Re: Notice of Intent — Measures under consideration to modernize tobacco and vaping products information reporting requirements (NOI) published in the Canada Gazette, Part I on March 2, 2024

Comments by Physicians for a Smoke-Free Canada
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General Comment

A quarter of a century ago, Health Canada, through its cooperation with British Columbia, was a pioneer in establishing reporting regulations on the tobacco industry. Canadian governments were among the very first to elicit ingredient lists and to establish meaningful emissions testing regimes. Subsequent change to the *Tobacco Reporting Regulations* expanded reporting obligations over other important aspects of tobacco product use, including research and toxicity.

The leadership of Canadian regulators in this area has been recognized (the "Health Canada method" has been adopted by other regulatory and scientific bodies). Nonetheless, there has been little engagement between civil society and the federal government on how to best use the information provided in these reports, how to ensure that these regulations improve public health and how to further develop a regulatory system. Over two decades, no routine sytem has been established and maintained to provide regular disclosure of non-confidential information, and no advances have been made to reflect Parliament's guidance on providing greater access.

In the meantime, other regulators have moved forward with different regulatory systems which might serve as illustrations of options available to Canada. These include the EU system of data capture or the US FDA requirements for post-market information on authorized tobacco products or the USA FTC requirements for periodic reporting. We are unaware of any attempt by Health Canada to engage researchers or civil society in assessing the appropriateness of adopting these or other reporting systems.

Without real dialogue among the sectors engaged in tobacco control, the input of our organization and others lacks a robust analysis of options, benefits and constraints of the options available or the constraints on their choices.

The absence of such discussions over such a prolonged period erodes the good faith that is required to design a reporting system that meets current public health needs and which benefits from advances in technology and capacity. The perception of Health Canada's good faith in this process is also hindered by the twinning of measures that have long been called for by health interests (reliable proactive disclosure) with measures that will benefit the tobacco industry (reduced reporting requirements).

PSC's general recommendation: Health Canada should implement a regulation which is narrowly focused on directing the government to release information from the industry which has previously been withheld. Examples of such information could be sales figures by brand and/or consumer research conducted in Canada including surveys of usage. As the release of this information will be challenged by industry, the resulting court decision can guide the department in the development of future reporting and public release regulations.

Specific Comments

Potential measure No. 1: Health Canada is considering consolidating all reporting requirements for tobacco and vaping product-related information into a single set of regulations.

PSC Response: The rationale for this change has not been made public. Without elaboration on the benefits and implications of this change, we are not in a position to support this change.

Potential measure No. 2: Health Canada is considering expanding the reporting regulations to include information requirements specifying which reports on tobacco and vaping products are to be made public.

PSC Response: This is an important step, but does not need to be included amongst other regulatory changes. Nor is there sufficient knowledge for a consensus on which information should be released or in what format. Because the industry will almost certainly oppose release of any information, the decision on the balance point between public interest and commercial rights will most likely be directed to the courts.

We recommend that Health Canada adopt a narrow but ambitious regulation on information disclosure and allow that to be tested by the courts before proceeding further with changes to the TRR.

Potential measure No. 3: Health Canada is considering adding information requirements on intra-industry promotion to the reporting regulations.

PSC Response: All forms of promotion should be fully reported to government (and made available to the public on a reliable and regular basis).

Potential measure No. 4A: Health Canada is considering prescribing electronic forms for the submission of all reports. / Potential measure No. 4B: Health Canada is considering prescribing an electronic portal for the submission of all reports.

PSC Response: This appears to be a sensible approach, but it is far from clear what the optimal elecctronic portal would be. Before adopting a method, the government should provide its analysis of the benefits and drawbacks of various approaches and consult on these. In light of persistent problems with data management within the federal government, we recommend that consideration be given to third-party administration of the system.

Potential measure No. 5: Health Canada is considering requiring manufacturers to keep, preserve and make accessible, either electronically or physically, all documents used to prepare the reports for a period of six years from the year in which the report was submitted.

PSC Response: This appears a sensible approach.

Potential measure No. 6: Health Canada is considering to repeal the requirements for consumer tobacco products and requiring manufacturing processes reports only for other types of tobacco products sold in Canada, i.e. tobacco products that are not currently subject to the regulations. The report would be due on or before the date a manufacturer first sells a type of tobacco product that was not previously sold by the same manufacturer.

PSC Response: Health Canada should not reduce the reporting requirements of industry until more comprehensive and informed discussions have taken place with other public health actors (provincial governments, researchers, civil society.)

Potential measure No 7A: Health Canada is considering requiring manufacturers submit a full emissions report (emissions generated both under ISO and modified ISO smoking conditions) for a subset of their cigarette brands, every two years. The Department is proposing provisions for an exemption based on the existence of a functional relationship of certain emissions be removed. Health Canada is also considering eliminating the annual emissions reporting and the exceptions for small manufacturers.

Potential measure No 7B: The subset of cigarette brands subject to a full emissions report as proposed in the potential measure No 7A would be selected based on a manufacturer's cigarette market share and additional criteria set out in the regulations. For example, the nicotine content (constituent) of the selected cigarette brands in the subset for a manufacturer should cover the range of nicotine content of the cigarette brands sold by the manufacturer. Any new brands of cigarettes introduced during the reporting period would also be part of the subset of brands selected.

Potential measure No 7C: Health Canada is considering requiring cigarette manufacturers submit a report on tobacco constituents, an ingredients report and a cigarette specifications report for the subset of cigarettes brands at the same time as the examined emissions report described in the potential measure No 7A.

PSC Response: Health Canada should not reduce the reporting requirements of industry until more comprehensive and informed discussions have taken place with other public health actors (provincial governments, researchers, civil society.)

Potential measure No. 8A: Health Canada is considering incorporating by reference all Health Canada Official Methods for the testing of tobacco products on an ambulatory basis, that would not require a regulatory amendment to update them.

PSC Response: This appears a sensible approach.

Potential measure No. 8B: Health Canada is considering expanding the list of emissions and constituents required to be tested. The Department is seeking input on which other emissions or constituents and the related test methods could be added. Please see Schedules 1 and 2 of the TRR for the list of emissions and constituents that are currently subject to reporting requirements.

PSC Response: This appears a sensible approach, but we have no comment at this time on which constituents be tested. Given changes to product types and designs (e.g. heated products), new toxins are of regulatory interest and public health importance. Further discussion amongst public interest health stakeholders is required.

Potential measure No. 9: Health Canada is considering requiring quarterly sales reports for all tobacco products , as defined in TVPA. This would include waterpipe tobacco and heated tobacco products. Sales reports for cigarettes and cigarette tobacco would remain on a monthly basis.

PSC Response: Expanding requirements appears a sensible approach. Without rationale for putting some products on a quarterly reporting basis, we are not in a position to endorse this relatively reduced obligation.

Potential measure No. 10: Health Canada is considering repealing the requirements to submit digital images of consumer tobacco products, the list of brand names and type of tobacco products.

PSC Response: We have been provided very little rationale for reducing the reporting obligation on industry and therefore cannot support this proposal.

Potential measure No.11A: Health Canada is considering eliminating the requirement to submit annual ingredient reports for all existing brands of consumer tobacco products, cigarette papers, filters or tubes for which an ingredient report has already been submitted. Instead, an ingredients report would only be required for all new brands of tobacco products, as defined in the TVPA, on or before the date on which the tobacco product is first sold. / Potential measure No. 11B: Health Canada is considering repealing ingredient inventory reporting requirements outlined in subsection 11(5) of the TRR.

PSC Response: We have been provided with very little rationale for reducing the reporting obligation on industry and therefore cannot support this proposal.

Potential measure No. 12A: Health Canada is considering removing constituent testing requirements for cigars, pipe tobacco and smokeless tobacco. / Potential measure No. 12B: Health Canada is considering requiring a constituents report for all little cigars by removing the sales volume exception of 1 million units sold per brand in one year. / Potential measure No. 12C: Health Canada is considering changing the reporting frequency from annual to every two years. This report would stagger with the full characterization under consideration described in Ite

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PSC Response to 12A and C: We have been provided with no rationale for reducing the reporting obligation on industry and therefore cannot support this proposal.

Potential measure No. 13: Health Canada is considering repealing the requirement to submit information on sidestream smoke.

PSC Response: We do not see any benefit to this proposal. We cannot support it at this time.

Potential measure No. 14: Health Canada is considering repealing sections 14.1 and 14.2 that require toxicity tests.

PSC Response: We do not see any benefit to this proposal. We cannot support it at this time

Potential measure No. 15A: Health Canada is considering repealing sections 17 to 24 of the TRR. These sections would be replaced with new requirements in line with Canada's obligations under article 13(4)(d) of the WHO Framework Convention on Tobacco Control. / Potential measure No. 15B: Health Canada is considering requiring manufacturers of tobacco products to submit, every 6 months, a list of the following: a. advertisements in publications that are addressed and sent to an adult who is identified by name (both print and electronic) and their expected or actual reach. b. advertisements on signs in a place where young persons are not permitted by law and their expected or actual reach. c. things, other than a tobacco product or an accessory, bearing a tobacco product-related brand element or the name of a manufacturer and the number sold, given or offered.

PSC Response: Of these two options, the first is the appropriate approach with respect to Canada's international obligations. The FCTC Article 13 4 requires that "As a minimum, and in accordance with its constitution or constitutional principles, each Party shall (d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21." Health Canada has failed to meet this obligation to require disclosure of permitted promotions (incentives to retailers, gifts, hospitality, etc).

Potential measure No. 16: Health Canada is considering requiring manufacturers of vaping products submit a full copy of every report on their research and development activities. If the research and development activity is not complete, any progress reports, synopses or outlines in respect of that activity, the date on which the activity began and the date of completion of the activity or the expected duration of the activity. This information would be required to be reported on an annual basis.

PSC Response: This measure would address a weakness in the current regulations. It should have been adopted with the initial reporting requirements for the vaping industry.

Potential measure No. 17: Health Canada is considering requiring manufacturers of vaping products to submit, semi-annually, a list of the following: a. information in respect of advertisements (audio, audio-visual and visual advertisements) and their expected or actual reach. Visual advertisements include advertisements on signs or in publications with no audio component. b. information in respect of a promotion by means of a thing, other than vaping product or accessory, bearing a vaping product-related brand element and the number sold.

PSC Response: This measure would address a weakness in the current regulations. It should have been adopted with the initial reporting requirements for the vaping industry. It is, however, unlikely to capture the range of vaping promotional activities about which information is needed.