May 1, 2015

Notice

Our file number: 15-104593-161

Release of the Final Guidance Document: *Drug Submissions Relying on Third-Party Data (Literature and Market Experience)*

Health Canada is pleased to announce the release of the final Guidance Document: *Drug Submissions Relying on Third-Party Data (Literature and Market Experience)*.

The Therapeutic Products Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD) and Marketed Health Products Directorate (MHPD) jointly developed the Guidance to promote predictability of evidence expectations and consistency in Health Canada's regulatory decision making around New Drug Submissions (NDSs) (or supplements) that substantially rely on literature and market experience to support the clinical safety/efficacy of the proposed commercial products. The document outlines criteria for assembling Submissions Relying on Third-Party Data *(*SRTDs) and clarifies evidence requirements for these products in an effort to improve submission quality.

This document applies to New Drug Submissions (NDSs) and Supplements to New Drug Submissions (SNDSs) involving pharmaceuticals, certain biologics, and radiopharmaceuticals submitted under Division 8 of the *Food and Drug Regulations*.

Stakeholder comments received on the draft guidance document during the 90 day consultation period (June 13, 2014 to September 13, 2014) were considered in the finalization of this guidance document. A summary of comments received is available upon request to the address below.

Questions or concerns regarding this guidance document should be directed to:

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