Pharmacovigilance responsibilities of medicine sponsors v3.0

Updated reporting requirements for safety issues

Understanding changes to the PV Guidelines

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Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Welcome

Housekeeping

- This Webinar is being recorded for data & analytics only
- The presentation will be made available in the upcoming weeks
- Q&A session will occur following todays presentation. All questions to be put through Slido ONLY.
- Live poll – how did we go, let us know
- Closed captions option available

Difficulties hearing from computer?

Check your settings located under

"**Audio & Video"** tab located top of your screen:

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How to access and use SLIDO

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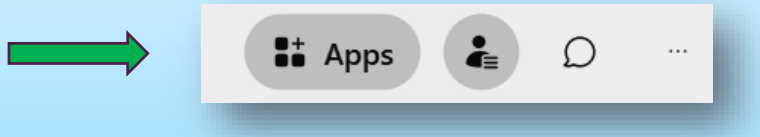


- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device

Future webinars

Webinar #3

- Dec 2023, date and time TBD
- Expected to cover learnings gained from the implementation period incorporating relevant industry feedback
- Opportunity for more Q&A

Why we've made changes

To support timely responses by the TGA to new safety information

- ✓ Clarifies requirements for urgent reporting
- ✓ Expected to increase the quality of notifications
- ✓ Will enable TGA to act on safety issues in a timeframe proportionate to the risk to public health

Key updates to PV Guidelines

- Two-tiered reporting system:
  - Significant safety issues (SSIs)
  - Other safety issues (OSIs)
- Quality defect issues remain in scope of SSI reporting if serious/urgent
- Alternative procedure for generic medicine sponsors to report COR-identified safety issues
- New safety issue reporting webform
- New safety issue reporting decision tree appended to the PV Guidelines

Two-tiered reporting system

Significant safety issues

- Require the urgent attention of the TGA
- Closely aligned with the EMA's 'Emerging Safety Issue'
- 72-hour reporting timeframe remains
- 3 calendar day timeframe for the communication from global to Australian affiliate

Other safety issues

- Safety related changes requested by CORs (that do not fit the definition of SSI)
- Safety issues from other sources that have been internally assessed and confirmed
- Report within 30 days

SSIs

- **Include:**
  - certain major safety-related actions by CORs,
  - major safety issues from studies, clinical trials, spontaneous reporting or published literature, and
  - serious quality defect issues
- **MUST** be reported ASAP and no later than **72 hours** following Australian sponsor awareness
- Communication from global to Australian personnel in no more than **3 calendar days** from global awareness – ***new requirement***
- Notification via the medicine safety issue webform – should contain information available at the time of initial reporting
- **DOES NOT** require a completed internal assessment at the time of notification

OSIs

- Safety issues that do not meet the definition of SSI

- **MUST** be reported within **30 calendar days** following Australian sponsor awareness of an **assessed** safety issue

- Your procedures should ensure that OSIs will be communicated from global to Australian personnel **in a timely manner**

- Notification via the medicine safety issue webform

- Internal assessment must be completed at the time of notification

What do we mean by **internally assessed**?

- A description of the safety issue
- The source
- Any available evidence
- Your assessment of the risk and potential impact of the issue in the local context
- COR requests: **Any action you propose to take in Australia** – or justification for no further action; OR

  Safety issues from other sources: **Any action you propose to take in Australia**

Alternative procedure for sponsors of generic medicines to report COR-identified safety issues

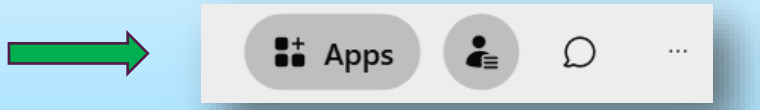
- Where a safety issue is identified via a COR action or request, sponsors of generic medicines can ‘report’ this via a timely submission to align their generic medicine PI with the innovator PI

- Where there is no identifiable Australian innovator product, or the innovator product has been withdrawn from the ARTG, the obligation to identify and report the safety issue, as per the SSI or OSI timeframes, lies with the generic sponsor

- This does not absolve generic sponsors of the obligation to identify and report all other safety issues (i.e. not COR-identified), as per the SSI or OSI timeframes

Q&A and POLLs

Slido App



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Safety issue reporting webform

Home > Guidance and resources > Resources > Forms

Medicine safety issues – Electronic notification form

For medicine sponsors to report medicine safety issues to the TGA

Listen Print Share

You are legally responsible to meet your pharmacovigilance reporting requirements for all the medicines you have registered or listed on the Australian Register of Therapeutic Goods (ARTG), regardless of marketing status. Please refer to the Pharmacovigilance responsibilities of medicine sponsors guidance document for further information.

Please submit a separate form for each safety issue you wish to report.

6 month implementation period

- **1 August 2023 – 31 January 2024**

- SSIs continue to require reporting within 72 hours

- All other changes to the PV Guidelines are encouraged but will not be enforced or inspected against during this period

- From 1 February 2024, PV Guidelines version 3.0 will be in full effect

Questions and Answers

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Survey - Poll

How did we go?

Don’t forget to complete the feedback poll!

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey

Contact Us

For enquiries related to SSIs and OSIs contact
SI.Coordinator@health.gov.au

For all other PV Guidelines related enquiries contact
pharmacovigilance.enquiries@health.gov.au

More information

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Department of Health and Aged Care

Therapeutic Goods Administration