Update from TGA's Pharmacovigilance Branch – June 2026

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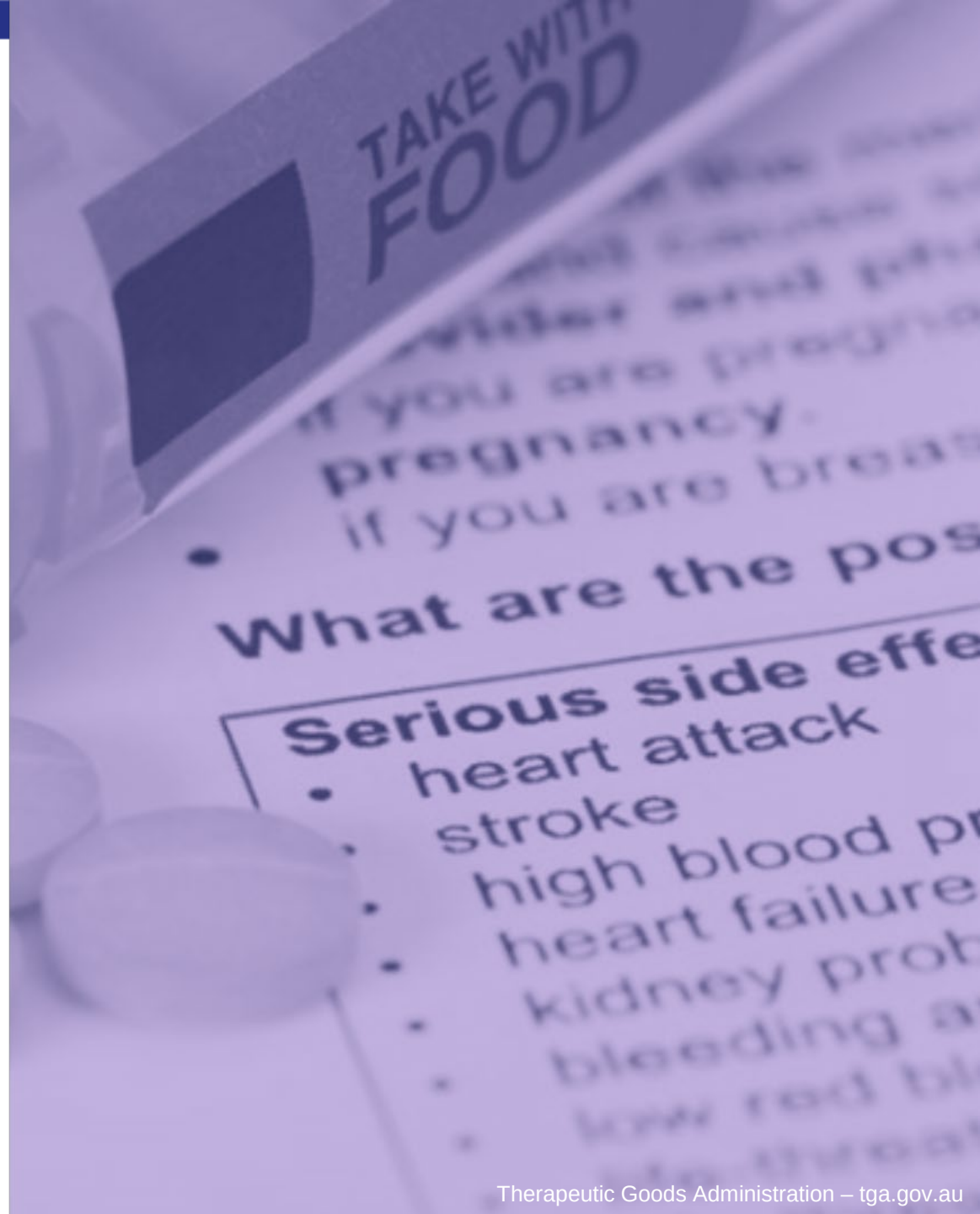
Session overview

- Reporting adverse events to the Therapeutic Goods Administration (TGA)
- Aligning PI updates with international regulators
- Black Triangle scheme update
- TGA safety communication
- Vaccine surveillance scenarios
- Medicine shortages update
- Pharmacovigilance inspection program



Pharmacovigilance at the TGA

Collect adverse events

+ manage adverse events database

Detect & investigate safety signals

+ regulatory action for medicines & vaccines

Monitor medicine defects

& monitor adverse events for complementary medicines

Manage medicine shortages

+ medicine shortages communication

Evaluate risk management plans

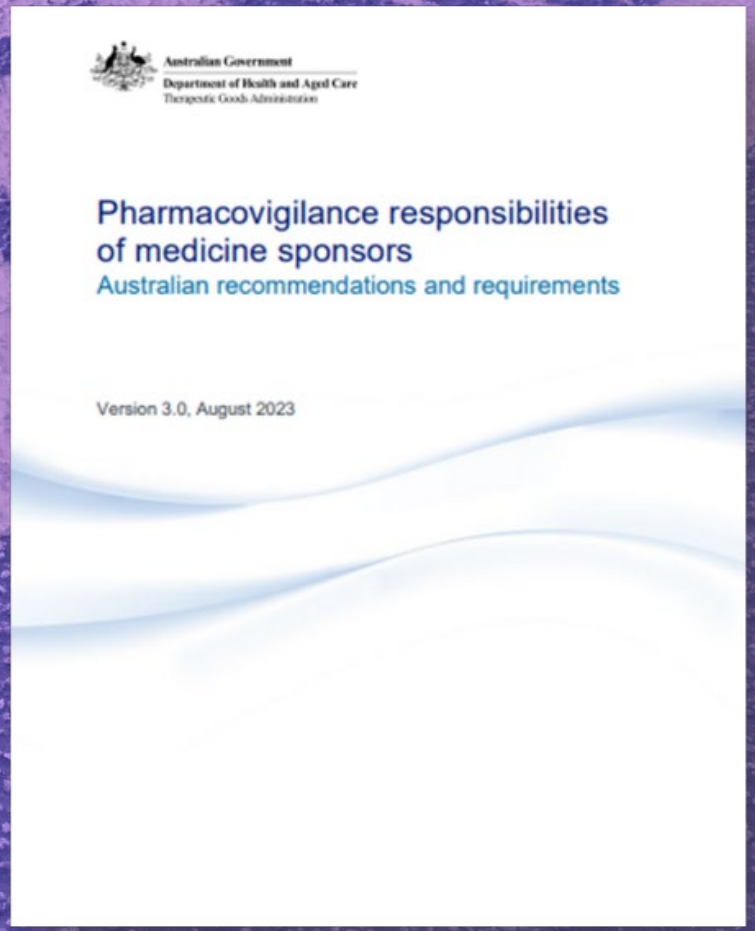
Manage access to clinical trials

Assess COVID-19 vaccines claims

Deliver Pharmacovigilance inspection program

+ Good Clinical Practice inspection program

Medicine adverse event report collection and monitoring



Reporting adverse events to the TGA

Significant safety issues – SSIs

- 72-hour reporting timeframe
- Closely aligned with the European Medicines Agency's 'emerging safety issues'
- Require the TGA's urgent attention

Other safety issues

- 30-day reporting timeframe
- Safety-related changes recommended by comparable overseas regulators (that do not fit the definition of a significant safety issue)
- Safety issues from other sources that have been internally assessed and confirmed

Improving readability of case narratives

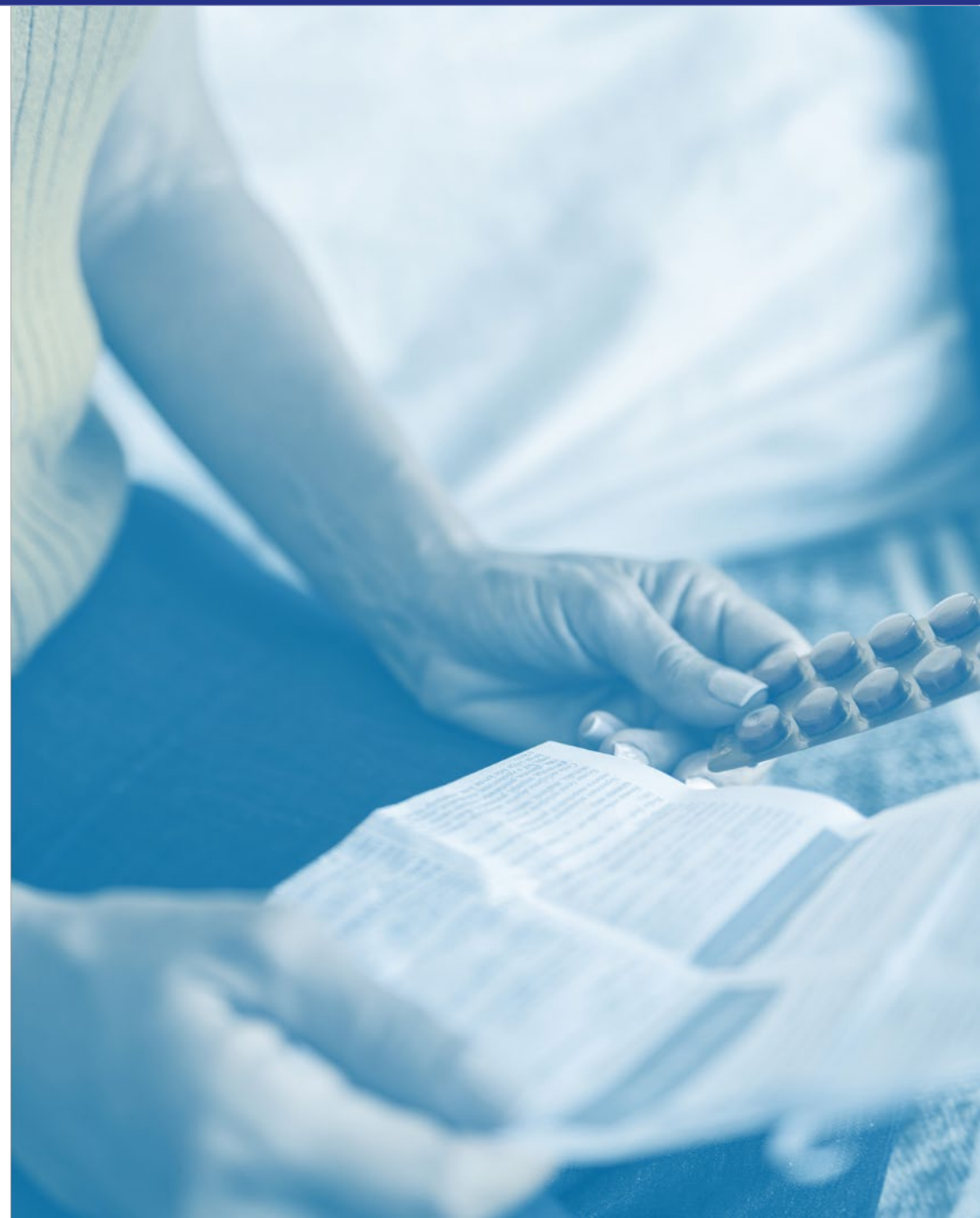
You can help!

- Please increase the spacing between lines and paragraphs, and add paragraph returns where possible
- Add subheadings to add structure and meaning to large blocks of text
- Use bullet points to highlight and summarise information

Thank you!

Aligning Australian Product Information with comparable overseas regulators’

When an overseas regulator adds safety information to their Product Information or Consumer Medicine Information, the Australian PI and CMI should be updated by the sponsor accordingly.



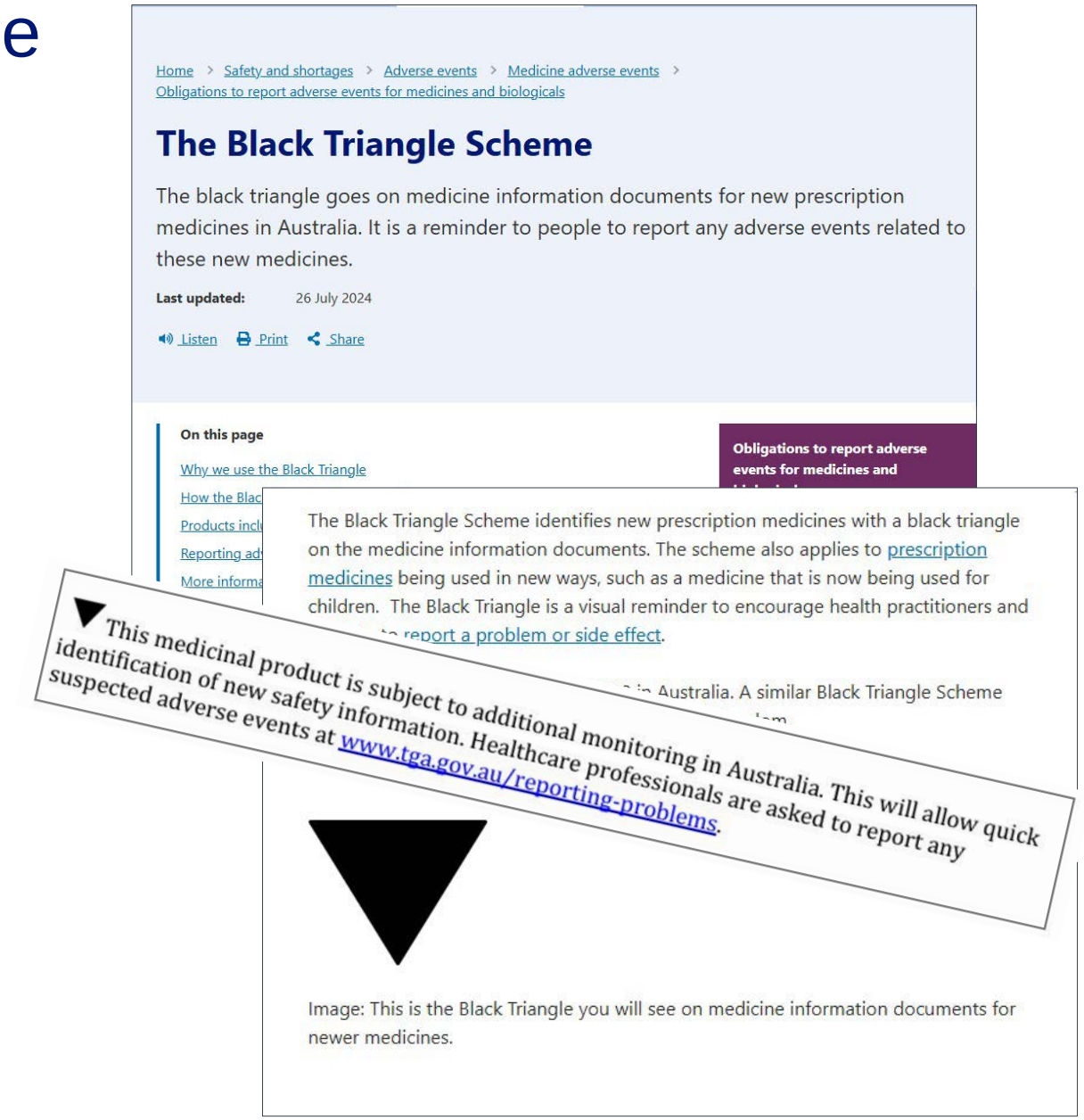
About the Black Triangle scheme

The **Black Triangle** is a reminder to health professionals and consumers to report suspected adverse events related to new medicines. It also applies to medicines being used in significantly different ways (for additional diseases, conditions or patient groups).

Products included in the scheme feature the black triangle symbol and accompanying text on:

- Product Information (PI) documents
- Consumer Medicine Information (CMI) documents
- other TGA material and literature.

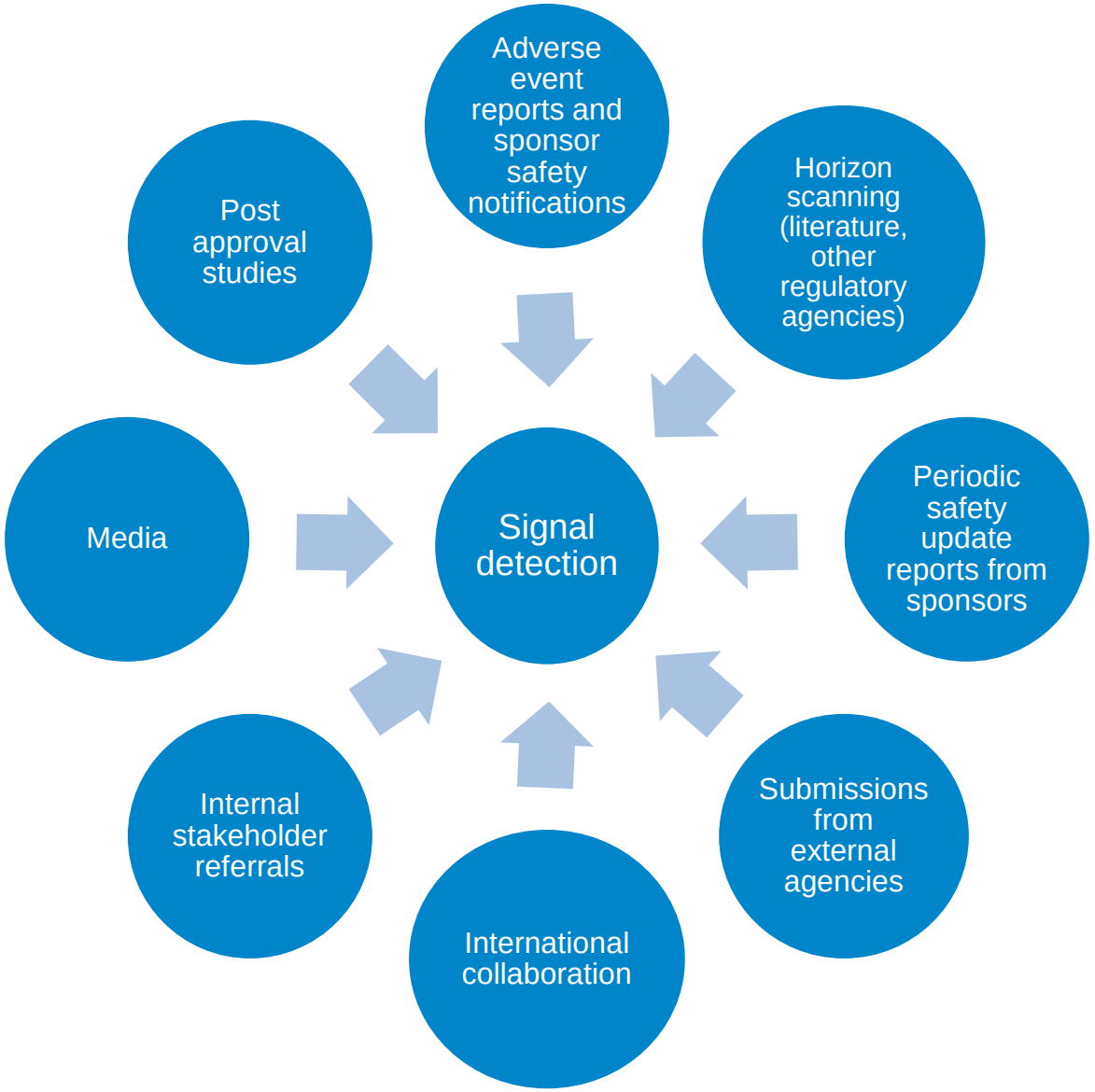
Inclusion in the Black Triangle Scheme is applied as a condition of registration.



Exiting the Black Triangle scheme

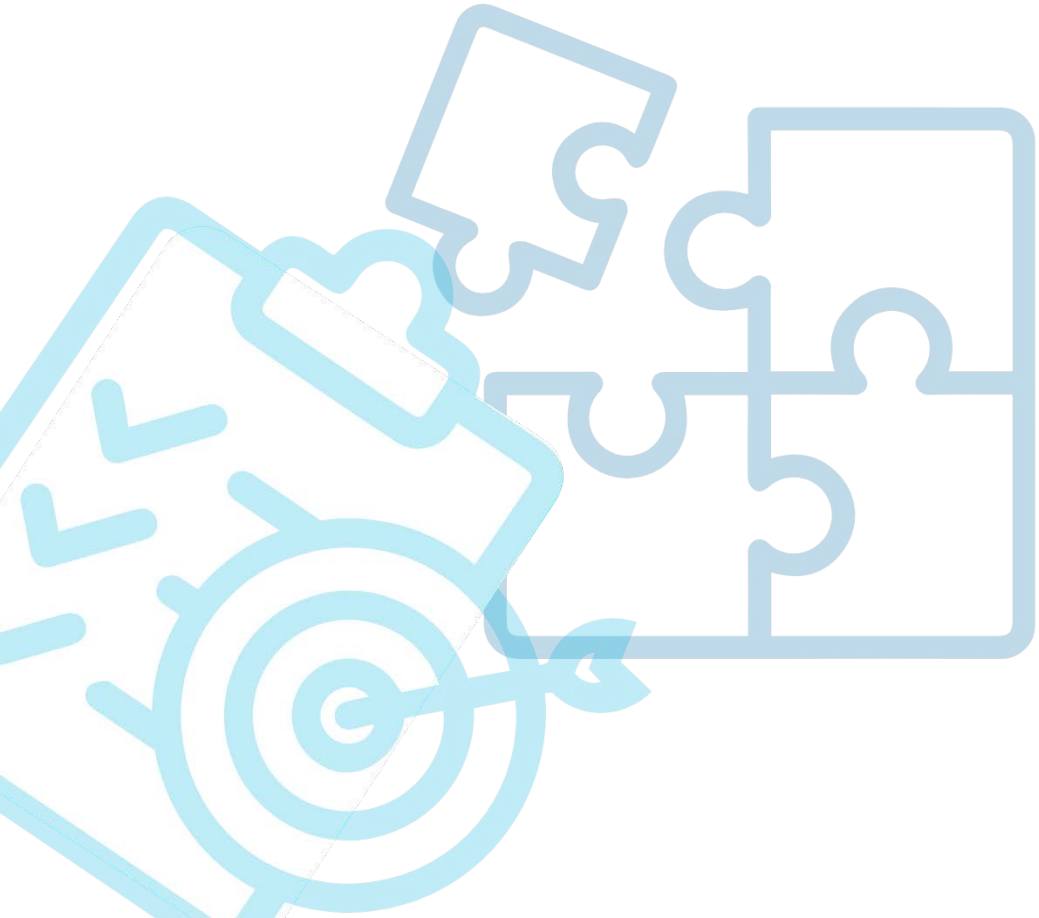
- The **black triangle symbol** and accompanying text are required to be included in the PI and CMI for a period of 5 years from the date of first supply or as specified in the approval letter for the product.
- At the end of this period, the requirement to include the black triangle symbol and text no longer applies.
- To remove the black triangle symbol and accompanying text, sponsors must submit a revised PI as a minor editorial change (MEC) application under section 9D(3) of the Therapeutic Goods Act 1989. (Variations to prescription medicines - excluding variations requiring evaluation of clinical or bioequivalence data: process guidance.)

How we identify safety signals



Outcomes after a signal investigation

- Ongoing routine monitoring
- Update Product Information, such as addition of warnings and precautions, restriction to indications
- Changes to information on the label



- Safety communication:
  - Safety alert
  - Medicines safety update (MSU) article
  - Targeted communication to health professionals
- Changes to Risk Management Plan
- Cancellation, recall, suspension or variation of conditions for a medicine/vaccine

TGA safety communication

- Product Information updates are listed monthly on the TGA website
- Medicine Safety Update articles are published on the TGA website when the information is clinically important or of special interest
- Safety alerts with a consumer focus are published on the TGA website when appropriate, and distributed via social media
- Summaries and links to Medicine Safety Update articles appear on the *Australian Prescriber* website and are disseminated via the Primary Health Network and social media

TGA Medicine Safety Updates

3 June 2025 Medicines containing GLP-1 and dual GIP/GLP-1 receptor agonists

23 June 2025 Correct administration of RSV vaccine and antibody products

26 September 2025 Results of our investigation into the safety and efficacy of Vyvanse

2 October 2025 Risk of overdose in infants when using prilocaine/lidocaine cream (EMLA and generics)

16 October 2025 New warning on hepatotoxicity risk for Veoza (fezolinetant)

21 November 2025 Strengthened warnings for fracture risk after discontinuation of denosumab (Prolia and biosimilars)

1 December 2025 Updated contraception advice for Mounjaro (tirzepatide)

1 December 2025 GLP-1 RAs: warnings aligned over potential risk of suicidal thoughts or behaviours

19 February 2026 Medicines containing vitamin B6 (pyridoxine, pyridoxal or pyridoxamine)

18 May 2026 Tranexamic acid: risk of serious adverse events after inadvertent spinal administration

Enhanced vaccine safety surveillance

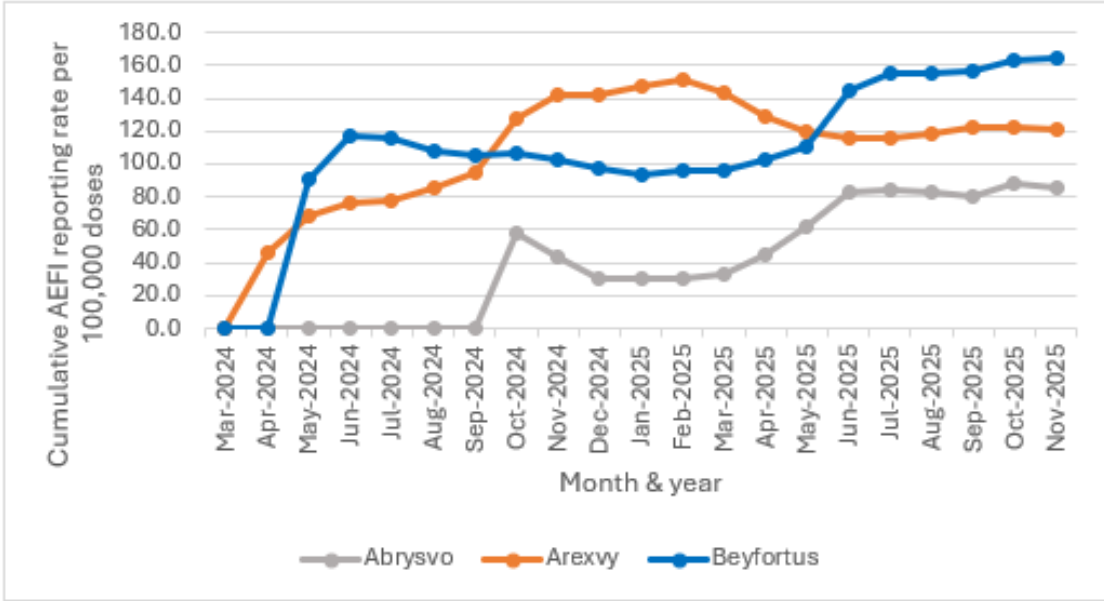
Each year, we conduct *enhanced* surveillance of certain vaccines, such as those recently added to the National Immunisation Program and seasonal influenza vaccines where preparations change slightly from year to year.

This involves detailed monthly analysis of adverse event reports (and dose data) for specific vaccines to detect and investigate signals early and take regulatory action if required.

Respiratory syncytial virus (RSV) enhanced surveillance

- Conducted in 2024 and 2025 as multiple new RSV vaccines/prevention products first became available in Australia
- Monitoring of most frequently reported adverse events following immunisation (AEFI), serious AEFIs, AEFIs of special interest, reporting rates, disproportionality analyses, safety notifications
- Enhanced surveillance resuming in 2026 with Arexvy now on National Immunisation Program for older Australians

Chart 17: Cumulative AEFI reporting rate per 100,000 doses for Arexvy, Beyfortus, and Abrysvo, charted by month (based on AEMS data and AIR dose data from 1 January 2024 to 30 November 2025, data extracted on 8 December 2025*, CM D25-5506847)



Example signal investigation

RSV prevention products and administration errors

Error reports across 3 RSV prevention products:

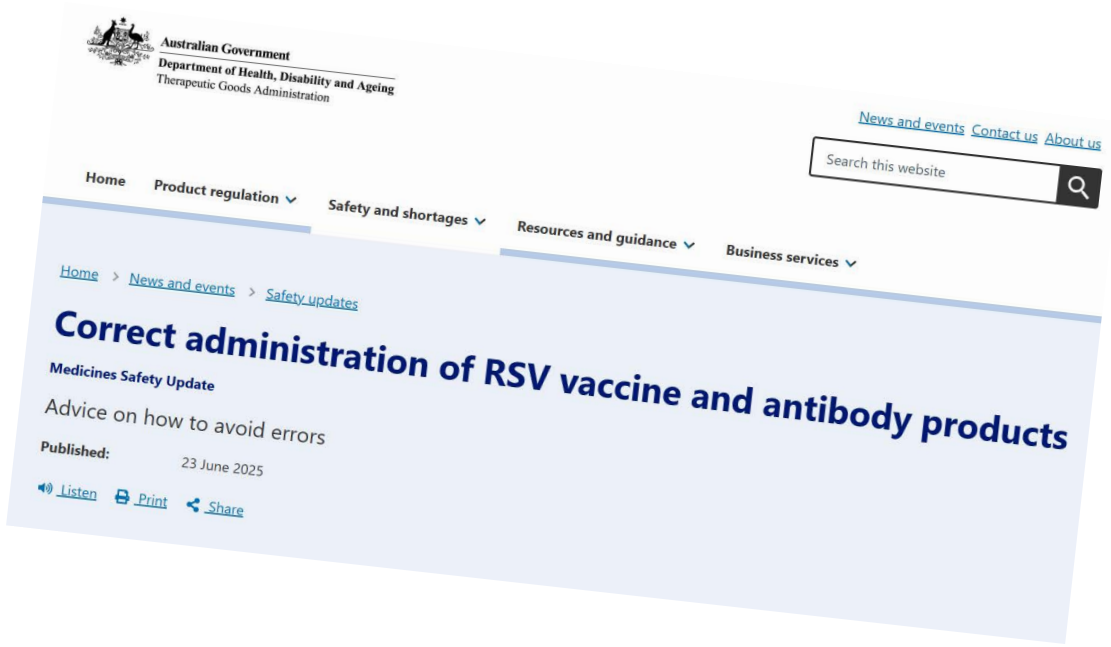
- Arexvy being given to pregnant women
- Abrysvo being given to children < 12 months of age
- Beyfortus being given to pregnant women

Example signal investigation

RSV prevention products and administration errors

Actions

- Medicines Safety Update by the TGA
- Referral to the Australian Technical Advisory Group on Immunisation Practices (ATAGI) who also published a statement on the prevention of administration errors
- The RSV Chapter in the Australian Immunisation Handbook (AIH) was updated on 31 July 2025 to include information about administration errors
- Update to prescribing software to remove ‘generic RSV vaccine’ prescription option

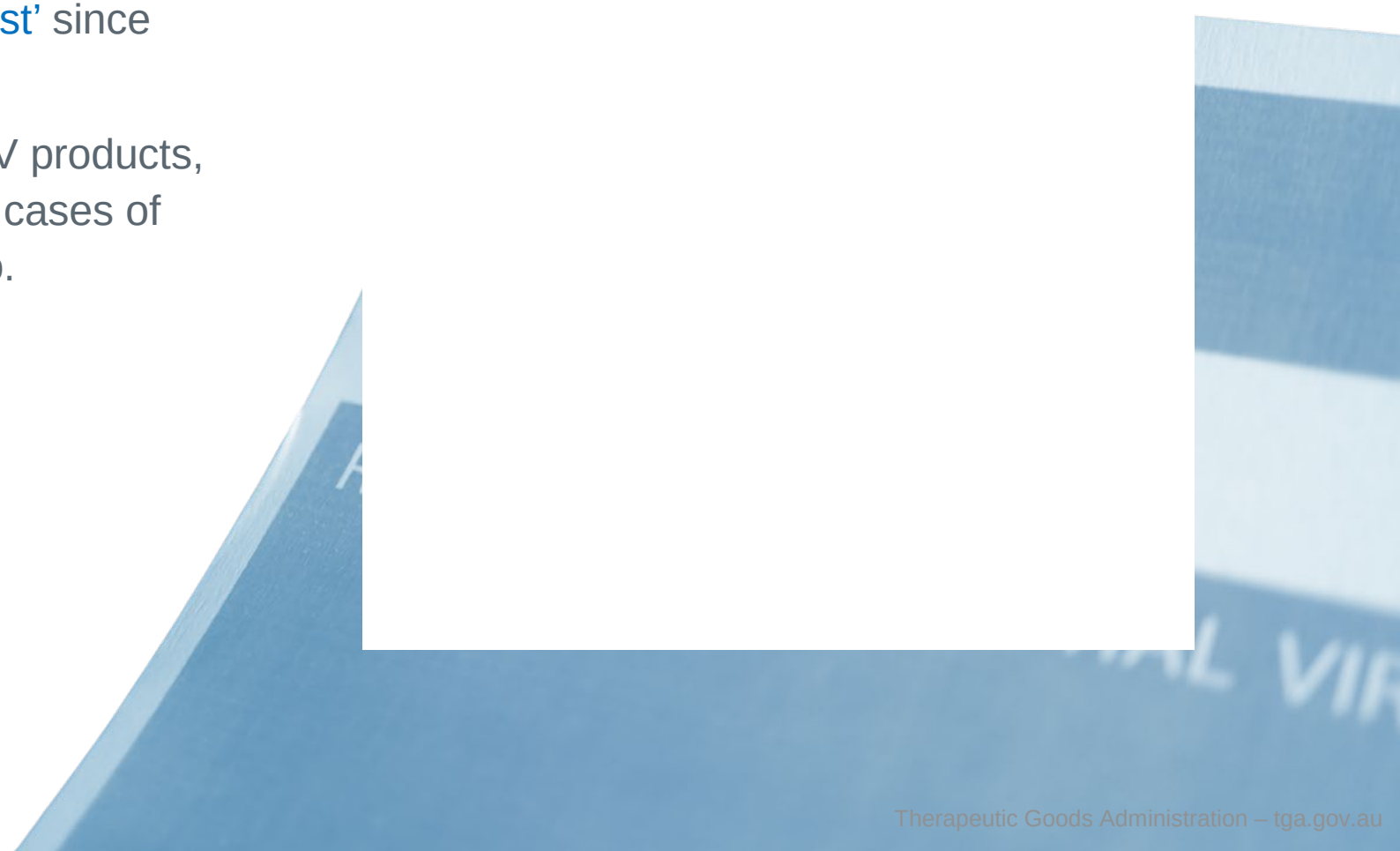


Example signal investigation

Abrysvo and preterm birth

Preterm birth was being monitored by the TGA as an ‘adverse event of special interest’ since Abrysvo registration.

During enhanced surveillance for RSV products, the TGA received reports of 8 unique cases of preterm birth associated with Abrysvo.



Example signal investigation

Abrysvo and preterm birth

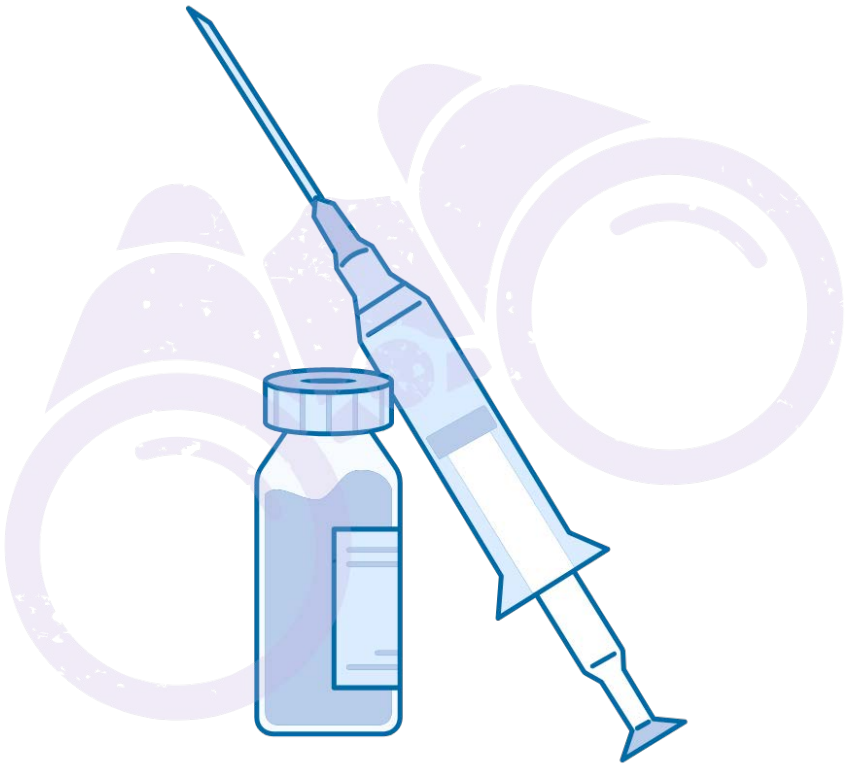
Outcome

- ACV agreed available data insufficient to demonstrate a causal association
- Reports submitted to TGA did not, in isolation, warrant referral to the National Immunisation Division or ATAGI for programmatic action
- ACV encouraged ongoing cross-agency collaboration to jointly explore opportunities to improve data sharing/capture in support of the ongoing surveillance of this signal

Influenza vaccine enhanced surveillance

Conducted annually since 2023

Monitoring of most frequently reported AEFIs, serious AEFIs, AEFIs of special interest, reporting rates, disproportionality analyses, safety notifications.



AEFIs of special interest monitored for influenza vaccines:

- Guillain Barre syndrome
- Myopericarditis/pericarditis
- Seizure and febrile convulsions
- Fever
- Cerebrovascular accidents

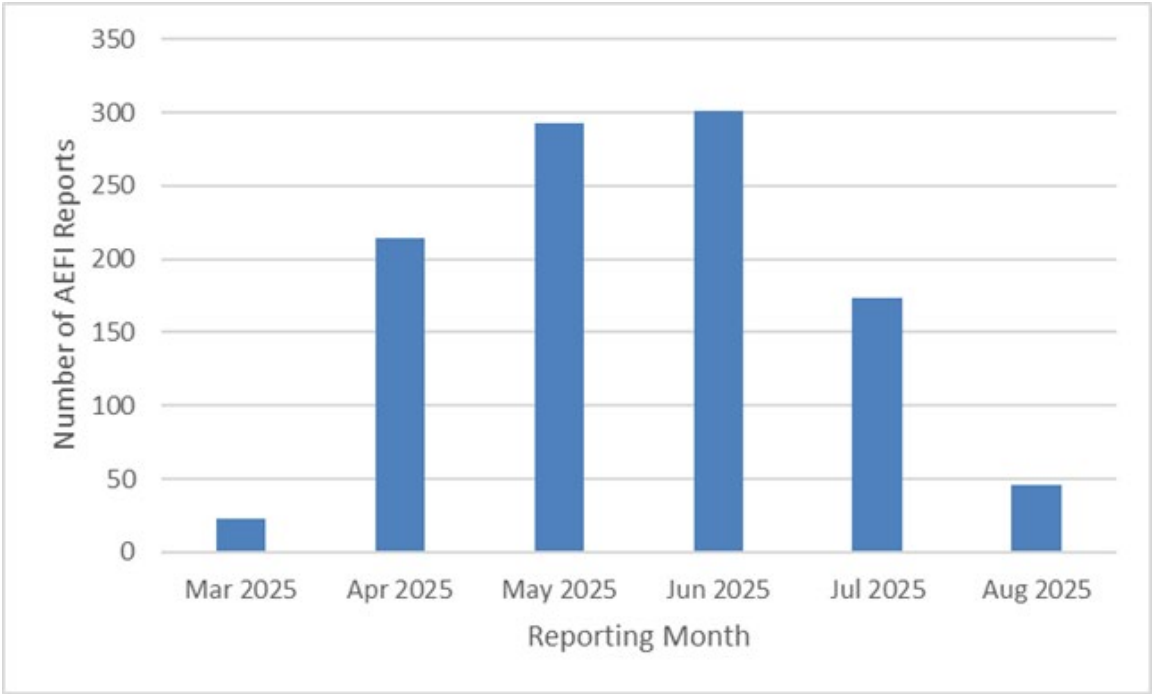
Influenza vaccine enhanced surveillance

In 2025, most AEFI were non serious and listed in the product information

Example signal investigation:

Shoulder injury related to vaccine administration (SIRVA) disproportionately reported with influenza vaccines – referred to ATAGI.

Number of AEFI Reports for Influenza Virus Haemagglutinin per Reporting Month



Medicine Shortages update

Monitoring impacts on the medicine supply chain

How you can assist

- Notify the TGA of any current or anticipated supply disruptions, and flag Middle East-related impacts
- Update existing notifications if impacts have changed
- Contact the TGA if you are unsure or have any other insights related to supply:

medicine.shortages@health.gov.au

TGA medicine shortages and discontinuations improvements roadmap

Priority Outcome 1
Updated legislative framework to better meet information needs

Priority Outcome 2
Critical improvements to data and digital infrastructure

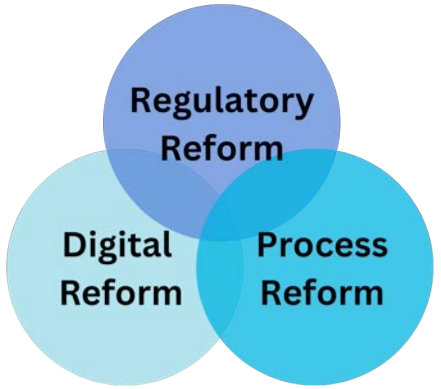
Priority Outcome 3
Better access to shortages information for health professionals

Priority Outcome 4
Better sponsor predictions on medicine demand and shortages

Priorities announced

November 2024

Improving the way we monitor, manage impacts and communicate about medicine shortages and discontinuations in Australia.



Progress over the last 12 months

Legislative proposals

Minor amendment to the *Therapeutic Goods Act 1989* (the Act) to enable earlier approval of s19A applications and their communication

(**Priority Outcome 1**)

Proposed Act changes to improve monitoring of shortages and discontinuations

(**Priority Outcome 1**)

Proposed changes to enable confidential sharing of data with other government agencies to support emergency preparedness and response to supply chain vulnerabilities

(**Priority Outcome 1**)

Non-legislative proposals

Improvements to the form and guidance for applications under section 19A

(**Priority Outcome 2**)

Development of a formal communication framework to improve access to shortages information for health professionals

(**Priority Outcome 3**)

Progress with legislative proposals

Information sharing to support health emergency preparedness and response to supply chain vulnerabilities

- Enable confidential sharing of therapeutic goods information with the Office of Supply Chain Resilience

Improving monitoring of medicine shortages and discontinuations – requiring amendments to the Therapeutic Goods Act 1989

- Require sponsors of any approved medicine to provide the TGA with detailed supply information on request
- Require sponsors to provide 12 months' notice of a decision to permanently discontinue a reportable medicine in Australia

Improving communication

Medicine Shortages Communication Framework

- Formal framework to improve communication about medicine shortages and discontinuations, and coordinating mitigating actions
- The framework is under development – industry stakeholders will have opportunities to provide feedback

Medicine shortages education campaign – 2026

- Priority topic for the TGA
- Continuation of the 2025 campaign (*Tools to manage medicine shortages*) – focusing on prescribers

For more information

Visit our website to see what we're doing to improve the monitoring of medicine shortages and discontinuations and reduce their impact:

www.tga.gov.au

Update on the Pharmacovigilance Inspection Program (PVIP)

Inspection program status

The program is integral to the TGA post-marketing monitoring of medicines and vaccines included on the ARTG.

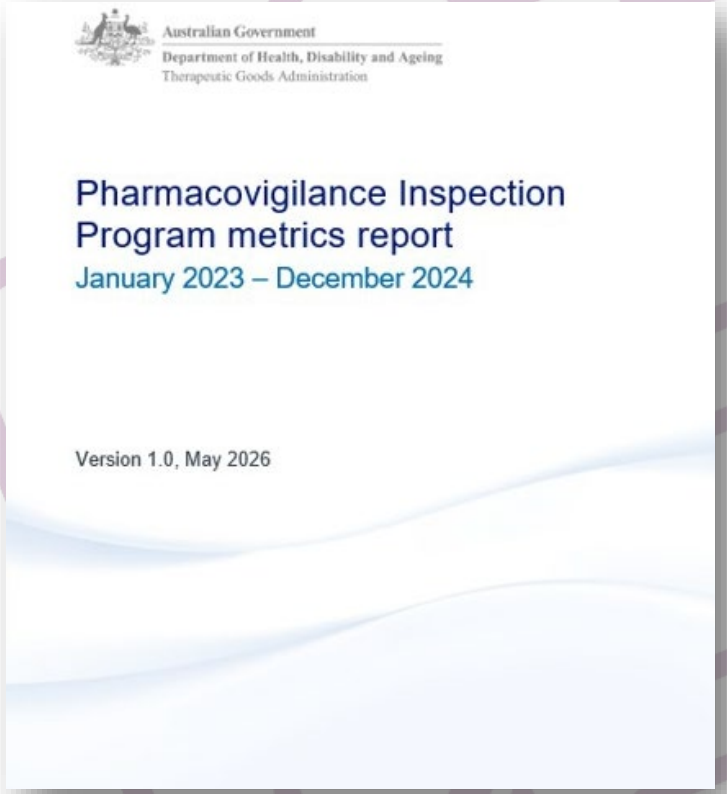
The PVIP is an established program, now in its 9th year.

The program is constantly evolving, including:

- Revamped approach to Metrics report (2023-2024)
- Sponsor feedback following inspection
- Increased delivery of inspections and education

Metrics report – summary of changes

- Annual reporting > biennial reporting frequency
- Most common areas of non-compliance still presented but in a more concise format
- Avoided duplication of the Guidelines and focused on actual examples of non-compliance
- More information and context provided for critical deficiencies
- Insights on compliance over time shared



Post-inspection feedback

Inviting sponsor feedback post-inspection is now embedded as a routine part of inspection lifecycle.

Sponsor feedback has indicated that the changes being implemented to the program are of benefit.

Sponsor feedback about inspections

Overall…

- Strong positive experience
- High educational value
- Effective inspection delivery
- Clear and actionable reporting

Sponsor feedback about inspections

But also… some key challenges and areas for improvement

- Pre-inspection burden
- Inefficient data collection
- Fit-for-purpose issues
- Resourcing and business impacts

Changes to inspection format and program delivery

Goal	Progress
Increase number of inspections	Two-fold increase in inspections
Shortening the duration of inspections to reduce disruption	Introduction of 2-day inspections
Identify areas of specific need and provide targeted education	Ongoing
More focused document requests	Ongoing

Metrics report insights

Pharmacovigilance inspections 2023 to 2024

- 14 pharmacovigilance inspections were conducted – 13 routine, 1 re-inspection
- Total of 98 deficiencies
- Average of 7 deficiencies per inspection

- Hybrid inspection format
- Inspected the pharmacovigilance systems of sponsors of both registered and listed medicines

Metrics report insights

Pharmacovigilance inspections 2023 to 2024

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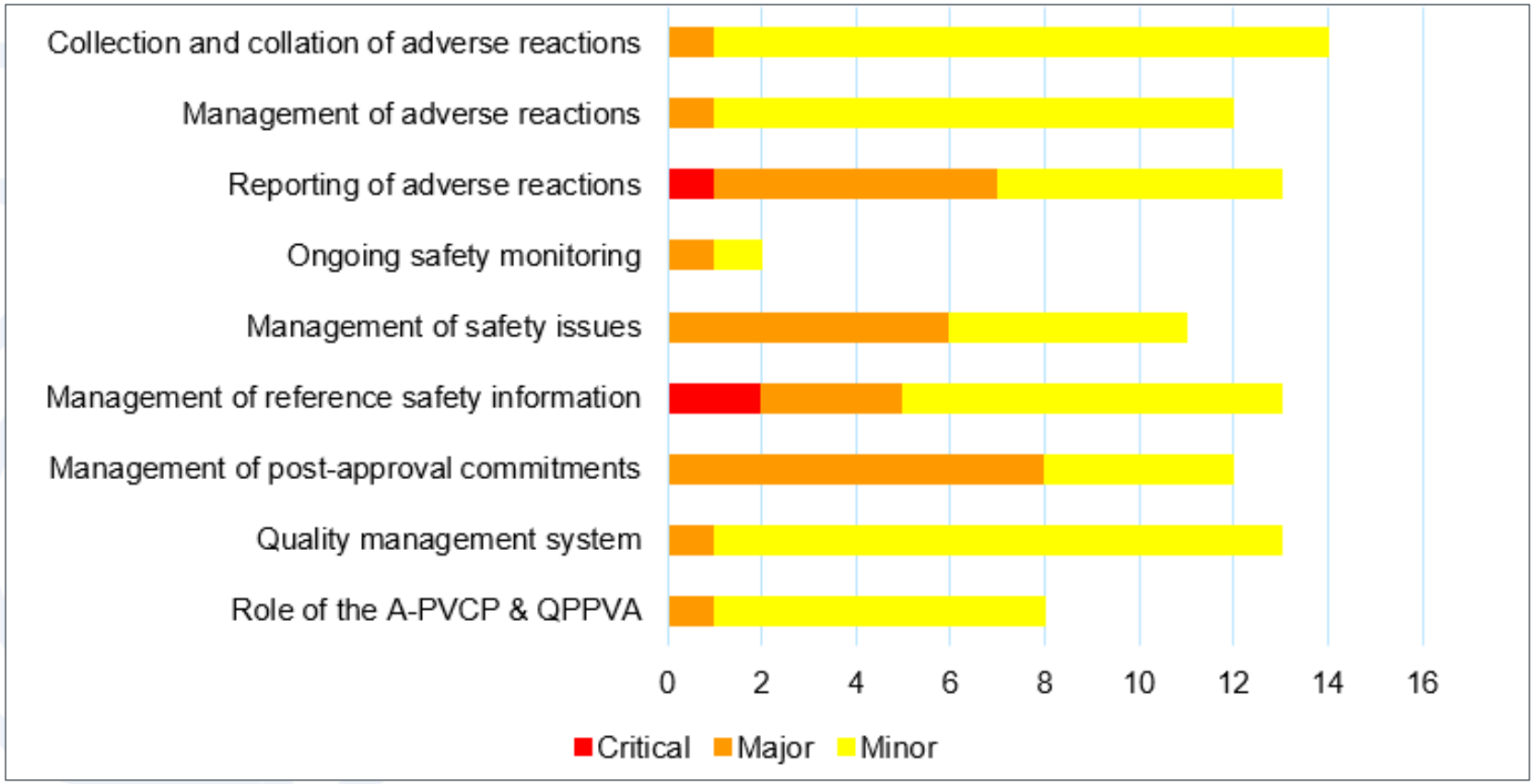
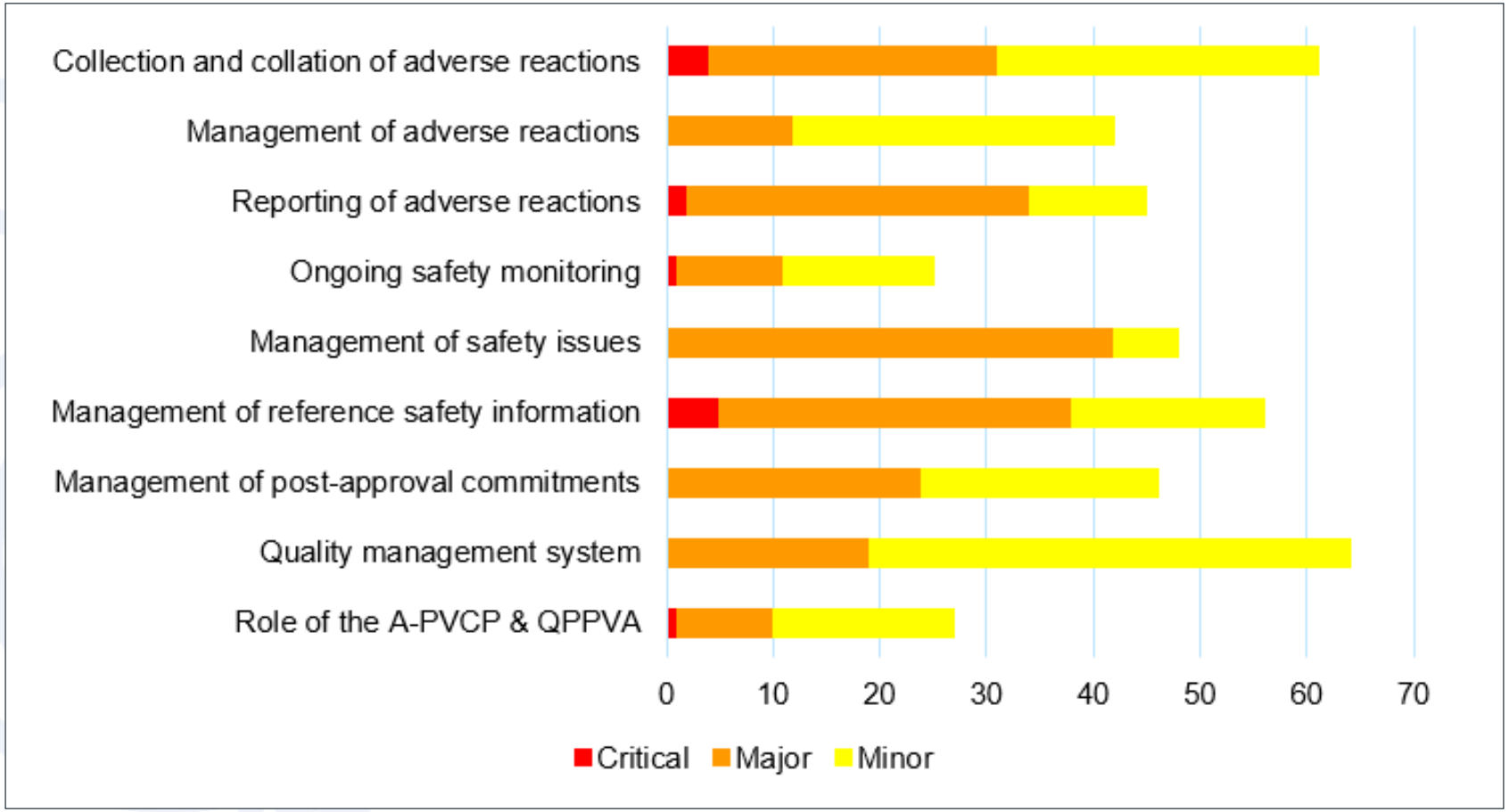
- Total of 98 deficiencies
- Average of 7 deficiencies per inspection
- Hybrid inspection format
- Inspected the pharmacovigilance systems of sponsors of both registered and listed medicines

Overview of deficiencies from inspections between 2023 and 2024

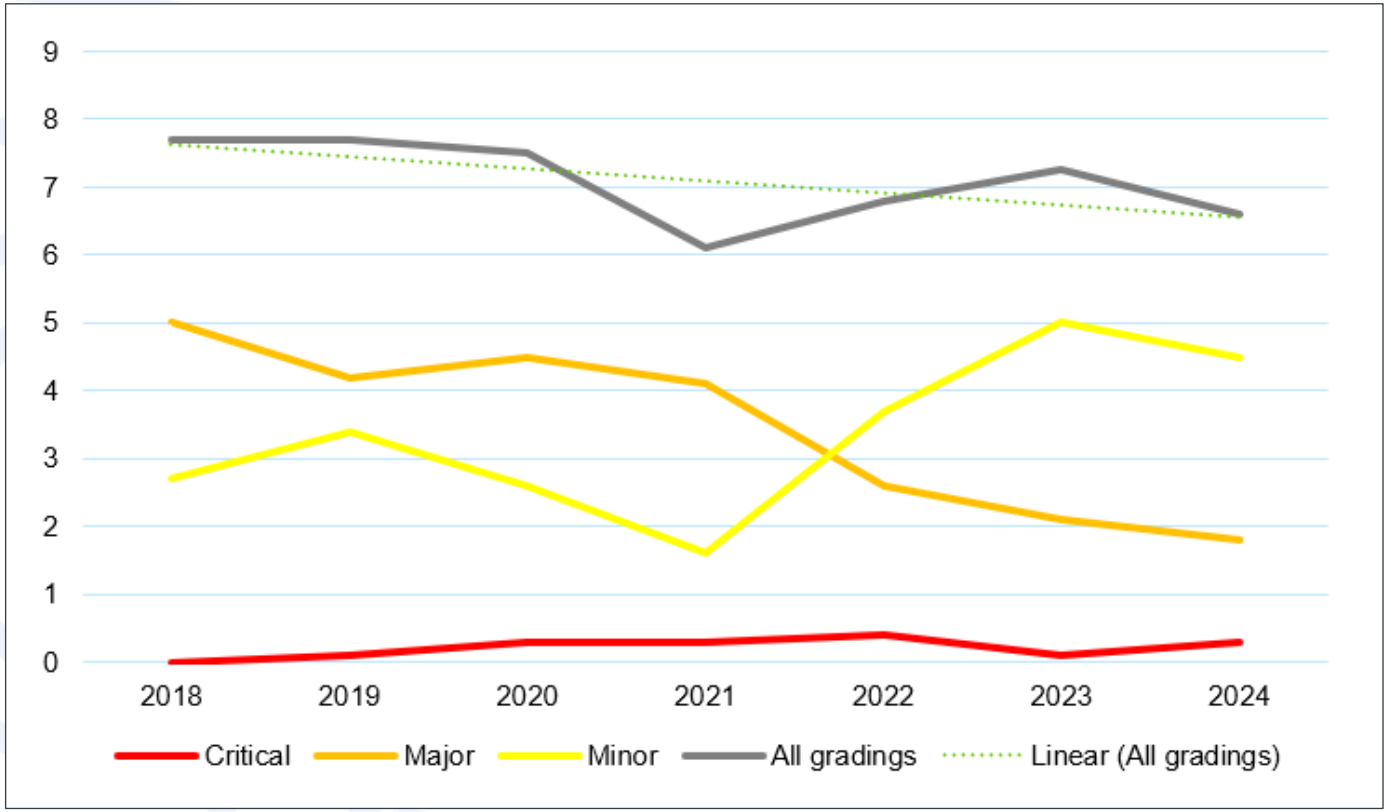


Overview of deficiencies from inspections between 2018 and 2024



Deficiencies since PVIP started

Data suggests an overall sustained improvement in sponsor adherence to pharmacovigilance requirements and recommendations.



Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration