Improved Labelling for Natural Health Products – Health Canada initiative

What is this new initiative?

On June 25, 2021, the Government of Canada posted, in *Canada Gazette 1* (*CG1*), a number of proposed changes to the Natural Health Products Regulation mainly focused on labelling requirements for this category of products. As is routine with proposed changes, Health Canada also launched a consultation process called *Proposed Regulations Amending the Natural Health Products Regulations – Improving Labelling for Natural Health Products*. The aim of this consultation is to "address poor communication of key information on health products labels that can lead to incorrect purchases and preventable harms". More information about the proposed changes and the consultation can be found at https://gazette.gc.ca/rp-pr/p1/2021/2021-06-26/html/reg4-eng.html

Is this related to the Plain Language Labelling initiative for non-prescription medicines?

Plain language labelling (PLL) is a Health Canada initiative that aims to support consumers in making informed choices about health products through clearer and more concise labels. When the PLL initiative was launched for self-care products it was limited to non-prescription medicines with Natural Health Products (NHP) specifically not included. The new initiative launched on June 25, 2021, is the evolution of the original PLL initiative with proposals being made specific to NHPs so that they are "in alignment with the rules already established for comparable non-prescription drugs (NPDs)".

These label changes are the first major part of the creating a cohesive self-care framework for health products. More information about the self-care framework can be found at selfcareproducts-produitsautisoins@hc-sc.gc.ca

How does Health Canada define a "label"?

In the Regulatory Impact Analysis Statement (RIAS) included in the consultation, Health Canada describes a label as:

> "an all-encompassing term that covers the affixed information on the actual health product package and other information that is made available to consumers and health professionals, including the product box and any inserts, tags, or leaflets. Important information should be clearly and consistently displayed so consumers can make comparisons between products, properly selected and use of NHPs, be fully informed of their benefits and harms, and be able to avoid preventable harms"

What changes are being proposed by Health Canada?

The proposed labelling changes fall into four basic areas:

- Inclusion of a Products Facts Table: a requirement that important product information such as ingredients, indication, risk information be presented in a table on the label with certain exemptions for very small packages, relatively low risk products and products with a short duration of use.

- Labelling of Food Allergens, Gluten and Aspartame: aligning with the existing food definitions, require products that contain a "priority food allergen", gluten or aspartame to state the source of the substance on the product's label.
- Clearly and Prominently Displayed Label Text: improved legibility requirements for label text by requiring such things as minimum type size, font types and contrast. Similar exemptions will exist as those identified for the Products Facts Table above.
- Modernized Contact information: removing the requirement for a postal address of the manufacturer or importer and instead the label must display an email address, telephone number or website address which must be within the Products Facts Table unless exempted for one of the reasons mentioned above.

The above information only provides a high-level overview of what is being proposed. More details can be found in the RIAS or the proposed regulatory changes both of which can be found at the website noted above.

Is this a one size fits all initiative or will it depend on the type of Natural Health Product?

Health Canada recognises that in some cases there could be practical challenges in complying with these regulations and consequently have included a number of "exemptions from use" of a Products Facts Table. These include:

- If there is no outer label and has a small inner label (77.5cm2 or less);
- Recommended duration of use is one day or less;
- Contains three or fewer dosage units; and
- The NHP has a localized rather than systemic effect and is for administration in the oral cavity, on the skin or as a throat lozenge or for topical aromatherapy.

In addition, during a technical briefing informing stakeholders of the posting of these proposed changes in *CG1*, Health Canada indicated that they were considering additional flexibility regarding the Products Facts Table for products with 4 or more ingredients.

What evidence is proposed to support these improvements?

Health Canada identifies several sources of evidence in the RIAS in support of this initiative. These include:

- observations from changes to non-prescription drug labelling seen in Canada and internationally;
- identification of risk associated with this category of health products such as potential drug interactions and adverse events;
- preferences identified by consumers during the consultation process;
- research published in peer review journals identifying the role labels play in consumer decision making around Natural Health Products;
- information from reported adverse events where NHPs potentially have caused harm including cases where labelling errors or confusion were suspected of being the issue; and
- findings from the report from Commissioner of the Environment and Sustainable Development within the Office of the Auditor General on the management of the NHP regulations published in April 2021. See our post on this report – Read More.

Although this evidence does not necessarily show a link between improved labelling and a decrease in incidence of harm, the argument put forward by Health Canada is that since NHPs play an increasing role in the health of Canadians, this new labelling initiative has the potential for reducing risks from NHPs.

How will this new approach to improved labelling for Natural Health Products be rolled out?

Recognising that these changes may require extensive changes to NHP labels, Health Canada is proposing a relatively long implementation period of three years after the date of implementation of the new requirements. In addition, all NHPs on the market at the time of these changes coming into force will have an additional three-year period before compliance is required with these new amendments.

What kind of consultations has Health Canada conducted with stakeholders?

The RIAS outlines the consultation process which took place over the past 4 years including:

- feedback from the proposed self- care framework which began in April 2016;
- results of an online consultation between September and October 2016;
- comments made from cross country in-person consultations in 2017; and
- technical briefings with key stakeholder groups throughout the process.

What will be the financial costs and environmental impact of implementing these improvements?

In the RIAS, Health Canada states that additional impact on the environment would be minimal. In making this statement, several assumptions are made such as manufacturers adopting peel back labels, inserts or leaflets instead of increasing package size. It also concludes that these new changes will result in little or no additional costs over and above what companies would normally invest in keeping labels current.

While many industry stakeholders were concerned that these proposed labelling changes would be a repeat of the negative impact they say occurred for non-prescription medicines, this was before the full proposal was published in *Canada Gazette 1*. We will see if their concerns are addressed now that the full proposal has been published.

Final Thoughts

Any initiative that improves Canadians' ability to make informed decisions about whether to include or not include NHPs in their health care options should be supported and championed. What the evidence also shows is that that accurate product labels presented in a standard format are important tools for consumers to use when making health care decisions including those about NHPs.

As with any new regulations. there will be issues that arise during their development and upon initial implementation. These issues will need to be resolved. Two immediate questions come to mind:

First – Is this the best time for Health Canada to be prioritizing improvement to the labelling of NHPs? Though intuitively, and as identified in the RIAS, these changes may help consumers make health care decisions related to NHPS, there is limited information about whether improved labelling for NHPs will help decrease harm to

Canadians taking NHPs. There is far more robust evidence identifying the risk posed to consumers through inadequate compliance and enforcement, and by not ensuring high quality products through good manufacturing practices. Both of these issues were identified as being more impactful than improvements to labelling in a recent report from the Commissioner for Sustainability and the Environment. Given this, any proposal aimed at improving product labels must be made in tandem to improvements in these other more pressing areas.

The second question relates to the practicalities of implementing these changes for a sector as complex as the NHP market notably around the requirements for the Products Facts Table. While having the Table will likely prove helpful for products with a single or limited number of ingredients, it could be physically impossible to include, in a useful way, all the information required for multi-ingredient products such as multi-vitamins or those used in many traditional medicines. Internationally, rather than require a Products Facts Table, Australia only encourages the majority of complementary medicines to include a Products Facts Table.[1] In the European Union, food supplements, such as NHPs, are exempted from the requirements for the food regulations.[2] While the United States does require that the label of a dietary supplement includes a Supplements Facts Table, the required information that it must contain is quite limited. It is important to note, and encouraging to see, that the issue of multi-ingredient products has already identified by Health Canada and additional flexibilities, including the impact on products with more than four ingredients, are already being explored.

About the author:
Michael Smith trained as a pharmacist and as a naturopathic doctor. He is recognized internationally as an expert in natural health products and complementary & alternative medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada and the Therapeutic Goods Administration in Australia. In addition to his international work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi, USA and an Adjunct Fellow at the National Institute of Complementary Medicine at Western Sydney University, Australia. Michael is a member of ISURA's Scientific Advisory Committee.

[1] https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=DA