



**Submission to the Senate Standing Committee on Social
Affairs, Science and Technology on
Bill C-69,
*Budget Implementation Act, 2024, No. 1***

May 22, 2024

Executive Summary

Imperial Tobacco Canada (ITCAN) welcomes the opportunity to comment on Bill C-69, *Budget Implementation Act, 2024, No. 1*. Our feedback is focused on proposed amendments to the *Food and Drugs Act* spelled out in Division 31 of Part 4.

The proposed amendments seem to be the method the Health Minister is using to address his concerns regarding ITCAN's ZONNIC nicotine pouches, the first and only such product approved as a Nicotine Replacement Therapy (NRT) in Canada. While reform of the regulatory framework for NRTs is necessary, the approach of the Health Minister, which seems to focus on a single NRT product from one company and is based on gross misinformation, raises concerns.

The proposed amendments grant the Health Minister extensive regulatory power over all natural health products, bypassing the established approval process and placing the fate of these products under the discretion of the current Minister, future Ministers, and Health Canada. We recommend the complete removal of Section 326 from the Bill to prevent this regulatory overreach. Instead, we suggest developing a new, equitable regulatory framework for all NRTs.

About ITCAN

ITCAN, established in 1908, is a wholly owned subsidiary of BAT – the world's largest vaping business by market share. ITCAN has made significant investments in scientific research and development to introduce a 'Reduced Risk Products' portfolio,¹ which includes vaping and cessation products.

ITCAN is dedicated to conducting its business responsibly, in a manner that meets society's expectations of a responsible tobacco and nicotine products company. ITCAN recognizes the health risks associated with tobacco and nicotine consumption and believes that youth under the legal minimum age ("Underage Youth") should not consume and should be prevented from accessing tobacco or nicotine products.

We support constitutional, proportional, reasonable, and evidence-based regulation, especially measures aimed at keeping tobacco and vaping products out of the hands of Underage Youth. At the same time, we are committed to contributing to tobacco harm reduction and ensuring that adult consumers are provided with a range of less risky alternatives to combustible cigarettes.

Context for Bill C-69

ITCAN welcomes the opportunity to comment on Bill C-69, *Budget Implementation Act, 2024, No. 1*. This comes at an interesting historic moment for ITCAN. We are in the process of an organizational transformation in which at its core lies our ambition to reduce the health impact of our business. A critical enabler to achieving this will be to encourage smokers to quit or switch to 'Reduced Risk Products' – like vaping products.

¹ We use the term 'Reduced Risk Products' (or RRP) to cover tobacco and nicotine products that are reduced risk compared to cigarettes based on the weight of evidence and assuming a complete switch from cigarette smoking. These products are not risk free and are addictive.

We acknowledge the Government’s goal of reducing the smoking rate to 5% by 2035 and feel Reduced Risk Products must be central to achieving that. As such, the regulatory and taxation regime for vaping products is of critical importance to ensure they remain appealing and affordable alternatives for adult smokers.

Meanwhile, in October 2023 we launched ZONNIC, the first nicotine pouch authorized for sale by Health Canada as a Nicotine Replacement Therapy (NRT). It provides consumers who want to quit smoking and using nicotine a new way to do so. ZONNIC nicotine pouches underwent extensive efficacy and safety review by Health Canada over two years and were granted a natural health product license in July 2023.² ZONNIC nicotine pouches do not contain tobacco, do not produce tar or carbon monoxide, and therefore do not present the same risks as cigarette smoke. A nicotine pouch works in a very similar way to NRT gum or lozenges. It helps smokers quit by delivering nicotine to the body, temporarily relieving cravings and nicotine withdrawal symptoms.

Providing adult smokers will less risky alternatives and NRTs will continue to be our ambition, driving all our business decisions in Canada.

Regulatory Overreach: Amendments to the *Food and Drugs Act*

Division 31 of Part 4 of Bill C-69 suggests amendments to the *Food and Drugs Act*, granting the Minister of Health considerable new powers to issue orders concerning natural health products. This bypasses the usual regulatory approval process. Under Bill C-69, the Minister has the authority to intervene if the use of a therapeutic product, beyond its intended purpose, is believed to pose a health risk. In such cases, the Minister can establish regulations regarding the import, sale, advertising, manufacturing, preparation, preservation, packaging, labeling, storage, or testing of the product to manage or control health risks.

In addition, “the Minister may, in the order, establish rules for the purpose of preventing the therapeutic product from being promoted for a use, other than the intended use, of a therapeutic product or preventing a use, other than the intended use, of a therapeutic product from being appealing.” Also, the Minister “may make the order despite any uncertainty respecting the risk of injury to health that the use of the therapeutic product, other than the intended use, may present.”

In an April 29 media scrum, Minister Holland suggested this power will be used to address nicotine replacement therapy (NRT) products in the form of nicotine pouches. However, the Committee should be aware that the proposed changes to the *Food and Drugs Act* will give the Minister, Health Canada and any future Minister the power to go after any natural health product that he/she/they dislike.

This raises questions about why this specific vehicle is being employed to target NRT nicotine pouches. It seems plausible the law could not be amended in a way that would grant Minister

² <https://health-products.canada.ca/lnhpd-bdpsnh/info?licence=80125630>

Holland the authority to regulate our NRT nicotine pouch product without similarly affecting other NRT products like gums, lozenges, and sprays. This appears to be part of a continuing trend where Minister Holland disproportionately focuses on our NRT product, overlooking others. It appears the Minister's push for broad new regulatory powers is driven more by personal motives and a grudge against the tobacco industry, rather than by public health objectives.

As noted earlier, in October 2023 ITCAN launched the first nicotine pouch product (ZONNIC) approved as an NRT by Health Canada.³ It remains the only such product approved in Canada. ZONNIC nicotine pouches underwent an extensive two-year efficacy and safety review by Health Canada before being approved.

Minister Holland has claimed ITCAN exploited a loophole to secure approval of ZONNIC as an NRT under the *Food and Drugs Act*. This is clearly untrue. We sought and secured approval for ZONNIC nicotine pouches in the same manner as any other NRT product. We followed Health Canada's legislative and regulatory process. That is not exploiting a loophole; it is following the law – and ZONNIC is the only nicotine pouch product in Canada that has done so.

In addition, while Minister Holland focuses on the three flavors of ZONNIC nicotine pouches available in Canada, it is worth noting these flavors were approved by Health Canada during the licensing process. Furthermore, our flavours are consistent with others in the NRT space, as is their naming. For example, Nicorette gum is listed in the following flavours on its Canadian website: extreme chill mint, ultra fresh mint, spearmint, fresh fruit, and cinnamon.⁴

Minister Holland has criticized our company for the use of colors in our packaging and our marketing approaches. However, it is important to note our packaging aligns with that of other NRT products and was reviewed by Health Canada during the approval process. Similarly, our marketing strategies, which are in line with industry standards, were fully disclosed to Health Canada as part of the approval process.

Finally, Minister Holland has suggested there is widespread youth addiction to pouches with resultant negative health effects. We have not seen any literature in this regard and the Minister has only offered anecdotes to support this claim. However, even if this is true – and there is no evidence from markets that have had similar products for years of the types of health effects the Minister has suggested – we are confident in saying it is not due to our product for four reasons:

- ZONNIC nicotine pouches were only introduced in Canada through a very limited number of retailers in October 2023 and in very limited volumes until February of this year.
- ZONNIC nicotine pouches are the only licensed NRT products in Canada that are currently stored behind the counter in convenience stores with retailers requiring age verification. We implemented age verification voluntarily; there are no minimum age requirements for the purchase of a natural health product (including an NRT) set out in the *Food and Drugs Act*, the *Natural Health Product Regulations*, or in any provincial legislation.

³ <https://health-products.canada.ca/lnhpd-bdpsnh/info?licence=80125630>

⁴ <https://www.nicorette.ca/products/gum>

- In retail locations such as grocery stores, convenience stores and gas stations, our ZONNIC product ordering terms and conditions on our retail product ordering platform require that retailers age verify consumers are 18 years of age or older and that the product be stored behind the counter. If retailers are caught in default of such terms, we will block their ability to order this product.
- On ZONNIC's e-commerce website, we require that consumers confirm they are 18 years of age or older before entering the website, and robust age verification is performed at purchase and at delivery of the product.

If there is youth use of nicotine pouches, we encourage the Government to look at the illegal market. We recently submitted 20 pages of data to Health Canada providing websites of vendors selling illicit pouch products to Canadian consumers. We are also aware of retailers selling illicit nicotine pouches in plain sight. This was occurring long before Health Canada authorized the sale of ZONNIC nicotine pouches.

This is why the provisions amending the *Food and Drugs Act* in Bill C-69 should alarm all Parliamentarians. It is a toolkit to circumvent the regulatory approval process for natural health products. No one has challenged the efficacy of ZONNIC nicotine pouches as an NRT; no evidence has been presented of youth use; no evidence of health harm has been presented; and no one has suggested we have done anything in violation of our natural health product license. In fact, we continue to go well beyond what is legally required with regards to protecting against youth access by forcing retailers to ask for proof of age before sale, amongst other things.

However, Bill C-69 gives the Health Minister the power to go after this product despite all the above and without even needing to prove harm or risk – and this power can be used in the future to target any other natural health product that the Minister or Health Canada does not like. Why even have an approval process for natural health products if the Minister can overrule it by decree? It opens up the regulatory process to bias based on the personal beliefs of the Minister, as opposed to an impartial science-based determination of what benefits the health of Canadians.

Recommendation: Remove Section 326 of Part 4 and instead launch a proper consultation on a new regulatory framework for all NRTs.

A New Regulatory Framework for NRTs

Our comments above should not be interpreted as suggesting no new rules are required for NRTs. In fact, we have been recommending a new regulatory framework since we launched ZONNIC nicotine pouches, and we continue to be the only provider of NRTs in Canada that self-regulates on things like age-gating and keeping products behind the counter at retail.

We believe a new regulatory framework for all NRTs should include the following:

1. Legal age of 18 to purchase NRT products.
2. Storage and display of products at retail in a way that makes them inaccessible to minors, such as behind the counter in all retail locations.

3. Requiring proof of age at the time of purchase.
4. Age verification for purchase and delivery for online sales.
5. Labelling requirements to prominently inform consumers the product is for adults only.
6. Severe penalties for those who sell or provide these products to youth.

Finally, Minister Holland and all Parliamentarians need to recognize that we have unique insights into the remaining 11% of adult Canadians who still smoke, for whom regulatory interventions and existing NRTs have proven ineffective. Consider that Quebec's National Institute of Public Health recently released a study that found over 95% of current and former smokers are aware of NRTs like nicotine patches, gums and lozenges, but fewer than 10% use them.⁵

ZONNIC nicotine pouches give them a new option. That should be welcomed by Minister Holland and the public health community, not challenged. And if the Minister and his former colleagues in the public health lobby cannot focus on the effectiveness of an NRT product rather than who is distributing it, then they really need to take a step back and examine their motives.

We have a shared goal of reducing Canada's smoking rate to the target of less than 5% by 2035, but convincing the remaining 11% of Canadians who smoke to switch to reduced risk products or to quit will be the toughest challenge yet. However, we can contribute to that. Huge numbers of Canadians have already switched from smoking to vaping; that is a positive development. We have also received overwhelmingly positive feedback from smokers about ZONNIC nicotine pouches, with many saying it is the first product to successfully get them off cigarettes. This context makes the approach taken in Bill C-69 to single out this product appear more misguided.

Conclusion

Parliamentarians should be alarmed at the power grab launched by Minister Holland through the amendments to the *Food and Drugs Act*, which give the Minister the ability to target any natural health product he chooses, without any requirement to justify his action. For now his target appears to be NRT nicotine pouches, but in the future it could be any other natural health product. The powers suggested in Bill C-69 would grant unprecedented control over an extensive portfolio of product categories to any current or future Minister, circumventing the regulatory approval process meant to ensure the best health outcomes for all Canadians.

At its core, Minister Holland's strong opposition to NRT nicotine pouches seems to be driven more by personal feelings than by an acknowledgment of the public health benefits that new NRT products could offer in helping smokers quit cigarettes. There is indeed a need for a new regulatory framework for all NRTs, but it should be established through an open, fair, and transparent process, rather than by a ministerial decree that targets a specific product or company.

⁵ <https://montreal.citynews.ca/2024/02/23/quebec-smokers-aware-tools-help-quit-dont-use-them/#:~:text=Research%20shows%20that%20although%20many,known%20services%20are%20rarely%20used.>