

## Health Canada proposal will result in fewer NHPs on store shelves



### WORDS

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On May 12 of this year, Health Canada published a cost recovery proposal for natural health products (NHPs). Modelled after the fee structure implemented for drugs and medical devices in 2020, the fee structure for NHPs has been projected for implementation by April 1 of 2025. The proposed framework has the potential to have a significant impact on the Canadian health products marketplace.

Three separate categories of fees have been outlined within the proposal: pre-market evaluation (EVAL) fees, site licensing (SL) fees, and annual right to sell (RTS) fees.

- Health Canada's proposed EVAL fees range from \$1,124 for a simple (Class I) product license application (PLA) to a staggering \$58,332 for a complex (Class III) PLA.
- Fees proposed for site licensing range from \$4,784 to \$40,071, based on the type of licensed activity being regulated (i.e., manufacturing, packaging, labelling, import).
- Proposed regulatory amendment fees range from \$1,124 to \$8,750 for PLAs, and are estimated at \$4,784 for SLs.
- Annual RTS fees have been proposed at \$542 per SKU.
- Health Canada has communicated to industry stakeholders that the scale of all proposed costs are relative to the volume of internal resources required to review these applications.

Of particular concern are the proposed fees for "Novel Class III" PLAs (which are priced at an astronomical cost of almost \$60,000 per application). After reviewing Health Canada's definition of "novel," it is clear that most innovative NHPs would fall into this category. This price point will be prohibitive to most companies operating in the NHP sector, which can result in a complete stifling of health product innovation in Canada.

Another major concern is that EVAL and SL performance standards are being extended, which will result in longer pre-market review times, impacting commercialization timelines.

For those of us that have serviced the NHP industry since its founding years, we have seen the potential that the Canadian natural health market holds on a global scale. Canadian NHPs are recognized internationally as a symbol of safe, effective, and high-quality health products. The proposed cost recovery framework has the potential to have a significant and detrimental effect on the number of NHPs marketed to consumers, both domestically and internationally.

- For Canadian natural health retailers, this will likely mean fewer NHPs on store shelves, resulting in a smaller variety of products for consumers to choose from. This reduced retail selection may also lead consumers to source NHPs on the internet, which can

have a further negative impact on retail health product sales. It can also lead to an increase in the purchasing of unapproved NHPs, which can pose a health risk to Canadian consumers.

- Canadian suppliers will undoubtedly need to re-evaluate their Canadian product portfolios, likely reducing their overall number of Canadian SKUs (due to the high product licensing fees).
- For SL holders (i.e., manufacturers, packagers, labellers), high Health Canada application fees will increase overall operational costs, which will undoubtedly need to be passed along to NHP production supply chains and/or consumers.
- The proposed cost recovery framework will likely result in international suppliers bypassing the Canadian marketplace entirely, having a detrimental impact on importers and distributors.

In summary, the proposed NHP cost recovery proposal has "missed the mark," and needs to be revisited by Health Canada. The proposal will discourage both Canadian and international companies from pursuing retail sales in the Canadian natural health market, resulting in a hugely detrimental impact on our economy. It will also limit the number of NHPs available for consumers to support their personal health under our current self-care paradigm. Canada has a world-class regulatory system, and Canadian consumers have a right to have access to safe, efficacious, and high-quality NHPs to support their self-care. The proposed cost recovery framework will undermine both of these core principles of the Canadian natural health regulatory system. //

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