Notice: Guidance documents for industry: Reporting adverse reactions to marketed health products and Preparing and submitting summary reports for marketed drugs and natural health products

The document Reporting Adverse Reactions to Marketed Health Products: Guidance Document for Industry has been updated with some minor revisions and the section on summary reports has been replaced by a complementary document Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products: Guidance Document for Industry.

Annual and issue-related summary reports serve to collect, monitor and analyze adverse reaction safety data. The new guideline describes acceptable formats in which these summary reports can be prepared.

Health Canada, as an official member to the International Council for Harmonisation (ICH), is committed to the adoption and implementation of ICH guidances and standards. In March 2013, Health Canada adopted the ICH E2C (R2) guidance on Periodic Benefit Risk Evaluation Reports (PBRER) and published a Notice to inform stakeholders that annual summary reports could be prepared in the ICH PBRER format. Subsequently, the section of the 2011 guidance that dealt with summary reporting has been expanded into its own guideline, which was posted for stakeholder comment in 2016.

The new Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products: Guidance Document for Industry - is intended to:

- Clarify Health Canada's expectations for preparing Annual Summary Reports (ASR) and Issue-Related Summary Reports (IRSR), further to Health Canada's adoption of ICH E2C (R2).
- Provide an optional non-ICH format for manufacturers.
- Provide an overview of the procedures for submitting ASRs and IRSRs to Health Canada.
- Simplify and streamline the format and content requirements for ASRs relating to Natural Health Products.

Revisions to the Reporting adverse reactions to marketed health products - Guidance Document for Industry are intended to:

- Promote electronic reporting as the preferred method for reporting adverse reactions (ARs), and change the language throughout the document which had previously precluded and/or was inconsistent with electronic reporting means.
- Provide general clarifications throughout of points which commonly result in inquiries to the Canada Vigilance Program and to the Regulatory Operations and Regions Branch.

These guidelines reflect the current thinking about adverse reaction and summary reporting and demonstrate Health Canada's contribution to international harmonization efforts related to pharmacovigilance.