

**RCC Working Group Work Plan**

Canada Lead(s) – Therapeutic Products Directorate (TPD)  
Health Products and Food Branch (HPFB)  
USA Lead(s) - Food and Drug Administration (FDA)

The objectives of the RCC common monograph working group are to conduct a pilot program to develop two or three aligned monographs for selected over-the-counter (OTC) drug categories (e.g. aligned properties, claims, indications and conditions of use). And subsequently, develop recommendations to determine the feasibility of an ongoing mechanism for alignment in review and adoption of OTC drug monographs.

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 determined through further discussion between regulators but the frequency will occur following the milestones detailed in the table below.

Timeline :

Working Group	Personal Care Products and Pharmaceuticals
<b>Action Plan Initiative</b>	Common Monographs for Over the Counter Products
<b>Deliverable outcome</b>	Development and adoption of common monographs (describe the active ingredients, 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.
<b>Task Team Members</b>	Canada Lead(s) – Therapeutic Products Directorate (TPD) Health Products and Food Branch (HPFB) USA Lead(s) - Food and Drug Administration (FDA)
<b>Scope and Governance</b>  (One to three months)	<p>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:</p> <ul style="list-style-type: none"> <li>• Establishing the roles, responsibility and governance of the working group;</li> <li>• leveraging existing senior officials’ governance structures and international standards to identify longer term opportunities for collaboration;</li> <li>• identifying the appropriate contacts within the respective regulatory groups;</li> <li>• continuing interaction including teleconference, shared documents or in-person meetings;</li> <li>• developing a mechanism to archive discussion content (i.e., reflections on process considerations, opportunities, barriers, etc.) and decision making;</li> <li>• sharing information on respective regulatory programs to allow the development of a sound basis for selecting and aligning monographs in the pilot program;</li> <li>• developing criteria for selecting monographs for the pilot; and,</li> <li>• sharing a list of monographs for mutual consideration.</li> </ul>
<b>Selection of Pilot Monographs</b>	Following the scoping and governance exercise, taking into account input from stakeholders,

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Action Plan Initiative	Common Monographs for Over the Counter Products
<p><i>(Three to six months)</i></p>	<p>regulators will select two or three monographs for the pilot project. The milestones associated with this stage of the project include:</p> <ul style="list-style-type: none"> <li>• on-going discussion of the status of the monographs shared between regulators and the factors that will effect assessment;</li> <li>• analysing respective regulatory processes (pre- and post-market) to inform the selection of monographs; and,</li> <li>• outlining a common approach for review for each selected monograph; and,</li> <li>• finalizing the selection of pilot monographs.</li> </ul>
<p><b><i>Development of Aligned Monographs</i></b></p> <p><i>(Six to 12 months)</i></p>	<p>During this time period regulators will finalize the selection of monographs for a pilot and begin to take steps to draft aligned requirements. The milestones associated with this objective include:</p> <ul style="list-style-type: none"> <li>• Continuing discussion and on-going review to generate scientific and regulatory alignment; and,</li> <li>• generating a draft revised monographs for discussion.</li> </ul>
<p><b><i>Public Process for Pilot Monographs</i></b></p> <p><i>(12 to 18 months)</i></p>	<p>This time period will be characterized by the publication of draft monographs for stakeholders and beginning the respective regulatory and policy processes to formalize the revisions of the selected pilot monographs. The milestone associated with this objective will be:</p> <ul style="list-style-type: none"> <li>• Proceeding with publication of draft monographs as defined by FDA and HC regulatory frameworks and policies.</li> </ul>
<p><b><i>Analysis of Pilot &amp; Developing Recommendations</i></b></p> <p><i>(18 to 24 months)</i></p>	<p>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:</p> <ul style="list-style-type: none"> <li>• Highlight important similarities and differences identified in the pilot program with</li> </ul>

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	<p>respect to the regulatory processes used by FDA and HPFB-TPD to regulate OTC drugs;</p> <ul style="list-style-type: none"> <li>• determine areas for improvement in each process and evaluate the opportunities for alignment;</li> <li>• identify the systematic barriers that inhibit development of an on-going mechanism for alignment; and,</li> <li>• bring conclusion to the RCC Common Monograph Workgroup activity</li> <li>• Based on the results of the pilots, the regulators will determine options regarding the implementation of an on-going mechanism for alignment of OTC drug monographs.</li> </ul>

Working Group and Task Team Leads:

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