Consumer Products Alliance for Innovation & Growth

Submission to Treasury Board Secretariat
Regulatory Modernization

Ms. Lindsay Wild
Director, Regulatory Reviews
Regulatory Affairs Sector
Treasury Board of Canada Secretariat
90 Elgin Street, 8th Floor
Ottawa, ON K1A 0R5

Dear Ms. Wild,

On behalf of The Consumer Products Alliance for Innovation and Growth (CPAIG) we are pleased to provide these comments in response to the Canada Gazette Notice published on July 27th, 2018 regarding the Treasury Board Secretariat's (TBS) Regulatory Modernization Initiative. CPAIG is an industry alliance made up of manufacturers and retailers who have come together to work on high-level issues of mutual concern. Alliance members include:

- Canadian Beverage Association
- Canadian Consumer Specialty Products Association
- Canadian Federation of Independent Grocers
- Consumer Health Products Canada (Chair)
- Cosmetics Alliance Canada
- Neighbourhood Pharmacies Association of Canada
- Retail Council of Canada
- Food and Consumer Products of Canada

Our members have decades of experience as key stakeholders in the development and implementation of government regulatory initiatives that affect both the retail and manufacturing sectors in Canada. Over the course of the last 18 months, CPAIG has made a series of submissions to the TBS on issues of regulatory reform (attached). In addition to the recommendations we have already made, CPAIG members are seeking specific regulatory/legislative amendments as outlined below which we believe to be in line with the government's objectives regarding the current regulatory review.
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1. Recommendation: Amendments to the *Food and Drugs Act* (definition of "manufacture")

When Health Canada introduces new regulatory requirements for consumer health products and foods, the implementation and enforcement of those requirements is almost always at the retail level. This presents a number of significant logistical problems for both manufacturers and retailers when requirements are specific to products and their packaging. For example, when Health Canada imposes a label change for a product, the enforcement of that change takes place at retail. However, it is the manufacturer who is responsible for making the change to their product(s).

The difficulty with enforcing such a change at retail relates to a number of factors including: complexities in the distribution chain, varying shelf-life of products, different sell-through times for high vs low volume products, volume of available stock etc. For example, a production run of high-volume OTC products can sell through at retail in a few months, whereas low-volume, or products with longer expiry dates, can take years to sell through. A further issue is that manufacturers lack control over products once they enter wholesale and retail distribution channels, meaning that enforcement becomes more complex for regulators and compliance less orderly and uniform.

By implementing regulatory changes to products at the retail level, the government can often end up forcing recalls of perfectly good products. Other than in the case where there is a public health emergency, in which case the government has all the necessary powers to cause the removal of products from retail shelves immediately, implementation and enforcement of regulatory changes to products or their packaging should take place at the manufacturing level. This would permit an orderly transition in the market and minimize impact on the regulated parties.

The problem with implementing and enforcing regulatory changes at the manufacturing level is a result of the fact that the *Food and Drugs Act* does not separate the actions of "manufacturing/producing" from "selling" which results in virtually all of the regulatory/legislative provisions applying at the retail level.

Definition of "sell" Food and Drugs Act: - ***sell*** *includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;*

For example, it is illegal under the *Food and Drugs Act* to sell a product that is not labelled in compliance with the regulations – even if the product label was compliant before regulations were changed. As such, the *Food and Drugs Act*, as well as the *Food and Drug Regulations*, do not allow for or account for the need for sell-through periods. Even when implementing future "coming into force" dates for new regulations, low volume products, or products with long expiration dates, may still be on retail shelves after the coming-into-force of new provisions that would require them to be returned to the manufacturer for destruction. Unlike the *Food and Drugs Act*, the *Tobacco and Vaping Products Act* has separate definitions for both "sell" as well as for "manufacture" allowing Health Canada to assign regulatory responsibilities to retailers versus manufacturers as deemed appropriate to the circumstance.

Definition of "manufacture" Tobacco and Vaping Products Act: ***manufacture****, in respect of a tobacco product or vaping product, includes the manufacture of a tobacco product or vaping product for export, as well as the packaging, labelling, distributing and importing of a tobacco or vaping product for sale in Canada.*

Specific amendments required:

- Amend the *Food and Drugs Act* to include a definition of manufacture and, where appropriate make additional amendments to the Act where implementation should be at the manufacturing level as opposed to the time of "sale".
- Make consequential amendments as necessary to the *Food and Drug Regulations* to appropriately implement certain regulatory provisions at the manufacturing level for products intended for sale in Canada.

2. Recommendation: Amendments to the Food and Drugs Act (sampling)

The *Food and Drugs Act* prohibits sampling of all drugs unless under prescribed conditions to a limited list of health practitioners. This prohibition was enacted in 1962 in response to concerns that the large number of prescription drug samples being distributed at that time were contributing to a high prescription drug prices. With the evolution and growth of the consumer health sector, this prohibition against sampling of all drugs has resulted in unintended consequences. The prohibition unduly restricts the distribution of direct-to-consumer samples of consumer health products that are otherwise accessed directly by consumers without a prescription. An amendment to the *Food and Drugs Act* is needed to address this issue along with a supporting policy framework in order to guide enforcement to ensure compliant direct-to-consumer sampling.

The inability to sample consumer health products in Canada actually runs contrary to many public health initiatives as it prohibits manufacturers from supporting actions in favour of those such as:

- Distributing sunscreens at outdoor events
- Making vitamins more accessible to lower socio-economic groups
- Distributing hand sanitizers at public events

Canadian consumers would directly benefit from the ability to obtain samples of OTCs, natural health products and disinfectants. Enabling greater access to safe and effective self-care options will help Canadians maintain and improve their health.

***Specific amendments required*:**

- Amend the *Food and Drugs Act* to:
    - Broaden the scope of health care practitioners that can sample prescription drugs to any provincially regulated prescribing health care practitioners according to the prescribed conditions set out in C.01.048 of the *Food and Drug Regulations.* This would expand the scope of health practitioner sampling to include nurse practitioners, and pharmacists in certain provinces and naturopathic doctors in certain provinces for certain drugs
    - Permit direct-to-consumer sampling of non-prescription drugs, natural health products and disinfectants to any person by any person.
- Make consequential amendments to the Food and Drug Regulations and Natural Health Product Regulations to enable direct-to-consumer sampling of non-prescription drugs, natural health products and disinfectants in accordance with supporting guidance and policy.

3. Recommendation: Revisit the decision to exempt regulatory charges (user fees) under the *Food and Drugs Act* from the requirements of the Services Fees Act (SFA) to ensure Parliamentary or central agency oversight.

The *Budget Implementation Act* 2017 replaced the former *User Fees Act* with the new SFA. However, at the same time, the F&DA was exempted from the SFA, and the Minister of Health was given authority to set fees by Ministerial Order. As a result, user fees charged for regulatory activities conducted under the *Food and Drugs Act* do not have to comply with the revised SFA to ensure accountability and Parliamentary oversight. CPAIG members believe that the decision to exempt the *Food and Drugs Act* was rushed through parliament without the necessary analysis and input from stakeholders at the time of the 2017 Budget and should be revisited to ensure public transparency and accountability remain paramount.

Since this change, Health Canada has exercised its right to set fees without Parliamentary or central agency oversight, and has done so in contravention of Treasury Board policies in a non-transparent manner. The new user fees will more than double the burden on industry and were not accompanied by a full costing analysis, as required by Treasury Board policy. The department has also signalled that further increases are forthcoming.

CPAIG members see no reason why the accountability and transparency required under the SFA should not apply to the user fee regime under the *Food and Drugs Act*. A reversal of the decision to exempt the *Food and Drugs Act* and return the authorities to set user fees back under the SAF should be seriously considered. At a minimum, changes to the fee regime must be subject to the Governor in Council regulatory process, to ensure the direct oversight of Treasury Board and strict adherence to Treasury Board *Guide to Setting a Cost-Based User Fee or Regulatory Charge.*

4. Recommendation: "Regulatory Experimentation" and Review of Labelling Initiative

Multiple regulatory initiatives are currently underway for the re-labelling of all consumer health and food products in Canada. These new labelling requirements are focused primarily on either adding new information, updating existing information or reformatting information that is present on the physical packages of products. Combined, these regulatory interventions are costing the consumer health products and food industries billions of dollars in re-labelling, repackaging and other costs. Not to mention the additional environmental, societal and economic costs associated with increased packaging and waste decreased availability and increased cost of goods as well as the negative impact on Canada's competitiveness in the global market.

This is a prime example where the exclusive reliance on "old technology" such as a product's physical packaging to convey important information to consumers is not only unjustifiably costly to industry, consumers and the environment, it is increasingly at odds with the reality that more and more consumers are seeking information from on-line sources. CPAIG members believe that there is a significant opportunity for "regulatory experimentation" to identify more effective and efficient mechanisms that would deliver information to consumers using technology that exists today.

As an example, the food industry in Canada has already moved to a fully integrated on-line source of information for products sold at retail. SmartLabel® provides consumers with easy and instantaneous access to detailed information about thousands of food, beverage, personal care, household and pet care products by either entering a URL or scanning the QR code on a product. The regulatory value of an on-line labelling system (that can be used to augment basic information that would remain on physical package labels) is that information can be updated immediately to provide additional health and safety messages as required as well as to provide far more information than can currently be accommodated on limited product package space. In the case of product labels, the use of technology would not only

save billions of dollars in costs, it would allow regulators to be far more nimble in addressing new information needs as they occur.

5. Recommendation: Other Administrative Issues

Inclusion of the term "Innovation":

As we look toward fulfilling the goals of the budget 2018 with respect to creating a regulatory reform agenda and ensuring that innovation is part of that discussion, CPAIG members would recommend that the Treasury Board guidance documents used for developing regulatory proposals be reviewed to ensure they include the goals of innovation and regulatory agility. Currently, most do not; and if they do mention the word "innovation", it is only mentioned once. As an industry sector that is regulated by a vast number of laws and regulations for our products, we find the discussion around innovation missing from most discussions with Government during the development of future regulations. We are hopeful that this initiative will spur the discussion and have those important questions asked during regulation development. By including the term innovation in pertinent regulatory development documents, this will be achieved. We wish to ensure our members can provide safe, beneficial products that are innovative and can prosper in a competitive Canadian marketplace.

Defining "Incorporation by Reference":

CPAIG members also recommend that the term "incorporated by reference" be clearly defined by Treasury Board in a guidance document. There is no clear definition that industry or regulators can point to in a document and we find the term being used/misused in many regulatory discussions.

On behalf of CPAIG's extensive membership, would like to thank you very much for providing us with the opportunity to submit these comments and recommendations. We would welcome an opportunity to discuss these in more detail and answer any questions you might have.

Sincerely,

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