

Update from the Pharmacovigilance Branch

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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration



Overview

- Findings of pharmacovigilance inspections
- Changes to safety reporting requirements – observations one year on
- Improving how we share adverse event data
- Increasing the reach of our safety communications
- Best practices for sponsors responding to medicine shortages



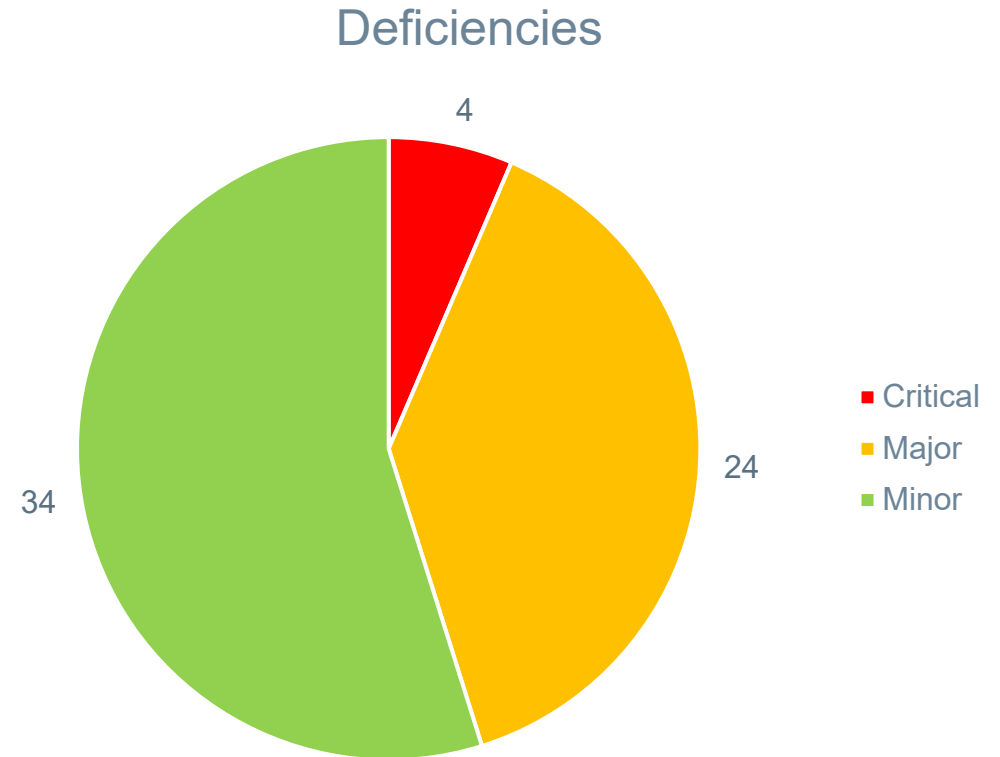
Pharmacovigilance Inspection Program

Findings and outcomes

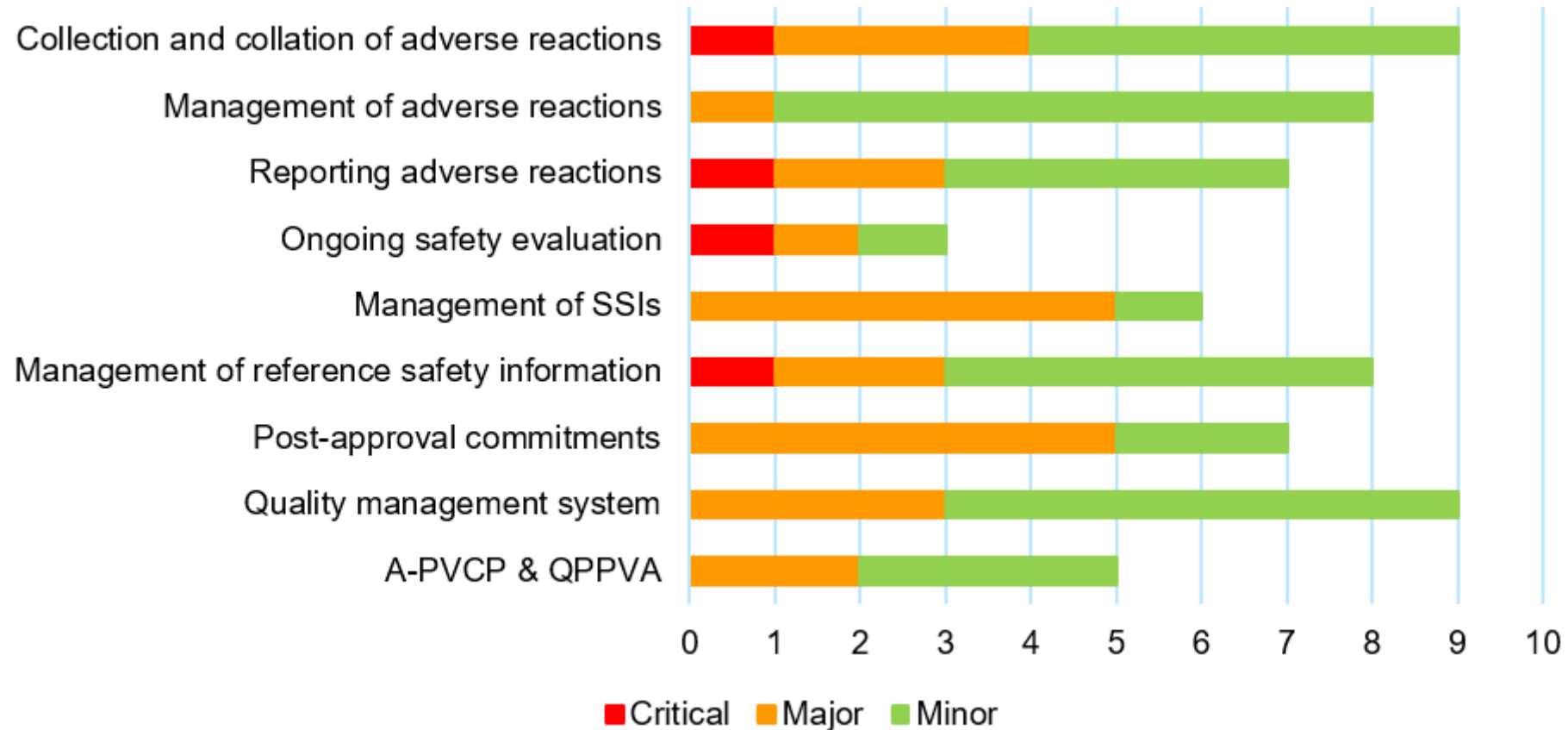


Pharmacovigilance inspections in 2022

- Nine pharmacovigilance inspections conducted
- Average 6.9 deficiencies per inspection



Number and grading of deficiencies in 2022



Critical: Collection and collation of adverse drug reactions

Specific findings that contributed to the deficiency were:

- Failure to perform case collection from the TGA's Database of Adverse Event Notifications (DAEN)
- Failure to monitor a sponsor-initiated social media account to collect spontaneous adverse reactions
- Failure to develop an Australian website to facilitate the collection of safety information from Australia
- Deficiency in the global literature search strategy
- Deficiencies in the reconciliation process

Critical: Reporting adverse reactions

Specific findings that contributed to the deficiency were:

- No on time reporting of serious adverse reactions reports to the TGA.
- Multiple examples of non-reporting and late reporting of serious adverse reactions reports to the TGA over a period of time were identified
- Failure to comply with pharmacovigilance record keeping obligation for SAR reports to the TGA

Critical: Ongoing safety evaluation

Specific findings that contributed to the deficiency were:

- Failure to collate individual cases into safety database
- Failure to perform cumulative review of safety information for signal detection

Critical: Management of reference safety information

Specific findings that contributed to the deficiency were:

Failure to implement mandatory warning statement as described in

- Therapeutic Goods (Permissible ingredients) determination
- TGO 92

Failure to implement an indication in line with the Therapeutic Goods (Permissible indications) Determination

Inaccurate information on sponsor's website

Lack of written procedures for the management of reference safety information

Third-party agreements – examples of findings

Seven sponsors inspected in 2022 received a deficiency regarding a contracted third party

Specific findings included:

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

Changes to pharmacovigilance reporting requirements

Observations



Changes to reporting requirements in 2023

Significant safety issues

- 72-hour reporting timeframe
- Closely aligned with the EMA 'Emerging Safety Issue'
- Require the urgent attention of the TGA

Other safety issues

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

What we've seen since the changes

- ✓ An increase in quality of the SSI and OSI reports being provided to the TGA
- ✓ Sponsors are mostly identifying and notifying the TGA of SSI appropriately

Common scenarios

A COR requests a signal review that results in a sponsor-initiated safety related update to overseas labelling. Does this meet the definition for reporting to the TGA as an OSI?

A COR requests a signal review that results in a sponsor-initiated safety related update to overseas labelling. Does this meet the definition for reporting to the TGA as an OSI?

Yes, this is considered a safety issue ‘from any other source’.

“Types of OSIs include:

- *safety issues from any other source that have been internally assessed and confirmed with subsequent risk mitigation strategies determined (that do not meet the definition of an SSI).”*

Page 17, Pharmacovigilance responsibilities of medicine sponsors

Common scenarios

A sponsor's regulatory affairs team has already submitted an SRR to the TGA in response to an OSI. Does the TGA still need to be notified of the OSI?

A sponsor's regulatory affairs team has already submitted an SRR to the TGA in response to an OSI. Does the TGA still need to be notified of the OSI?

Yes, a safety-related request submission is not an OSI notification.

Safety-related actions by overseas regulators

SSI reporting is required following major safety-related actions by comparable overseas regulators (CORs):

- the withdrawal or suspension of the medicine's availability
- the modification or removal of an indication (for safety reasons),
- or the addition of a boxed warning or contraindication to the PI document or label.

TGA expects that the Australian PI/CMI is subsequently updated in line with overseas regulators where safety-related changes have been implemented.

Improving sharing of adverse event data

The MAEDX project



Improvements to sharing of AE data

New DAEN – medicines

Automated AEFI sharing

Sponsor adverse event search

Sponsor self-service – November 2023

Search parameters

Report date* Search for reports from 1 July 2018 to 14 days ago

01/07/2018 16/05/2023

Modified date* Search for cases that have been modified recently

01/07/2018 30/05/2023

Medicines

All selected

System organ class

All selected

MedDRA reactions

All selected

Report type

All selected

Causality Identify accepted, rejected and withdrawn cases

3 selected

Case identifiers Search by TGA ID, ICSR identifier, etc

Report source Identify reports submitted by your organisation or others

All selected

Age range

All selected

Sex

All selected

How does it work?

Accessed via TGA online

Use eBS credentials to login.

- ✓ Users can only see reports relevant to their organisation
- ✓ New user guidance is available

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Adverse Event Reporting

[Back to tga.gov.au](#)

Welcome

Why report an adverse event?

The TGA monitors adverse events (such as side effects) related to medicines and vaccines to safeguard and enhance the health of the Australian community. Unfortunately, it is not possible to know all potential adverse events of a medicine or vaccine before it is approved for use.

When people tell us about their experiences using a particular medicine or vaccine, it helps us to monitor the safety of those products.

More information: [Reporting adverse events involving medicines, vaccines or medical devices.](#)

About reporting

We prioritise issues that may:

- have adverse health consequences for consumers as a result of public access to dangerous or inappropriate goods,
- affect confidence in our regulatory processes or contribute to a loss of confidence in therapeutic goods in Australia.

Report an adverse event to a medicine

You can submit an adverse event as either a registered or unregistered user. As a registered user, your contact details will be pre-populated, you can save drafts and also view or amend previously submitted reports.

You can report adverse events of any medicine or vaccine, including medicines you get on prescription and over-the-counter, or complementary medicines that you buy from a pharmacy, supermarket, health food shop or the internet.

If you believe you are experiencing an adverse event it is important to speak to a health professional.

[Login](#) [Register](#) [Report \(without registering\)](#)

Download CLLs and PCDs

Search results - 3 cases found (3 selected)

Report name:

[Generate PCD](#) [Generate CLL](#) [View reports](#)

Show entries

<input checked="" type="checkbox"/>	TGA Case ID	Report date	Serious	Sender type	Age	Sex	Medicines	Reactions	Modified on
<input checked="" type="checkbox"/>	AU-TGA-0000475588	01/09/2022	No	Patient/Consumer			COVID-19 Vaccine (TNS) (active ingredients: COVID-19 Vaccine (TNS)) - Suspect; Tradename not specified (active ingredients: Ibuprofen lysine) - Suspect	Headache	10/10/2022
<input checked="" type="checkbox"/>	AU-TGA-0000420328	06/08/2021	No	Health Professional	41	Male	Tradename not specified (active ingredients: Amantadine hydrochloride) - Suspect	11-beta-hydroxylase deficiency	20/08/2021
<input checked="" type="checkbox"/>	AU-TGA-0000417588	03/08/2021	Yes	Pharmaceutical Company	2		Tradename not specified (active ingredients: Paracetamol) - Suspect; Tradename not specified (Product not coded) - Concomitant	Pyrexia	04/08/2021

Safety communications

Increasing our reach



Publishing safety-related updates for medicines and vaccines

- Product Information updates are listed every month on the TGA website:
- *Medicine Safety Update* articles are published for critical safety issues or topics of special interest
- Summaries of *Medicines Safety Update* articles appear in *Australian Prescriber*
- PI updates and Medicines Safety Update articles are through the Primary Healthcare Networks.

The logo for Australian Prescriber features the word "Australian" in a large, bold, purple font. The letter "A" is stylized with a pink and red circular element. Below it, the word "Prescriber" is written in a similar bold, purple font.

AN INDEPENDENT REVIEW

australianprescriber.tg.org.au

Promoting adverse event reporting

- Updated learning module for healthcare professionals on why, how and what to report to the TGA
- Social media campaign for general public to report suspected adverse event reports to therapeutic products



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**Every report helps to keep others safe.
You don't need to be certain, just suspicious.**



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Report adverse events to help keep other Australians safe.



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You can report an adverse event online or over the phone.

Medicine shortages

Best practices for managing
and communicating about
shortages



Responding to medicine shortages

Act early

- Tell the TGA about potential shortages as early as possible
- Invest early in planning communication and managing supply
- Tell us about regulatory processes that could facilitate supply

Develop a communication plan

- Distribute information to key stakeholders as soon as practical
- Consider publishing your own webpage about the shortage
- Work with us to ensure consistent messaging

Responding to medicine shortages

Take actions to manage supply

- Constraining and/or allocating orders to wholesalers.
- Holding emergency stock for patients who are unable to use alternatives during the shortage.
- Consider applying for a section 19A approval

Therapeutic Goods Administration (TGA)

Exhibition booth No.1

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