Pharmacovigilance for sponsors of complementary and listed medicines

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Session overview

- Pharmacovigilance (PV)
- PV responsibilities of the regulator and sponsor
- PVIP
- Common deficiencies and tips

Pharmacovigilance

What is it and why is it important?

“the discipline and set of activities aimed at the identification, evaluation and prevention of adverse effects or other problems related to the use of medicines”

- WHO

Pharmacovigilance in Australia

Regulator responsibilities

The Therapeutic Goods Administration (TGA) collects and evaluates information related to the benefit-risk balance of medicines in Australia to monitor their safety and, where necessary, take appropriate action.


Home > News and Community > Safety alerts
Medicines containing Withania somnifera (Withania, Ashwagandha)
Safety advisory – potential for gastrointestinal symptoms and very rare cases of liver injury
Published: 22 February 2024
Listen Print
Home > News and Community > Safety alerts
Medicines containing Garcinia gummi-gutta (Garcinia cambogia) or hydroxycitric acid (HCA)
Safety advisory - potential for rare cases of liver injury
Published: 8 August 2024
Listen Print Share
Home > News and Com
Medicines containing Andrographis paniculata safety advisory

Pharmacovigilance in Australia

Sponsor responsibilities

Medicine sponsors are **legally responsible** for the **quality**, **safety** and **efficacy** of the ARTG entries they hold.

Sponsors are expected to establish and manage an **ONGOING pharmacovigilance system** to:

- Collect and analyse adverse events
- Detect and investigate safety issues
- Report to the TGA, any information that indicates that the quality, safety or efficacy of the medicine is unacceptable
- Take action to minimise risk (e.g. update labels, recall product)
- Create and maintain accurate pharmacovigilance records.

Legal basis of your Pharmacovigilance responsibilities

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods Regulations 1990*
- *Pharmacovigilance responsibilities of medicine sponsors Australian recommendations and requirements* (referred to as the *Pharmacovigilance Guidelines*)
- Conditions – standard and specific, applying to registered or listed therapeutic goods
- Label requirements set out in Permissible Ingredient and Indication Determinations, TGO 92

Pharmacovigilance Inspection Program

Purpose

- Protect public health by strengthening and broadening TGA post-market monitoring activities

Objective

- Assess the sponsor's compliance with Pharmacovigilance requirements
- Enable the TGA to help sponsor to meet their Pharmacovigilance obligations

Expectation of sponsors

- Create and maintain an effective pharmacovigilance system to help you meet your regulatory obligations

Priorities and changes

Complementary and Listed Medicines

- Limit/revise the inspection timeframes
- Formulate more focused document requests
- Review the scope of the inspection
- Use technological advances to gather information/ documents
- Increase the number of inspections per year
- Re-inspecting where appropriate
- Empowering sponsors with the responsibility of CAPAs with limited regulatory involvement
- Identify areas of specific need and provide targeted education
- Publishing more concise biannual PVIP reports

PVIP process (routine announced inspections)

Pre-inspection → Inspection → Post-inspection

Education and opportunity to ask questions

Pre-inspection (6-8 weeks)	Inspection (≈3 days)	Post-inspection
Notification and confirmation of inspection date Provision of Australian Pharmacovigilance System Summary (APSS) by the sponsor Development of inspection plan Pre-inspection document requests Pre-inspection call (1 week before inspection) Further document requests and review	Opening meeting Interviews and document requests and review to verify interview responses Closing meeting with presentation of preliminary deficiencies	Sponsor to prioritise outstanding document responses. Inspection report issued by the TGA (≤30 days) Initial Corrective and Preventative Action (CAPA) Plan provided by the sponsor (≤30 days from the issue of the inspection report) TGA evaluation and acceptance of CAPA Plan Close-out of the inspection

PVIP inspection topic areas

1) Collection and collation of adverse reactions

2) Management of adverse reactions

3) Reporting of Adverse Reactions

4) Ongoing Safety Monitoring

5) Management of Significant Safety Issues

6) Management of Reference Safety Information

7) Post-approval commitments

8) Quality Management System

9) Role of the A-PVCP and QPPVA

APVCP = Australian pharmacovigilance Contact Person
QPPVA = Qualified Persons Responsible for Pharmacovigilance in Australia

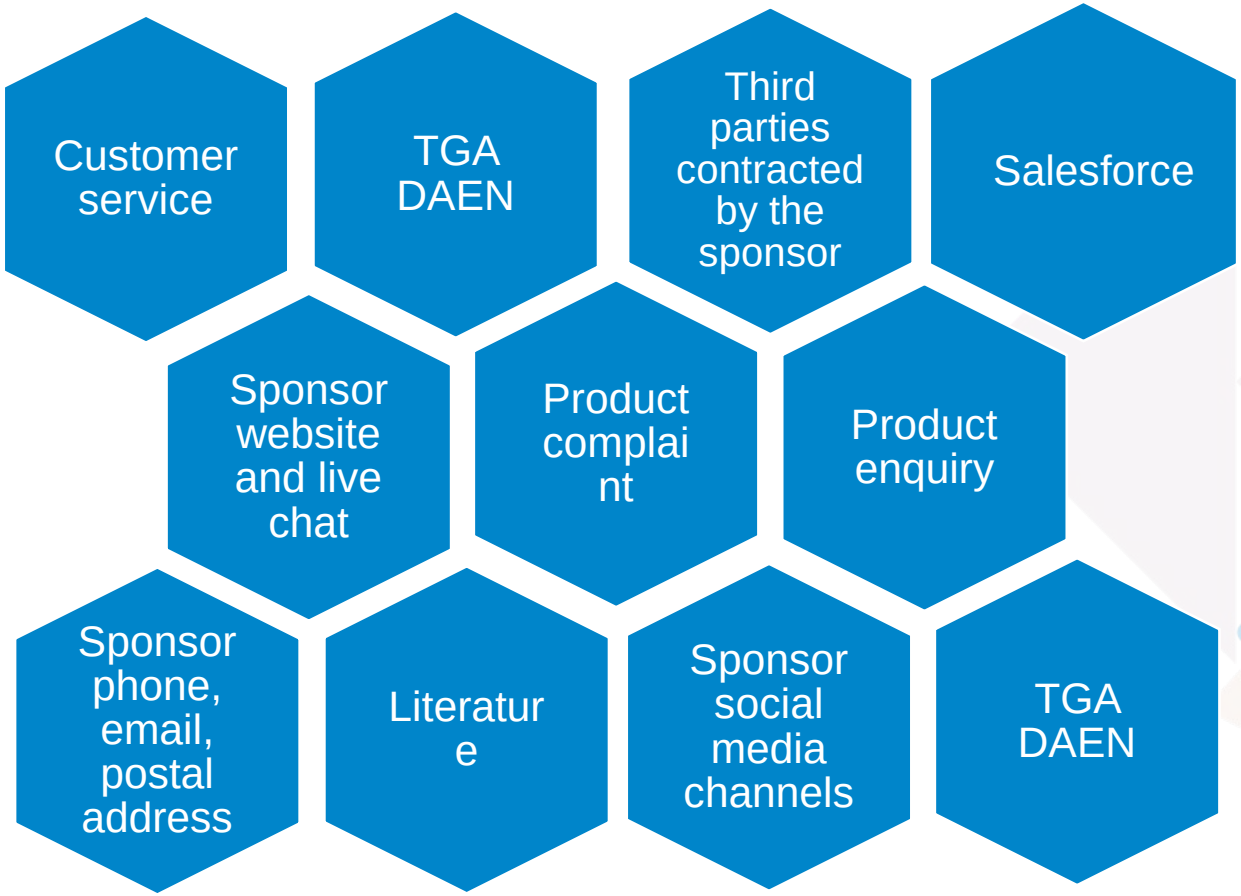
Common findings in PVIP (focus on listed medicine sponsors)

Deficiencies are frequently identified in topic areas:

- Collection, management and reporting of adverse reactions
- Quality management system
- Management of reference safety information

Collection of Adverse Reaction Reports

Common deficiencies:



- Failure to collect adverse reaction reports from **all sources**
- Failure to **identify** all safety information
- Failure to **follow up**
- Insufficient PV **training**

Knowledge check:

Q: Are you required to monitor sponsor-initiated media accounts?

Collation of Adverse Reaction Reports

Common deficiencies

- Failure to establish access to safety data from a **single access point** in Australia
- Poor **quality** reports recorded in the sponsor database/repository e.g. missing adverse reactions, inaccurate outcome or suspect product(s) recorded
- Inadequate collation of special situation reports
- Inadequate collation of invalid reports (e.g., drug-event pairs)

Reporting of Adverse Reaction Reports

Common deficiencies

- Failure to report serious adverse reaction reports within 15 days
- Incomplete and/or inaccurate reports
- Missed follow up reports

Quality Management System for pharmacovigilance

Common Deficiencies:

- Failure to implement formal written procedures for pharmacovigilance activities
- Outdated procedures
- Failure to conduct, or delayed, PV training

Quality Management System

Third-party agreements

The majority of inspections result in a deficiency regarding a contracted third-party, such as:

- Failure to implement a pharmacovigilance agreement in a timely manner upon engagement with business partners / prior to the service commencing
- Omission of important pharmacovigilance requirements from relevant third-party agreements
- Failure to clearly define pharmacovigilance roles and responsibilities between third party and the Australian sponsor
- Failure to **maintain** agreements to ensure it contains up to date information and complies with changing regulatory requirements

QMS scenario

Implementation of PVA with a third-party

You are a sponsor engaging a third party (influencer) for a social media campaign for 4 weeks for a listed medicine.

Promotion of listed medicine on the influencers Instagram and Facebook account.

Functionality of comments and direct messages will be enabled on these posts and reels.

Knowledge check:

Q: Do you need a pharmacovigilance agreement with third third-party?

a) Yes

b) No

Knowledge check:

Q: What procedures and responsibilities should be stipulated in the agreement?

- PV training of vendor
- Definition of adverse reactions, special situations, non-valid reports
- Exchange of safety information
  - Timeline
  - Method
- Reconciliation of safety information collected
- Record retention

Reference safety information

Common deficiencies

- Non-compliance with Permissible Ingredients and Permissible Indications Determinations
- Out of date labels with no process to become aware of and implement updates
- Inaccurate label information depicted in marketing materials such as social media and websites

Therapeutic Goods Administration (TGA)

Exhibition booth **No.60**

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