Cost Recovery for Natural Health Products: Health Canada's Proposal and its impact on the NHP Sector?

Health Canada published a draft of its proposed cost recovery fees for Natural Health Products (NHPs) on May 12, 2023. This is part of Health Canada's ongoing updates to its management of NHPs as part of its self-care framework and in response to the report published by the Commissioner for Sustainability and Environmental Development in the Spring of 2021. The complete proposal can be found at https://www.canada.ca/en/health-canada/programs/consultation-proposed-fees-natural-health-products/fees-fee-policy.html. There is a 90-day consultation period with all comments required by August 10, 2023.

What is Cost Recovery?

Simply put, cost recovery is a mechanism by which a regulator can charge fees to either completely or partially cover their costs for operating a regulatory framework. The reasoning behind charging industry such fees is that these government functions provide direct commercial benefit to an industry and so it is fair that industry bear some of the financial burden. This is not a new concept – Health Canada has had a cost recovery mechanism in place for other therapeutic goods such as prescription and non-prescription drugs since the 1990s.

Is this new for NHPs?

Regarding NHPs, the need for a cost recovery system was identified back in 1999 as part of the 53 recommendations from the Standing Committee on Health. While the plan to include NHPs within cost recovery has been previously identified, this is the first formal "consultation" from Health Canada and was posted with little warning.

What functions does this proposed cost recovery framework cover?

The proposed framework will apply to NHP product licence applications; NHP site licence applications; and other on-going functions such as post-market activities which will be captured under a fee called Annual Right to Sell (RTS). In addition to these fees, the proposed framework also contains performance standards that Health Canada must meet. The framework also proposes a new class of NHPs for review called a Class III novel application - although there are few details available re the parameters for this "class".

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Who will have to pay these fees?

These fees will apply to any organisation with a Health Canada regulatory requirement. This includes sponsors of product licences, manufacturers, distributors, and importers of NHPs. Health care facilities that receive government funding or any branches of the federal, provincial, or territorial government will not be included in this framework.

How much will this cost?

The proposed cost recovery framework is very detailed with fees for a variety of functions carried out by Health Canada. Specific suggested fees can be found in the proposed framework at https://www.canada.ca/en/health-canada/programs/consultation-proposed-fees-natural-health-products/fees-fee-policy.html; some examples are:

- an annual $542 RTS fee for each Natural Products Number (NPN) or DIN-HM (Drug Identification Number - Homeopathic Medicine);
- an annual site licence manufacturing no sterile dosage forms of $23,071;
- Class I application or amendment fee of $1,124;
- Class II application or amendment fee of $2,761; and
- $58,332 for a Class III novel application.

If the performance standards proposed in the framework are not met by Health Canada, they will remit 25% of the fee. An important point here is that Health Canada can "pause the clock" in specific circumstances.

What about smaller businesses?

As with other health products, the proposal contains a mitigation for small businesses: companies with fewer than 100 employees or between $30,000 and $5 million CAD in annual revenue. In these cases, the proposal states that "businesses would have fee remissions of 100% for pre-market evaluation fees for the business's first ever NHP product submission; 50% for pre-market evaluation fees for all subsequent product submissions; and 25% for site licence fees and the annual RTS fee".

How do other countries deal with cost recovery?

As is correctly stated within the proposal, differing approaches to regulation means that it is hard to make a comparison between different jurisdictions. This is further complicated by the fact that the terminology used in this proposal and by other countries is not consistent and makes an international comparison confusing. For example, what is called a NHP in Canada may or may not be called a dietary supplement in the USA or a complementary medicine in Australia.

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While a detailed comparison of how different countries approach cost recovery would not be possible here, the main points are:

- In the USA, since dietary supplements (products typically akin to NHPs in Canada) are not reviewed before entering the market, there is not a cost recovery mechanism in place related to these products and most manufacturing sites. For the small proportion of products that would be considered NHPs in Canada but are regulated as non-prescription drugs in the USA, the American cost recovery mechanism for non-prescription drugs is applied.
- While most herbal medicine in the European Union (EU) is regulated as drugs, many herbal products are available as food supplements[1] For the relatively small number of traditional herbal medicines, a cost recovery mechanism exists for functions related to the product and to the manufacturing processes. This varies between different EU members states. Since food supplements are not reviewed, typically there is no cost recovery mechanism.
- In Australia, for all therapeutic goods (this includes NHPs referred to as complementary medicines), one hundred per cent of the costs incurred by the regulator are recovered from industry. An error made in the document that in Australia Listed Medicines (which make up the majority of products equivalent to NHPs) stating that they cannot make health claims. In fact, they can make indications for a direct health benefit (e.g. relieves a cough) or more non-specific such as refer to general health maintenance.[2]. For listed medicines, which makes up the vast majority of complementary medicines in that market. The approval for uncomplicated products being quickly processed electronically through the Electronic Listing Facility. The relatively small number of registered complementary medicines must undergo a complete review. Irrespective of the type of complementary medicine, costs for inspections manufacturing sites are one hundred per cent cost recovered.

There are ISURA information pieces about the US approach to regulation of NHPs/dietary supplements at https://isura.ca/2022/04/12/comparing-nhp-regulations-from-canada-and-the-usa/ and the Australian approach to the regulation of NHPS/complementary medicines at https://isura.ca/2022/11/05/comparing-nhp-regulations-from-canada-and-australia/

[1] https://www.efsa.europa.eu/en/topics/topic/food-supplements

[2] https://www.tga.gov.au/resources/resource/guidance/permitted-indications-listed-medicines#:~:text='Indications'%20are%20statements%20that%20describe,refer%20to%20general%20health%20maintenance).

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What needs to happen before this cost recovery framework to be approved?

While inclusion of NHPs under the proposed Health Canada cost recovery model will require a regulatory change typically through the Canada Gazette process, the minister themselves have the authority to set and adjust the fees.

If successful, when will this cost recovery framework come into operation?

The current proposed implementation date is April 1, 2025.

Final Thoughts?

While the document states, "*multiple factors are considered, such as financial or competitive advantage, market access and innovation development in Canada"* there is limited, detailed information about how this has been done:

- What impact will this implementation have on the Canadian NHP industry, both manufacturing and retail and if the impact is negative, will any revenues lost from cost recovery be offset by the impact it has on jobs and taxes?
- Without any data protection for NHPs, what effect will this have on innovation, not only with the impact on developing new products but also the employment opportunities for Canada's strong NHP research sector?
- How will these changes affect access to NHPs which are high quality, safe and efficacious products including traditional medicines such as Ayurvedic medicines and traditional Chinese medicines.
- Finally, and something that goes to the heart of the reason for regulations – risk to the consumer, will this decrease the number of NHPs approved and limit access by Canadians to approved products. Will this in turn push consumers to further increase the online purchase of NHPs from jurisdictions with less rigorous oversight than Canada, and will this put Canadians at risk?

To be successful, any regulatory framework needs to have a stable funding base. Obtaining stable funding from industry through a transactional, fee-based cost recovery system is one option used by governments. At the same time, for a fee-based cost recovery system to work, a relevant regulatory framework must be established and be efficient, reflecting the work required with the risk proposed by the product. This is not the current situation given the very inefficient review process currently in place and the fact that Health Canada faces significant backlogs in many parts of the existing approval process. In addition, with all the other work underway including changes to NHP labelling and an ambitious work plan already in place, implementing a new cost recovery plan could hinder these planned initiatives.

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Before a cost recovery process can proceed a number of questions still need to be answered and the current system has to be made more efficient. For the moment, it would be wise for Health Canada to wait, continue their improvement agenda and complete the implementation of the self-care framework and then conduct an open and collaborative consultation process with respect to a cost recovery plan.

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.