# Comments from Physicians for a Smoke-Free Canada on:

Canada Gazette, Part I, Volume 156, Number 24: Regulations Amending the Tobacco Products Regulations (Plain and Standardized Appearance)

August 2022

## **Summary**

Physicians for a Smoke-Free Canada generally welcomes and supports the proposal to extend requirements for tobacco labelling and the approach proposed for the display of health warnings and toxicity information.

These proposals have benefitted from lengthy consideration and from frequent consultation with health stakeholders, including our organization. We recognize and appreciate the opportunity to have participated in the development of these proposed changes to packaging requirements. The benefits of this consultative process are reflected in the high quality of the proposed warnings that will be identified in the Source Document.

The requirement for warnings on cigarettes is an important innovation, and it is appropriate for Canada to take the leadership in advancing this aspect. As it did with graphic health warnings at the beginning of the century, this leadership could include both the establishment of the regulation and also investments in post-implementation monitoring.

The regulations also address the government's long and unjustified delay in meeting its FCTC obligations with respect to other tobacco products.

With respect to technical and drafting issues regarding the placement of the warnings and other issues, we support and echo the comments of the Canadian Cancer Society.

We would also like to take the opportunity to identify potential future actions that the department and the Government of Canada could take in this area. We propose that Health Canada develop ways to: a) expand health education and increase public awareness of the risks of tobacco use, including those not identified in warnings labels; b) establish consistency in federal criteria for health cautions; c) enhance and expand information that must be provided to consumers by tobacco and vaping product manufacturers beyond those on package labels.

## Recommendations

## The need to accelerate regulation-making

The current health warnings messages have been on the cigarette packages for over a decade. Compared with other countries, Canada rotates health warning messages less frequently than most countries. <sup>1</sup>

## **Recommendation #1**

The proposed regulations, strengthened in line with the advice from the Canadian Cancer Society and others, should be implemented as soon as possible.

## The need for expanded health education and health warnings

The scope of damage caused by smoking and involuntary smoking is too vast to be communicated within the space of a cigarette package, and the number of rotations is too small to cover all of the diseases for which smokers deserve to be informed. (See illustration from 2014 Surgeon General's report below).

The benefits of the proposed regulatory change can be strengthened and reinforced by a concurrent public education campaign that provides information on the additional risks. Health Canada, for example, currently includes information on smoking in its information resources related to rheumatoid arthritis,<sup>2</sup> but is silent on this topic in its information related to smoking. <sup>3</sup>

#### **Recommendation #2**

The beneficial impact of the warning on individual cigarettes should be reinforced by a concurrent mass media campaign and refreshing of Health Canada website, with the goal of renewing and expanding public awareness of the harms of smoking.

**Chronic Diseases** Cancers Blindness, cataracts, age-related macular degeneration Congenital defects-maternal smoking: orofacial clefts Oropharynx Periodontitis Aortic aneurysm, early abdominal aortic Larynx atherosclerosis in young adults Esophagus Coronary heart disease Pneumonia Trachea, bronchus, and lung Atherosclerotic peripheral vascular disease Chronic obstructive pulmonary disease, tuberculosis, Acute myeloid leukemia asthma, and other respiratory effects Stomach Diabetes Liver Reproductive effects in women Pancreas (including reduced fertility) Kidney and ureter Hip fractures Cervix Ectopic pregnancy Bladder Male sexual function-erectile dysfunction Colorectal Rheumatoid arthritis Immune function

Overall diminished health

Figure 1A The health consequences causally linked to smoking

Source: USDHHS 2004, 2006, 2012.

Note: The condition in red is a new disease that has been causally linked to smoking in this report.

## The need for consistency in federal criteria for health cautions

Tobacco is only one of several areas in which the federal government regulates with the aim of reducing health risks by placing requirements on suppliers to provide warning labels. Other areas include cannabis, radiation emitting devices, motor vehicles, pesticides, animal feeds, medical products and devices, natural health products, consumer products and workplace hazards.

The Hazardous Products Regulations (HPR) illustrate the variety of approaches taken by Health Canada in determining whether cautionary health notices are required. Under the HPR, suppliers must identify "category 2" carcinogens, which are defined as "A substance in respect of which (a) human data support a positive association between exposure to the substance and the development of cancer, but do not support a conclusion of a causal relationship, based on established scientific principles." These regulations are part of the federal contribution to the Workplace Hazardous Material Information System.

The approach taken by Health Canada with respect to establishing the risks for which mandatory cautions are required for tobacco users differs from that for workplace exposure. In this current proposal for revisions to the *Tobacco Products Regulation* (TPR) Health Canada explains that its rejection of a requirement for a warning on breast cancer is because its policy is not to require a caution for those carcinogens which have been identified in category 2: "However, Health Canada is not recommending such a message at this time because the scientific evidence is not sufficient to establish a causal effect between smoking and breast cancer. Health Canada will continue to monitor the medical literature for evidence of a causal link between tobacco use and breast cancer." The decision of the department to limit warnings on tobacco and vaping products to those for which there is "sufficient evidence to conclude causation", and to have causation "reported by a reputable source, such as the United States Surgeon General's Reports" is an administrative policy of the department, and not one that has been codified or developed in a transparent and consultative process.

### **Recommendation #3**

Health Canada should develop consistent criteria for the evaluation of health risks and formalize the process by which evaluation is made.

## The need to enforce tobacco manufacturers responsibility to warn.

The *Hazardous Products Regulations* and the *Tobacco Products Regulations* also provide examples of the different approaches taken by the department with respect to manufacturers' duty to warn. The HPR illustrates the potential for additional requirements on tobacco manufacturers.

These two regulatory systems are alike in that they both use labelling requirements to address problems caused by preventable exposure to health-harming substances; they both intersect with public health regulations managed by other levels of government; and they both seek to direct supplier behaviour.

Under the HPR, however, manufacturers of industrial chemicals have greater responsibilities to caution on risks than do manufacturers of tobacco products under the TPR, and workers have greater rights to information than smokers:

- In addition to mandatory labelling, the HPR require that Safety Data Sheets be provided. The content of these Safety Data Sheets is developed by the manufacturer, following a structure established by the regulation. There is no equivalent federal statutory obligation for manufacturers to identify the risks associate with the use of their products.
- The HPR requires a comprehensive set of cautions in the Safety Data Sheets, where as the TPR requires cautions only for those diseases for which mandatory labelling is required.

• The TPR attribute the health warnings to the federal government, further reducing the involvement of manufacturers in the caution process.

For these reasons, the TPR could be strengthened by requiring the combination of mandatory standardized labelling and mandatory risk information, as is done under HPR/WHMIS. Tobacco companies could be required to display the labeling as set out in these regulations, which provide information that has been developed and tested to increase awareness of the health hazards of smoking. At the same time, they could be required to provide additional information to consumers in a regulated format (analogous to Safety Data Sheets). This information need not be provided with every package but could be made available to smokers through signage at retail outlets and in other channels (websites, etc.). This ancillary information would return to manufacturers the responsibility to inform their customers of more details about the risks of product use in ways that are likely to be consistent with the 1995 Supreme Court rulings on unattributed health warnings.<sup>5</sup>

#### Recommendation #4

In future regulatory revisions, Health Canada should require manufacturers of tobacco and vaping products to provide information on all health risks, of similar level of detail required under HPR/WHMIS.

#### References

- 1 Canadian Cancer Society. Cigarette Package Health Warnings. International Status Report. Seventh Edition, October 2021.
- 2 Health Canada. Rheumatoid arthritis in Canada. https://www.canada.ca/en/public-health/services/publications/diseases-conditions/rheumatoid-arthritis.html
- Health Canada. Smoking Diseases. https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/smoking-your-body/smoking-diseases.html#fs
- 4 Information shared in meeting with NGO & Academic Experts. February 17, 2021.
- 5 RJR-MacDonald Inc. v. Canada (Attorney General), [1995] 3 SCR 199