Consumer Health Products Canada
Advancing evidence-based self-care

An unprecedented opportunity to resolve a decades-old barrier to self-care

Summary:

- Both the Federal and Provincial/Territorial governments have a role in regulating over-the-counter medicines and natural health products (consumer health products).
- After the federal decision to approve a consumer health product for self-care, overlapping federal and provincial territorial regulations govern conditions/place of sale ("drug scheduling").
- The F/P/T overlap in regulating conditions/place of sale creates delays in consumer access to new products, which is compounded by delays imposed by international obligations, and adds layers of complexity and costs for industry, and by separating the product approval and conditions of sale decision-making processes, makes both more difficult for regulators.
- Consumer Health Products Canada (CHP Canada) is seeking federal and provincial leadership to integrate and streamline the decision making process for approving and determining the conditions/place of sale for consumer health products under Health Canada's proposed self-care products framework to produce better, more consistent and more timely outcomes for Canadian consumers.

Background

The Federal and Provincial & Territorial governments all play a role in the process for regulating consumer health products.

- The process begins with the Federal government's (Health Canada) decision to approve a product for sale in Canada, and a determination as to whether the product can only be sold with or without a prescription.
    - When Health Canada approves the "switch" of a product from a prescription drug to non-prescription status, the Prescription Drug List (established under the Food and Drug's Act) is amended to enable the ingredient at a certain dose, route of administration or for a specific use, to be made available without a prescription.
- The "switch" process then continues with the Provincial/Territorial governments, under the authority derived from their respective Pharmacy Acts, who re-assess the need for a prescription requirement and consider further conditions of sale, through drug scheduling.
    - For example, some consumer health products can only be sold through direct pharmacist intervention and are located behind the pharmacy counter; other products require a

pharmacist to be present and must be sold in a pharmacy, while other consumer health products can be sold in any retail outlet.

- The National Association of Pharmacy Regulatory Authorities (NAPRA) was established in 1995 in part to achieve national harmonization of the conditions of sale for consumer health products by establishing National Drug Schedules.
- However, not all provinces fully recognize the National Drug Schedules and retain separate processes for regulating the conditions of sale for consumer health products, which has created delays for market access and inconsistencies in how products are permitted to be sold across the country.

Current Status

- The cumulative effect of (1) Health Canada's review process for switching an ingredient (2) the resulting WTO notification process and (3) the duplication of the federal decisions at the provincial level has created lengthy and unpredictable switch process for industry. As a result, Canada trails its major trading partners in attracting new consumer health products to the market.
    - Canadians typically wait 7-9 years longer than consumers in the US or EU to gain access to new consumer health products that have been switched from prescription status. This is 7-9 years during which provincial governments continue to pay doctors to prescribe medications that are available without a prescription in other jurisdictions.
- Health Canada has launched consultations on a new self-care products regulatory framework. The proposal includes a vision for an integrated governance approach to consumer health products that could be used to bring together the federal Health Portfolio, the provincial and territorial governments and relevant stakeholder associations to address point of sale issues for these products.
- NAPRA is questioning its ongoing role in the National Drug Schedules for a variety of reasons, including: the lack of a legislative and regulatory framework to underpin its role; the lack of an adequate consultative and policy capacity to maintain the National Drug Schedules in a changing healthcare and industry landscape; and, concerns about the ability to enforce the drug schedules in non-pharmacy settings.
- The provincial drug scheduling process leads to uneven access to consumer health products, from province to province, especially to new products that have had the prescription requirement removed federally.
- The NAPRA scheduling decisions sometimes conflict with the Health Canada decisions, leading to uncertainty and barriers to access.

Considerations

- Federal integration of drug scheduling would:
    - Improve access to new consumer health products and reduce unnecessary doctor visits by eliminating the need to revisit the federal decision at the provincial level.
    - Allow for better decision making, by allowing product approvals to be made with full knowledge of and control over the conditions under which the product will be sold.
    - Reduce unnecessary duplication and red tape, and produce more consistent and predictable outcomes for Canadians and for industry.
    - Align with all governments' commitments to strengthen and modernize the Agreement on Internal Trade to achieve the free flow of goods across the country, strengthen Canada's economic union and create a level playing field for trade within Canada.
    - Align with the recent F/P/T re-engagement a new Health Accord and on strategies to improve access to affordable medicines, providing an ideal forum to discuss a way forward.

Recommendations and Rationale

Federal, Provincial and Territorial governments have a role to play to resolve barriers to internal trade and innovation that have been imbedded within the process for switching a product from prescription to non-prescription status. CHP Canada is seeking:

- Federal and provincial leadership to integrate the drug scheduling process within the consumer health product approval process at the federal level, under existing authorities in the *Food and Drugs Act.*
    - This would centralize decision-making where there is adequate administrative and policy capacity and lead to better outcomes for Canadian consumers, the healthcare system and industry.