Technical Alert - Public

Mandatory Sponsor pharmacovigilance requirements

There are 5 mandatory requirements that sponsors must adhere to in relation to pharmacovigilance (safety monitoring) of listed medicines, as well as best practice requirements.

Both mandatory and best practice requirements are subject to audit as part of the TGA's Pharmacovigilance Inspection Program. As a sponsor of medicines approved for supply in Australia, there are legal responsibilities for meeting pharmacovigilance reporting requirements. Non-compliance to the mandatory legal reporting requirement can attract civil or criminal penalties, including infringement notices and fines.

CMA recommends that all industry sponsors are aware of, and make sure that they are conforming to all pharmacovigilance requirements and in particular the below 5 mandatory requirements:

1. Letting the TGA know who your pharmacovigilance Contact Person is

- Sponsors must have a pharmacovigilance contact person who resides in Australia.
- Sponsors must provide the TGA with the name and contact details of the Australian pharmacovigilance contact person **within 15 calendar days of your first medicine's entry on the ARTG**. Sponsors must also notify the TGA of the updated name and contact details **within 15 calendar days of any changes to the Australian pharmacovigilance contact person or their details**.

The Australian pharmacovigilance contact person can be nominated, and/or their details updated, through the TGA Business Services electronic portal.

2. Submit any serious adverse reactions* reports to the TGA

- Sponsors must report expected and unexpected serious adverse reactions associated with the use of their medicine that occurred in Australia.
- Sponsors must report expected and unexpected serious adverse reactions associated with the use of their medicine that occurred in Australia and were reported in the published international or local scientific and medical literature.
- Sponsors also must report all clinical and medically relevant follow-up information related to serious adverse reaction reports occurring in Australia.
- These reports to the TGA must occur as soon as possible and **no later than 15 calendar days from receipt**

*A serious adverse reaction is any medical occurrence that in relation to a medicine, at any dose:

- results in death
- is life-threatening
- results in inpatient hospitalisation or prolonged hospitalisation
- results in persistent or significant disability or incapacity
- is associated with a congenital anomaly or birth defect (see Reports in pregnancy and breastfeeding)
- is a medically important event or reaction.

3. Notify the TGA of any significant safety issues* you identify

- Sponsors must report all significant safety issues related to their medicine **within 72 hours of awareness**.
- When you report significant safety issues to the TGA, you must indicate the points of concern and whether you plan to take any regulatory action in Australia for the medicine.
- Sponsors must provide the TGA with any additional information they ask for within a specified timeframe including, but not limited to:
    - the volume of sales or prescriptions of the medicine
    - details of the frequency assessment
    - copies of any relevant foreign adverse reaction reports you hold.

* A significant safety issue is a new safety issue or validated signal considered by a sponsor in relation to their medicine that requires urgent attention of the TGA. This may be because of the seriousness and potential major impact on the benefit-risk balance of the medicine and/or on patient or public health, which could warrant prompt regulatory action and/or communication to patients and healthcare professionals.

4. Keep records pertaining to the reporting requirements and safety for your medicine

- Sponsors must retain records pertaining to the reporting requirements and safety for your medicine indefinitely for the life of the medicine and for:
    - a period of 10 years after removal from the ARTG for registered medicines; and
    - a period of 5 years after removal from the ARTG for listed medicines.
- Retained information must include, but is not limited to:
    - all adverse reaction reports (serious and non-serious); and
    - information surrounding significant safety issues, special situation reports, reference safety documents and non-valid reports containing drug-event pairs.

General safety information on your medicine should also be retained indefinitely for the life of the medicine. The TGA may also ask to review these records on request, or as part of the Pharmacovigilance Inspection Program. This information includes, but is not limited to:

- ongoing monitoring activities, PSURs, literature reviews, contracts with pharmacovigilance providers, documentation regarding changes to reference safety information.
- pharmacovigilance procedural documents and pharmacovigilance training documents should also be retained indefinitely for the life of the medicine.

5. Answer TGA requests for additional information

- Under Subsection 31(1) of the Act, sponsors must answer any request from the TGA for additional information fully and within the specified timeframe.

The below table provides a summary of what, how and when you **MUST** report:

Report type	How to report	Reporting timeframe
Australian pharmacovigilance contact person	Submitted via TGA Business Services	**≤ 15 calendar days** of first ARTG entry or of any detail updates
Significant safety issues	In writing to the PSAB Signal Investigation Coordinator, via email to: si.coordinator@health.gov.au	**≤ 72 hours** of sponsor notification
Serious adverse reaction reports that occurred in Australia	Blue card/CIOMS form/E2B reports Email: adr.reports@health.gov.au Online: TGA Business Services	**≤ 15 calendar days** of receipt of minimum information
Quality defect issues, adulterated products, counterfeit products	For notifications of significant safety issues associated with medicine quality defect issues, email: si.coordinator@health.gov.au For reports of serious adverse reactions associated with medicine quality issues or confirmed medicine quality issues unlikely to warrant a recall, email: adr.reports@health.gov.au For notifications of medicine quality defect issues that is likely to warrant a recall, email: recalls@health.gov.au For notifications of GMP compliance issues, email: GMPCompliance@health.gov.au	In accordance with the timeframe for serious adverse reactions or a significant safety issue as applicable
Non-serious adverse reaction reports and overseas adverse reaction reports	These are not required to be routinely reported. However, they must be presented as a cumulative table in a Periodic Safety Update Report (PSUR) where one is required, or supplied to the TGA upon request in the requested format.	As specified by the TGA PSUR reporting requirements or specific request

Resources

- Pharmacovigilance responsibilities of medicine sponsors Australian recommendations and requirements: Includes information on reporting and record keeping requirements
- Pharmacovigilance Inspection Program: Includes information for sponsors on the inspection process
- Pharmacovigilance inspection program: Guidance for medicine sponsors
- TGA Business Services electronic portal
- Adverse event reporting
- Therapeutic Goods Act 1989