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RCC Personal Care Products and Pharmaceuticals Working Group:
Over-the-Counter Therapeutic Products Approval and Licensing Work Plan

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Proposal to explore and develop joint proposals to identify on-going systemic alignment mechanisms between the U.S. Food and Drug Administration (FDA) and Health Canada (HC)

A goal of collaboration between HC and the FDA is to better align our regulatory systems, reduce unnecessary duplications and differences, and, to the extent feasible, better leverage resources to help both agencies meet their public health missions within the parameters allowed by prevailing laws and regulations subject to available human and financial resources.

Building on the strong, extensive and long-standing bilateral regulatory cooperation between the agencies, the FDA and HC will explore and develop proposals outlining joint regulatory collaborations in areas of mutual benefit, such as personal care products and pharmaceuticals for human and animal use. These proposals will outline key elements to help facilitate on-going better systemic alignment of regulatory systems, strategies, and practices between HC and FDA. When exploring potential proposals, FDA and HC will:

- Take stock of collaboration and experience gained to date between the FDA and HC;
- Identify mechanisms for possible regulatory alignment and mutual reliance in such areas as product review and inspection of manufacturing facilities, as well as establishing requirements/standards where appropriate; and
- Examine enablers and barriers related to implementation and identify options for addressing barriers (e.g. legislative and administrative barriers).

These proposals will foster the pursuit of real opportunities to further leverage capacity and expertise, as well as the identification and implementation of effective ongoing systems strategies to help better align regulatory requirements and avoid unnecessary duplication in areas of mutual benefit.

Health Canada and FDA will up-date stakeholders, on a regular basis, on progress and developments emanating from the four current HC-FDA RCC initiatives and future developments, as appropriate.

Preamble:

The objectives of the RCC monograph alignment working group are to conduct a pilot program to develop aligned monograph elements for a selected over-the-counter (OTC) drug category (e.g. aligned directions, warnings, indications and conditions of use). And subsequently, develop recommendations to determine the feasibility of an ongoing mechanism for alignment in review and adoption of these OTC drug monograph elements.

Regulators have made a preliminary identification of the following key stakeholders for engagement in the RCC initiative:

- Consumer Health Products Canada (CHP)
- Consumer Healthcare Products Association (CHPA)
- Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)
- Personal Care Products Council (PCPC)
- Groupement Provincial de l'Industrie du Médicament (GPIM)
- National Association of Pharmacy Regulatory Authorities (NAPRA)
- Canadian Pharmacists Association (CPA)

Working Group Structure: This working group will be co-chaired by the FDA and HPFB-TPD. Discussions on the composition of the working group and decision making authority are pending.

Meeting Frequency: The frequency of working group meetings will be determined after further discussions between regulators. Regulators will agree on the means of communications (i.e. teleconference, in-person meetings or shared documents) during a scoping exercise which will occur over the next two months.

Stakeholder Engagement: The method of stakeholder engagement will be via a web posting and the frequency will occur following the milestones detailed in the table below.

Timeline:

Deliverable outcome	Development and adoption of aligned monograph elements (describe labelling requirements including, indications, warnings, conditions of use, and any other information that may be required for optimal, safe, and effective use of the product) for these low-risk products to streamline costs for manufacturers and distributors and enhance consumer access to these types of therapeutic products on either side of the border. This alignment would likely include common labelling elements, especially directions and warnings statements, and age or weight based dosing regimens.
One to three months (Scope and Governance)	During this timeframe regulators will establish the scope and the governance of the project with an objective of establishing a sound basis for the alignment of selected monographs. The milestones associated with this objective include: • Establishing the roles, responsibility and governance of the working group; • leveraging existing senior officials' governance structures and international standards to identify longer term opportunities for collaboration; • identifying the appropriate contacts within the respective regulatory groups; • continuing interaction including teleconference, shared documents or in-person meetings; • developing a mechanism to archive discussion content (i.e., reflections on process considerations, opportunities, barriers, etc.) and decision making; • sharing information on respective regulatory programs to allow the development of a sound basis for selecting and aligning monograph elements in the pilot program;

	• sharing a list of monographs for mutual consideration; and, • developing criteria for selecting monographs for the pilot.
Three to six months (*Selection of Pilot Monographs)*	Following the scoping and governance exercise, regulators will select one monograph for the pilot project. The milestones associated with this stage of the project include: • on-going discussion of the status of the monographs shared between regulators and the factors that will affect assessment; • analysing respective regulatory processes (pre- and post-market) to inform the selection of the pilot monograph elements; • outlining a common approach for review of the selected monograph elements; and, • finalizing the selection of the pilot monograph elements.
Six to 12 months (Development of Aligned Monographs)	During this time period regulators will begin to take steps to draft aligned elements. The milestones associated with this objective include: • Continuing discussion and on-going review to generate scientific and regulatory alignment; and, • generating a draft of revised monograph elements for discussion.
12 to 18 months (Public Process for Pilot Monographs)	This time period will be characterized by the publication of the aligned draft monograph elements for stakeholders and beginning the respective regulatory and policy processes to formalize the revisions of the selected pilot monograph elements. The milestone associated with this objective will be: • Proceeding with publication of the draft monograph element changes as defined by FDA and HC regulatory frameworks and policies.
18 to 24 months (Analysis of Pilot & Developing Recommendations)	During this stage the pilot workgroup will be engaged in a series of discussions to evaluate the prior activities and establish recommendations for implementation of an on-going mechanism for aligned monograph review and adoption processes. The objectives of this stage will be to: • Highlight important similarities and differences identified in the pilot program with respect to the regulatory processes used by FDA and HPFB-TPD to regulate OTC drugs; • Using lessons learned during development of the aligned pilot monograph elements, determine areas for improvement in each process and evaluate future opportunities for alignment by considering the selection of additional pilot monograph elements for alignment; • identify the systematic barriers that inhibit development of an on-going mechanism for alignment; and, • The development of options/mechanisms to address barriers, including related stakeholder engagement, will be the purview of subsequent activities wherein regulators will develop an on-going mechanism for alignment of OTC drug monograph elements.

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