner label. Key information includes the key elements (refer to section 2.4.1, "Key Elements on the Principal Display Panel") and label information required by regulations.
- To enhance legibility when using smaller type sizes (e.g., on small containers), consider using a background colour that is significantly different from the type colour.[11] (Refer to section 2.3.4, "Colour and Contrast" for further information.)
  - Type of very small size may be made more easily readable in combination with other characteristics, e.g., font, colour, white space, bolding, etc.
- The *Food and Drug Regulations* require that the type of the proper or common name be, at a minimum, half the size used for the brand name.[17]

General formatting
- To enhance readability, use flush left, ragged right alignment of multiple lines of text (as in this document). This form of alignment provides visual points of reference that guide the reader's eye smoothly from line to line. Since each line is either shorter or longer than the next, the eye is cued from one to the next.[11]
- To enhance the readability of information, use bullet lists, with items in point form instead of complete sentences, if possible.[12]

- When providing stepwise directions, use numbered lists and keep all text for each individual step on one line, if possible. This makes it easier for users to follow the instructions and enables them to find their place again if interrupted.[12]
- Use contrasting characteristics (e.g., type size, weight, bolding, colour, and spacing) to help users distinguish one product from another, and to highlight important information to facilitate safe use of the product, and enable the user to quickly find the information needed.[12] For example, if it is necessary to present information in paragraph form, use of bold type for key words or phrases or use of subheadings can make it easier and quicker for users to find the information they need.[12] The following example shows how bold type or subheadings might be used on a product label:

> **CAUTION: Keep out of reach of children**. This package contains enough medication to seriously harm a child. Use the smallest effective dose. **Do not** take more than the recommended dose unless advised by your physician.

2.3.2 Proximity and compatibility of information on the principal display panel

Background

The Proximity Compatibility Principle specifies that all information relevant to a common task or mental operation should be displayed close together.[18,19] For example, the name, strength and dosage form are distinct but closely related elements used to identify a health product and would be placed in close proximity on a product label. Conversely, the net quantity in the package is not related to this information or needed to identify the product and would therefore be placed in a separate location. Confusion errors have been reported when the product strength (a numeric value) and the unit or pack size (another numeric value) were placed in close proximity.

Proximity and compatibility can be affected by other label and type attributes, such as colour, type style, and type size and weight. Use of the same colour(s), type style, point size, and markings or graphics can inadvertently link pieces of information (e.g., numeric values) even when there is physical distance between them on the label.

Recommendations
- Place items that are relevant to a common task or mental operation (e.g., health product name, strength, dosage form, route of administration) close to one another on a product label.[19,20]
- Consider how the various elements of the label are presented as a whole. In addition to grouping closely related information together on the principal display panel, consider how the colour, type style, and type size and weight visually separate or connect different pieces of information. For example, if the number of tablets in a package (unit pack size) is presented in the same colour as the product strength, but has a more prominent appearance (e.g., in bold type or larger type size), the number of tablets may be misinterpreted as the strength or dose.
- List the net quantity in the package separately from, and less prominently than, the product strength. Displaying this information together (e.g., 10 mg/7 tablets) has been a contributing factor in medication errors.[8] The number of units can remain on the principal display panel but should be separated either physically or through design features so to reduce the chance for it to be misread as the product strength.

- Avoid separating unrelated information with marks that could be misinterpreted. For example, if a point or a dash is positioned between the dose and the total volume in the container, the volume might be misinterpreted as part of the dose (e.g., "1000 units • 25 mL", where "25 mL" refers to the total volume in the container, not the strength per total volume, and might be interpreted as "1000 units **per** 25 mL").
- When possible, avoid placing unrelated information (including graphics) between the product name and its strength.[21,22]
- To ensure that key information is legible and not subject to misinterpretation, avoid superimposing text and images (or logos).[23]
- List the standard of manufacture, as applicable (e.g., United States Pharmacopeia [USP], British Pharmacopoeia [BP]), in close proximity to a product's proper name.[5]

2.3.3 White space

Background

White space is an important aspect of design and requires careful consideration during the design phase. It should be used as liberally as possible to enhance the readability of health product labels,[24] so that consumers and healthcare professionals can quickly find the information they need to facilitate safe product use.[12]

The term "white space" does not necessarily refer to space on a label that appears white. Depending on the background colour, it may be more accurate to use another term, such as "blank space". Such white space on a health product label or package refers to any space not covered by print, markings, coloured graphics, watermarks, or other elements of the label.

White space surrounding text can create a feeling of openness.[25] It can also help readers to focus on what they are reading.[13] Importantly, it may improve readers' willingness to read and their ability to find and process the information presented, because it helps to reduce the concentration and mental workload required.[25,26]

Recommendations
- Incorporate white space as part of the design and layout of information on health product labels as early as possible in the design process. White space should be used for the following purposes:
  - to frame a particular grouping of text (e.g., bulleted lists) and to separate unrelated information
  - to separate one sentence from another
  - to separate paragraphs (to help distinguish one idea from another)
  - around headings and key information (e.g., warnings) to emphasize their importance
- Maximize the use of white space to avoid crowding information on the label when smaller type size is used. Increasing the space between lines may be especially helpful for elderly users.[13]
- Standard formatting of the Drug Facts table per Part 3, "Drug Facts Table for Non-prescription Drugs", may assist in creating appropriate white space.

2.3.4 Colour and contrast

Background

Colour on the inner and outer labels of health products must be carefully applied to help, and not hinder, the selection of appropriate products by users. The application of colour is just one of many factors to be taken into account in the design of health product labels and should not be considered in isolation.

People with normal colour vision are able to detect differences between similar colours only when the colours are placed side by side. Without side-by-side comparison, similar colours cannot be easily distinguished, and errors can be made if colour is the only variable used on a health product label. For example, problems may arise if different strengths of the same product are differentiated by using variations of one specific colour.[11]

In addition, under less-than-optimal conditions, the ability to discern colours can be further reduced, for example, when print appears on small containers or labels, when viewing time is short (e.g., urgent situations, distractions), when a lower level of lighting is used, and when colours of similar products are physically separated (i.e., not viewed together).[27]

The effect of colour in label design can be affected by colour-blindness.[6,23,28-30] Certain types of colour-blindness are more common than others. Colour-blind users may have limitations in their perception of specific colours[23,31] (e.g., red-green) or may have difficulty in reading text in particular colour combinations or on particular colour backgrounds[27].

Contrast

Contrast is a fundamental design principle that is used to help the user detect differences in what is seen.[32] It is an important factor for the readability of text, particularly on packages with a coloured background.[1,9,15,20,22,23,29,30,33-36] For example, it has been recommended that text of a dark colour be used on pale backgrounds to ensure sufficient contrast for optimum visibility.[9,14,15,22,23,35,37]

Colour differentiation

While trade dress and logos can assist in the selection process, care must be taken to appropriately differentiate products within a product line to increase user understanding and decrease the potential for confusion. Colour differentiation is generally used to highlight particular features on a product label or to help distinguish one product from another.[9,38] However, repeated use of this particular technique can lead to look-alike product labels,[9,23,33,37] which can in turn predispose users to confirmation bias (i.e., users see what they expect to see). Colour differentiation can also reduce the prominence of key information if it is not used skilfully.[14,33]

By convention, some colours are typically recognized as conveying certain meanings (e.g., red may convey danger, orange may convey a warning, yellow may convey the need for caution).[27] Such conventions are commonly used for signage in dangerous or hazard-prone environments, e.g., for traffic signs or for containers holding hazardous chemicals.[39] Aside from these examples, subjective meanings for colour may also exist in specific populations of users.[40]

Recommendations

Refer to Part 3, "Drug Facts Table for Non-prescription Drugs", for specific colour and contrast recommendations for the facts table.

Use of colour

- The application of colour is just one of many factors to be taken into account in the design of health product labels and should not be considered in isolation.
- Colour choices should take into account the following general principles:
  - Hue: Colours opposite each other on the colour wheel (e.g., blue and orange, yellow and violet) are considered to have more contrast than colours closer together on the wheel (e.g., violet and blue, orange and red) and therefore provide greater differentiation in hue.[41-43]
  - *Saturation:* Fully saturated (bright) colours combined with low-saturation (dull) colours provide greater contrast than combinations of colours of a similar saturation level.[41]
  - *Value:* Colours with a low value (dark colours) placed beside or against colours of a high value (light colours) have greater contrast than colours with similar values.[43]
- Use colour for the following purposes:
  - to draw attention to important label information,[9] such as the name of a health product and its strength[20]
  - to bring attention to or enhance the prominence of warning statements[9,22,44]
  - to differentiate one product from another[29] or to differentiate between strengths within a product line[29,33,45,46]
- While trade dress and logos can assist in the selection process, care must be taken to appropriately differentiate products within a product line to decrease the potential for confusion.
- To enhance differentiation among product strengths, use a colour with a different hue, rather than a different intensity or value of the same colour.[15] For example, avoid using different shades of blue for various strengths, and instead use distinctly different colours.
- Consider using more than just colour to distinguish between products.[22] Other techniques for differentiation include colour bands, frames or keylines (i.e., boxes around text).
- When selecting colours for labelling and packaging, consider the potential implications of colour-blindness (e.g., avoid using both red and green together,[6] because they may not be easily distinguished by those with red-green colour-blindness). Computer simulation programs, such as Vischeck,[47] may be used to determine how colours will be perceived by individuals with different forms of colour-blindness.
- Match the styles of inner and outer package labels so that the visual appearance, including use of colour, is identical or related.[23,33] This approach can help to ensure that users (re)place an inner container into the correct outer package as needed. It can also help users to identify the corresponding outer (secondary) packaging when they need information that may be available only on that outer package (e.g., directions related to a health product in a small-volume container). Such matching between a container label and its outer package or box label reduces the amount of information that needs to be processed simultaneously by the user.[48]

Contrast

- Maximize the legibility of text by ensuring good contrast between text and background[9,20,22,33,49] (e.g., apply dark text on a pale background[15,29,35,36]). Avoid the use of type and background colour

combinations that are known to be very difficult to read (e.g., black or yellow type on a red background[35]).

- Use opaque labels on clear or translucent containers to ensure that type is legible and does not show through the container.[23] Ensure that sufficient clear area remains after application of the label to allow the user to view the contents of the container.[23]
- If a paper label is not an option, use contrasting type ink on an opaque background on the translucent container to maintain readability.[23]
- Engraving (i.e., embossing and debossing) of type onto a container may not provide sufficient contrast on its own; therefore, if such methods are used, highlight the type with ink.[15]
- Ensure that any symbols required by regulations have sufficient contrast against the background colour.[17]

Containers
- Graduation scales on oral dosing devices (e.g., oral syringes) should be easily legible. For example, use black ink on a white field of view.[14]
- For blister packs, use a non-reflective material for the backing, so that information is legible.[21-23,33]
- For liquids in clear containers, affix labels with colourless glues to prevent misperception of container contents as being discoloured.[14]

2.3.5 Use of abbreviations, symbols, and dose designations

Background
The use of certain abbreviations (e.g., OD), symbols (e.g., μ), and dose designations (e.g., 1.0 mg) to convey health product-related information has been identified as an underlying cause of serious, even fatal errors.[50] An abbreviation may have more than one meaning and may therefore be susceptible to misinterpretation,[22] particularly if users are unfamiliar with the intended meaning. Practices and terminology may vary among different individuals or groups (e.g., consumers, physicians, pharmacists, naturopathic doctors and homeopaths).

Recommendations
General
- Minimize use of abbreviations, symbols, and dose designations in health product packaging and labelling.[22,50]
- Avoid the use of **error-prone** abbreviations, symbols, and dose designations.[22,50] Refer to ISMP Canada's "Do Not Use" list for further details.[50] This list (adapted from a list prepared by ISMP US[51]) takes into account medication errors voluntarily reported to ISMP Canada for which the reporter identified an abbreviation, symbol, or dose designation as a potential contributing factor in incidents causing harm or having the potential to cause harm.
- Ensure that any abbreviations used provide information that is useful and easily identifiable to the users (e.g., consumer, healthcare professionals).[52]
- An abbreviation should not be ambiguous or otherwise have the potential to be misinterpreted by the user. In particular, avoid abbreviations that indicate dosing schedules. (For example, "QD" may be read or misinterpreted as "QID", and "OD" may be interpreted as either "oculus dexter" [Latin, meaning "right eye"] or "once daily"[52]).

- Use international or national standards for abbreviations (e.g., abbreviate "milliliters" as "mL"[53]). Note: The symbol "µg" (meaning "microgram") conforms to the International System of Units (SI) and is often used in scientific literature. However, for labelling purposes, the abbreviation "mcg" should be used instead.[5] The Greek letter "µ" may be difficult to see in some print and size formats and may be misread as the letter "m" (i.e., "mg" for "milligrams", rather than the intended "µg" for "micrograms").
- The proper or common names of health products and any active or medicinal and inactive or non-medicinal ingredients in the product should not be abbreviated.[5,14,15,50]
- Define abbreviations used on any product dose delivery devices provided. Ensure that abbreviations used on such devices are consistent with abbreviations used on product labels and packaging, such as label directions, outside packaging (carton labelling), containers, and any accompanying written materials.
- Comprehension testing for any new abbreviation is highly recommended (refer to Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging").

Route of administration
- Express in full the route of administration, so that the consumer is provided with clear information for safe and appropriate use.

2.3.6 Bilingual labelling

Background
Bilingual labelling may pose challenges for the readability of inner and outer labels because of the possibility of crowding of information. Consumer and healthcare professional feedback gathered in the development of the guide highlighted the following concerns:

- ensuring adequate space for both English and French text, while preserving white space especially when space is restricted (e.g., small containers); French text tends to be slightly longer than the corresponding English
- ensuring accuracy and meaning of health product information is preserved in both languages
- ensuring standardization and consistency of formatting for bilingual text on health product labels (e.g., product name, salt forms of the active or medicinal ingredient, placement of certain pieces of information, prominence of specific information)
- recognizing subtle differences between English and French in how information is presented and interpreted (e.g., use of a period [English] or a comma [French] to denote the decimal)

Recommendations
General principles
- Consider bilingual labelling early in the label and package development process, to accurately determine the amount of label space needed to accommodate required product information.
- Note: Separate unilingual packaging is not acceptable for non-prescription drugs and natural health products. At a minimum, adequate directions for use in both English and French should be provided for non-prescription drugs.[1,5,6] (With respect to natural health products, refer to section 87 of the *Natural Health Products Regulations*.[4]) Some provincial regulations may have additional language requirements for labelling, e.g., Québec Charter of the French Language.[54]

- If including English and French on the same panel where space is limited, consider how best to display key information in a consistent manner, within and across product lines. (Refer to Appendix 1, "Glossary" for the definition of "key information".)
- Refer to Part 3, "Drug Facts Table for Non-prescription Drugs", for formatting recommendations specific to the facts table that may help to accommodate information in both languages.

Organization of information
- For product packages or containers with multiple panels or sides (e.g., an outer box), it is preferable to dedicate an entire label panel for information in English and another for information in French.
- Where packages have only one or two panels available or packages have limited space, consider using different types of labels or innovative labels (e.g., peel-back labels) to accommodate information in both languages. Novel label formats should comply with applicable regulations and guidance documents.[1,5] (Refer to section 2.5.2, "Small Containers and Small-Volume Containers".)
- Identify commonalities in English and French for the key information, and determine if the information can be combined to save space. When information (i.e., the drug name) is the same in English and French, consider combining this, instead of repeating all details in both languages.

Expression of strength or concentration
- For large numbers (greater than 9999), use a thin space, rather than a comma, to separate digits into groups of three (e.g., 10 000). (Refer to section 2.4.2, "Expression of Strength".)
  - Although in English a comma is frequently used to separate groups of digits in large numbers (e.g., 10,000), in French a comma may be used to denote the decimal point. The meaning of a comma may therefore be unclear for some users.[53]
  - According to the SI system of units, a decimal or decimal marker "shall be either the point on the line or the comma on the line" and "for numbers with many digits, the digits may be divided into groups of three by a thin space, in order to facilitate reading. Neither dots nor commas are inserted in the spaces between groups of three."[53]
  - Ensure that the gap between numbers is large enough to indicate that the numbers are grouped in threes, but not too large, so that the groupings will still be interpreted as representing one number.
- Consider how to standardize the display of product concentration when the unit of measure differs in the two languages (e.g., "units" in English, "unités" in French). Considering the commonalities of key information may help for combining information.
- For product packages with no distinct panels or sides (e.g., eye drops), take into account the field of view available for the key information. (Refer to section 2.4.2, "Expression of Strength", for information on displaying more than one expression of strength on a label.)

2.3.7 Logo, branding, and trade dress

Background

Whereas logos, trade dress and branding can assist in differentiating products from different manufacturers, incident reports have indicated that they have the potential to contribute to errors and impede the safe use of health products.[8] The following issues, among others, have been identified:

- Trade dress may be a factor in look-alike labelling and packaging, particularly for
  - products from the same sponsor
  - items across a product line, where the trade dress and brand names are similar, despite the use of modifiers such as "Plus"[8,55,56]
- Graphic elements and "branding" text may interfere with the clear presentation of information that is important to the user.[57] In particular, these aspects of labelling may prevent differences in important information (e.g., strengths, ingredients, indications) from being clearly evident and noted at the time of selection or administration.

Issues can also arise after redesign of a well-known product label. Reasons for a redesign may include standardizing the look of products nationally or internationally,[58] fulfilling marketing purposes, or revising certain aspects of the label to help ensure that errors do not recur. Label redesign requires a balance, such that any existing positive design aspects are maintained for the benefit of users. It has been noted that "while not always feasible, it is important to retest the label designs as they are modified for various purposes, to ensure the changes cause no disruption to the system and user performance."[59]

Recommendations

- Logos and trade dress on product labels should not distract the user or impede the effective communication of key information to the user.[5,8,16,29]
- Strive for balance between the use of corporate trade dress and the presentation of key information on labels. While prominence of trade dress and branding may assist in locating a specific product within the retail environment, it may make it difficult for users to distinguish between different products or different strengths of the same product.[8]
- Consider the amount of space required for a logo and how much space will be available for product information on the remainder of the label.
- Ensure that key information within a product line is clearly differentiated among products to avoid look-alike confusion and the potential for selection error.
- Clearly distinguish different strengths of the same health product or the presentations of different health products by the same manufacturer. Consider the use of colour, together with other elements of the label and package, such as size, shape, or features of the container closure.[8,60]
- When making changes to the label or package, consider consumer use studies before release on the market, to help reduce the potential for unintended consequences (e.g., when rebranding or adding to a product line).[20]

2.3.8 Permanence

Background

The safe labelling of health products ensures that all information is readable for the duration of the shelf-life of the product.[6] It has been noted that important information on product labels may be inadvertently removed with handling and use.[61]

Recommendations
- Ensure that print on products will remain legible for the entire life of the product, taking into consideration transportation and storage conditions, as well as environments of use.[6]
- Consider special technologies, such as smudge-resistant paper stock[62] and inks containing adhesives, which will bond to a variety of surfaces, including plastics.
- Use inks that will be durable enough to withstand normal handling.[15]

2.4 Label information

2.4.1 Key elements on the principal display panel

The principal display panel of a label is the first interface between the user and a health product. It is an important factor in product identification and selection. Health Canada regulations specify information that is required to appear on the principal display panel of a product (*Food and Drug Regulations* C.01.004;[17] *Natural Health Products Regulations* 93(1)[4]).

Sponsors are expected to be familiar with the regulatory requirements for their particular product.

In addition to the information required by regulations, eight key elements were identified by the expert advisory panel of consumers, healthcare professionals, and regulators providing input during the development of this guide. These key elements assist the user to correctly select a product and use it appropriately. These were noted to be the key pieces of information for inclusion on the principal display panel of health product inner and outer labels (see note below). They align with national and international standards and safety literature, but do not incorporate all of the information required by regulation or guidance for each type of health product. For example, the drug identification number (DIN) or natural product number (NPN), as applicable, is required by regulation, yet is not listed among the eight key elements.

The eight key elements are:
1. brand name of health product
2. non-proprietary name (proper or common name) of health product
3. strength
4. dosage form
5. route of administration (other than for oral solids, such as tablets)
6. warnings, as relevant
7. population, as relevant (e.g., pediatric)
8. storage instructions, as relevant

Note: It is vital to consider each specific product, its users, the environment(s) of use, and the regulatory requirements to determine which of the eight key elements may be needed to ensure safe use. (Refer to section

2.5.2, "Small Containers and Small-Volume Containers".) For example, oral liquid products may be used in environments such as hospitals or even homes where intravenous access may exist. Because it is possible for any liquid product to be injected,[63] or a suppository to be ingested, it is critical to state the intended route of administration (oral for the liquid, rectal or vaginal for the suppository) on the principal display panel of the label on such products.

At the same time, certain non-prescription drugs, such as cough and cold medications and many natural health products, have multiple ingredients. Listing the proper name of each ingredient and its strength can crowd the principal display panel, particularly for small containers. The use of the Drug Facts table for non-prescription drugs and the Product Facts table for natural health products will assist consumers in being able to select and properly use products. (Refer to part 3, "Drug Facts Table for Non-prescription Drugs" and section 3.7, "Product Facts Table for Natural Health Products".)

Storage instructions are one of the key elements that are not addressed in a separate section of this guide. It may be relevant to include such instructions on the principal display panel if the typical storage requirement for the product is other than room temperature. For example, products that require refrigeration are less typical, and refrigeration instructions for products requiring low storage temperatures should therefore appear on the principal display panel as an alert to users.

2.4.2 Expression of strength

Background
Expression of strength (also referred to as the quantity of a medicinal ingredient for natural health products) is a key piece of information on a health product label. Unclear expression of strength, or a missing expression of strength, can impede correct selection and use of products. Individual products may be available in multiple strengths, and strength may be expressed in a variety of units; as a result, product strengths can be easily misinterpreted.[9]

The following list presents examples of labelling practices that may introduce confusion because of the way in which the strength of a health product is expressed:
- using different units for volumes[64] (e.g., "per mL", "per tsp")
- placing the drug strength (a numeric value) and the unit or pack size (another numeric value) in close proximity[22] (refer to section 2.3.2, "Proximity and Compatibility of Information on the Principal Display Panel")
- using trailing zeros (e.g., "2.0", "2.50") or naked decimals (e.g., ".2") (if the decimal point is not correctly perceived, a 10-fold over- or under-dosing error could occur[8,50])
- using certain SI unit abbreviations that are prone to being misread (e.g., for "microgram", the use of "μg" rather than "mcg" may be difficult to discern in some print and size formats and could be misread as "mg"[5])
- inconsistency between the labelled product strength and the directions for use

Other important issues related to the expression of a product's strength may increase the possibility of confusion and error. With regard to health products in the form of a salt, potencies and content of the active component can differ significantly among various salt forms. Therefore, there may be inconsistency in how information is presented and how users refer to (or understand) the strength. Users may find it difficult to distinguish between the dose of an active ingredient's salt form and the dose of the active moiety itself.[65] It is also important to

differentiate between two or more formulations of the same active ingredient, especially when the doses differ significantly.

Dosage forms that release or deliver an amount of product different from the total amount in the container may need careful consideration. An example is a nicotine inhaler, which contains 10 mg per cartridge but delivers only 4 mg. Such a discrepancy may cause confusion for both the prescriber and the user, because of a mismatch between how the prescribed dose is communicated and how the strength is presented on the label. Furthermore, if the available drug is interpreted as 10 mg of nicotine per cartridge, this could also result in a higher dose and an unnecessary step-up of nicotine therapy when converting from the inhaler to a longer acting transdermal nicotine patch.

Recommendations
General principles
- Express the dose strength of a health product ("the quantity of a medicinal ingredient" in the case of a natural health product) in an appropriate metric system unit.[14,15] Exceptions are situations where other units of measure are accepted and required, such as units of potency (e.g., international units), percentage strength for topical preparations,[20] expressions of dilution for homeopathic medicines, and colony-forming units (abbreviated as "CFU") for probiotics. Numbers without units of measure should not be used to express product strength.
- Use "mcg" rather than "µg" for "micrograms".[50]
  - Health Canada recommends that the abbreviation "mcg" be used.[5] The use of "µg" may be difficult to see in some print and size formats and the Greek letter "µ" might be misread as "m",[5] which can be a contributing factor to dose errors. (Refer to section 2.3.5, "Use of Abbreviations, Symbols and Dose Designations".)
- For numbers with five digits or more, separate the digits into groups of three by a thin space to help prevent misreading (e.g., 1000 mg but 10 000 mg).[53] This format is compatible with both official languages (unlike use of the comma or period) and is the format recommended by the SI system[53] and by Public Works and Government Services Canada.[66]
- Consider spacing between text characters to enhance clarity. For example, leave sufficient space around the slash character ("/") to optimize legibility, given that this character could be misinterpreted as the number "1" (one) or the letter "l" (L).
- Do not use the slash character ("/") to denote the word "or", and minimize its use for separating different pieces of information, if possible. Misinterpretation resulting in error has been reported with such uses of this character.[67]
- Avoid the use of trailing zeros (e.g., "2.0", "2.50") and naked decimals (e.g., ".2").[53]
- To the extent possible, ensure consistency between the units expressing the product strength and the units used for dosing instructions.[22]
- Avoid placing expressions of strength near other numeric information, such as the number of units in the package.[8] (Refer to section 2.3.2, "Proximity and Compatibility of Information on the Principal Display Panel".)
- Take older expressions of strength into consideration when comparable products or products of the same class are prepared for market.
  - Changes to expressions of strength, particularly for critical and specialty products, may be problematic. Before changing the expression of strength of a product to different units or a different format, it is recommended to have the new label and package undergo user testing.

(Refer to "Consumer Use Studies" in Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging".)

Expressing strength

- Avoid using both metric (SI) units and other units (e.g., milligrams combined with international units)[68] to express the strength of a given ingredient on the principal display panel of the label. Equivalencies may be better expressed and presented on a side or back panel.
- For dosage forms such as transdermal patches, and inhalers or inhalators include the total quantity of the medicinal ingredients (per patch or inhaler) and the dose delivered per unit of time and the duration of use on both the inner and outer labels.[5]
  - Label the dosage form or delivery unit itself (e.g., patch, cartridge) with the delivery rate of the drug (e.g., "x mg / day").[5]
  - Where the total quantity in the delivery unit does not correspond to the delivered dose, the total amount of drug in the unit may be presented on a side or back panel of the package, rather than on the principal display panel. This is intended to reduce confusion about dosing and to make the information readily available in the event of misuse. (Refer to section 2.5.5, "Transdermal Patches".)
- For mineral supplements in the form of a salt, follow these recommendations:
  - Both the strength of the element and that of the compound, salt or source may be needed on the principal display panel to ensure correspondence with instructions from the healthcare professional to the consumer. The salt form may affect not only the elemental strength, but also absorption characteristics (e.g., for iron and calcium products).

    Examples of expressions of strength for mineral supplements:

    Iron 35 mg
    (provided in each ferrous gluconate 300 mg tablet)

    Calcium 500 mg
    (provided in each calcium carbonate 1250 mg tablet)

Expressing concentration

- For liquids intended for oral administration, declare the quantity of each medicinal ingredient per millilitre (e.g., 5 mg / mL)[5,20] or per usual volume to be taken[5,69] (e.g., 25 mg / 5 mL). Products that are intended for use by consumers of different ages may best be labelled with the quantity of medicinal ingredient per millilitre. This allows the user to calculate the needed dose across a range of ages, with specific instructions to be provided in the Drug Facts table (refer to Part 3, "Drug Facts Table for Non-prescription Drugs") and product monograph. Oral dosing devices are important tools to assist in correct dosing. (Refer to "Dosing Devices" section 2.5.1, "General Packaging Considerations".)
- Use one or more of the techniques described in sections 2.3.1, "Type Style and Size", and 2.3.5, "Colour and Contrast", of this guide (e.g., display the information first, print the information in a larger type size, use bold type, display the information with greater contrast).
- For containers with less than 1 mL total volume, express the strength as the quantity of active ingredient in the volume provided (e.g., 3 mg / 0.5 mL).[70]
- The expression of strength should match the units of measure described in the prescribing information to avoid error.[22]

Reconstitution and dilution

- For health products that require reconstitution or dilution before use, include a relevant warning statement on the principal display panel of both inner and outer labels. (Refer to section 2.4.3, "Warnings".)
- For products to be reconstituted or otherwise manipulated (e.g., powders requiring reconstitution for oral administration, powders or teas to be mixed or steeped before oral ingestion), show the total amount of powder or dry product in the primary container on the principal display panel of both the inner and outer labels. Ensure that this number is most prominent and that it is not placed close to the expression of final strength. (Refer to section 2.3.2, "Proximity and Compatibility of Information on the Principal Display Panel".)

Expressions of strength for pediatric products

- For products intended for either adult or pediatric use, present the expression of strength on the principal display panel in a format that simplifies calculation of pediatric doses. Bear in mind that expressions of concentration may need to be applicable to both populations. For example, a product that is normally administered to an adult as a 1 g dose may be administered to a child as a weight-based dose (e.g., milligrams per kilogram [mg / kg]). Thus, if a product contains 1000 mg in 10 mL (100 mg / mL), it may be better to state the primary strength expression as "1 g / 10 mL" to aid in adult dosing, with the secondary strength expression, 100 mg / mL, facilitating calculation of doses smaller than 1 g.
- For products that require different dilutions for adult and pediatric administration, a warning may be needed on a side panel to indicate the specific dilutions required to produce a ready-to-administer dose for the intended consumer population.

2.4.3 Warnings

Background

A warning is a statement that must be highlighted and conveyed to every user before product administration, to facilitate correct product use and to prevent an error that may result in harm. Warnings must attract the attention of users and must create a balance between being explicit yet concise.[39,71] Their goal is to ensure that users notice, read, understand, and comply with the warning message.[72]

Recommendations

Refer to Part 3, "Drug Facts Table for Non-prescription Drugs", for specific recommendations relating to the addition of warnings in the facts table.

General principles

- Refer to pertinent Health Canada regulations, policies, monographs and labelling standards for warning statements and symbol requirements applicable to specific products.
- Ideally, a warning should have the following features:
    - It should appear on both the inner and outer labels of the health product,[21,33] and a reference should be made to a package insert or consumer leaflet distributed with the product.
    - It should be located in an area where users will have to interact with it in the course of using the product. For multiple-use products, warnings should not be located in an area that would be discarded after an initial interaction.[72,73] The most noticeable and effective warnings are placed in such a way that the task is temporarily interrupted and the user must physically interact with the warning before continuing.[39,44]
    - It should be suitable for the intended users, taking into account the knowledge, lowest level of ability, training, and experience of those who may encounter the warning.[39,44]
- Warnings should **not** be
    - broken up by other information (e.g., logos, background text-graphics)[25]
    - placed only on the inside panel of the outer package (e.g., printed on the inside of the box)

Warning statements

- Use statements that are as brief as possible, with words that are as explicit as possible.[5,71,73-75] Warnings provided in this manner are effective in holding the attention of users, align with the principles of plain language, accommodate the requirements of bilingual labelling, and can assist in avoiding clutter on a label.
- Use of a signal word (e.g., "WARNING" or "ALERT") is one component of an effective warning that can help to draw attention to important information.[39,44,73,75]
- If space allows (e.g., on the outer label), consider the following additional components that can help to effectively communicate the warning:
    - a description of the hazard (e.g., "Contains hydrogen peroxide.")
    - the consequence of non-compliance (e.g., "May cause burning and stinging.")
    - the required or desired behaviour (e.g., "Not for direct use in the eye.")
- Use affirmative statements,[21,72] such as "For Topical Use Only" Affirmative statements are less prone to confusion than are non-affirmative statements (such as "Not for oral use"), in which the word "not" may be overlooked.

Prominence

The following recommendations related to prominence are not intended to be applied to the warning section as a whole but rather to individual components of a warning statement that may require more prominence.

- Avoid presenting entire sentences in capital letters or italic type, as these formats are difficult to read.[29,33,44,76]
- Use white space around a warning to help emphasize the information.[29,44,71,73]

- Use colour sparingly to bring attention to components of a warning statement and to differentiate these from other text.[22,29] Red is typically used to communicate the highest level of hazard, followed by orange and yellow.
  - Particular colour combinations for words and background are associated with each of the following three signal words: red background with white lettering for "DANGER", orange background with black lettering for "WARNING", and yellow background with black lettering for "CAUTION".[72,77]
- Consider a combination of the following features to draw attention to components of a warning statement, as the combination may be more effective than any one attribute on its own:[39,72]
  - upper case letters to emphasize signal words[29,33,76]
  - large, bold print[9,22,28,76,78]
  - high contrast
  - colour[9,22,76]
  - borders[73]
  - box frames or keylines[9,74]
  - pictorial symbols[79]

Symbols
- Limit the use of symbols to warnings required by Health Canada and those that have demonstrated effectiveness in enhancing user understanding and product use.[51,75,80] Warning statements can be identified more quickly if they include symbols or pictures that are bold, have high contrast, are simple in form, and closely represent the intended message.[44,81]
- To ensure that these criteria are met, consider user testing of new or unfamiliar symbols, particularly if the product label and package are to be used across cultural groups.[39]

2.4.4 Expiry date

Background
Numerous variations exist in how expiry dates are expressed, including differences in the date format, the order of various details, and the grouping of information. These variations may present challenges to users. Incident reviews have shown concerns in two key areas: comprehension and readability.

Issues with comprehension
- Representation of the year in a 2-digit format has resulted in confusion between the year and the month (e.g., "03-04" may be interpreted as either "March 2004"or "April 2003").[9,21,22]
- Where only the year and month of the expiry date are shown (e.g., "2014-02" for "February 2014"), users, including consumers, may not be aware that expiry occurs on the last day of the month.
- Use of a 2-digit format for both the month and the day may lead to confusion between these two elements of the date when the day of the month is 12 or below (e.g., "2015-01-09" may be interpreted as either "January 9, 2015" or "September 1, 2015").
- Where no introductory word or descriptor (e.g., EXP) is included to distinguish the expiry date from the lot number, users may confuse one for the other, particularly if these two details are placed in close proximity or side by side on the product label.[9]

Issues with readability
- Users may be unable to identify the date because of poor contrast (e.g., black print on a dark background). Embossing, particularly when there is little or no colour contrast, is a related issue that may significantly affect the ability to find and read information on a label.[9,21]
- Problems may arise if the ink lacks permanence.
- Backgrounds that are shiny and reflect light may impede readability.[9]

Recommendations

Enhancing comprehension
- Include all three components of the date (year, month, day) when applicable and when space permits.[5] Where the expiry date must include the day of the month, use the 4-digit format for the year and express the month using letters (as outlined below).
  - Use hyphens between the three elements (e.g., YYYY-MM-DD for year, month, and day) for added clarity.
  - For the month, use the following abbreviations (which are compatible with both English and French): JA, FE, MR, AL, MA, JN, JL, AU, SE, OC, NO, DE.[5,6,14,15]
    Note: It is possible that "JN" will be mistakenly interpreted as "January" instead of "June"; however, this potential misinterpretation would result in a product being discarded prematurely, rather than being used beyond its expiry date, so carries no health risk. The same would apply if "MA" were interpreted as "March", instead of "May".
  - If the space available on a small container does not permit inclusion of all three components of the date, present the year in a 4-digit form and the month in a 2-letter form, as in the examples below.[5]
- Include a descriptor before the date to alert users to the meaning of the information: e.g., "EXP",[9] "EXPIRATION", "EXPIRATION DATE", "DATE D'EXPIRATION",[5] "EXP DATE", "EXPIRY", "EXPIRY DATE", or "EXPIRES".[69]
  Examples:

  When all components of the date are applicable:
  YYYY-MM-DD: 2024-OC-31

  For small containers, if there is space for only the year and the month:
  YYYY-MM: 2024-OC

Enhancing readability
- Separate expiry dates from lot numbers with enough space to prevent confusion and to prevent their being read in combination as a single piece of information. When possible present expiry dates and lot numbers on separate lines.
- Use inks that will not be easily smeared or rubbed off the product or package during normal use (e.g., resistant to alcohol used for disinfection).[14,15,23] (Refer to section 2.3.9, "Permanence".)
- Avoid embossing or debossing of information that results in little or no contrast.[9,23,82] Engraving (i.e., embossing and debossing) of text onto a container may not provide sufficient contrast on its own; therefore, if such methods are used, highlight the text with ink.[15]

Location
- Place the expiry date on the inner and outer labels of all products,[17] in an easy-to-locate area[23]. This can avoid the potential for information to be overlooked. For example, consider placing the expiry date on a side or back panel of the product package.[20]
- Place the expiry date in an area that will not be removed or destroyed when the container is opened.[5,23]
- Refer to section 2.5.4, "Blister Packaging".

Other considerations
- When labelling a product that contains more than one item with differing expiry dates, use the shortest expiration date on the finished outer product label.

2.4.5 Lot or batch number

Background

Concerns have been described about confusion when a lot number has been misinterpreted as the expiry date or confusion caused by the lot number being combined with the expiry date.[9] Users have also reported difficulty reading the lot number on some labels. Readability is hindered when the text is embossed, when there is a lack of contrast between the text and the background, and when the printed text lacks permanence.[9,23]

Recommendations
Reducing ambiguity
- Use a term or an indicator word such as "Lot number", "Lot no.", or "Lot" before the lot information to alert the user to this information in the event of a recall.[5,69]
- Separate lot numbers from expiry dates with enough space to prevent confusion and to prevent their being read in combination as a single piece of information. When possible present lot numbers and expiry dates on separate lines.

Enhancing readability
- Use inks that will not be easily smeared or rubbed off the product or package (e.g., resistant to alcohol used for disinfection).[14,15,23] (Refer to section 2.3.9, "Permanence".)
- Avoid embossing or debossing of information that results in little or no contrast.[9,14,15,23] Engraving (i.e., embossing and debossing) of text onto a container may not provide sufficient contrast on its own; therefore, if such methods are used, highlight the text with ink.[15]

Location
- Place the lot number on the inner and outer labels of all products,[17] in an easy-to-locate area[23]. This can avoid the potential for information to be overlooked. For example, consider placing the lot number on a side or back panel of the product package.[20]
- Avoid placing lot numbers on the top (circle) surface of vial ferrules, if applicable, in accordance with USP standards.[83]
- Place the lot number in an area that will not be removed or destroyed when the container is opened (e.g., **not** on rip-off tabs).[22,23]
- Refer to section 2.5.4, "Blister Packaging".

Other considerations
- When labelling a product that contains more than one item, with each component having its own lot number, a new lot number may be used to represent the combination product.

2.4.6 Automated identification (e.g., bar coding)

Background

Automated identification "is the use of bar codes, radio frequency identification (RFID) and other machine-readable codes to identify, quickly and accurately, an item or process".[84] Although not a mandatory requirement in Canada, automated identification systems offer opportunities to improve the safety and efficiency of health product use at various stages of the product-use process, including procurement, inventory management, storage, preparation, dispensing, and administration.[85] Automated identification systems can also support product traceability (e.g., during recalls) and verification of the authenticity of health products as they move through the medication-use system.[84]

Recommendations
- Include within automated identifiers the key information necessary to ensure appropriate selection and safe use of the product.[15] The information contained within the automated identifier should not be considered a substitute for providing all required information directly on inner and outer labels.
- Legibility and readability of key information on the label should **not** be impeded by the presence of automated identifiers.
- Information embedded within the automated identifier should not include anything other than approved product information. It should also be focused on the needs of users and be non-promotional in nature.[21] This recommendation applies to any type of automated identifier that appears on the label or package of a health product, including embedded QR (quick response) codes or microchips that can be read with a portable device.
- Information contained within the automated identification must comply with regulatory requirements for health product labelling. Additionally, sponsors must ensure that quality assurance processes are in place, including verification of the accuracy (e.g., the right bar code appearing on the right label) and readability of automated identifiers on health product labels. For automated identification of pharmaceutical products in Canada, consider the information and standards adopted by the Canadian Pharmaceutical Bar Coding Project.[86]

2.5 Packaging

2.5.1 General packaging considerations

Background

Health product packaging is an important factor in promoting the intended and proper use of a product. The type or format of a container often gives users a cue as to the intended route and method of administration.[8] If a health product container, its format, or its appearance looks similar to that of other products intended to be handled differently, errors may occur, and serious harm may result. For example, some contact lens disinfectants containing hydrogen peroxide require a crucial step of neutralization. In these cases, the product may be inadvertently used in the same manner as similarly packaged 0.9% sodium chloride solutions, for which a neutralization step is not required.[87-89]

Outer Packaging or Overwrap

The outer packaging or overwrap is a good medium for displaying important information about the product. It may also provide a reliable way of keeping product components together (e.g., health product, dose delivery device, and consumer leaflet).[61] However, caution must be exercised in using this type of packaging, as overwraps, and outer packaging can also impede the proper identification and use of a product. For example, reflective material used for the outer label or the overwrap itself may reduce the visibility of key information on the label.[23]

Multi-part Products

Health products consisting of multiple items to be used together can be packaged such that all components are provided in one package; alternatively, the items may be packaged separately. Errors can occur when the labelling or packaging does not support correct use of the separate components by the user, as in the following examples:

- poor labelling not clearly indicating that the product has multiple components and that all must be used together[90,91]
- poor visibility of one of the components (e.g., obscured or not clearly visible or accessible) in the combined package, leading the user to assume that only the visible component is required.
- lack of prominence of key information for product-specific diluents[90]

Although the above examples are related to prescription drugs, lessons learned can provide important and valuable information and concepts that can be applicable to all health products preventing any future confusion or errors.

Dose Delivery Devices

Many health products and medications, typically those intended for the pediatric population, are provided as oral liquid formulations for ease of administration.[92] Many of these products are packaged with a measuring or dose delivery device intended to assist with the administration of a specific volume or dose by the consumer. This presentation of the oral dose delivery device is intended to give users a way to accurately prepare and administer the dose.[20]

Recommendations

General

- A number of factors can be considered when choosing a package. These include maintenance of product stability, ease of manufacturing, choice of distribution system, product security, ease of use, and even user compliance.[93]
- Provide health products in a container that facilitates correct selection and use, rather than relying only on labelling features such as warnings. Well-designed packaging can help to minimize the risk of medication errors.[93]
- Consider how the product will be used at the point of administration. Design the package and label such that the information is oriented for optimal readability.
- When a completely new type of container is being considered for a health product with no market experience to draw upon, consider consumer use studies as part of product development.[60] This is especially important when a new type of container is used for an existing product.

- If space permits, consider providing additional cues to assist the user in identifying, selecting, and using the product.

Outer Packaging or Overwrap
- To improve the visibility of key information, avoid using reflective materials for overwrap; use matte materials whenever possible.[23]

Multi-part Products
- Whenever possible, avoid separately packaging the different components of a multi-part product. Instead, provide and package together all components of the product that must be used to prepare and administer the dose.[90]
- Create a package that, when opened, allows clear visualization of (1) all co-packaged products intended to be used concurrently, and (2) instructions for combining them. Ensure that the labels clearly identify the number of parts and how they must be combined and used.[5,60]
- Each component of co-packaged products that are intended to be used separately (e.g., day and night cough and cold products) should be packaged in separate immediate containers (e.g., blisters).

Dose Delivery Devices
- Include dose delivery devices with all liquid health products intended for oral ingestion, with dose information expressed in units of measure corresponding to the calibration of the dose delivery device.[94-96] (Refer to section 2.5.3, "Pediatric Products".)
  - The dose delivery device should have a marking for the smallest recommended single dose to allow measurement of such a dose.[94,95]
  - The dose delivery devices should **not** be significantly larger than the largest single dose recommended on the product label.[95]
  - A dosing device should be recalibrated when changes are made to the strength of the product with which it is intended to be used.
- Provide clear and specific instructions on how to measure and administer a precise dose. The addition of drawings showing time, method, and route of administration may be helpful for some users.[97] Drawings should undergo user comprehension testing. For products requiring a Drug Facts table, refer to Part 3, "Drug Facts Table for Non-prescription Drugs".
- Use SI and metric units for measurements on oral dose delivery devices and other label information.[22,53,98]
- Use sufficient colour contrast for graduations or markings on dose delivery devices, to prevent the markings being obscured when the liquid product is added to the device.[95] For example, use black ink on a white field of view.[14]
- Avoid the use of trailing zeros after decimal points ("2" not "2.0") to help avoid 10-fold dosing errors.[50,99]
- Use leading zeroes before decimal points ("0.2" not ".2") to help avoid 10-fold dosing errors.[50,99]
- To prevent inadvertent parenteral administration of liquids intended for oral use, an oral applicator (e.g., oral syringe) provided as a dose delivery device should not accommodate a needle.[100]
- Ensure that container caps used as dose delivery devices for oral liquids are of adequate size and design to not pose a choking hazard to children.[100]
- For oral liquid preparations that have a narrow therapeutic window or that require dosing volumes less than 5 mL, spoons or cups are not considered acceptable.[100]

2.5.2 Small containers and small-volume containers

Background

The terms "small container" and "small-volume container" are reserved for containers with obvious restrictions on the amount of information that can appear on the product label or package.[34,101] This includes special containers that are too small to accommodate a full label.[5]

The use of small containers may give rise to errors because of difficulties in reading or understanding labels on the product.

Recommendations

The following recommendations are not applicable to products requiring a Drug Facts table. (Refer to Part 3, "Drug Facts Table for Non-prescription Drugs".)

- Consider container size and label design in the early stages of product development.
- Consider any container not large enough to accommodate an inner label complying with C.01.004(1) of the *Food Drug Regulations*[17] or 93(1) of the *Natural Health Product Regulations*[4] to be a small or small-volume container, for which these recommendations should apply.
- Discuss with Health Canada the determination of what is acceptable as a small or small-volume container before submission of product application and as early as possible during the product development stages.
- Reserve the use of small or small-volume containers for situations where their use does not negatively influence the product's safety profile.
- To enhance readability of key information by users, consider the size and orientation of text on small containers.[23] The orientation of text should be the same as the field of view so that it is not limited by physical aspects of the small container, such as curvature.
- Consider using a larger container, larger labels, or innovative package and label designs when space is limited (e.g., use larger containers than required to accommodate the total volume of eye drops or tablets or use tag, fold-out, or peel-back labels). Novel label formats should comply with applicable regulations and guidance documents.[1,5]

2.5.3 Pediatric products

Background

The pediatric population is inherently at high risk of harm from medication errors.[94] The number of preventable medication errors in this population is three times higher than among adults being treated in hospital.[102] When an error does occur, infants and children are at greater risk of harm or death from an error than are adults.[103] The following labelling and packaging factors can put the pediatric population at increased risk:

- requirement for individualized dose calculations based on age, weight (e.g., mg / kg), or body surface area[94]
- misinterpretation of labels or of markings on dose delivery devices, leading to under- or over-dosing[96]
- presence of graphics and text pertaining to children or infants on the front of products available for self-selection, which may adversely influence caregivers' perceptions of the appropriateness of

medications for young children. The following three features of product packaging most commonly influenced caregivers' perception of age appropriateness:

- o the word "infant" on the package
- o infant-related graphics (e.g., depiction of infants, teddy bears, droppers)
- o particular text on the package (e.g., symptoms intended to be treated, the words "pediatrician recommended")[104]

Recommendations

- If a pediatric formulation is significantly different from a similar adult product, consider making the labelling and packaging noticeably different for the two products.[97]
- Design product packaging and container closures to prevent or limit children from accessing the contents.[93]
- If appropriate, separate bilingual information to prevent any misinterpretation of details about pediatric products intended for children but **not** infants. For example, in French, the word "enfants" means "children", but this word differs by only one letter from the English word "infants".
- Use illustrations and graphics to assist the user in narrowing down the number of relevant products on the basis of visual cues, thereby avoiding the chance of unknowingly selecting an adult formulation and administering it to a child. For example, products intended for use in older children or adolescents should not contain illustrations depicting infants and vice versa.[104,105]
- Provide clear and specific instructions on how to measure and administer a precise dose. The addition of drawings showing time, method, and route of administration may be helpful for some users. Drawings and graphics should undergo comprehension testing (refer to Appendix 2, "Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging").
- Supply a measuring or dosing device for liquid formulations intended for pediatric use.[106]
- The instructions provided should be consistent with the measuring or dosing device supplied with all liquid formulations for products intended for pediatric use.[106]

2.5.4 Blister packaging

Background

Blister packs can be manufactured in a number of configurations, including individual blister cells in a strip that is perforated to allow separation as unit doses or a sheet containing multiple doses to be used as needed or intended for a particular duration of therapy (e.g., 3 days, 2 weeks, 1 month).[22] A blister pack can be removed from its outer package, cut into smaller units, or torn along perforations. Such actions can leave the product information unclear or unavailable, thus jeopardizing safe use of the product. The following concerns have been raised about the design of blister packs:

- illegibility of health product name or strength, for reasons such as use of reflective foil and lack of contrast between type and background[8,21,22,29,34]
- inability to identify health product name or strength of remaining tablets, capsules or lozenges after some have been removed from the blister pack[8,29]
- printing of the product name and strength across two blister cells, making it unclear whether labelled strength is provided by the contents of two cells or just one[8,57]
- mismatch between display of information and perforations on a blister pack[8]

- reduced ability to identify the product once the blister pack has been removed from the outer packaging or box (i.e., difficulty matching the blister pack with the outer box[29]), a particular problem for consumers who have more than one health product packaged in this format
- difficulty removing the product from blister packs[107]
- presentation and sequencing of doses in ways that do not match the product's approved usual dosage:[22,108]
    - labelling of doses with days of the week, when such labelling is not required[22]
    - numbering of blister cells in sequence[22]
    - provision of more doses than needed for a usual single course of treatment[22]

Recommendations

General
- Select a blister material that will not impair legibility of key information on the blister cell. For example, foils may be unsuitable for this purpose, as their reflective nature can reduce the legibility of printed information.[21,29]
- Provide the following information on each blister cell:
    - proprietary (brand) name (or product name, if there is no brand name)
    - established (common, proper) name or, for a drug with more than one medicinal ingredient, the brand name of the drug or health product
    - strength of the health product, except where the name used is unique for a particular strength of the product (e.g., for a product with more than one medicinal ingredient)
    - route of administration (other than for oral solids, such as tablets)
    - lot number
    - expiry date
- If information cannot be placed on each blister without becoming illegible, present it in a way that prevents the drug or product name (brand name at a minimum) and strength from being detached or destroyed when any dosage unit is removed. For example, consider repetitive diagonal[21] or random display[22]. It may be acceptable to place the lot number and expiry date on one end or both ends of the blister strip.[21]
- Avoid perforations, if separation of blister cells along these perforations will inappropriately break up certain information (e.g., brand name and strength).
- Design the blister pack to be consistent with product information and instructions for use:[22]
    - Avoid placing product information directly across two blister cells, to prevent the user from thinking that two tablets or capsules are equivalent to the dose actually provided in one tablet or capsule.[8,108]
    - Include only one dosage unit (e.g., one tablet, one capsule, one lozenge) in each blister cell.[22] If multiple dose units are indicated to be taken as a single dose, this should be specified in the dosing instructions.
    - If perforations are used between blister cells, they should allow for separation of each individual blister from the original pack.[8] Perforations which include more than one blister cell may indicate dosing different to that intended (e.g., two cells within a perforated unit, rather than one, could be interpreted as the contents of two cells are to be taken per dose).
    - Consider use of new technologies where the inner label adheres to the blister pack, so that key information remains for the duration of product use.

- In circumstances where the label could become detached during use, print key information on each blister cell.

Health products intended for sequential use
- Avoid perforations on this type of blister format, as the medicine or product is intended to be taken in a specific order, and individual blisters may contain different products and product doses.
- Ensure that the legibility of the required information on the blister pack is not affected as doses are removed.[5] For example, required information may be placed in a single location that is not removed or destroyed for the duration of product use.
- Expiry Date and Lot Number:
    - Ideally, print the expiry date and lot number over each blister, so that they are still legible when only the last dose remains, especially if individual blisters are detachable.
    - Place the expiry date and lot number in a single location on "race-track" blister packs (e.g., oral contraceptives), such that they will not be torn during use (e.g., on the heat-sealed end of the package).
    - Place the expiry date and lot number so that they are aligned between perforations, if present (i.e., printed on areas between perforations, so that the information will not be lost when individual blisters are torn away).

2.5.5 Transdermal patches

Background

The use of transdermal medications and the properties unique to this delivery system have led to errors resulting in harm.[109] The following general issues have been reported with the use of transdermal patches:

- Transdermal patches manufactured from a clear translucent or skin-coloured material (to make them less conspicuous when in use[109]) can make it difficult to see a patch on the skin. There is a possibility of overdose if consumers or their caregivers cannot visually identify an existing patch and a second patch is applied without removing the first one. Poor patch visibility can also lead to unintended drug exposure if a caregiver, child, or pet comes into contact with a patch that has fallen off or has been improperly discarded.[60]
- Key information, such as the drug name and strength, should be clearly presented on the patch itself. This provision is especially important for consumers who are unable to communicate their medication use and for caregivers and healthcare professionals who are unfamiliar with or have not had previous contact with the consumer (e.g., emergency department staff at a hospital, emergency medical services staff). Healthcare professionals must be able to identify the contents of a patch so they can take appropriate measures with regard to that therapy (e.g., pain management, blood pressure control, smoking cessation) or potentially contraindicated therapy.[110]

Recommendations

The recommendations presented here are important for any transdermal format.

- Ensure that the information required on transdermal patches is visible and legible and that the ink is long-lasting.[111]

- For any text on a transdermal patch, use a colour that will ensure visibility of the patch when applied to the skin.[111,112]
- Consider using a colour for transdermal patches that will further increase their visibility when applied[112] regardless of the consumer's skin tone. "Clear or translucent patches may also be difficult to find if they detach prematurely from a consumer; thereby increasing the potential for secondary or accidental exposure" to the drug.[60]
- Based on findings from incident reports, the following information should appear on a transdermal patch:
  - brand name
  - proper or common name
  - delivery rate of the drug (e.g., "X mg / hour")

3 Drug Facts Table for Non-prescription Drugs

3.1 Background

The safe use of non-prescription drugs depends on consumers being able to identify the desired product and also being able to understand and act upon the information presented. The current general practice in Canada is to present key information within blocks of text on the product label, which sometimes makes it difficult for the consumer to easily identify information necessary for appropriate selection and proper use of the product. In some cases, the information appears in small type, and there is poor contrast between the label text and the background. Furthermore, there is no standard location for the various pieces of information presented on labels for these health products. All of these factors can prevent the consumer from finding the information needed to make informed decisions in a timely manner, particularly at the time of selecting the product. Important product information should be placed in a consistent location on the label and be easy to read and understand. The aging of the population and the significant increase in the number of non-prescription drugs on the market add to the importance of addressing these issues.

As part of Health Canada's Plain Language Labelling Initiative, the outer label of non-prescription drugs is required by regulations to display a table containing specific information.[1] The purpose of the Canadian Drug Facts Table is to display the information required by the regulations in a standardized, easy-to-read format in order to enhance the safe and effective use of non-prescription drugs. The concept is similar to that of the Nutrition Facts table for foods in Canada[113] and the Drug Facts box required by the FDA for over-the-counter (OTC) drugs in the United States.[24, 114, 115]

The Drug Facts table will enable consumers to:

- compare different products, specifically where there may be similarities in the name, packaging, or ingredients, to help in selection of the product most suitable for their needs or symptoms
- identify the same medicinal ingredient in multiple products, to avoid the potential for unintentional overdose
- quickly locate the directions for safe use and associated warnings
- quickly locate the list of product ingredients, to avoid the potential for allergic reactions

This section of the guide provides information on the design specifications and required sections of the Canadian Drug Facts Table.

Scope
The requirement for a Drug Facts table applies to all non-prescription drugs available for self-selection, as well as to contact lens disinfectants. The following four product categories are excluded from this requirement:

(1) drugs on the federal Prescription Drug List;
(2) biologics and radiopharmaceuticals;
(3) drugs that are permitted to be sold without a prescription but that are administered or obtained only under the direction of a healthcare professional (e.g., exempted codeine preparations per the *Narcotic Control Regulations* 36(1),[2] nitroglycerin, insulin, injectable epinephrine for anti-allergic purposes); and
(4) drugs that are represented as being solely for use as disinfectants on hard non-porous surfaces.

Specifications

A consistent order and format must be used for the Canadian Drug Facts Table (CDFT), The information should be written at a grade 6 to grade 8 reading level, avoiding technical language and using short sentences or bullet form wherever possible.

At the time of selection and purchase, the Drug Facts table must be visible on the outer label of the retail package or, if there is no outer label, on the immediate container label. If the Drug Facts table is displayed on an innovative label, the label must be accessible to the consumer prior to purchase.

Information not included in the Drug Facts table but required by regulations must appear elsewhere on the label, including, but not limited to: the brand name, the name and address of the sponsor (product licence holder) or importer, the lot number, the expiry date, DIN, and any secure-packaging (tamper-evident) statement.

This part of the guide outlines the design and format for the standard CDFT and available flexibilities to reduce the need for package size increases or innovative labels while maintaining the integrity of the Plain Language Labelling Regulations. Formatting specifications are presented for the following:
- Standard CDFT format
- CDFT with graduated flexibilities
- Innovative labels, and
- Category IV products, mouthwash and toothpaste

In conjunction with Part 3 of this guide, sponsors should also consult the *Guidance Document: Drug Facts Table for Non-prescription Drugs* and the *Guidance Document: Electronic Canadian Drug Facts Table (eCDFT) Technical Standards.*

3.2 Content

Table 1 describes the content to be included under each heading and subheading within the Drug Facts table. The order of the content must be respected as outlined below. However, if a heading or subheading is not applicable, it should be omitted. Promotional wording should be avoided to ensure adequate space for the required information (e.g., 'fast and effective relief of pain' can be rephrased as 'pain relief'.) Pictograms or graphic images (including the UPC code) must not appear within the Drug Facts table, other than symbols required by regulations or for a telephone or telephone receiver before the 'Questions?' heading.

The *Guidance Document: Drug Facts Table for Non-prescription Drugs* provides sponsors, market authorization holders and license holders with direction on the development of plain language content.

The use of graduated flexibilities (as described in section 3.4, "Application of graduated flexibilities") will not change the order of the information presented in the Drug Facts table, however this will mean that some products will have a full CDFT on the outer label or package whereas others may have some information on a package insert (or a URL for Category IV products, mouthwash and toothpaste). All situations require that the information important to the safe selection of the product is available on the outer label or package.

Table 1: Content information for the Canadian Drug Facts Table

Title / Heading / Subheading	Description and comments regarding content
Drug Facts **Information sur le médicament**	The title to be used is 'Drug Facts'. If the table is split, each subsequent component of the table must include the title 'Drug Facts (continued)' or 'Information sur le médicament (suite)'.
Active ingredient(s) **Ingrédient(s) actif(s)**	Include in this section a quantitative list of the product's active ingredients by their proper names or, if they have no proper names, by their common names.
Purpose(s) **Utilité(s)**	Indicate the general pharmacological category or principal intended action of the product or, where the product contains more than one active ingredient, the general pharmacological categories or the principal intended actions of each active ingredient.
Use(s) **Usage(s)**	List in this section the indication(s) for use of the product.
Warnings **Mises en garde**	Warning statements are to be included in this section in the specific order (sequence) as listed below. Only the subheadings that apply to the product should be used. Warning statements must comply with pertinent regulations and other Health Canada labelling guidance.
For external use only **Pour usage externe seulement** **For rectal use only** **Pour usage rectal seulement** **For vaginal use only** **Pour usage vaginal seulement**	Include warning statements regarding route of administration when applicable. No text is required other than the warning statement.
Reye's syndrome **Syndrome de Reye**	Include in this section the statement regarding Reye's syndrome when applicable.
Allergy alert **Alerte aux allergies** **Asthma alert** **Alerte à l'asthme**	List in this section any specific allergic reaction warnings (e.g., eggs, milk, mustard, peanuts, seafood [fish, crustaceans and shellfish], sesame, soy, sulphites, tree nuts, wheat),[116] or asthma warnings.
Flammability warning **Avertissement d'inflammabilité**	Include in this section flammability warnings with appropriate signal words when applicable.
Choking **Étouffement**	Include in this section choking warnings (e.g., water-soluble gum warning) when applicable.

Title / Heading / Subheading	Description and comments regarding content
Alcohol warning **Avertissement concernant l'alcool** **Liver warning** **Avertissement concernant le foie** **Stomach bleeding warning** **Avertissement concernant les saignements gastriques**	Include in this section these types of warnings when applicable.
Sore throat warning **Avertissement concernant les maux de gorge**	Include in this section this type of warning when applicable.
Dosage warning **Avertissement concernant la posologie**	Include in this section dosage warning, such as "taking more than the recommended dose in 24 hours can be harmful", when applicable.
Sexually transmitted diseases (STDs) alert **Avertissement concernant les maladies transmissibles sexuellement (MTS)**	Include in this section warnings such as "this product does not protect against HIV/AIDS or other STDs" when applicable.
Do not use **Ne pas utiliser**	In this section, list all contraindications for use with the product. This is reserved for situations in which consumers should not use the product unless a prior diagnosis has been made by a doctor, or for situations in which certain consumers should not use the product under any circumstances, regardless of whether a doctor or healthcare professional is consulted.
Ask a doctor or pharmacist before use if you **Consultez un médecin ou un pharmacien avant l'utilisation si vous**	In this section, list all warnings for persons with pre-existing conditions or when experiencing particular symptoms. List all drug-drug, drug-NHP and drug-food interaction warnings. Include a statement here regarding use in pregnancy and breastfeeding.
When using this product **Lorsque vous utilisez ce produit**	In this section, list the side effects that the consumer may experience and identify the substances (e.g., alcohol, sedatives) or activities (e.g., operating machinery, driving a car) that should be avoided while using the product.
Stop use and ask a doctor if **Cessez d'utiliser ce produit et consultez un médecin si**	In this section, list any signs of toxicity or other adverse reactions that would necessitate immediately discontinuing use of the product.
Other warnings **Autres avertissements**	Include here any other required warnings that do not fit under the other warnings subheadings. Include a statement to indicate that additional information is available on other parts of the label and package insert, if applicable.

Title / Heading / Subheading	Description and comments regarding content
Keep out of reach of children. **Garder hors de la portée des enfants.**	Include in this section this general warning and a warning about accidental overdose or ingestion. For example, "In case of overdose, call a poison control centre or get medical help right away."
Directions **Mode d'emploi**	Provide in this section the directions for use, which could include dose instructions, duration, route of administration, maximum daily dose.
Other information **Autres renseignements**	This should be limited to storage instructions, any special instructions (e.g., for disposal), and a list of certain ingredients (e.g., calcium, magnesium, potassium and sodium content).
Inactive ingredients **Ingrédients inactifs**	Provide in this section a qualitative list of inactive ingredients listed either in alphabetical order or in descending order of predominance by their proportion in the product. Any information required by regulation related to preservatives (e.g., mercurial) should appear here. This section could also be used to indicate whether the product is gluten-free, lactose-free, etc., when appropriate.
Questions?	Provide in this section the sponsor's contact information for consumers to obtain answers to questions about the product or to report concerns or adverse events (adverse reactions or medication incidents) associated with the product. Contact information may be the full numeric representation of a telephone number, an email address, website address, postal address or any other information that enables communication with a contact person in Canada.

3.3 Design and format

Table 2 presents the format for the standard Canadian Drug Facts Table. Certain modifications to the standard format are permitted, as described in section 3.4, "Application of graduated flexibilities."

Refer to Figure 1 for an example of the standard CDFT, labelled with the design specifications.

Table 2: Standard Canadian Drug Facts Table Format

Label or Design Element	Standard Canadian Drug Facts Table Format (CDFTF)
Principal Display Panel ("Branding Panel")	If space permits, two branding panels can be used (i.e., one in English and one in French).
Font Style	The approved font for all elements is Helvetica Neue, 55 Roman for text or 75 Bold for headings. If Helvetica Neue is not available, the following sans serif fonts are considered acceptable: • Univers, 55 Roman and 65 Bold • Frutiger, 55 Roman and 65 Bold • Arial MT Std, Regular and Bold • Benton Sans, Regular and Bold Where needed, the character width of the type may be reduced by no more than 10% horizontally (i.e., 90% horizontal scale). Use of the following styles is not permitted: • condensed fonts • the light style of a font family (e.g., Helvetica 45 or 47) • italicized font • upper case text Characters (in titles, headings, subheadings or body text) should not touch each other or touch lines.
Font Weight	Boldface font is required for the table title 'Drug Facts', the headings and the subheadings. No other bolding is permitted unless required by the regulations. Refer to the permitted fonts above for details of acceptable weights for regular and bolded type.
Font Size	• Facts Table title 'Drug Facts': 8 point Helvetica Neue 75 Bold*, 8.5 point leading minimum • Facts Table title 'Drug Facts (continued)': 7 point Helvetica Neue 75 Bold except for the word (continued) which is not bold (i.e., 55 Roman) • Headings: 7 point Helvetica Neue 75 Bold, 7.5 point leading minimum • Subheadings: 6 point Helvetica Neue 75 Bold, 6.5 point leading minimum • Text: 6 point Helvetica Neue 55 Roman, 6.5 point leading minimum *If Helvetica Neue is not available, an acceptable font as per 'Font Style' above must be substituted.
Print Colour	• For optimal contrast, all text and lines must be printed with a 100% line black on white. Where a line black is not available, the colour must be displayed in the strongest contrasting colour being used • 100% screen black, dark blue, dark brown, dark green and dark purple are acceptable • Colours with a lower contrast to white, such as light green, cyan, magenta, yellow and silver are not permitted • In cases where a non-white substrate is being used, the CDFT must be backed with white ink for greater contrast • Reverse printing is not permitted • Additional colours are not permitted unless required by Health Canada regulations

Label or Design Element	Standard Canadian Drug Facts Table Format (CDFTF)
Title: Drug Facts	Left justified First letter of each word in this title is capitalized
Title: Drug Facts (continued)	If the table is split over more than one face of the package, the title on subsequent faces must be left justified. The word "(continued)" is not bold, abbreviated or capitalized.
Headings (e.g., Uses, Warnings, Directions)	Left justified For combined bilingual headings, the two headings are permitted to appear side by side, separated by a slash, e.g. 'Warnings / Mises en garde' The combined heading must be left justified Only the first letter of the first word is capitalized, e.g., Active ingredients
Subheadings (e.g., Do not use, Alcohol warning)	Left justified For combined bilingual subheadings, the two subheadings are permitted to appear side by side, separated by a slash, e.g., 'Allergy alert / Alerte aux allergies' The combined heading must be left justified Only the first letter of the first word is capitalized, e.g., Do not use
Bullets	Solid square or solid round bullets are acceptable. Helvetica Neue 55 Roman bullet character should be set to a minimum width of 3 points and must not be horizontally scaled.
Bulleted text	Bulleted text may appear on the same line as a heading or subheading, with the exception of the 'Warnings' heading In the case of a section with multiple bullets, a bulleted statement may continue to the next line of text. The end of one bulleted statement is separated from the beginning of the next bulleted statement by at least two square "ems" i.e., two squares the size of the letter "m" Smaller sub-bullets may be used to organize text related to a bulleted statement (see section 3.3.1, Formatting recommendations).
Box frame, rules and hairlines	A 1.5 point keyline or box frame must border the table. Rules (to separate headings) • 1.5-point weight • the rule extends to touch each side of the box frame Hairlines (to separate subheadings within the 'Warnings' section) • 0.375-point weight • there must be space the width of 2 characters between each end of the hairline and the box frame The distance between rules or hairlines and type should be consistent overall.

Figure 1: Format specifications: standard Drug Facts table

Left Justified

Title: Drug Facts
8 pt Helvetica Neue Bold*

Headings:
7 pt Helvetica Neue Bold*

Subheadings:
6 pt Helvetica Neue Bold*

Body text:
6 pt Helvetica Neue Regular
with 6.5 pt leading

Title for "continued" panel:
7 pt Helvetica Neue Bold*
except for "continued" which
is not bold

Box frame 1.5 pt line weight

Rules:
1.5 pt line weight, extend from
one edge of frame to the other

Hairlines:
0.375 pt line weight, gap of 2
character spaces on either end
between hairline and frame sides

Lines and characters do not
touch

Bullet:
3 pt width solid square or circle
Sub-bullets must be smaller than
main bullets

Insert graphic (arrow or similar)
leading to next panel when
applicable

*or other approved sans serif font

3.3.1 Formatting recommendations

General

- Information about the 'Active ingredients' and 'Purpose' must appear on the same horizontal line (with the exception of flexibilities for Category IV products, mouthwash and toothpaste, in which 'Purpose' can be removed). When more than one active ingredient has the same purpose, the information can be presented in a manner that readily associates each active ingredient with its purpose (by using brackets, dot leaders, or other graphical features). For example:

- To arrange additional text related to a single bulleted statement, use sub-bulleted statements. For example:[115]

  > **Uses** ● temporarily relieves pain and itching due to: ▪insect bites ▪minor skin irritations ● dries the oozing and weeping of: ▪poison ivy ▪poison oak ▪poison sumac

- Directions can be presented completely in a table format, as bulleted statements, or as a combination of a table and bulleted statements. For products with directions for use in more than two age groups or populations, these instructions should appear in an embedded table format, to make it easier for the consumer to read (refer to Figure 1, "Format specifications: Drug Facts table").
- Fractions may be expressed in numeric notation or as text (e.g., "½" or "one-half"). The text for fractions should be in the same type style and type size used for the other text in the Drug Facts table.

Bilingual information
- Type specifications (e.g., sizes, styles) must be consistent across both languages.
- When possible, the information should be organized by language for better readability (refer to Figure 2, "Drug Facts table [unilingual layout: English and French]").

Figure 2: Drug Facts table (unilingual layout: English and French)

Note: Figure 2 is not drawn to scale.

- A bilingual Drug Facts table may be the preferred format when space on the label is limited. Separate blocks of English and French text may alternate (as in Figure 3a, "Drug Facts table [bilingual layout: alternating English and French]" or they can be combined (as in Figure 3b, "Drug Facts table [bilingual layout: combined English and French]") within the same table.

Figure 3a: Drug Facts table (bilingual layout: alternating English and French)

Drug Facts / Information sur le médicament

Active ingredients (in each tablet)	Purpose
Ingredient A xxx mg...Xxxxxxxxxxx xxxxxx	
Ingredient B hydrochloride xxx mg..Xxxxx xx xxxxxxxxx	
Ingredient C sulfate xxx mg..Xxxxxxxxxxxxxxxxx	

Ingrédients actifs (dans chaque comprimé)	Utilité
Ingrédient A xxx mg..xxx xx xxx français xxxxxxxxxx	
Chlorhydrate d'Ingrédient B xxx mg ....Xxxxx français xxxxx	
Sulfate d'Ingrédient C xxx mg ....Xxxxxxxxx français xxxxxxxxx ▼	

Drug Facts (continued) / Information sur le médicament (suite)

Uses Relief of •xxxxxxxxxxx •xxxxx xxxxxxxxxx •xxxxxxxx •xxxxx
Usages Soulagement de(s) •xxxxxxxxx •xxxxxxxx •xxxxxxxx •xxx xx xxxx

Warnings
Allergy alert: Ingredient A may cause a severe allergic reaction.

Do not use •if you are taking any other medication containing these ingredients •if you are allergic to xxx, xxxxx or any ingredient in this product •right before or right after surgery •with a particular drug or for xx days after stopping this drug

Ask a doctor or pharmacist before use if you •have •condition •another condition •liver, kidney, thyroid, lung or heart disease •certain health issues •any other serious condition •take xxxxxxxxxxxx medication(s) •are pregnant or breastfeeding

When using this product do not drive a motor vehicle or operate machinery. This product may cause drowsiness.

Stop use and ask a doctor if •condition lasts longer than x days •you develop a skin rash

Keep out of the reach of children. In case of an overdose, call a poison control centre or a healthcare professional immediately.

Mises en garde
Alerte aux allergies : L'ingrédient A peut causer une réaction allergique sévère.

Ne pas utiliser •si vous prenez n'importe quel autre médicament contenant les mêmes ingrédients •si vous êtes allergique à xxx, xxxxxxxx, ou à l'un des ingrédients dans ce produit •avant de subir, ou après avoir subi une chirurgie •en même temps qu'un certain médicament, ni dans les xx jours après l'arrêt de ce médicament

Consultez un médecin ou un pharmacien avant l'utilisation si vous •souffrez d'/de •condition •autre condition •maladie du foie, des reins, des poumons, de la glande thyroïde ou du cœur •autre condition de santé •toute autre condition sérieuse •prenez xxx xxxxxxxxxxx médicament(s) •êtes enceinte ou vous allaitez

Lorsque vous utilisez ce produit ne pas conduire un véhicule motorisé ni utiliser des machines. Ce produit peut causer de la somnolence.

Cessez d'utiliser ce produit et consultez un médecin si •la condition dure plus de x jours •vous développez une démangeaison de la peau

Garder hors de la portée des enfants. En cas de surdose, appelez un centre antipoison ou obtenir de l'aide médicale immédiatement. ▼

Drug Facts (continued) / Information sur le médicament (suite)

Inactive ingredients List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs

Ingrédients inactifs Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux

Questions? Call / composez le 1-8XX-XXX-XXXX

Drug Facts (continued) / Information sur le médicament (suite)

Directions •Children over 12 and adults to 65 years: take x tablet(s) every y hours as needed •do not take more than xx tablets in 24 hours

Mode d'emploi •Enfants de plus de 12 ans et adultes jusqu'à 65 ans : prendre x comprimé(s) chaque y heures, au besoin •ne pas prendre plus de xx comprimés en 24 heures

Other Information Please read enclosed package insert before use. Store at room temperature (15-30° C).

Autres renseignements SVP lire la notice d'emballage avant l'utilisation. Conserver à la temperature ambiante (15 à 30° C). ►

Note: Figure 3a is not drawn to scale.

Figure 3b: Drug Facts table (bilingual layout: combined English and French)

Drug Facts / Information sur le médicament

Active ingredients / Ingrédients actifs (in each tablet) / (dans chaque comprimé)	Purpose / Utilité
Ingredient A xxx mg……………………………………………………………………Xxxxxxxxxxx xxxxxx	
Ingrédient A xxx mg…………………………………………………Xxx xx xxx français xxxxxxxxxx	
Ingredient B hydrochloride xxx mg………………………………………….....Xxxxx xx xxxxxxxxx	
Chlorhydrate d'Ingrédient B xxx mg …………………………………………Xxxxxx français xxxxxx	
Ingredient C sulfate xxx mg….……………………………………………………Xxxxxxxxxxxxxxxxx	
Sulfate d'Ingrédient C xxx mg …………………………………….…Xxxxxxxxx français xxxxxxxx ▾	

Drug Facts (continued) / Information sur le médicament (suite)

Uses / Usages Relief of / Soulagement de(s)   •xxxxxxxxxxx   •xxxxx xxxxxxxxxx   •xxxxxxxx   •xxxxx / •xfrançaisx   •xxxxxxxx   •xxxxxxxx   •xxx xx xxxx

Warnings / Mises en garde

Allergy alert / Alerte aux allergies : Ingredient A may cause a severe allergic reaction. / L'ingrédient A peut causer une réaction allergique sévère.

Do not use   •if you are taking any other medication containing these ingredients   •if you are allergic to xxx, xxxxx or any ingredient in this product   •right before or right after surgery •with a particular drug or for xx days after stopping this drug
Ne pas utiliser   •si vous prenez n'importe quel autre médicament contenant les mêmes ingrédients   •si vous êtes allergique à xxx, xxxxxxxx, ou à l'un des ingrédients dans ce produit   •avant de subir, ou après avoir subi une chirurgie   •en même temps qu'un certain médicament, ni dans les xx jours après l'arrêt de ce médicament

Ask a doctor or pharmacist before use if you   •have   •condition   •another condition •liver, kidney, thyroid, lung or heart disease   •certain health issues   •any other serious condition   •take xxxxxxxxxxxxx medication(s)   •are pregnant or breastfeeding
Consultez un médecin ou un pharmacien avant l'utilisation si vous   •souffrez d'/de •condition   •autre condition   •maladie du foie, des reins, des poumons, de la glande thyroïde ou du cœur   •autre condition de santé   •toute autre condition sérieuse   •prenez xxx xxxxxxxxxxxx médicament(s)   •êtes enceinte ou vous allaitez

When using this product do not drive a motor vehicle or operate machinery. This product may cause drowsiness.
Lorsque vous utilisez ce produit ne pas conduire un véhicule motorisé ni utiliser des machines. Ce produit peut causer de la somnolence.

Stop use and ask a doctor if   •condition lasts longer than x days   •you develop a skin rash
Cessez d'utiliser ce produit et consultez un médecin si   •la condition dure plus de x jours   •vous développez une démangeaison de la peau

Keep out of the reach of children. In case of an overdose, call a poison control centre or a healthcare professional immediately.
Garder hors de la portée des enfants En cas de surdose, appelez un centre antipoison ou obtenir de l'aide médicale immédiatement.   ▾

Drug Facts (continued) / **Information sur le médicament** (suite)

Inactive ingredients List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs **Ingrédients inactifs** Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux Liste des ingrédients nonmédicinaux

Questions? Call / composez le 1-8XX-XXX-XXXX

Drug Facts (continued) / Information sur le médicament (suite)

Directions / Mode d'emploi   •Children over 12 and adults to 65 years: take x tablet(s) every y hours as needed   •do not take more than xx tablets in 24 hours /
•Enfants de plus de 12 ans et adultes jusqu'à 65 ans : prendre x comprimé(s) chaque y heures, au besoin   •ne pas prendre plus de xx comprimés en 24 heures

Other Information / Autres renseignements Please read enclosed package insert before use. Store at room temperature (15-30° C). / SVP lire la notice d'emballage avant l'utilisation. Conserver à la temperature ambiante (15 à 30° C).   ►

Note: Figure 3b is not drawn to scale.

- English and French text should be organized so that the information can be easily read in the language of choice. Warning statements with many bullets are more readable if grouped together in the same language, rather than alternating English and French statements for each bullet. For example:
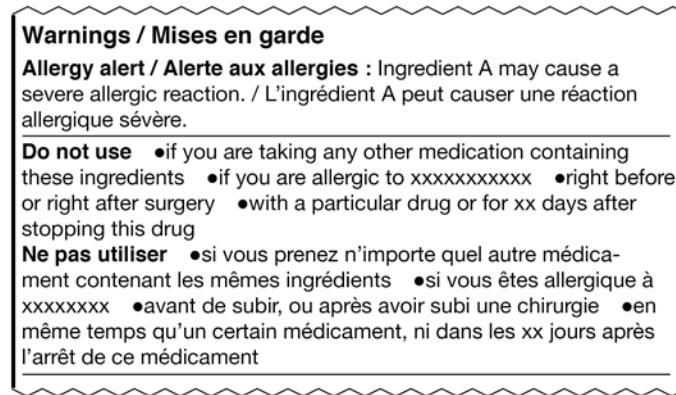
Display considerations
Orientation
- In general, a vertical presentation of the table is recommended, to enhance readability and facilitate product comparison. However, an alternative orientation (refer to Figure 4, "Drug Facts table [Bilingual layout: alternative orientation]") may help to maximize available label space and, in some instances, may improve readability (e.g., in the case of elongated packages, such as packages for topical ointments).

Splitting the table
- Where there is insufficient room on a single face of a package, the Drug Facts table may be split over more than one face. However, the overall format and sequence of the information should remain the same. Depending on the layout, sections may continue on subsequent panels. Consider whether starting the Drug Facts table on a side panel may make the table easier to follow (refer to Figure 4, "Drug Facts table [Bilingual layout: alternative orientation]").
- If the table is split, a mechanism should be provided to allow the consumer to clearly follow the contents of the Drug Facts table from the beginning to the end (i.e., it should be clear where the table starts and ends). A graphic symbol, such as an arrow, should be used to signal continuation of the Drug Facts table to the next panel. The title 'Drug Facts (continued)' must appear at the top of the next panel, although with the application of graduated flexibilities this may be omitted.

Figure 4: Drug Facts table (bilingual layout: alternative orientation)

Drug Facts / Information sur le médicament

Purpose / Utilité

Active ingredients / Ingrédients actifs
Xxxxxyxxxxb 0.2% w/v / xxxxxyxxxxb à 0.2% p/v......................................Xxxxxxx xxxxxxxxx / Xx français xxxxxx
Xxxxxxxxxxxxxxx 0.1% v/v / xxxxxxxxxxxxxxx à 0.1% v/v.......................Xxxxxx xx xxx / xxxxx français xxxxxx

Uses / Usages Relief of xxxxxxx xxx xx xxxxx xxxxxx xxxxxxxxxx / Soulagement de xx xxxxxxxxxx xxxxxxxxxx
xxx xxxxxxxxxxx xxxxxxxxx xxxxxxxx

►

Drug Facts (continued) /
Information sur le médicament (suite)

Warnings
For use in the eyes only

Do not use if •you have •glaucoma •serious eye disease •the drops change colour or become cloudy

Ask a doctor or pharmacist before use If you are pregnant or breastfeeding

When using this product •do not touch tip of container to any surface •replace cap after use •you may feel a brief tingling sensation or have temporarily larger pupils

Stop use and ask a doctor if you have •headache •eye pain •vision changes •symptoms get worse or last longer than 3 days

Keep out of reach of children. If swallowed, call a doctor or a Poison Control Centre at once.

Mises en garde
Pour usage dans les yeux seulement

Ne pas utiliser si •vous souffrez •du glaucome •d'une affection oculaire grave •les gouttes changent de couleur ou deviennent troubles

Consultez un médecin ou un pharmacien avant l'utilisation si vous êtes enceinte ou vous allaitez

Lorsque vous utilisez ce produit •ne pas laisser le bout du compte-gouttes toucher à aucune surface •remettre le capuchon après l'emploi •vous pourriez ressentir un léger picotement ou avoir temporairement les pupilles dilatées

Cessez d'utiliser ce produit et consultez un médecin si vous souffrez de •maux de tête •douleur oculaire •changement de vision •les symptômes s'aggravent ou durent plus de 3 jours

Garder hors de la portée des enfants. En cas d'ingestion, appelez un centre antipoison ou obtenir de l'aide médicale immédiatement.

Directions •remove contact lenses before using •adults & children 6 years and over: 1 or 2 drops in the affected eye(s) up to 4 times a day

Mode d'emploi •retirer les lentilles de contact avant l'emploi •adultes et enfants de 6 ans et plus : 1 ou 2 gouttes dans l'œil (les yeux) affecté(s) jusqu'à 4 fois par jour

►

Drug Facts (continued) / **Information sur le médicament** (suite)

Other Information / Autres renseignements Store at 15-30°C. / Conserver entre 15-30°C.

Inactive ingredients Xxxxx xxxd, dxxxxxxx XXXX, pxxxxxxxx bxxxxxx, xxxxxxx xxxxxx, xxxx
Ingrédients inactifs Xxxxx bxxxxxy, xxxxxxx, xxx, XXXX xx xxxxxxxxx , xxxxxxx xx pxxxxxxxxx

Questions? Call / composez le 1-XXX-XXX-XXXX

Note: Figure 4 is not drawn to scale.

Using columns

- When two or more columns appear on the same side of a package, the first column should be positioned to the left of a second column and so on.
- Columns should be approximately the same size.
- If two or more columns are placed on the same side of a package, the right side of the first column and the left side of the second column may share a common vertical box frame extending from the top to the bottom of the Drug Facts table (see example below). This also applies to the right side of the second column and the left side of the third column, if a third column is used.

Drug Facts	Information sur le médicament
Active ingredients (in each xx mL) Purpose Ingredient A xxx mg..........................Xxxxxxxxxxxxxx Ingredient B hydrochloride xxx mg......Xxxxxxxxxxxxxxx Ingredient C sulfate xxx mg..........Xxxxxxxxxxxxxxxxxx	**Ingrédients actifs (dans chaque xx mL)** Utilité Ingrédient A xxx mg.........…...........Xxxxxxx xxxxxxxxxxx Chlorhydrate d'Ingrédient B xxx mg.................Xxxxxxxxx Sulfate d'Ingrédient C xxx mg……..............Xxxxxxxxxxxx
Uses Relief of ●xxxxxxxxxx ●xxxxx xxxxxxxxxx ●xxxx ●xxxxxxxxxxxxxx ●xxxxx xxxx	**Usages** Soulagement de(s) ●xxxxxxxxxx xxxxxxx ●xxxxxxxxx xxxxxxxx ●xxxx xx xxxxx ●xxxxxxx
Warnings **Allergy alert:** Ingredient A may cause a severe allergic reaction. **Do not use** ●if you are taking any other medication containing these ingredients ●if you are allergic to xxxxxxxxxxx	**Mises en garde** **Alerte aux allergies :** L'ingrédient A peut causer une réaction allergique sévère. **Ne pas utiliser** ●si vous prenez n'importe quel autre médicament contenant les mêmes ingrédients ●si vous êtes allergique à xxxxxxxxxxxxx

- A graphic symbol (e.g., an arrow) should be used at the bottom of the first column (and at the bottom of subsequent columns, where needed) to signal continuation of the Drug Facts table to the next column. The title 'Drug Facts (continued)' must appear at the top of each subsequent column, although with the application of graduated flexibilities this may be omitted.

3.4 Application of graduated flexibilities

All products under the scope of the regulations must apply the Canadian Drug Facts Table format. However, some products and package sizes may not present sufficient space to accommodate the standard format of the Drug Facts table on the label.

In some cases, an innovative label may be the most effective way to accommodate the space requirements of the Drug Facts table. This determination should be made early in the label and package development process. In other cases, a *modified* format with graduated flexibilities may be considered according to the criteria outlined in Table 3, "Canadian Drug Facts table format with graduated flexibilities" and Table 4 "Tailored flexibilities for Category IV products, mouthwash and toothpaste". The purpose of the available flexibilities is to gain space on the label and in some cases, may prevent the need for innovative labels or increased package sizes.

Branding

- Sponsors using two branding panels may apply any one or more of the Level 1 flexibilities indicated in Table 3. Sponsors are not permitted to apply flexibilities beyond those in Level 1 if they choose to retain two branding panels in the design of their packaging, i.e., use of a condensed font is not permitted.

- When a single bilingual branding panel is in place, sponsors may apply additional flexibilities (Levels 2 to 4). Sponsors are not required to apply all Level 1 flexibilities prior to moving to Level 2 (font modifications).

Moving Information from the CDFT
- Any information removed from the Drug Facts table (after application of graduated flexibilities) must appear on a package insert, following the same specifications as the standard CDFT. This does not apply to Uses, Inactive ingredients or product storage information since these elements are required by regulations to appear on the outer label.
- Category IV products as well as mouthwash and toothpaste that limit information in the CDFT on the physical label (as per the Minimum Information Requirements, see Table 4) are required to include either a patient insert (following the same specifications as the standard CDFT), or a URL linking consumers to a complete CDFT (as outlined in *Guidance Document: Electronic Canadian Drug Facts Table (eCDFT) Technical Standards*).
- For Division 8 drugs, the CDFT is required to be located on the outer label. However, if required information cannot fit the standard CDFT, available flexibilities should be applied or an innovative label can be used. A package insert (Part III of the Product Monograph) is required to be included in the packaging for all Division 8 drugs.

Table 3: Canadian Drug Facts Table format with graduated flexibilities

Level 1 Flexibilities Available for Products with Two Unilingual Branding Panels (see Figure 5)	
- Move content from 'Uses' heading to the principal display panel (with conditions, see below) - Remove hairlines from 'Warnings' section - Remove 'Drug Facts (continued)' title (with conditions, see below) - Begin text immediately following 'Warnings' section heading - Reduce weight of rules to 1.0 point - Continuous box frame (with conditions, see below) Sponsors are not required to apply all flexibilities in conjunction. Sponsors are only permitted to apply the flexibilities described above.	
Flexibilities Available for Products with One Bilingual Branding Panel	
Level 1	- Move uses to the principal display panel (with conditions, see below) - Remove hairlines from 'Warnings' section - Remove 'Drug Facts (continued)' title (with conditions, see below) - Begin text immediately following 'Warnings' section heading - Reduce weight of rules to 1.0 point - Continuous box frame (with conditions, see below) Sponsors are not required to apply all Level 1 flexibilities in conjunction, or to apply all of Level 1 prior to applying Level 2.

Level 2 – Use of a condensed font	The approved font for all elements is Helvetica Neue 57 Condensed and 77 Bold Condensed. If Helvetica Neue is not available, the following condensed fonts are considered acceptable: • Univers, 57 Condensed and 67 Bold Condensed • Frutiger, 57 Condensed and 67 Bold Condensed • Arial MT Std, Condensed and Bold Condensed • Benton Sans Condensed, Regular and Medium The character width may be reduced by no more than 10% horizontally (i.e. 90% horizontal scale).
Level 3 – Move storage information and inactive ingredients	Storage information (usually placed under the heading 'Other information') and inactive ingredients can be moved from the CDFT. However, this information must be included elsewhere on the outer label as required by regulations. The 'Inactive ingredients' subheading must remain in the Drug Facts table with a note directing the consumer to the location of this information.
Level 4 – Move 'point of use' warning information	With the exception of information related to drowsiness or excitability that may occur with use of the product, , the following 'point of use' warnings (i.e., information which is important to the consumer when taking the product, but which is not necessarily needed at the point of selection) can be moved from the outer label or package and included in a package insert: • 'When using this product' subsection • 'Stop use and ask a doctor if' subsection Wording in the 'Warnings' section that describes symptoms (e.g., symptoms of liver damage may include yellow skin or eyes, dark urine, etc.) The information on a package insert must follow the same format specifications required for the standard CDFT.

Conditions

1 Content from the 'Uses' heading can be moved from the CDFT to the principal display panel. However, uses cannot be combined with non-approved statements that are promotional in nature.

2 Removal of the 'Drug Facts (continued)' heading must be accompanied by a strategy to point the consumer to continued information (e.g., arrowhead).

3 Where multiple panels are sequential, sponsors are permitted to use a single, continuous box frame rather than a frame around each individual panel. Text is not permitted within 3.175 mm (1/8 inch) of a fold line. Note that when applying a continuous box frame, all panels of the Drug Facts table must maintain a consistent orientation.

Drug Facts / Information sur le médicament

Active ingredients / Ingrédients actifs (in each tablet) (dans chaque comprimé) — Purpose / Utilité

Ingredient A xxx mg ....Xxxxxxxxxxx xxxx relief
Ingrédient A xxx mg...Soulagement de xxxxxxxxxxxx xxxxxxxx
Ingredient B hydrochloride xxx mg Xxxxxxxxxxxxxxxx
Chlorhydrate d'Ingrédient B xxx mg ....Xxxxxxfrançais xxxxxx
Ingredient C sulfate xxx mg Xxxxxxxxxxxxxxxxx
Sulfate d'Ingrédient C xxx mg ....Xxxxxxxfrançais xxxxxxx

Warnings / Mises en garde Allergy alert / Alerte aux allergies Ingredient A may cause a severe allergic reaction / L'ingrédient A peut causer une réaction allergique sévère
▼

Do not use •if you take any other medication containing these ingredients •if you are allergic to xxxxxxxxx xxxxxxxxxxx •right before or right after surgery •with a particular drug or for xx days after stopping this drug
Ne pas utiliser •si vous prenez n'importe quel autre médicament contenant les mêmes ingrédients •si vous êtes allergique à l'xxxxxxxxxxxxx xxxxxxxxxxxx •avant de subir, ou après avoir subi une chirurgie •en même temps qu'un certain médicament, ni dans les xx jours après l'arrêt de ce médicament
Ask a doctor or pharmacist before use if you •have •condition •another condition •liver, kidney, thyroid, lung or heart disease •certain health issues •any serious condition •take xxxxxxxxxx medication(s) •are pregnant or breastfeeding
Consultez un médecin ou un pharmacien avant l'utilisation si vous •souffrez d'/de •condition •autre condition •maladie du foie, des reins, des poumons, de la glande thyroïde ou du cœur •autre condition de santé •toute autre condition sérieuse •prenez xxx xxxxxxxxxxx médicament(s) •êtes enceinte ou vous allaitez
When using this product •it may cause drowsiness •do not drive a motor vehicle or operate machinery
Lorsque vous utilisez ce produit •il pourrait causer de la somnolence •ne pas conduire un véhicule motorisé ni utiliser des machines
Stop use and ask a doctor if •symptoms last longer than x days •you develop a skin rash
Cessez d'utiliser ce produit et consultez un médecin si •les symptômes durent plus que x jours •vous développez une démangeaison de la peau
Keep out of the reach of children In case of an overdose, call a poison control centre or get medical help right away.
Garder hors de la portée des enfants En cas de surdose, appelez un centre antipoison ou obtenir de l'aide médicale immédiatement.
▼

Directions / Mode d'emploi •Children over 12 and adults to 65 years: take x tablets every xx hours as needed •do not take more than xx tablets in 24 hours / •Enfants de plus de 12 ans et adultes jusqu'à 65 ans: prendre x comprimé(s) chaque xx heures, au besoin •ne pas prendre plus que xx comprimés en 24 heures

Other Information / Autres renseignements •read enclosed package insert before use •store at room temperature (15-30° C) / •lire la notice d'emballage avant l'utilisation •conserver à la temperature ambiante (15 à 30° C)

Inactive ingredients / Ingrédients inactifs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs / Liste des ingrédients non médicinaux Liste des ingrédients non médicinaux Liste des ingrédients non médicinaux Liste des ingrédients non médicinaux Liste des ingrédients non médicinaux

Questions? Call / composez le 1-8XX-XXX-XXXX

Side panel

Fold lines

Sequential back panel

Sequential side panel

Box frame 1.5 pt weight
Rules (between sections) 1.0 pt line weight
There must be an indication to point the consumer to continued information (arrowhead used in this example)
Continuous box frame – text not permitted within 1/8 inch, or 3.175 mm of a fold line
Uses / Usages - have been moved to principal display panel

3.5 Category IV products, mouthwash and toothpaste

Category IV products as well as mouthwash and toothpaste that limit information in the CDFT on the physical label (as per the Minimum Information Requirements below) are required to include either a patient insert (following the same specifications as the standard CDFT), or a URL linking consumers to a complete CDFT. The inclusion of a URL will be optional for products that include a full CDFT on the physical label or within an insert.

Sponsors may apply any of the flexibilities described in Table 4, "Tailored flexibilities for Category IV products, mouthwash and toothpaste" to the Drug Facts table on the outer label. Note that conditions for the use of these modifications remain the same as previously indicated for the CDFTF with graduated flexibilities.

Table 4: Tailored flexibilities for Category IV products, mouthwash and toothpaste

Minimum Information Requirements
The Drug Facts table on the outer label of Category IV products, mouthwash and toothpaste must include the following minimum information: 'Active ingredients' ('Purpose' is not required)   'Uses' (if not present on the principal display panel)   - Point of selection warnings (as per the approved Monograph and Guidance Documents). Point of selection warnings refer to information that is needed by the consumer when selecting a product for purchase, such as: - Warning statements regarding route of administration   'Do not use' subsection   'Ask a doctor or pharmacist before use if you' subsection   - Warnings regarding drowsiness or excitability   'Directions' (to assist in appropriate product selection, including any age-specific restrictions)   'Inactive ingredients'   'Questions?' and contact information   - A statement directing consumers to a URL where they can view a complete CDFT.   Sponsors may choose to include the 'Keep out of reach of children' warning statement in the Drug Facts table or may place it elsewhere on the outer label. Should a sponsor wish to include any other 'point of use' information on the outer label (e.g., 'When using this product'), the information must be presented in the CDFT format.

Available Formatting Flexibilities
- Remove hairlines from 'Warnings' section   - Remove Drug Facts (continued) title (with conditions, see below)   - Begin text immediately following 'Warnings' section heading   - Reduce weight of rules to 1.0 point   - Continuous box frame (with conditions, see below)   - Use of a condensed font is permitted (see level 2 flexibilities in Table 3)   - Move the list of inactive ingredients to elsewhere on the outer label or on a tag attached to the package. The 'Inactive ingredients' heading must remain in the CDFT with a note directing the consumer to the location of this information

1. Content from the 'Uses' heading can be moved from the CDFT to the principal display panel. However, uses cannot be combined with non-approved statements that are promotional in nature.
2. Removal of the 'Drug Facts (continued)' heading must be accompanied by a strategy to point the consumer to continued information (e.g., arrowhead).
3. Where multiple panels are sequential, flexibilities allow for the use of a single, continuous box frame rather than a frame around each individual panel. Text is not permitted within 3.175 mm (1/8 inch) of a fold line. All panels of the Drug Facts table must maintain a consistent orientation.

URL
Information on the standards to be used in applying a URL in order to enable consumers to access a complete electronic version of the CDFT can be found in the *Guidance Document: Electronic Canadian Drug Facts Table (eCDFT) Technical Standards.*

3.6 Innovative labels

The choice to use an innovative label may be made early in the package and label development process, or when graduated flexibilities have been applied and space is still lacking. Examples of innovative labels include peel-back, fold-out, or a tag attached to the package. Novel label formats should comply with applicable regulations and guidance documents.[1,5] URLs or QR codes are not considered to be examples of an innovative label.

An innovative label must be accessible to the consumer at the time of product selection, before purchase. The Drug Facts table must be accessible without destroying or compromising the integrity of the label or the package.

The 'Drug Facts' title, and the 'Active ingredients' and 'Purposes' sections of the Drug Facts table must be visible at the time of product selection prior to manipulation of the innovative label. A statement directing the consumer to the continuation of the table on the innovative label must also be visible.

Permitted Flexibilities
Sponsors are permitted to apply the flexibilities listed in Table 5 to their innovative labels, respecting the same conditions as outlined in section 3.4 Application of graduated flexibilities.

Table 5: Flexibilities Available for Innovative Labels

Sponsors are not required to move to a single branding panel before applying these flexibilities.
• Move content from the 'Uses' heading to the principal display panel (with conditions, see below)
• Remove hairlines from 'Warnings' section
• Remove 'Drug Facts (continued)' title (with conditions, see below)
• Begin text immediately following 'Warnings' section heading
• Reduce weight of rules to 1.0 point
• Continuous box frame (with conditions, see below)
• Use of a condensed font is permitted (see level 2 flexibilities in Table 3)

Conditions

1. Content from the 'Uses' heading can be moved from the CDFT to the principal display panel. However, uses cannot be combined with non-approved statements that are promotional in nature.
2. Removal of the 'Drug Facts (continued)' heading must be accompanied by a strategy to point the consumer to continued information (e.g., arrowhead).
3. Where multiple panels are sequential, flexibilities allow for the use of a single, continuous box frame rather than a frame around each individual panel. Text is not permitted within 3.175 mm (1/8 inch) of a fold line. All panels of the Drug Facts table must maintain a consistent orientation.

3.7 Product Facts table for natural health products

Although a facts table is not required under the *Natural Health Products Regulations*[3], for consistency and as a good practice, sponsors may wish to adapt the Drug Facts table format to natural health products (NHPs). The table must be titled '**Product Facts**' and must not use the title 'Drug Facts'. The content of the Product Facts table is identical to that outlined in Table 1: Content Information for the Canadian Drug Facts Table, with the following exceptions:

- The 'Purposes' heading is not required
- The headings 'Active ingredients' and 'Inactive ingredient's become 'Medicinal ingredients' and 'Non-medicinal ingredients'.
- The subheading 'Ask a doctor or pharmacist before use if you' becomes 'Ask a doctor or healthcare practitioner before use if you'. This section should list all NHP-NHP, NHP-drug and NHP-food interaction warnings.
- Nutritional information (e.g., calories, fat and sugar content) should be placed in the section Other information.

Under the 'Warnings' heading of the Product Facts table, only the subheadings that apply should be included. Warning statements must comply with pertinent regulations and other Health Canada labelling guidance.

Appendix 1 - Glossary

Active ingredient: "means a drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect." (*Food and Drug Regulations*, Section C.01A.001[17])

Aggregate analysis: see "Multi-incident analysis"

Brand name (Drug): "means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,
(a) that is assigned to the drug by its manufacturer,
(b) under which the drug is sold or advertised, and
(c) that is used to distinguish the drug" (*Food and Drug Regulations*, Section C.01.001[17])

Brand name (NHP): "means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual
(a) that is used to distinguish the natural health product; and
(b) under which a natural health product is sold or advertised." (*Natural Health Products Regulations*, Section 1[4])

Close proximity: "means, with reference to common name, immediately adjacent to the common name without any intervening printed, written or graphic matter" (*Food and Drug Regulations*, Section B.01.001[17])

Common name: "means, with reference to a drug, the name in English or French by which the drug is
(a) commonly known, and
(b) designated in scientific or technical journals, other than the publications referred to in Schedule B to the *Act*"
     (*Food and Drug Regulations*, Section C.01.001[17])

Confirmation bias: a phenomenon that "leads an individual to 'see' information that confirms their expectations, rather than to see information that contradicts expectations." (Human factors and substitution errors. ISMP Can Saf Bull. 2003;3(5):1-2.[117])

Critical incident: "an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence." (Davies J, et al. Canadian Patient Safety Dictionary. 2003[118])

Dosage form (NHP): "The final physical form of the NHP [natural health product] which may be used by the consumer without requiring any further manufacturing." (Licensed Natural Health Products Database (LNHPD) - Terminology Guide[119])

Drug: "includes any substance or mixture of substances manufactured, sold or represented for use in
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
(b) restoring, correcting or modifying organic functions in human beings or animals, or
(c) disinfection in premises in which food is manufactured, prepared or kept;" (*Food and Drugs Act*, Section 2[3])

Drug in dosage form: "means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing." (*Food and Drug Regulations*, Subsection C.01.005(3)[17])

Expiration date or Expiry date: "means the earlier of
(a) the date, expressed at minimum as a year and month, up to and including which a drug maintains its labelled potency, purity and physical characteristics, and
(b) the date, expressed at a minimum as a year and month, after which the manufacturer recommends that the drug not be used." (*Food and Drug Regulations*, Section C.01.001;[17] *Natural Health Products Regulations*, Section 1[4])

Font: "A complete set of characters in one design, size, and style. In traditional metal type, a font meant a particular size and style; in digital typography a font can output multiple sizes and even altered styles of a typeface design." (Carter R, et al. Typographic design: Form and communication, fifth edition. 2012[11])

Healthcare Practitioner (Product Facts Table for Natural Health Products): "means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person". (*Canada Health Act*, R.S.C., 1985, c. C-6[120])

Human factors engineering: "the discipline concerned with understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology, and cognitive science, to define the parameters and restraints that influence human performance. This knowledge can be used to design systems so that they are compatible with human characteristics. Conversely, if systems are not compatible with human characteristics, performance can be adversely affected." (Institute for Safe Medication Practices Canada. Failure mode and effects analysis (FMEA): A framework for proactively identifying risk in healthcare. Version 1. 2006[121])

Immediate container: "means the receptacle that is in direct contact with a drug" (*Food and Drug Regulations*, Section C.01.001[17])

Inner label (Drug): "means the label on or affixed to an immediate container of a food or drug" (*Food and Drug Regulations*, Section A.01.010[17])

Inner label (NHP): "means the label on or affixed to an immediate container of a natural health product." (*Natural Health Products Regulations*, Section 1[4])

Key Elements: For the purposes of this guide, eight elements were identified by the expert advisory panel as being the key pieces of information for inclusion on the principal display panel of a health product label. These elements assist the user to correctly select a product and use it appropriately. They are intended to complement international regulatory recommendations and align with national and international standards and safety literature. They do not incorporate all of the elements required by regulation or guidance for various types of health products. For example, the drug identification number (DIN) or natural product number (NPN), as applicable, is required by regulation, but neither is listed among the eight key elements.

Key Information: For the purposes of this guide, key information includes the key elements (refer to section 2.4.1, "Key Elements on the Principal Display Panel" for further information) and label information required by regulations.

Label: "includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package" (*Food and Drugs Act*, Section 2[3])

Legibility: Ease of identifying each letter or character; affects the readability of words and sentences.

Lot number (Drug): "means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution" (*Food and Drug Regulations*, Section A.01.010[17])

Lot number (NHP): "means any combination of letters, figures, or both, by which a natural health product can be traced in manufacture and identified in distribution." (*Natural Health Products Regulations*, Section 1[4])

Main panel: see "Principal display panel"

Manufacturer or distributor: "means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug" (*Food and Drug Regulations*, Section A.01.010[17])

Medication error: see "Medication incident"

Medication incident: "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use." (Institute for Safe Medication Practices Canada. Definitions of terms.[122])

Medicinal Ingredient (NHP): "is a substance which is set out in Schedule 1 of the NHPR, is biologically active and is included in an NHP for the purposes of: diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. A medicinal ingredient is characterized by its physical form, its chemical attributes, its source, its preparation, as well as its dose and pharmacological action." (Pathway for Licensing Natural Health Products Making Modern Health Claims, Section 1.5, Definitions[123])

Microgram: one-millionth of a gram, 1×10^{-6} gram.

Mock-up: In the context of medication labelling and packaging, a full-colour, actual-size copy of the labels and a colour representation (e.g., photograph) 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).

Multi-incident analysis: "a method for reviewing several incidents at once instead of one by one, by grouping them in themes (in terms of composition or origin) … This method of analysis can generate valuable organizational and/or system-wide learning that cannot be obtained through the other methods." (Canadian Incident Analysis Framework. 2012[124])

Natural health product (NHP): "means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(b) restoring or correcting organic functions in humans; or

(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2." (*Natural Health Products Regulations*, Section 1[4])

Non-medicinal / inactive ingredient (Drug): "means a substance—other than the pharmacologically active drug—that is added during the manufacturing process and that is present in the finished drug product (*Food and Drug Regulations*, Section C.01.001[17])

Non-medicinal / inactive ingredient (NHP): "Any substance added to a NHP formulation to confer suitable consistency or form to the medicinal ingredients. In a manner consistent with existing regulations for conventional pharmaceuticals, non-medicinal ingredients should not exhibit any pharmacological effects of their own, should not exceed the minimum concentration required for the formulation, and should be safe in the amounts used. The presence of a non-medicinal ingredient must not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients. As well, non-medicinal ingredients must not interfere with assays and tests for the medicinal ingredients and, when present, antimicrobial preservative effectiveness. Non-medicinal ingredients should be the least toxic available that are appropriate to the formulation.

Non-medicinal ingredients can include, but are not limited to, diluents, binders, lubricants, disintegrators, colouring agents, fragrances and flavours that are necessary for the formulation of the dosage form. Non-medicinal ingredient purposes such as surfactants, which are only applicable to topical products, are also indicated. Antimicrobial preservatives and antioxidants will be considered as non-medicinal ingredients but should not be used as alternatives to Good Manufacturing Practices. (Licensed Natural Health Products Database (LNHPD) - Terminology Guide[119])

Non-prescription drug: a drug not listed on Health Canada's Prescription Drug List and available without a prescription.[5]

Non-proprietary name: describes the drug substance. International Non-proprietary Names are unique, universally applicable, and globally accepted names. A non-proprietary name is the proper name of an ingredient (or the common name if the ingredient has no proper name). (*Food and Drug Regulations*, Section C.01.001[17])

Outer label (Drug): "means the label on or affixed to the outside of a package of a food or drug" (*Food and Drug Regulations*, Section A.01.010[17])

Outer label (NHP): "means the label on or affixed to the outside of a package of a natural health product. (*Natural Health Products Regulations*, Section 1[4])

Package: "includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed" (*Food and Drugs Act*, Section 2[3])

Parenteral use: "means administration of a drug by means of a hypodermic syringe, needle or other instrument through or into the skin or mucous membrane" (*Food and Drug Regulations*, Section C.01.001[17])

Plain Language: "is a clear writing style designed to be easy to read and understood 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 of instructions, design elements and color. (*Guidance Document: Questions and Answers: Plain Language Labelling Regulations*[125])

Point: "A measure of size used principally in typesetting … It is most often used to indicate the size of type or amount of leading added between lines." (Carter R, et al. Typographic design: Form and communication, fifth edition. 2012[8])

Point size: "the approximate distance from the top of an uppercase letter to the bottom of a lowercase letter with a descender (for example, the bottom of a 'j')." (Singer JP, et al. Manufacturer's guide to developing consumer product instructions. 2003[126])

Potency: "The amount per dosage unit of the standardized component(s) which further characterizes the quantity of the ingredient. It is required only when a claim on the potency is to be on the label, or it is required for a specific product (i.e. when literature supports the product with that standardized component). In the Supplementary Good Manufacturing Practices for Homeopathic Medicines, potency refers to the degree of dilution of a homeopathic medicine." (Licensed Natural Health Products Database (LNHPD) - Terminology Guide[119])

Principal display panel (also referred to as "main panel"): "means
(a) in the case of a container that is mounted on a display card, that part of the label applied to all or part of the principal display surface of the container or to all or part of the side of the display card that is displayed or visible under normal or customary conditions of sale or use or to both such parts of the container and the display card,
(b) in the case of an ornamental container, that part of the label applied to all or part of the bottom of the container or to all or part of the principal display surface or to all or part of a tag that is attached to the container, and
(c) in the case of all other containers, that part of the label applied to all or part of the principal display surface." (*Consumer Packaging and Labelling Regulations*, Section 2[127])

Proper name (Drug): "means, with reference to a drug, the name in English or French
(a) assigned to the drug in section C.01.002,
(b) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part, the name of the dispensing form,
(c) specified in the Canadian licence in the case of drugs included in Schedule C or Schedule D to the Act, or
(d) assigned in any of the publications mentioned in Schedule B to the Act in the case of drugs not included in paragraph (a), (b) or (c)" (*Food and Drug Regulations*, Section C.01.001[17])

Proper name (NHP): "means, in respect of an ingredient of a natural health product, one of the following:
(a) if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;
(b) if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and

(c) if the ingredient is other than one described in paragraphs (a) or (b), the chemical name of the ingredient." (*Natural Health Products Regulations*, Section 1[4])

Readability: "Readability refers to how easy a piece of writing is to read and understand." (Plain Language Commission. Readability Reports [128])

Recommended use or purpose, health claim: "A statement that indicates the intended beneficial effect of an NHP [natural health product] when used in accordance with the recommended conditions of use. The term 'recommended use or purpose' is often used interchangeably with 'health claim' or 'indications for use'". (Licensed Natural Health Products Database (LNHPD) - Terminology Guide[119])

Root cause analysis: "an analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans." (Canadian Patient Safety Institute. Canadian Root Cause Analysis Framework. 2006[129])

Security package: "means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase." (*Food and Drug Regulations*, section A.01.010; *Natural Health Products Regulations*, Section 1[4])

Substitution error: an error where the wrong product is selected instead of the intended product.

Le Système international d'unités (The International system of units, also known as the "SI"): "consists of a set of base units, prefixes and derived units…:
- The SI base units are a choice of seven well-defined units which by convention are regarded as dimensionally independent: the metre, the kilogram, the second, the ampere, the kelvin, the mole, and the candela.
- Derived units are formed by combining the base units according to the algebraic relations linking the corresponding quantities. The names and symbols of some of the units thus formed can be replaced by special names and symbols which can themselves be used to form expressions and symbols of other derived units.

The SI is not static but evolves to match the world's increasingly demanding requirements for measurement." (Bureau International des Poids et Mesures. The International System of Units (SI), 8th edition. 2006[53])

Trade dress: "any material quality of a product's packaging or physical appearance that serves a branding function."[130] This includes "the manner in which a company packages, wraps, labels, a drug or biologic product including the use of colour schemes, sizes, designs, shapes, and placements of words or graphics on a container label and/or carton labeling."[22] In Canada, for the purpose of this guide, trade dress is also applicable to natural health products.

Type size: is commonly measured in points. See "Point" and "Point size".

User: group or individual who will use a health product in the sponsor's original container with its original label. Users can be identified through product use mapping and can include a sponsor's internal staff as well as users across the supply chain, including the point of administration of a health product.

Warning: A warning is a statement that must be highlighted and conveyed to every user before product administration, to facilitate correct product use and prevent harm.

- "Point of selection" warning: information in the 'Warnings' section of the Drug Facts table that is needed by the consumer when selecting a product for purchase
- "Point of use" warning: information in the 'Warnings' section of the Drug Facts table which is important to the consumer when taking the product, but which is not necessarily needed at the point of selection

White Space: "the 'negative' area surrounding a letterform" (Carter R, et al. Typographic design: Form and communication, fifth edition. 2012[11]) Such white space on a product label or package refers to any space not covered by print, markings, coloured graphics, watermarks, or other elements of the label.

Appendix 2 - Human Factors Principles and Assessment Methods Relevant to Labelling and Packaging

Human Factors: An Overview

Human factors engineering is a discipline concerned with understanding human characteristics and how humans interact with the world around them.[131] These characteristics and interactions can be referred to as "human factors". The discipline draws upon applied research in many areas (e.g., cognitive science, physiology, kinesiology, biomechanics) to define the things that influence human performance. This knowledge can then be used to design processes, systems, or objects that humans use or interact with so that performance is enhanced and errors are minimized.

It is important that product labels and packages be designed with the user in mind and with consideration of the environment and processes in which the product will be used (stocked, selected, and administered). Users are not designers, and designers are not users.[132] Although it is the designers who are primarily responsible for the design process, consideration should be given to involving users in all aspects of product design from the outset. In particular, designers must go beyond simply asking users what they may need or want.

Label and package designs may also benefit from ongoing review, also known as iterative design[133] Making stepwise changes to a label or package design and tracking the rationale for each design change can help to optimize the design process. Part of the process can include asking the following questions. Is the information on the label grouped in a manner that will be understood by the user? What information is most prominent? What does the container tell the user about how the product is to be used? Do the product's appearance and how the information is presented infer the appropriate meaning to the user?

The following subsections present sample questions that can be used to define users and environments of use.

Users

Most products will have multiple types of users with different visual acuity, underlying diseases or conditions, and the number of health products already being used. Each category of user will have different requirements. To optimize safety, label and package design features may need to accommodate these differing requirements. Ideally, testing should involve novice users (people with little to no experience or knowledge of the product), occasional users (people with limited previous experience, who may not recall details of previous use), transfer users (people whose previous experience involves only similar health products, not the product in question), and expert users (people with extensive experience and knowledge of the product under consideration).[134]

- Will the product be used by consumers with or without help from healthcare professionals?
- What age groups of consumers are expected to interact with the health product?
- Should problems with vision (e.g., partial sightedness, deficiencies in colour perception) be considered in product design? Visual capacity may be particularly relevant for products intended to treat eye problems or support eye care, as well as for products for conditions in which vision may be compromised (e.g., diabetes mellitus). Computer software can be used to process digital images of health product labels and packages to simulate the effects of common colour deficiencies.
- How knowledgeable is the typical user?

- What characteristics might the users have that could affect their ability to use the product correctly (e.g., physical strength, dexterity, coordination, vision, hearing, memory, disease state, mental clarity, ability to swallow, tolerance of medications that are unpalatable or are difficult to swallow or ingest)?
- How simple or complex is it to use the product, i.e., are multiple steps or excessive manipulation needed to use the product?
- What critical tasks are users expected to perform simultaneously?

Health Literacy

Health literacy is a potential risk factor for medication incidents.[135,136] Several instruments for assessing literacy are available, including the Rapid Estimate of Adult Literacy in Medicine (REALM) test,[137] the REALM-Teen test for determining adolescents' literacy levels,[138] the Test of Functional Health Literacy in Adults (TOFHLA),[139,140] the Flesch-Kincaid Test,[141] and the Suitability Assessment of Materials (SAM) instrument.[142]

- What is the health literacy range of users of the product? See below information on health literacy.
- What are the users' native languages?

Environments of Use

Health products may be used in retail pharmacies, retail outlets for natural health products, hospitals, long-term care facilities, healthcare professionals' offices, dispensaries, or specialty pharmacies, emergency transport settings, and the consumer's home. Although all interactions with health product labels and packages will ideally occur in optimal environments, health products are often used and stored in poorly lit rooms with multiple high stress variables contributing to the complexity of choosing and using a product.

- What are all the possible environments where users may interact with the health product?
- Are similar products already being used within these environments? If so, is their mode of use similar to that of the proposed product?
- Have there been errors with similar products in the environment?
- Could the choice of colours and contrast negatively impact the ability to select and use a product in low-light environments?
- What other types of products may be stored in close proximity?

Any form of assessment, whether internal or external, requires a good understanding of who the users are, how the product will be used, the environments in which it will be used, and how users will interact with various aspects of the product, such as the container, the inner and outer labels, the packaging itself, and dosing devices.

Consumer Use Studies

What are Consumer Use Studies?

The term "consumer use studies" refers to a set of methods for assessing usability, identifying problems experienced by consumers, and developing solutions to eliminate or reduce the consequences of these problems. Consumer use studies simulate or mimic the circumstances of product use to provide a realistic view of how the label and package function within the intended environments. Consumer use studies are not quality assurance testing, nor are they market research. They are performed under controlled conditions to determine whether consumers can accomplish specific goals with the product or system of interest.

How Can Consumer Use Studies Help?

Consumer use studies help to determine whether consumers can safely and effectively perform the critical tasks involved in selecting and using the health product or whether they will make errors, have difficulty, or be unable to use the product at all. This is beneficial for non-prescription drugs or natural health products, as the consumer must be able to understand the labelling to use the product safely and effectively in the absence of health professional support. It may also be necessary to consider whether incorrect use might lead to a delay in seeking medical treatment, and if so, whether the consumer would suffer serious health consequences as a result. Consumers should also be able to recognize contraindications and understand essential precautions and warnings. They should be able to distinguish adverse reactions that can be experienced with the use of the product as well as when they should stop taking the product and seek medical advice.

Consumer use studies can be used to discover more specific information about users' experiences with a product and can help to identify problems beyond the general principles outlined in this guide.

When Should Consumer Use Studies Be Considered?

Although not mandatory, sponsors are encouraged to consider consumer use studies in label and package design in the following situations:

- new label or package design (e.g., design that is novel or not normally associated with the product)
- additions to a product line (e.g., addition of an extended-release formulation)
- changes to a currently marketed product (e.g., new packaging configuration, new indication of use, new delivery system, new target population)
- significant changes to layout or colour of a label (e.g., changes that may affect readability or reorganization of key information)
- change in drug status (e.g., from prescription to non-prescription. In certain situations, consumer use studies may be required[143])
- post market safety issues with the product label or package

Consumer use studies carry certain costs, however these up-front investments are often much lower than the economic costs of correcting poorly designed packages and labels that increase the risk of serious harm after the products have been released on the market. Well-designed packages and labels improve user satisfaction and can ultimately cost less for a wide variety of reasons.

Consumer Use Study Methods

Information and links are provided below to a number of methodologies that may be used to assess labels and packages. With higher levels of risk, additional and more rigorous testing methods are typically recommended. Development of product-use process maps are an integral component of these methodologies.

Comprehension Testing[61,144-148]

Comprehension testing assesses user understanding of the communication elements of a label based on language, layout and graphics.[143] It should ideally be applied to all key messages on product labels.[61] Comprehension testing involves having an interviewer show the health product or a mock-up to participants and asking them to state the meaning of the label's content (e.g., abbreviation). The interviewer then asks additional questions to assess any discrepancies between intended and interpreted meanings and to identify potential solutions to these discrepancies.

Self-Selection Studies[143]

Self-selection studies test whether consumers can apply the label information to their personal medical situations and make correct decisions to use or not use the product (self-selection decision). The key questions to be addressed are: Can consumers identify the purpose for the product and, based on their health conditions, can they demonstrate good judgment about whether the product is right for them? Self-selection studies therefore evaluate the ability of consumers to determine whether a potential non-prescription or natural health product is appropriate for their use based on the recommended use(s) of the product, the precautions/warnings specified on the proposed product label and their personal health history.

Cognitive Walkthrough[121,149-151]

Cognitive walkthrough involves guiding a small number of users through a process or task, often early in the design process, to examine mental activities and challenges experienced.[149,150] It can be used as part of an FMEA and can be applied in any setting.[121] Cognitive walkthrough can be used to assess health products that are contraindicated in specific populations.

Users walk through the assigned tasks, "thinking out loud" as they do so, to allow the investigator to gain a detailed understanding of users' expectations and challenges. Potential design solutions identified through the cognitive walkthrough should then be applied to improve the design of health product labels and packages.

An accurate understanding of the situation, achieved by involving users in their own environments (either real life or "high-fidelity simulations"), will enhance the value and benefit of findings of the cognitive walkthrough.

Failure Mode and Effects Analysis[60,121]

Failure Mode and Effects Analysis (FMEA) is a type of proactive risk assessment that can be used to systematically evaluate product-related hazards and points of risk within the broader system where a product will be used (users, environments). It represents a way to identify and prioritize these risks, identify strategies to mitigate or address problems or potential errors (e.g., to reduce the probability of occurrence of the error, to reduce the severity of consequences of an error, or to increase the likelihood that the error will be noticed), and evaluate the mitigation strategies.

Actual Use Studies[143]

An actual use study incorporates elements of both a self-selection study and a label comprehension study, but also provides information about consumer compliance with the recommended dosing and dosing regimen, and provides insight on potential misuse of the product. An actual use study determines the safety and effectiveness of the product under the proposed non-prescription and natural health product conditions of use, based on consumer compliance with respect to warning(s), dosage instructions, and other advice that constitutes non-prescription and natural health product labelling. These studies are intended to demonstrate the way consumers will use the product in everyday life

Appendix 3 - Product-Use Process Maps

Product-use process maps outline where and how a product will be used, according to its indications and who will potentially come into contact with it. They are intended to provide a complete and accurate understanding of how the product will be used, the environments of use, and how users will interact with it (e.g., with the container closure, container label, packaging and package labels, dose delivery devices) to identify and make decisions about using the product.

Product-use process maps can be helpful when human factors-based user testing is planned, as such maps will help in identifying the scope of use and the primary users.

An example of a product-use process map is presented below. Selection and administration are the key points in the process where users interact with product (specifically with the label and the package). In the example below, these points of interaction are presented in red italic text.

Sample Product-Use Process Map for Natural Health Product (NHP) Recommendation Made by a Naturopathic Doctor
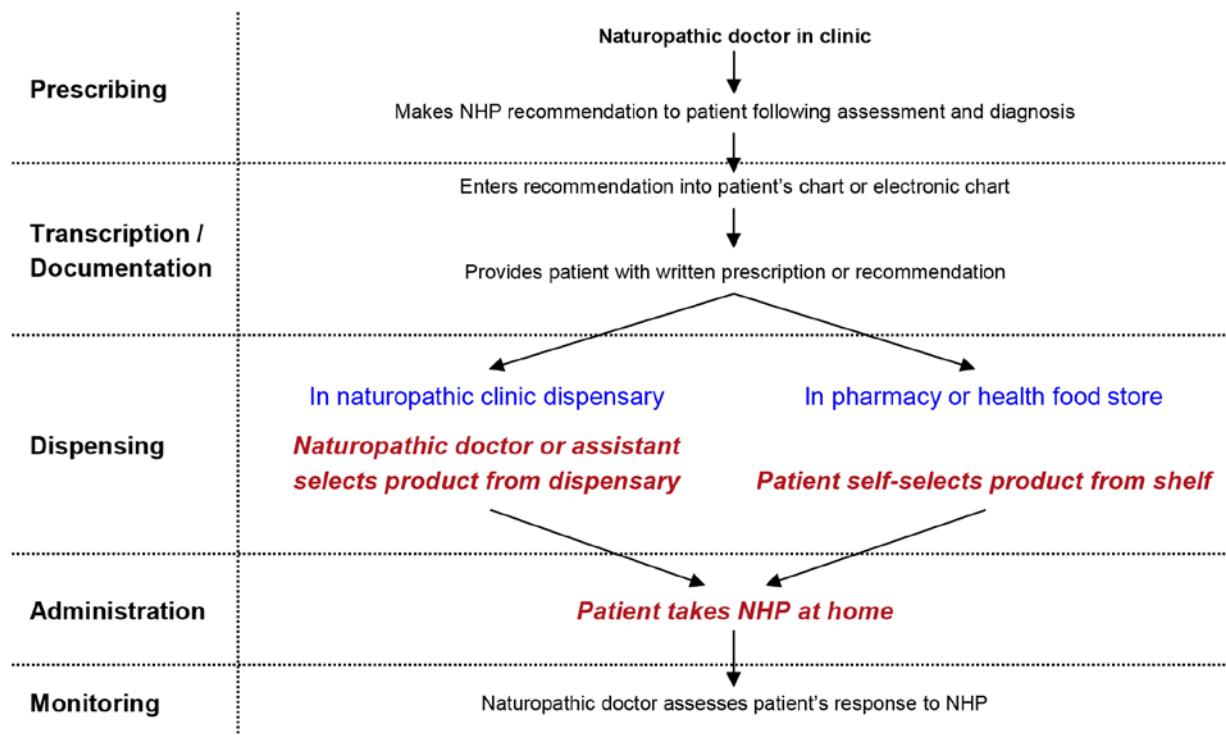
Note: Naturopathic doctors are required by regulation to advise patients, by the posting of a notice, that they may purchase a recommended NHP from the naturopathic doctor or from a pharmacy or health food store of their choice. Information presented in red italic text highlights the processes involved in selection and administration—key points in the process where users interact with products.

Appendix 4 - Acknowledgements

References

Where possible and applicable, references have been sourced from publicly available Internet sites.

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