IPRP
International Pharmaceutical Regulators Programme

Mandate Document

Pharmacovigilance Working Group

Version 1.0

endorsed by the MC on 19 November 2020

Document History

Version number	Action	Date of endorsement
v1.0	Draft version of the Mandate document (dated 26 October 2020) presented to the MC for endorsement at the virtual meeting in November, 2020.	**19 November 2020**

1. General Considerations

1.1. Statement of the Perceived Problem

All members of the ICMRA Pharmacovigilance Working Group have spontaneous reporting systems (SRS) in place to capture adverse drug reaction data. However, SRS alone do not provide complete information on medicine safety. Limitations include the inability to estimate the total number of reactions or patients exposed to a medicine, a lack of detailed patient health information, the potential for underreporting, and limited ability to compare adverse reactions between different medicines. The use of other types of structured and unstructured data sources (i.e. data triangulation) has the potential to augment SRS by supporting signal validation and causality assessment, complement traditional tracking systems, improve trend analysis, enable investigations within sub-populations, and control for confounders. Common challenges to the implementation of data triangulation in pharmacovigilance include issues related to security and privacy, partnerships, infrastructure and capacity, and determining standards for data management and data analytics.

1.2. Expected Benefits

The PVWG was formed to provide a platform for discussions and information sharing about data sources that are available to regulators for detection and evaluation of medicine safety signals. The PVWG aims to improve collaboration among regulators by sharing information about tools and initiatives for monitoring the safety of medicines. Eventually, these activities are expected to have a positive impact on the safety of marketed medicines.

1.3. Background to the proposal

Reporting to the IPRP Management Committee, the primary objective of the Pharmacovigilance Working Group is to advance the regulatory approach to pharmacovigilance from its current dependence on spontaneous reporting of suspected adverse drug reactions, to a state where multiple data sources can be leveraged to inform regulatory decision making. This scope of work arises from a series of recommendations made by the ICMRA Big Data Working Group in their policy paper for the ICMRA Pharmacovigilance Project [1].

2. Scope

The scope of the PVWG is aligned with the IPRP Terms of Reference. The working group will focus on tools and methodologies used in pharmacovigilance for the collection and analysis of structured and unstructured data.

The PVWG's areas of work will complement and not duplicate established international initiatives and collaborations that are in progress.

3. Objectives

The following PVWG objectives will be completed sequentially:

- Objective 1: To describe the current landscape of pharmacovigilance tasks, methods and data

[1] ICMRA Big Data Working Group. 2016. *ICMRA Pharmacovigilance: a Draft Policy Paper for ICMRA Pharmacovigilance Project.* www.icmra.info/drupal/en/strategicinitatives/pharmacovigilance/bigdata

sources used by national regulatory authorities

- develop a common understanding of regulatory tasks and terminology for pharmacovigilance
- develop and maintain an environmental scan of regulatory activities, data sources and methodologies employed by regulators for pharmacovigilance

- Objective 2: Share information on pharmacovigilance best practices for signal detection and evaluation (as defined by mature national regulatory authorities)
  - share pharmacovigilance best practice technical documents from mature national regulatory authorities on data sources and methods for signal detection and evaluation
  - identify gaps and areas for strengthening signal management in national PV systems
- Objective 3: To collaborate on signal management
  - explore opportunities for multijurisdictional collaboration on signal detection and validation using common data sources, tools and protocols
  - conduct collaborative investigation of a safety signal utilising multiple data sources (i.e. data triangulation).

4. COMPOSITION

Argentina: ANMAT

Brazil: ANVISA

Europe: EC

United States: FDA

Canada: Health Canada

New Zealand: Medsafe

Republic of Korea: MFDS

Japan: MHLW/PMDA

WHO: PAHO/PANDRH

Russia: Roszdravnadzor

South Africa: SAHPRA

Saudi Arabia: SFDA

Chinese Taipei: TFDA

Turkey: TITCK

5. SPECIFIC ORGANISATION

5.1. Designation of a Chair Supporteur

None – the co-chairs are responsible for secretariat support, e.g. setting up teleconferences, writing meeting agenda, records of discussions.

5.2. Organisation of meetings

The PVWG meets on regular basis by teleconference (about every 6-8 weeks).

5.3. Contact with stakeholders

None