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Tobacco Control Directorate
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Submitted via e-mail to hc.pregs.sc@canada.ca

Re: RBH Submission to the Consultation on *New Health Related Labelling for Tobacco Products* (Responses to Specific Questions)

Rothmans, Benson & Hedges Inc. (RBH) welcomes the opportunity to provide its comments on Health Canada's consultation regarding *New Health Related Labelling for Tobacco Products*. In the accompanying document, RBH sets forth its general comments on the topic, including its view that tobacco products should be regulated consistent with where they fall on the continuum of risk, and that regulatory policy should encourage smokers who would otherwise continue to smoke to switch to less harmful alternatives. Below, we provide our responses to several of the specific questions posed in the consultation.

1. Labelling on Cigarettes

RBH does not believe that displaying information directly on cigarettes would be effective in informing Canadians of the health hazards and effects of cigarettes. For decades, Canadians have been well aware of the serious health risks of smoking. In addition to public health campaigns, every cigarette pack and carton today – and since the early 1970s – have carried a prominently displayed health warning. We are not aware of any research in Canada or elsewhere that would suggest that messages displayed directly on cigarettes would provide any benefit beyond the health warnings Canadians already receive regarding the health effects of smoking.

Furthermore, RBH does not recommend that Health Canada require printing information on the cigarette paper itself since the paper burns during the use of the product.

2. Labelling Content and Design

RBH does not have specific comments on sections 2(A) or (B) other than our general position, articulated in more detail below, that all such messages be accurate, truthful and not misleading about the product.

With respect to 2(C), linking health warning messages and toxic statements on the shell of a shell and slide pack is feasible, as both would be printed on the shell portion of the pack. RBH meets the rotation obligations under the regulations by manufacturing so that all sixteen graphic warnings are produced consecutively during each production batch. Given that the shell and slide are separate packaging pieces, RBH is not aware of any technical way to achieve linking the health information message, which will appear on the slide portion of the pack, with the other two messages. RBH is not aware, using current product methods, of any way to synchronize the correct slide with the corresponding shell on every package produced.

With respect to section 2(D), RBH supports the recommendation that all tobacco product packaging contain quitline information.

3. Labelling Size and Placement

3(A) *Percentage of coverage of health warnings on tobacco products other than cigarettes and little cigars*

RBH supports expanding the 75% health warning requirements for cigarettes and little cigars to other combustible tobacco products, such as cigars, pipe tobacco and roll-your-own. Combustible tobacco products are the most harmful type of tobacco product and therefore should be subject to the most restrictive health warning requirements. As Health Canada has recognized, “[m]any of the toxic and cancer-causing chemicals in tobacco and the tobacco smoke form when tobacco is burned,”¹ and “cigar and pipe smokers experience the same types of health problems as cigarette smokers.”²

For the same reason, RBH does not support extending the 75% health warning requirements to non-combustible products. While no tobacco product is risk-free, the risks associated with non-combustible tobacco products are very different than those associated with combustible products. This is particularly the case for innovative heated tobacco products, which do not combust tobacco but rather heat tobacco to release a nicotine-containing aerosol. As discussed in more detail in RBH’s response to Question 4 below, the totality of evidence regarding the heated tobacco product that RBH currently sells in Canada shows that it is substantially different than a combustible tobacco product, both in terms of its characteristics and the level of risk it poses to existing smokers.

Health Canada’s existing tobacco product labelling regulations already distinguish among different types of tobacco products and require different size warnings for products depending on the type of tobacco product. For example, under current regulations, combustible products like cigarettes and little cigars must carry large graphic health warnings that occupy 75% of both principal display areas, while some smokeless products, including chewing tobacco, oral snuff and nasal snuff, must bear text warnings on 50% of both principal display areas.³ This approach is consistent with the recommendations of the WHO, which has advised that countries “consider requiring different health warnings and messages for different tobacco products such as cigarettes, cigars, smokeless tobacco, pipe tobacco, bidis and water pipe tobacco, in order to better focus on the specific health effects related to each product.”⁴ It is also the approach taken by the European Union⁵, which requires different sized health warnings for smoke-free tobacco products than are required for combustible ones.

Health Canada should continue its approach of requiring different sized health warnings based on the characteristics and risks of different categories of tobacco products. Particularly in light of Health Canada’s proposal to require plain packaging for all tobacco products, the size and

¹ Health Canada, Webpage on Vaping, available [here](#) (accessed Dec. 10, 2018).

² Health Canada, Webpage on Risks of Smoking, available [here](#) (accessed Dec. 5, 2018).

³ Tobacco Products Labelling Regulations (Cigarettes and Little Cigars), SOR/2011-177, available [here](#); Tobacco Products Information Regulations, SOR/2000-272, available [here](#).

⁴ WHO Guidelines for the implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products), available [here](#).

⁵ European Union Tobacco Products Directive 2014/40/EU, April 2014, available [here](#). In the EU, heated tobacco products are considered smokeless novel tobacco products and therefore must carry the following warning on 30% of the principal sides of the package: “This tobacco product damages your health and is addictive.”

content of the health warnings will be one of the only ways for consumers to understand that there are meaningful differences between different types of tobacco products. Indeed, requiring all tobacco products to carry the same size health warning, including those that do not produce smoke and where the existing evidence suggests they are a much better alternative than continuing to smoke, is likely to mislead consumers into believing that they are just as harmful as combustible products like cigarettes. Such a result is likely to undermine, rather than further, Health Canada's objective of reducing smoking rates as quickly as possible.

3(B) Minimum size of health warnings on tobacco products other than cigarettes and little cigars

RBH believes that in deciding whether a minimum health warning should be required on tobacco products other than cigarettes and little cigars, Health Canada should consider whether the requirement would inadvertently result in a tobacco product - particularly a novel tobacco product that is less harmful to smokers than cigarettes - being inadvertently banned. Furthermore, should Health Canada decide that research supports requiring a minimum health warning size on all tobacco products other than cigarettes and little cigars, RBH believes that the requirement should take into account the size of the underlying product, consider where the product lies on the risk spectrum, and the minimum size requirement should only apply to the outer unit or format sold to consumers.

4. Labelling for All Tobacco Products that Do Not Currently Require Labels

All tobacco and nicotine-containing products are addictive and not risk-free. Therefore, RBH supports Health Canada's proposal to extend health warning requirements to tobacco products that do not currently fall within existing regulations, including heated tobacco products. At the same time, those health warning requirements should accurately reflect the existing scientific evidence regarding the risks specific to heated tobacco products, so that consumers can be better informed about the health effects of the different tobacco products in the market.

In December 2016, RBH began selling *IQOS* in Canada. *IQOS* is the first in a series of innovative non-combustible products developed by the Philip Morris International family of companies. It is a tobacco heating system comprised of the *IQOS* device and specially-designed tobacco heatsticks (i.e., the consumable portion which contains tobacco) that RBH markets in Canada under the name *HEETS*.

Heated tobacco products like the *IQOS* system⁶ do not combust tobacco but rather heat tobacco to release a nicotine-containing aerosol. RBH has previously submitted to Health Canada data and evidence showing that *IQOS* is a much better alternative than continuing to use combustible products.

The totality of evidence available to date on *IQOS* shows that:

- There is no combustion when *IQOS* is used as intended;
- The aerosol emitted by *IQOS* contains significantly lower levels (on average, 90%) of all classes of measured harmful and potentially harmful constituents (HPHCs) (excluding nicotine) compared to the smoke of the 3R4F reference cigarette;
- The *IQOS* aerosol is significantly less toxic than smoke from a 3R4F reference cigarette as demonstrated in well-recognized *in vitro* and *in vivo* tests;

⁶ Under the TVPA, both the *IQOS* device and the *HEETS* (i.e., the consumable portion of the product) fall within the definition of "tobacco product."

- The *IQOS* aerosol has a significantly reduced impact on disease mechanisms and disease progression relative to cigarette smoke as demonstrated through innovative systems toxicology assessments;
- Significant reductions in the levels of the HPHCs in the *IQOS* aerosol compared with cigarette smoke lead to similar reduction in exposure as demonstrated with the reductions in biomarkers of exposure to HPHCs.
- These result in substantial reductions in toxicity and mutagenicity, reduced impact on biological networks as well as significant favorable changes in clinical risk endpoints.⁷

RBH's recommendations below regarding the health warning requirements for heated tobacco products are informed by the evidence regarding *IQOS* that RBH has already submitted to Health Canada.

Size of Health Warning on Consumable Heated Tobacco Products

As discussed in RBH's response to Question 3A, the size of the health warnings for heated tobacco products should be significantly smaller than those which currently apply to most combustible products, so that consumers understand that the products are different. Currently, Health Canada requires certain non-combustible tobacco products, including chewing tobacco and oral and nasal snuff, to carry health warnings on 50% of the packaging of those products. RBH recommends that the consumable portion of a heated tobacco product (e.g., *HEETS*) also be required to carry a health warning that occupies no more than 50% of the pack. In fact, RBH already voluntarily applies a 50% health warning on its *HEETS* packaging.

Content of Health Warning on Consumable Heated Tobacco Products

The health warnings on the packaging of the consumable portion of a heated tobacco product (e.g., *HEETS*) should be truthful, non-misleading and should accurately reflect the risks of that product. Today, RBH voluntarily places the health warnings required for chewing tobacco and oral snuff on its *HEETS* packaging. However, several of the warnings applicable to chewing tobacco and oral snuff do not accurately depict the risks of consuming *HEETS*. For example, there is no evidence that the consumption of heated tobacco products increases the risk of mouth disease or oral cancer.

At the same time, heated tobacco products are not risk free and are addictive due to the presence of nicotine, and RBH supports health warnings on heated tobacco products that communicate these facts to consumers. RBH would also support health warnings on heated tobacco product packaging that make it clear heated tobacco products are only intended for adult smokers. Such warnings would be consistent with Health Canada's proposal for health warnings on vaping products,⁸ as well as the EU's approach to health warnings for non-combustible products. For example, in the EU, where *HEETS* are considered novel smokeless tobacco products, they must

⁷ TECHNICAL & SCIENTIFIC DOSSIER For the Electrically Heated Tobacco Product (EHTP) as part of the Tobacco Heating System (THS) submitted to Health Canada on September 6, 2018 as part of the RBH Submission to the Consultation on the Proposed Tobacco Products Regulations (Plain and Standardized Appearance); *see also* RBH Submission to the Consultation on the List of Statements for Use in the Promotion of Vaping Products, September 17, 2018 (summarizing the data and evidence regarding *IQOS*).

⁸ Health Canada, *Proposals for the Regulation of Vaping Products, Document for Consultation*, August 2017, available [here](#). For example, Health Canada has proposed the following health warning on vaping products that contain nicotine: "WARNING: This product contains nicotine. Nicotine is an addictive substance. Use of nicotine during pregnancy may harm the fetus."

carry the following health warning, “This tobacco product damages your health and is addictive.”⁹ The EU also requires e-cigarettes to include one of the following health warnings: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers” or “This product contains nicotine which is a highly addictive substance.”¹⁰

Information to Consumers on the Differential Risks of Heated Tobacco Products

In addition to requiring health warnings that clearly communicate that heated tobacco products are intended for smokers, are not risk free and are addictive, Health Canada should draft the health warning messages in a way that leaves smokers with a clear understanding of how the risks of consuming heated tobacco products compare to the risks of consuming combustible products like cigarettes. This is especially important given that the Tobacco and Vaping Products Act (TVPA) prohibits manufacturers from including such factual information on the packaging for heated tobacco products or in any promotional materials.¹¹ Health Canada is already providing Canadians with information that makes it clear how the risks of consuming vaping products should be understood compared to smoking. For example, on its webpage regarding vaping, Health Canada makes it clear that while vaping can increase risks for non-smokers, vaping is also less harmful than smoking because it reduce smokers’ exposure to toxic and cancer-causing chemicals.¹² Similar statements could be required on health warnings for heated tobacco products.

Presenting information on the health risks of heated tobacco products in reference to smoking would also serve a two-fold purpose of: (1) making it clear that heated tobacco products are only for adult smokers who want to continue to consume tobacco, and not for non-smokers or former smokers; and (2) providing an incentive for existing smokers who do not quit cigarettes to switch to a better alternative. Both purposes are in line with Health Canada’s stated objective of rapidly reducing smoking, including through the offering of less harmful alternatives for smokers.

Finally, regardless of whether Health Canada requires health warnings that present the risks of consuming heated tobacco products compared to the risks of smoking, Health Canada should avoid statements or information that may inadvertently equate the risks of heated tobacco products with combustible products. For example, Health Canada currently requires chewing tobacco and oral and nasal snuff to carry the warning, “This product is not a safe alternative to cigarettes.” While heated tobacco products are not risk free, a warning that communicates that they are not a safe alternative to cigarettes is likely to mislead consumers into believing that cigarettes and heated tobacco products present the same level of risk. In the U.S., research has shown that smokers greatly overestimate the health risks of smokeless products such as snus, despite long-term epidemiological evidence showing that snus is less harmful than smoking. Kozlowski and Kiviniemi explain that this is likely due at least in part to the mandatory health warning on smokeless tobacco products in the U.S.:

[T]he finding here that 75% of US adults hold the misperception that smokeless tobacco products are just as harmful as cigarettes is both a considerable lack of

⁹ European Union Tobacco Products Directive 2014/40/EU, April 2014, available [here](#).

¹⁰ *Id.*

¹¹ TVPA § 20.1, available [here](#).

¹² Health Canada, Webpage on Vaping, available [here](#) (accessed Dec. 10, 2018).

knowledge and a serious public health problem. If a smokeless tobacco user, for example, believes that smokeless tobacco products carry higher oral cancer risks than cigarettes, and therefore switches to cigarettes, this is objectively a step toward greater harm rather than reduced harm. One of the official warnings from the FDA on smokeless tobacco is “WARNING: This product is not a safe alternative to cigarettes.” This message may contribute to the perception of harm from smokeless tobacco. While “not safe,” it is clearly proven that smokeless tobacco products can be much safer than cigarettes.¹³

Health Canada should avoid a similar misleading message in the health warnings for heated tobacco products.

Warnings on the Electronic Device Portion of a Heated Tobacco System

As discussed above, a heated tobacco system like *IQOS* consists of both an electronic device and the actual consumable product. Unlike the consumable portion of a heated tobacco product, an electronic device does not contain tobacco or nicotine, and both the size and content of the health warnings on the device packaging should reflect this fact. For example, in Health Canada’s proposal for the regulation of vaping products, only products that contain nicotine (e.g., vaping liquids or single-use e-cigarettes) would be required to carry a warning related to nicotine and addiction. A similar approach should be followed for heated tobacco products.¹⁴

At the same time, the purpose of an electronic device like *IQOS* is to consume a tobacco product, and therefore RBH agrees that the device packaging should be required to include certain mandatory information that informs consumers about the purpose of the device and for whom it is intended. For example, RBH includes the following phrase on the packaging of its *IQOS* devices: “This product is intended for adult use only.” The current version of the *IQOS* manual includes other important information for consumers, including the following warnings: “*IQOS* is not risk-free”; “*HeatSticks* contain nicotine, which is addictive”; and “The best way to reduce tobacco related health risks is to quit tobacco and nicotine use altogether.”

5. Labelling Rotation

RBH believes that certain rotation requirements may be overly disruptive to the business and not justified. In the event that Health Canada adopts a new rotation scheme, RBH requests that it be reasonable and that Health Canada provides sufficient time and flexibility for implementing each of the changes.

¹³ Kiviniemi, M. & Kozlowski, L., *Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey*, 12 Harm Reduction J. 1, 2 (2015), available [here](#); see also Kozlowski, L. & Sweanor, D., *Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines*, 32 Int’l J. Drug Pol. 17 (2016), available [here](#).

¹⁴ Health Canada, *Proposals for the Regulation of Vaping Products, Document for Consultation*, August 2017, available [here](#).