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Bureau of Program Policy, Risk Management and Stakeholder Engagement,  
Natural and Non-prescription Health Products Directorate, HPFB  
Health Canada  
Email: [hc.nnhpd.consultation-dpsnso.sc@canada.ca](mailto:hc.nnhpd.consultation-dpsnso.sc@canada.ca)

## **Re: ISMP Canada Feedback on Draft Guidance Document: Labelling of Natural Health Products**

### **About ISMP Canada**

The Institute for Safe Medication Practices Canada (ISMP Canada) is a national, independent, and not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national, and international patient safety organizations, the pharmaceutical industry, and the public to promote safe medication practices.

ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives. This includes safer ways to prescribe, package, dispense or take medication. Canadians trust that self-care products, including natural health products (NHPs) in Canada are safe; we commend the identification of gaps in the current system and the steps towards strengthening Health Canada oversight. Any clarity that can be provided to consumers is important. The Draft Guidance Document for Labelling of NHPs was reviewed by a multi-disciplinary team including a prescriber, pharmacists, and a consumer, to provide this feedback response.

### **Executive Summary**

#### **ISMP Canada requests reconsideration of the following 2 key areas of the Draft Guidance Document:**

1. The development of this Draft Guidance Document for Labelling of NHPs is commended. The Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG for NPDs and NHPs) complements this Guidance Document by providing additional helpful tips for safe design of labelling that can be used by industry and label reviewers. For prescription medications, a guidance document for labelling co-exists with the GLPPG for prescription products. As such, this Draft Guidance Document for Labelling of NHPs should not replace the GLPPG for NPDs and NHPs. ISMP Canada would be pleased to support regular updates of the GLPPG to ensure alignment with this Guidance Document and to include

new helpful learning as it emerges. In this way the GLPPG can also inform updates to the Guidance Document.

2. As evidenced by medication error reports and resultant patient harm, it is key that both the elemental and salt content for calcium, iron, magnesium, and zinc are displayed on the front panel of the label.

Further details and additional feedback are shared below.

## Detailed Feedback

### Section 1 - Introduction

Draft Guidance Document Section	ISMP Canada Feedback
<p><b>Page 2, Section 1.1</b> – It replaces the previous Labelling Guidance Document published in 2006 and the Good Label and Package Practices Guide (GLPPG) for Non-prescription Drugs and Natural Health Products.</p>	<p>ISMP Canada recommends that the Draft Guidance Document for Labelling of NHPs not replace the GLPPG for NHPs and non-prescription products. Rather, the 2 documents can complement each other in supporting safe labelling of NHPs.</p> <ul style="list-style-type: none"> <li>○ For prescription medications, a guidance document for labelling co-exists with and complements the GLPPG for prescription products.</li> <li>○ The GLPPG guides the use of an ideal label for safety and helps to advance label designs for safety, while the Draft Guidance Document for Labelling of NHPs provides concise regulatory guidance.</li> </ul>
<p><b>Page 5, Section 1.3</b> - Definitions</p>	<p>Suggest the addition of “Proper Name” and its definition. “Proper name” is used in Table 7, Section 7b.</p>

### Section 2 - Content

Draft Guidance Document Section	ISMP Canada Feedback
<p><b>Page 9, Section 2.1</b> – Units of Measure</p>	<p>Suggest including a statement that requires the use of “units” rather than the abbreviation “U” to depict “units” (per <a href="#">ISMP Canada Do Not Use Dangerous Abbreviations, Symbols and Dose Designations</a>), in the section of Units of Measure.</p>

<p><b>Page 9, Table 4 – Units of Measure</b></p>	<p>Suggest the following abbreviations without capitalization of the first letter (except for “litre[s]) to describe the different units of measure that are consistent with both English and French:</p> <table border="1" data-bbox="651 520 1377 831"> <thead> <tr> <th>Complete Word –English</th> <th>Complete Word –French</th> <th>Correct Bilingual Abbreviations</th> </tr> </thead> <tbody> <tr> <td>gram(s)</td> <td>gramme(s)</td> <td>g</td> </tr> <tr> <td>kilogram(s)</td> <td>kilogramme(s)</td> <td>kg</td> </tr> <tr> <td>microgram(s)</td> <td>microgramme(s)</td> <td>mcg</td> </tr> <tr> <td>milligram(s)</td> <td>milligramme(s)</td> <td>mg</td> </tr> <tr> <td>litre(s)</td> <td>litre(s)</td> <td>L</td> </tr> </tbody> </table>	Complete Word –English	Complete Word –French	Correct Bilingual Abbreviations	gram(s)	gramme(s)	g	kilogram(s)	kilogramme(s)	kg	microgram(s)	microgramme(s)	mcg	milligram(s)	milligramme(s)	mg	litre(s)	litre(s)	L
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litre(s)	litre(s)	L																	
<p><b>Page 10, Table 5 – Recommended Expiry Date Formats</b></p>	<p>Per the GLPPG, include all three components of the date (year, month, day) when applicable and when space permits. The month should be expressed using letters (see examples below) to avoid confusion.</p> <ul style="list-style-type: none"> <li>• When all components of the date are applicable: YYYY-MM-DD: 2024-OC-31</li> <li>• If there is space for only the year and the month: YYYY-MM: 2024-OC</li> </ul>																		
<p><b>Page 14, Table 7, Section 7b – Medicinal Ingredients</b>          Black cohosh (6:1 extract)...40mg (Actaea racemosa) (root) equivalent to 240mg of Black Cohosh</p>	<p>Suggest consistent use of spacing in between the strength and unit (e.g., 40 mg rather than 40mg).</p>																		

### Annex B – Single Entity Minerals

Draft Guidance Document Section	ISMP Canada Feedback
<p>The strengths should be located in close proximity to the corresponding name (that is, strength of salt near salt name, strength of element near element name). Placing the strength of the elemental content near the</p>	<p>Consumers and some health care providers may not fully understand or recognize the differences between expression of the salt entity or the elemental mineral strength. As noted in the Guide, this is a recurring factor identified in reported medication errors.</p>

<p>salt name, without clearly identifying it as the strength of the element, should be avoided as it may lead to misinterpretation and dosing errors.</p>	<p>Display of the element and salt on the same line with one strength is confusing. When displayed this way, it is unclear if the strength refers to the element or the salt.</p> <p>Example:</p> <p><b>Calcium (carbonate) 500 mg</b> is confusing</p> <p><b>Calcium 500 mg (as calcium carbonate 1250 mg)</b> provides greater clarity</p> <p>It is imperative to give consumers greater clarity about the form of the product (elemental vs. salt) to which the strength refers.</p>
<p>If space is an issue and the principal display panel cannot accommodate both the salt name/strength and the element name/strength, the strength that appears on the principal display panel must correspond to the description of the ingredient, and be placed in close proximity to that name (either the source material or the medicinal ingredient). In other words, if the brand name is the salt name, then the strength must correspond to that of the salt.</p>	<p>ISMP Canada concurs with the 4 minerals (calcium, iron, magnesium, and zinc) specifically named in the draft Guide. ISMP Canada recommends that both the salt name/strength and the element name/strength appear on the principal display panel for these products.</p> <p>The same principles should be considered for other mineral elements (e.g., potassium) available as single entity products.</p>
<p>Examples of acceptable descriptions of a calcium product:</p> <p>If both the element and its salt with their corresponding strengths cannot be accommodated on the principal display panel, one of the following formats is acceptable:</p> <ul style="list-style-type: none"> <li>• Calcium 500 mg</li> <li>• Calcium Carbonate 1250 mg</li> </ul>	<p>ISMP Canada has evidence of errors and near misses resulting from confusing labelling and/or inconsistencies between how products are displayed (elemental vs. salt) in technology, how NHPs are prescribed, and how they are labelled on the products themselves.</p> <p>Consistent use of either the elemental or salt strength (but not both) throughout the medication use system (i.e., in EMRs, in pharmacy systems, on product labels)</p>

<ul style="list-style-type: none"><li>• Calcium Carbonate (along with '500 mg elemental calcium' spaced away from the name)</li><li>• Calcium 500 mg (derived from calcium carbonate)</li></ul>	would support safe use of these products by both consumer and practitioners. ISMP Canada would be pleased to support the education and knowledge translation work that is required.
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### Relevant ISMP Canada Safety Bulletins

The value of reporting to a Canadian Medication Incident Reporting and Prevention System (CMIRPS) is increasingly being recognized. ISMP Canada Safety Bulletins and Consumer Newsletter, products of the CMIRPS reporting program, demonstrates the value of reporting, analysis, and learning to keep consumers safe. Select Bulletins and Newsletters highlighting the opportunities to build in improvements into the medication use system include:

- <https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i1-Calcium.pdf>
- <https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2009-3-LabellingofIronProducts.pdf>
- <https://safemedicationuse.ca/newsletter/downloads/202002NewsletterV11N2-Iron.pdf>

ISMP Canada is appreciative of the opportunity to provide feedback. Any additional questions can be directed to:

ISMP Canada  
4711 Yonge St., Suite 706  
Toronto, ON  
M2N 6K8  
(416) 733-3131  
[info@ismpcanada.ca](mailto:info@ismpcanada.ca)