Plain Language Labeling for Natural Health Products – the current Health Canada initiative

What exactly is Plain Language Labeling?

Plain language labeling (PLL) is a Health Canada initiative aimed at supporting consumers in making informed choices about self-care products through clearer and more concise labels. When the PLL initiative was launched it was limited to non-prescription medicines and Natural Health Products (NHP) were specifically not included. You can find more general information about this at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/questions-answers-plain-language-labelling-2019/document.html

Health Canada plans to publish the final proposal for PLL in *Canada Gazette I* in the late Spring 2021. Until then we will not know the exact details of this new NHP labeling approach. Unfortunately, as with all regulatory changes of this kind, Health Canada is limited in how much information it can share on the final plan before this publication.

How does this relate to NHPs?

In March 2018, Health Canada proposed that the current NHP regulations be changed to require product labels to:

- include a "facts" table to standardize the format for important information;
- include "modernized" contact information such as e-mail and toll -free telephone numbers; and
- use comprehensible and readable language.

This would be in addition to the existing core NHP label regulations requiring information such as lot number, expiry date, etc.

Until the final regulatory amendments are published, we won't really know what this means for NHP labelling but a key consideration is what the product "facts" table will look like. The aim seems to be to separate the information into that which is useful at point of selection (when you buy the product) and that which is useful at point of use (when you use the product).

At the point of selection, the main product label, in addition to the product name, would have an abbreviated facts table which includes product uses (if not on the main label); the medicinal/active ingredients; warnings such as: do not use warnings, warnings around drowsiness or excitability for example; what is described as first directions; contact information and links to where more information about the product information can be found.

The proposed change would require that more information be available through a full product facts table either on a label insert or potentially on a website/URL link. This "point of use" information would contain items such as: a more complete list of warnings not deemed necessary on the main label; what is described as second or third directions of use or subsequent directions for use.

As with all other product labels in Canada, all information will have to be in both official languages (English and French) and there will be required font size, etc.

At this time, Health Canada has not posted more specific information. The limited information available on what is being proposed was included in the cost-benefit survey required for this type of regulatory change. Some more general information about the self-care approach can be found at https://www.canada.ca/en/health-canada/topics/self-care-products.html.

Is there anything we can learn from how the PLL initiative is working for non-prescription medicines?

The PLL for non-prescription medicines is in the process of being implemented. Though different from the NHP sector, the real-world implementation experience for PLL for non-prescription medicines could provide important and useful information regarding the implementation of PLL for NHPs:

- Implementation costs originally estimated by Health Canada at $3 to $4 million are in reality in excess of $100 million.
- Implementation has also resulted a huge increase in packaging. The increase in packaging size has also created a challenge for retailers to find enough space on their shelves.
- Since implementation one in six non-prescription medicines is no longer being marketed in Canada.

Until Health Canada shares its projected costing for implementation of PLL for NHPs, the information from the implementation of PLL for non-prescription medicines is the only available evidence from industry. The PLL implementation for non-prescription medicines does give Health Canada the opportunity to learn from the challenges and experience in this sector. This should enable Health Canada to work more effectively with the NHP industry develop ways in which these problems can be avoided or mitigated.

Could PLL implementation impact the number of NHPs available in Canada?

Again, until we know what exactly is being proposed, we don't know for sure, but it could have a very negative impact on the NHP sector. If for no other reason, the cost of implementing and managing this new approach to NHP labels could run many companies out of business and deter companies from bringing products to market.

Is there an upside to the proposed PLL initiative?

Any initiative that improves Canadians' ability to make informed decisions about whether to include or not include NHPs within their health care options should be supported and championed. The recently published report of an audit by the Office of Auditor General (OAG) of Canada on the Natural Health Products regime in Canada clearly indicates the importance of effective product labels for Natural Health Products and the need to strengthen the way the current regulations are monitored and enforced.[1] The question is whether or not the PLL initiative will actually do this?

[1] https://www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html

One opportunity here is for Health Canada to review how they deal with theoretical risks – that is ones that may in theory happen compared those have actually happened in practice. At the moment, many NHP monographs focus largely on the theoretical risks rather than the actual. Using data and evidence generated since the NHP regulations came into force, labels could reflect real world risks, side effects and contra-indications supporting Canadians in making informed health-based decisions.

How will this new approach to PLL be rolled out?

Health Canada was proposing an initial 1-year "coming into force" period to provide companies with sufficient time to modify their product license applications. NHPs already on the market when the regulations come into force will have a 4-year period before they need to comply with the new labelling requirements.

Health Canada has not indicated whether there will be any consumer education about this new approach or whether any financial support will be provided to help small companies deal with the new costs associated with implementation.

What would be the Environmental Impact?

From what we know and the experience from PLL for non-prescription medicines, the environmental impact could be huge and flies in the face of the basic sustainability values of many consumers, not to mention those of the current government. Although Health Canada has said in the past that they will consider allowing "point of use" information on websites, by limiting the physical information found on the package, there would be multiple steps required in order to access the information. This could be challenging for some consumers.

What kind of consultations has Health Canada conducted with stakeholders?

Throughout this process, Health Canada has consulted with Canadians both through formal online consultations (including costing exercises), public presentations some time ago and focused meetings with key stakeholders. While some information from the open consultation has been published (available at selfcareproducts-produitsautosoins@hc-sc.gc.ca), input and feedback from the key stakeholders meetings has not been shared.

What is apparent is that a number of the NHP industry associations who were part of these consultations are still very concerned by what is being proposed. In a letter sent to the Minister of Health by five national NHP and Food trade associations representing manufacturing companies, retailers, direct sellers and traditional Chinese medicine, serious concerns were raised, and especially given the impact of COVID 19 pandemic, a request made to pause plans to move the PLL process forward in spring 2021 and to sit down with stakeholders for more detailed consultations.

This letter has been made public and a copy can be found at:
https://chfa.ca/Portals/30/RegAffairs/NHPs/2021/FHCP%20CHFA%20DSA%20CCHMC%20%20Letter%20Hajdu%20NHP%20PLL%20March%205%202021%20Final.pdf?ver=2021-03-05-114923-183

Final Thoughts

To ensure that we are following the science and developing evidence-based policy and regulation, the basic question remains: why does the Government of Canada want to expand the PLL initiative to NHPs? Even with the OAG Report, little substantive, external, objective evidence has been shared that shows that such changes to PLL will support Canadians in making informed choices about NHPs. If we look at the experience of the implementation of PLL for non-prescription medicines there is a very real risk that implementing PLL changes for NHPs will only have unnecessary and significant financial and environmental costs, while potentially decreasing Canadians' access to NHPs.

In making regulatory and policy changes, consulting with stakeholders is always difficult and it is always hard to gauge when enough is enough. While publishing in *Canada Gazette I* does give Canadians the opportunity to comment on proposed changes, at that stage typically most opinions are known. Given the huge impact PLL could have on Canadians' ability to access and use NHPs together with the lack of current specific information on what is actually being proposed as well as more Canadians buying NHPs online as a result of the COVID pandemic, is now the time for major change?

Now is the time to learn from past experience and the knowledge gained in the almost 20 years since the NHP regulations were put into place to make sure that any proposed changes to product labelling will work. Changes should follow the recommendation made by the Standing Committee on Health back in 1999 and include a public education campaign and a focus on supporting independent research in this subject. This would be a far better place for government and the private sector to invest their limited resources.

My hope is that Health Canada has reflected on what they learnt from the PLL experience with non-prescription medicines, focused on the findings of the recent report and, most importantly, listened to what Canadians told them during the PLL for NHPs consultations. The result being a set of positive and practical changes for NHP labels and, if not, then the process should be paused. What is needed now is a continuing open and transparent conversation with Canadians to ensure that labels are useful tools that help consumers make informed decisions about the NHPs they choose to take.

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.