Natural Health Products Program – What the Office of the Auditor General Found

What report?

On April 22, 2021, the Office of the Auditor General or OAG tabled a report on an audit they had conducted investigating how effectively Health Canada ensured that natural health products (NHPs) available for sale in Canada are safe and accurately represented to consumers. The report also contained recommendations to the federal government as to how these issues could be addressed as well as the government's response.

What is the Office of the Auditor General of Canada?

The OAG is an arms-length organisation that serves parliament providing it with "objective, fact-based information and expert advice on government activities"[1]. It does this by conducting audits on activities across the federal government as well as certain crown corporations, the territorial governments and numerous territorial corporations and agencies. Increasingly it explores environmental matters and in fact the recent report was conducted by the Commissioner of the Environment and Sustainable Development which is part of the OAG.
Something of note is that while the OAG may comment on policy, it does not set policy, that is the role of the elected government. In effect, the OAG assesses how the government does something and not why it is doing something.

When and how was the audit conducted?

In addition to assessing existing materials (e.g. regulations, policy documents and guidelines), the audit also included various information gathering exercises such as interviews and surveys to assess whether Health Canada did what they were meant to do with respect to the regulation of NHPs. More details can be found in the report itself: 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development.

Though most of the audit was conducted between February 2017 and December 2019, additional information was gathered in the Spring of 2020 in order to assess the impact of the COVID-19 pandemic. All information was gathered before December 3, 2020.

Did the audit have a specific focus or scope?

The audit did not examine all parts of the NHP regulations but rather focused on the pre-market approval of NHPs and site licensing as well as how Health Canada ensured that products were safe and accurately represented and that there was industry compliance with the regulations. A number of topics were not included within the scope of the audit such as

- the proposed self-care framework,
- classification of self-care products, and
- non-NHP items such as cosmetics and consumer health products.

What did the audit find?

[1]https://www.oag-bvg.gc.ca/internet/English/au_fs_e_371.html

Unfortunately, apart from the response to the COVID- 19 pandemic, the report was not glowing for Health Canada or, indirectly, the Natural Health Products industry. The general finding was that while the current approval process of products for both safety and efficacy was based on evidence, there were serious failings in a number of areas. In particular, the report noted that Health Canada fell short in ensuring products on the market were safe and effective.

The OAG condensed what they found into three findings:

1. Health Canada did not directly verify that facilities followed good manufacturing practices before products arrived on the market. The audit identified that Health Canada depended largely on manufacturers' attestation that they were following guidelines rather than actually inspecting sites (as is the case with other regulators such as the European Union and Therapeutic Goods Administration in Australia).
2. Health Canada did not check natural health products after they entered the market and was not always successful in responding to:
    - serious problems identifying inaccurate/poor information on labels;
    - advertising that was not in keeping with the product's licence application; and
    - there was limited monitoring of products once on the market, as well as limited monitoring of unlicensed and unauthorised activities and
    - only partial success on dealing with such issues once they were identified.
3. Health Canada responded effectively to natural products related to COVID-19 in that it exercised due diligence implementing a risk-based approach for the manufacturing/sale of hand sanitizers and identifying/acting on companies making false claims.

In addition to these findings, the OAG identified a number of challenges with the current regulations and policies that, as noted in the report, hindered the regulations from being effectively implemented and enforced. These included:

- absence of mandatory on-site inspection of manufacturing facilities,
- lack of mandatory recall provisions for NHPs together with low financial penalties for infringement as compared to other health products,
- lack of financial resources needed to effectively manage the regulatory framework due in part to the last of a cost recovery system,
- significant workload caused by the sheer number of product licences submitted for review especially when many were for products not brought to market by the sponsor.

How did the federal government respond?

The government accepted all the recommendations and laid out the actions that they will take moving forward. For a number of the recommendations, the government tied the actions to work either underway or already planned by Health Canada. These include:

- the Plain Language Labeling of NHPs,
- the pilot on-site inspection program,

- increasing powers and fines for NHPs included within *Vanessa's Law*[2] and
- developing a cost recovery model.

Final Thoughts

The OAG report contains some important messages for both the government and the Natural Health Products industry not only with regards to how the current regulations are implemented and enforced but also as to improvements that need to be made.

While an OAG audit and report does not always result in change, it is a good bet to think that changes will be in the cards with such things as a push for NHPs to be included under *Vanessa's Law* and the start of discussions around appropriate cost recovery to cover implementation of the regulatory framework. The OAG report also identified examples of serious concerns related to product labeling which need to be urgently addressed. From the government's response, it looks like Health Canada is taking the OAG report as providing tacit approval for the Plain Language Labeling initiative currently underway.

One recommendation, long advocated by many parts of the NHP industry, is to look at the current largely documentation review-based approach to obtaining a site licence. The use of on-site inspections to confirm compliance with regulations is a fundamental quality management approach and is already utilized by most other jurisdictions such as the USA, Australia, and the European Union. It is long past time that Canada implemented a similar system. A current pilot project underway of site inspections to complement the current site licence approach is a good start, with the support of industry more needs to be done.

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.

[2] *The Protecting Canadians from Unsafe Drugs Act* known as Vanessa's Law strengthens Health Canada's ability to identify and respond quickly to serious health risks caused by a drug or medical device. More information at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/education/module-1.html