NHP Research Society of Canada
Société Canadienne de Recherche PSN

Comments provided by the Natural Health Products Research Society of Canada in response to Canada Gazette Part 1, Vol. 155, #26 titled *Proposed Regulations Amending the Natural Health Products Regulations – Improving Labelling for Natural Health Products.*

Summary

The ability of consumers to make an informed decision about including, or not including, a Natural Health Product (NHP) within their health care choices is fundamental to the development of both appropriate regulations and research. Consequently, any initiative that promotes this aim in a practically and clinically relevant way should be encouraged and promoted.

While in principle the approach proposed in this Canada Gazette 1 (CG1) posting will establish the most comprehensive, up to date and innovative approach to NHP labelling on a global scale, questions and concerns exist about the impact this will have on the current and future NHP industry and research community. If concerns raised by stakeholders are accurate in that these changes will be expensive to implement, the balance (risk versus benefit assessment) will not be favorable.

These concerns include:

- The research identifying NHP labelling as a priority area for improvement in preventing harm is incomplete. The research which has been presented in many cases comes from an extrapolation and interpretation from harm seen in other health product sectors, notably non-prescription drugs (NPD);
- Given limited resources available, focusing on improving NHP labels could detract attention from other areas which have a higher potential of harm supported by a more robust evidence base. Some notable examples include evidence standards, product quality, and inadequate compliance and enforcement of the NHP regulations;
- If concerns raised by the NHP industry (both in Canada and internationally) regarding the costs and ability to implement these changes are accurate, this could have a domino effect, decreasing the ability to fund research and therefore stifling innovation in the marketplace;
- An increased regulatory burden could decrease the ability of Canadian NHP companies, both those manufacturing and importing, to operate. This in turn could decrease access to safe, efficacious and high-quality NHPs by Canadian consumers. This is particularly important for certain niche markets such as health care

practitioner brands, where a significant number of products are imported from foreign companies which have less rigorous domestic regulatory frameworks; *and*
- Inadequate information has been provided in the Regulatory Impact Analysis Statement (RIAS) to accurately ascertain the impact on the environment. This is especially important given the environmental impact seen when similar labeling improvements were implemented for the Canadian NPD sector.

Recommendations

- Health Canada should proactively strengthen and foster dialogue and collaborations with domestic partners within the NHP community, notably within the Canadian research community;
- Engaging with the broader NHP community both in Canada and internationally, conduct a more rigorous and comprehensive analysis of the environmental impact of these proposed labelling changes by obtaining research conducted in support of labeling initiatives implemented by global regulators;
- Following current research, develop (either alone or in partnership with stakeholders) a campaign aimed at educating and informing consumers and practitioners about these changes and what they mean;
- Providing Canadians with useful and clinically relevant information by reviewing information currently required on labels with prominence given to that seen clinically rather than more theoretical in nature, notably around risk information;
- Recognizing the lack of quality of evidence linking improved labeling to reduced harm to consumers, Health Canada should promote directly, as well as work with government partners, to identify and support this topic as a research priority. Health Canada should concurrently be assisted in addressing other priority areas identified in the recent AGO audit, notably those around product quality;
- The implementation of a labeling improvement initiative for NHPs must not detract from more immediate issues such as product quality and strengthened enforcement, where risks are more definitively supported by more robust evidence;
- Research on NHPs needs to be supported to increase the evidence base concerning the perceived benefits of labeling changes and other approaches on the reduction of the risk of harm, such as product quality and better enforcement of NHP regulations;
- Building on the flexibilities identified within the RIAS and in consultation with stakeholders, identify additional barriers or challenges and how they can be addressed notably around universal application of the Product Facts Table;

- In addition to the three regulatory and policy options identified within the RIAS, consider a fourth policy option of keeping the status quo with enhanced compliance and monitoring of labelling with changes implemented over this transition period.

Health Canada describes in the Regulatory Impact Analysis Statement (RIAS) that the rationale behind moving forward with this initiative is as follows "*The proposed amendments are necessary to make NHP labels more legible and easier to understand for consumers in order to reduce the risk of harm associated with ineffective and inadequate communications of important safety information*".

Given the role and nature of the Natural Health Products Research Society of Canada (NHPRS), the Society's comments are focused and grouped into two distinct categories, namely the strength of the scientific rationale in reducing harm; and the impact on access, innovation, and the Canadian research agenda. Recommendations related to each section of the following comments have been grouped above immediately after the Summary. Since the Society represents the scientific and research community from all parts of the sector, where applicable, comments related to other topics notably related to industry and practitioners are included to assist with context.

1. Strength of the scientific rationale in reducing harm

<u>Limited information relating label changes to a reduction in harm</u>

- Though intuitively it may be hypothesised that improved labeling will result in a reduction of harm, no independent, quality evidence is provided to support this assumption. Indeed, a recent review of the literature has come to the conclusion that changes in labeling of NHPs has little impact on the behaviour of consumers.[1] The lack of scientific support for the proposed labeling changes therefore limits the ability to develop science- and evidence-based health policy and regulations;

[1] Boon H and Bozinovski N. A Systematic Narrative Review of the Evidence for Labeling of Natural Health Products and Dietary Supplements. Journal of Alternative and Complementary Medicine, Vol. 25, Number 8, 2019, pp.777-788

- While there are examples in the RIAS that identify demonstrable risks posed by NHPs especially with regards to drug interactions (i.e., St. John's Wort and HIV therapies) as well as warnings required around NHPs such as Green Tea Extract, no clear evidence is provided regarding the reduction in the potential to cause harm which could result from the proposed labelling changes;
- The recent report from the Commissioner for Sustainability and the Environment in the Auditor General's Office titled *Natural Health Products – Health Canada* is used as a reason linking poor readability of the printed label with incorrect product use.[2] It is important to note that in reaching this conclusion, work from Health Canada is cited on page 9 of this report as the reference making the use of this reference rather circuitous at best;
- This situation is somewhat inferred within the RIAS with the statement " *While it is difficult to precisely identify the total number of preventable errors associated exclusively with NHPs, their widespread use and a growing demand increases the potential for preventable harms related to confusion or illegibility of label information".*

<u>Reasons for identifying improved labelling as an over-riding short term priority</u>

- The RIAS does not identify the reason why improving labeling is given a higher priority over other sources of potential harm caused by NHPs which are supported by a significantly more robust evidence base. Notable examples of higher priority areas include inadequate enforcement and compliance of the existing regulations and the need for improvements related to product quality;[3]
- In addition to significant external evidence identifying these other topics as being of higher risk to the consumer, they are also given higher prominence in the recent Report from the Commissioner for Sustainability and the Environment in the Auditor General's Office;[4]

[2] Reports of the Commissioner of the Environment and sustainable Development to the Parliament of Canada. Report 2. Natural Health Products – Health Canada. Independent Auditor's Report 2021. https://www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html
[3] Reports of the Commissioner of the Environment and sustainable Development to the Parliament of Canada. Report 2. Natural Health Products – Health Canada. Independent Auditor's Report 2021. https://www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html
[4] Reports of the Commissioner of the Environment and sustainable Development to the Parliament of Canada. Report 2. Natural Health Products – Health Canada. Independent Auditor's Report 2021. https://www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html

- The internal consultations conducted by Health Canada with stakeholders, notably consumers and consumer groups, presented as a reason for moving forward largely focus on the latters' attitudes and desires. While this information is crucially important, there is only anecdotal links to the potential harm reduction and to justify making this a priority course of action.

Selective and unclear use of the evidence available

- While many (but not all) of the statements are supported by references, such statements as well as the resources supporting them often lack detail. Examples of this include:
    - The RIAS identifies six incidents of adverse effects reported that could well be linked to misunderstandings related to poor NHP labeling, with the reference cited being the Health Canada's Adverse Event Reporting Database rather than specific cases; *and*
    - Information cited from the Ontario Poisons Control Center identifying essential oils as a potential point of harm lack clarification around whether these cases are linked to essential oils in NHPs, or to essential oils found in personal care products or cleaning supplies which (as the resource identifies), are products linked to accidental poisoning of children[5];
- In several places, some key evidence cited in the RIAS supporting this initiative are used quite selectively, picking some conclusions (but not others) which directly impact on the validity of moving forward with improved labeling. An example here is reference [6]. Though this reference does accurately state that labels are a useful tool, especially when information is provided in a standardized format, the RIAS fails to note other observations from this same work, notably that many consumers did not regularly read product labels nor understood the information that they contained, as well as the fact that labels alone will not change consumers' attitudes and selecting practices.

Lack of data from independent sources

[5] https://www.ontariopoisoncentre.ca/common-poisons/current-top-10/

[6] Boon, H. (2018). Presentation to Health Canada. Available at: https://www.liebertpub.com/doi/full/10.1089/acm.2018.0533

- A significant amount of evidence used to support the need for improved labeling has been generated internally by Health Canada rather than from external sources. Though the need to conduct this work reflects the lack of external research and should be commended, using internally managed research generation to this extent in the absence of quality external data is a limiting factor in its applicability;
- A significant amount of evidence comes from research conducted (and observations made) when label changes were made related to prescription and non-prescription drugs, and then extrapolated to NHPs. It should be noted here that the non-prescription industry questions some of these observations[7].

Impact on Access, Innovation, and the Canadian Research Agenda

Impact on the Canadian NHP research agenda;

- This initiative has shown that there are gaps in the research base regarding the role and impact of NHP labels on consumer behaviour, especially with respect to the most effective methods of communicating risk information;
- As direct government support for NHP research has decreased, direct support from the industry sector has become one of the primary sources of funding for NHP research. If implementation of these new labeling requirements is too costly, industry partners may not be able to maintain support for the Canadian research community.

Impact on industry and innovation;

- Though the RIAS states that these changes are anticipated to only result in a small additional burden on industry, questions still remain about the practicalities of implementing such changes, especially for multi-ingredient products. As it plays a key role in any risk-based analysis, the cost of implementation is important. It should be noted and is very encouraging to see that Health Canada has already identified these practical challenges and has considered/is considering potential flexibilities to the proposed regulations;
- Implementation of the proposed new labelling changes will be very costly to the NHP sector. The Non-Prescription Medicines industry has identified that implementation of new labeling guidelines for that sector was far more expensive than anticipated. Given this, a Cost Benefit Analysis heavily focused on saving from decreased returns

[7] 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

of NHPs bought in error could be insufficient to truly estimating the financial burden posed by these new labeling requirements;

- Recognizing the impact on industry, it is positive to see that Health Canada is proposing a very generous timeline for implementation. This will facilitate sponsors in complying with the new regulatory requirements;
- The information contained within the RIAS regarding international comparisons is overly general and sometimes inaccurate in stating that these changes would better align Canada with international partners, notably the United States, the European Union and Australia. This is especially true regarding the use of tabulated information.[8,9,10] As the NHP market continues to become more global, there is a concern that these new labeling requirements could hinder international trade, both for domestic companies exporting internationally and for foreign companies importing into Canada.

Environmental Impact

- As identified at the 2021 conference of the NHPRS of Canada, where an entire session was dedicated to global stewardship and sustainability, the challenge faced by the NHP industry is real and one embraced by the larger community;
- The analysis of the environmental impact of these proposed changes in the RIAS is quite limited and largely assumes that the NHP industry can (and will) adequately accommodate these new regulatory requirements. From experiences learned for Non-Prescription Drugs (NPD) and voiced by many NHP industry groups, this assumption may not be feasible. This raises the concern that Health Canada has underestimated the negative impact of these changes on the planet;
- In this era of fighting climate change and the government's priority of a new, green, economy, the importance of impact on the environment cannot be underestimated;

Ability of Canadians to make informed decisions and have access to safe and high quality NHPs;

[8] https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92,
[9] https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide
[10] Directive 2002/46/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=DA

- This proposal contains a number of very important changes, such as improved contact information, serious considerations around use of electronic media and sources of information which will assist consumers in making informed choices;
- Building on the existing evidence and recognizing practical limitations identified above, the use of a formatted label approach including tabulated information will in particular support consumers in making informed choices;
- A concern is that the RIAS focuses on how the information will be presented rather than the quality of information required on the labels. At present, especially with regards to risk information, there is little to distinguish between theoretically possible risk and risk posing a real potential for harm as observed in practice;
- Recognizing that allergens (as identified in the RIAS) pose a risk to health and are already required to be included on NHP labels, any way of strengthening identification of this to the consumer and identifying the source of the allergen is a useful step. Since NHPs are not foods, this requirement for clearer identification should not be limited to classic food allergens but expanded to include other allergens, notably those present in herbal medicines. This may require additional support for research in this area in order to distinguish risks seen in a real-world setting from the current theoretical risks.
- Given that these new requirements are significantly more detailed and prescriptive than those used by Canada's main trading partners (notably the United States), there is a concern that this may be a barrier to the import of products to Canada. This in turn may lead to a decrease in access to high-quality NHPs to Canadians, specifically in niche markets, such as practitioner-focused products used by health providers such as naturopathic doctors.

Conclusion

The NHPRS has closely examined the CG1 posting and recognizes the effort made by Health Canada to improve NHP labeling and to thus provide Canadians with higher quality information. Nevertheless, we have identified several concerns that we strove to present in a constructive manner. These relate firstly to the limited strength of the scientific rationale linking the proposed labeling changes to a reduction of harm and, secondly, to the considerable impact that the proposed changes will have on access, innovation and the Canadian research agenda. We have also presented several recommendations that aim to prevent or mitigate the negative risk versus benefit balance that we perceive and that could pose a threat to the NHP sector if Health Canada moves forward with the proposed changes.