# Adverse Reaction (AR) Reporting and Patient Support Programmes/Market Research Programmes at Health Canada

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## Patient Support Programmes(PSPs)/Market Research Programmes (MRPs)

- Programs are designed to use methods to encourage contact between consumers and the MAH
- Examples: telephone consumer call line, nurse-initiated calls for medicine compliance, registries, surveys collecting other patient data etc.
- ARs from patient support and market research are considered solicited reports as these reports are not generated in the usual spontaneous manner

# Guidance - AR reporting & PSPs/MRPs

- Included in ICH E2D Guideline - Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting
- Canada Vigilance - Post-market reporting requirements in Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/pubs/medeff/guide/2011-guidance-directrice_reporting-notification-eng.pdf

# AR Reporting and PSPs /MRPs - Canada Vigilance

- Reports generated through these programs are considered reportable to Health Canada in accordance with the Regulations
- Reports are regarded as solicited in nature and one cannot infer implied causality, the convention for spontaneous reports
- Solicited reports are only submitted if there is a reasonable possibility that the health product caused the AR as determined by a qualified health care professional of the MAH

# Causality Assessment - Solicited Reports

- Using the World Health Organization criteria for causality those reports that are considered unassessable or unclassified are not required to be submitted
- Any case reports that fall within the criteria  of certain, probable, possible or unlikely must be reported
- In any case where an underlying illness or another health product may have contributed to the adverse event, the report should still be considered an adverse reaction, as the causality cannot be ruled out

# Solicited AR Reporting Compliance

- PSPs/MRPs involve **post-market** AR reporting (serious domestic and serious unexpected foreign reports)
- Good Vigilance Practice Inspections of MAHs include verification of the submission of solicited reports in accordance with the Regulations

## Experience - Solicited Reports

- In 2012, Canada Vigilance received  17,342 domestic solicited reports out of a total of 53,737 domestic reports
- Statistics are not available for the number of foreign solicited reports out of the total of 542,052 foreign reports received
- Unassessable and unclassified reports are received (although not required) and are of limited value

## Experience - Solicited Reports

- It has been noted that important data elements may not always be present in solicited reports since the original method of data collection was not designed for the purpose of collecting adverse reaction reports
  - For example, limited information on medical history, narrative description of reaction, concomitant products, product therapy dates
- As a result, solicited reports are weaker reports for signal detection
- Adverse reaction reports are reported through PSPs/MRPs and the methods of data collection should aim to collect as many AR report data elements as possible