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Notice

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Regulatory Cooperation Council (RCC) Over-the-Counter (OTC) Products - Common Monograph Working Group

Selection of a Monograph for Alignment

Health Canada is pleased to announce the launch of the first pilot initiative of the RCC Common Monograph Elements Working Group. The working group has selected as its first area of alignment common cold indications for certain over-the-counter antihistamine ingredients. This initiative is the first of its kind between Health Canada and the United States Food and Drug Administration (FDA) and falls within the RCC's two-year mandate (<http://actionplan.gc.ca/en/page/rcc-ccr/regulatory-cooperation-council>). This particular class of ingredients was selected because it fits into the established RCC timelines, and because it meets the goals of aligning the ongoing work of both regulators and reducing unnecessary differences.

Stakeholders are anticipated to have an opportunity to comment on the content of the Canadian and the United States draft monographs by the second half of 2013. United States rule processes limit information sharing with stakeholders to the official public comment period and Health Canada has followed these policies for the purposes of this activity.

This is one step in the ongoing collaboration between Health Canada and the FDA to better align our regulatory systems and reduce unnecessary differences, to the extent feasible. With the completion of this pilot monograph, the working group will explore if there may be opportunities for greater stakeholder engagement on any future OTC monograph initiatives.

Further information on the work plan can be found on Canada's Economic Action Plan website (<http://actionplan.gc.ca/page/rcc-ccr/health-and-personal-care-products-and-workplace-chemicals>).

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For questions regarding the content of this notice, please contact:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower 'B', Address Locator 3102C5
Ottawa, Ontario
K1A 0K9

Telephone: 613-948-4623

Fax: 613-941-6458

E-mail: Policy_Bureau_Enquiries@hc-sc.gc.ca