Improved Labelling for Natural Health Products – The Final Regulations

Summary of Health Canada's Process for Improving Labelling for NHPs

In 2016, Health Canada announced that it wanted to develop a more consistent approach to self care products: non-prescription medicines, natural health products and cosmetics. As this initiative developed, Health Canada identified a need to improve Natural Health Products (NHPs) labels making them more consistent with those for similar products notably non-prescription medicines.

On June 25, 2021, the Government of Canada posted in *Canada Gazette 1* (CG1) proposed changes to the Natural Health Products Regulation (*NHPR*) dealing with labelling requirements for this category of products. As is routine, Health Canada also launched a consultation process called *Proposed Regulations Amending the Natural Health Products Regulations – Improving Labelling for Natural Health Products*. The stated 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

A previous ISURA article provides more background with respect to Health Canada's Plain Language Labelling initiative at https://isura.ca/2021/08/24/improved-labelling-for-natural-health-products-health-canada-initiative/

On July 6, 2022, Health Canada published the new regulations in *Canada Gazette II* with more information found at https://canadagazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors146-eng.html and a new guidance document at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/labelling.html

What was the response like to this consultation?

There was a lot of interest in the consultation with Health Canada with 139 stakeholder submissions received from a wide spectrum of stakeholders including "health" stakeholders, patient safety groups consumers and industry. In the Regulatory Impact Analysis Statement (RIAS), Health Canada states that "the majority were supportive of the overall objectives of the proposal".

As for the comments made, the RIAS identified non-industry groups as being supportive of such points as:

- product fact tables,
- labeling of food allergens,

- clearly and prominently displayed label text for contents such as gluten,
- a requirement for modernised contact information.

The RIAS noted that comments from industry centred around concerns about the costs, both financial and environmental, for implementing these new labelling regulations.

Key elements of the new regulations

The main areas of the new regulations remain largely unchanged to those stated in the *Canada Gazette I* proposal. The four areas key elements identified and described in the RIAS as follows:

- *"*A Product Facts table: Important product information is required in the format of a standardized facts table. Certain exemptions are provided to accommodate products in very small packages, products that are relatively low-risk, products that are to be used within one day or less (as per the directions on the label), and products with package(s) that contain, at most, three dosage units.
- Labelling of food allergens, gluten, added sulphites and aspartame: If a product contains a priority food allergen (i.e., one that is likely to lead to anaphylaxis in affected communities), gluten or added sulphites, a food allergen source, gluten source and added sulphites statement is required on the label. If a product contains aspartame, a statement to this effect is required on the product's label.
- Clearly and prominently displayed label text: Regulatory text on the label, including within the Product Facts table, is subject to improved legibility requirements, including a minimum type size, font types, and contrast. Utilizing a risk-based approach, exemptions from these requirements are provided for certain label information (e.g. the product number and marketing information), as well as for products with very small packages, products that are to be used within one day or less (as per the directions on the label), and products with package(s) that contain, at most, three dosage units.
- Modernized contact information*:* A manufacturer or importer is required to display an e-mail address, telephone number, or website address within an NHP's Product Facts table (or elsewhere on the label if the NHP is exempt from the facts table requirement), instead of a postal address of the manufacturer and the importer (if there is one), as is currently required"

How will these new labelling regulations be rolled out?

Recognising that these changes will require extensive changes to NHP labels, there will be an implementation period of 3 years for new products with an additional 3 years for existing NHPs. This implementation period started on July 6, 2022, when the new regulations were published in *Canada Gazette II*.

Will these new regulations mean a change to existing NHP monographs?

Since the Health Canada NHP monographs play an important part in the approval process, making sure that they are current will be key to the effective implementation of the new regulations. Health Canada has recognised this and, in the RIAS, stated that they "will undertake a review of the compendium of monographs in order to help product licence holders accommodate a product facts table on their label". Health Canada has also committed to removing unnecessary warning statements from the monographs as well as amending them to make the language more "concise and understandable". A guidance document will be prepared to help companies accommodate the new requirements for a product facts table. In the RIAS, Health Canada also notes that "any necessary changes to product monographs will be finalized prior to the coming into force of the regulations". These commitments are very welcome and essential to the successful implementation of these new labeling regulations.

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

Health Canada recognised that in some cases there could be practical challenges to implementing these labelling regulations and have added additional flexibilities to those indicated in the original proposal. These include products with

- small labels,
- short/limited duration of use,
- containers that contain three or fewer dosage units, and
- NHPs that have a localised effect such as topical aromatherapy.

Once specific requirements are met, these new flexibilities apply to the inclusion of non-medicinal ingredients, and statements regarding quantity of mercury and source materials for medicinal ingredients. In addition, the definition of a small package size has increased from $75cm^2$ to $90cm^2$ which includes more products notably those from traditional forms of medicine.

A proposal to exclude multi-ingredient NHPs with more than 4 ingredients which was raised by Health Canada during a virtual consultation after Canada Gazette 1 has not been included in the newly published regulations.

More information and details may be found in the RIAS.

Final Thoughts

After receiving the proposed regulations in *Canada Gazette I* in July 2021, I identified two immediate items of concern: 1. Notably about the strength of the supporting evidence identifying labelling as a priority, and 2. Concerns about the practicalities of implementing changes with respect to the mandatory use of Product Fact Tables especially for multi-ingredient products. Now that the final regulations have been posted, I cannot say Health

Canada has addressed either item satisfactorily. The same can be said for addressing concerns around the environmental impact these changes will have as well as the cost to industry of implementation and the potential impact on imported products particularly those from the United States. Given the limited time and resources, an overriding concern that remains is that while these changes are made, other larger issues concerning safety such as product quality will not be addressed.

You can read more about the comparison between the US and Canada NHP regulations including labelling at https://isura.ca/2022/04/12/comparing-nhp-regulations-from-canada-and-the-usa/ and make your own mind up. Another piece on the labelling requirements in Australia should soon be available.

As I said in my previous post on NHP labelling regulations, any initiative that improves Canadians' ability to make informed decisions about whether to include or not include NHPs in their health options should be supported and championed. A number of the new requirements just published in *Canada Gazette II* will help accomplish this—notably the requirements for improved labelling for allergens and substances which may cause health issues such gluten and aspartame, and the requirement to use electronic resources to provide consumers with more detailed information.

In the end, it remains to be seen if Health Canada is correct and that the changes to the labelling of NHPs implemented through these new regulations really will provide benefits that outweigh the costs of implementing these changes.

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 Associate Professor at the National Centre for Naturopathic Medicine at Southern Cross University, Australia. Michael is a member of ISURA's Scientific Advisory Committee.