Update from the Pharmacovigilance Branch

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Signal detection and investigation and regulatory action for medicines and vaccines

Adverse event collection

Systems support and project management

Complementary medicines and defect monitoring and action

Safety and shortages communications

Good Clinical Practice Inspection Program

RMP and PSUR evaluation

Medicine shortages management

Pharmacovigilance Inspection Program

COVID-19 vaccine claims assessment

Clinical trials access pathways

Overview

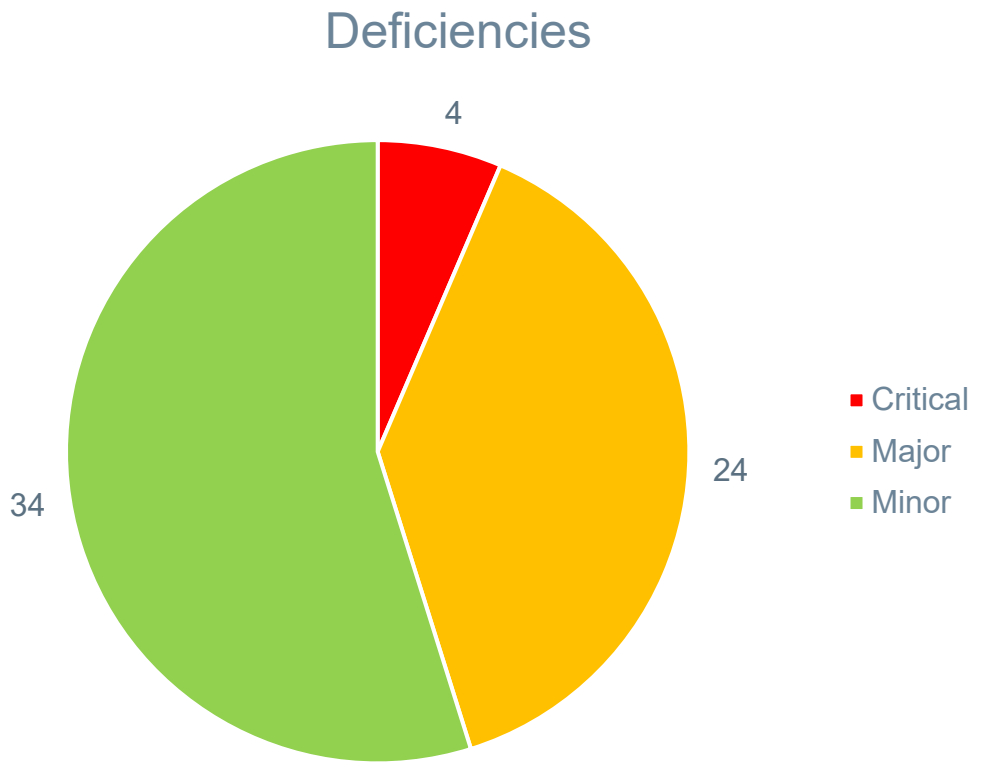
- Findings of pharmacovigilance inspections
- Changes to safety reporting requirements – observations one year on
- Improving how we share adverse event data
- Increasing the reach of our safety communications
- Best practices for sponsors responding to medicine shortages

Pharmacovigilance Inspection Program

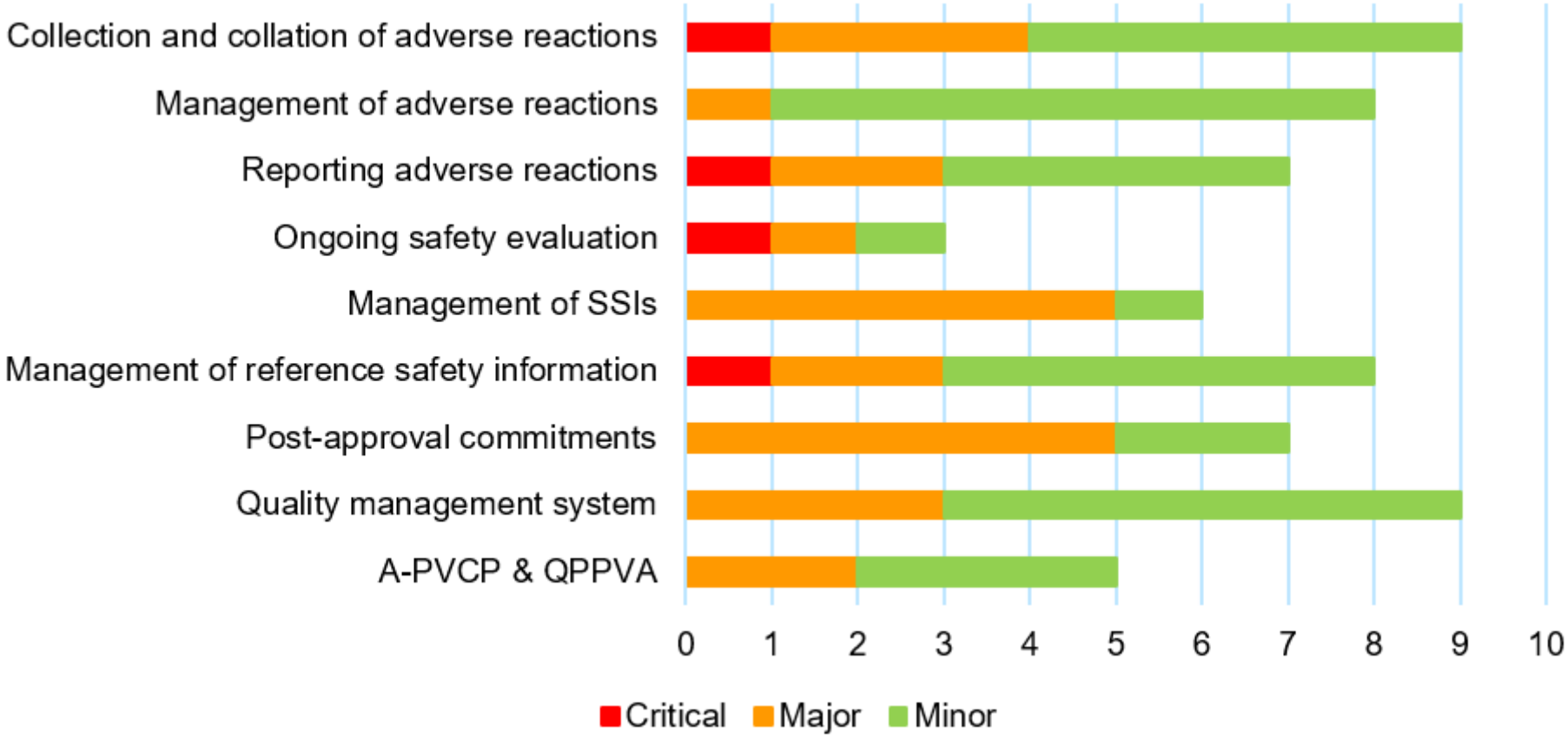
Findings and outcomes

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?

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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?

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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.

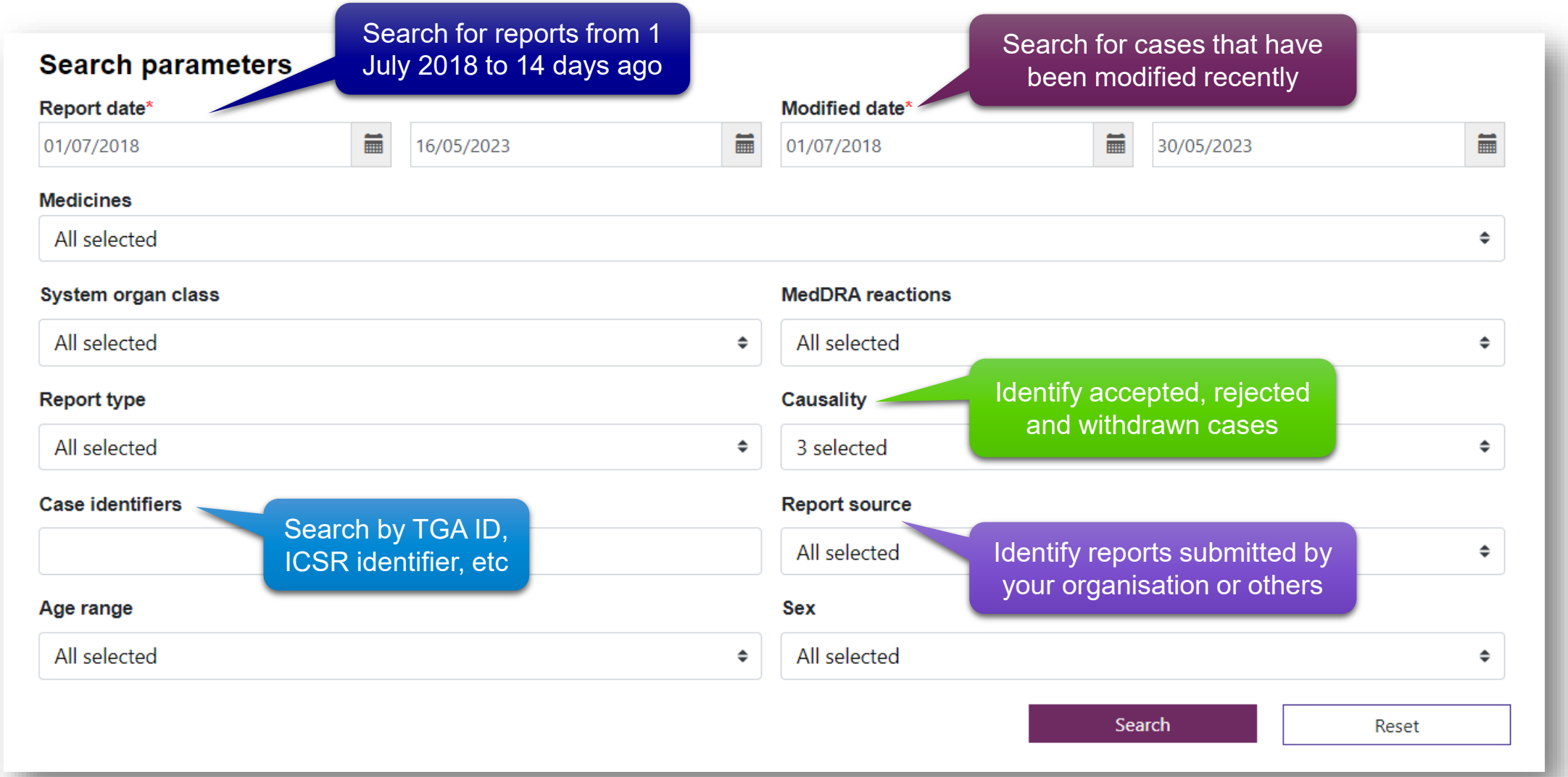
Improving sharing of adverse event data

The MAEDX project

Improvements to sharing of AE data

- New DAEN – medicines
- Automated AEFI sharing
- Sponsor adverse event search

Sponsor self-service – November 2023

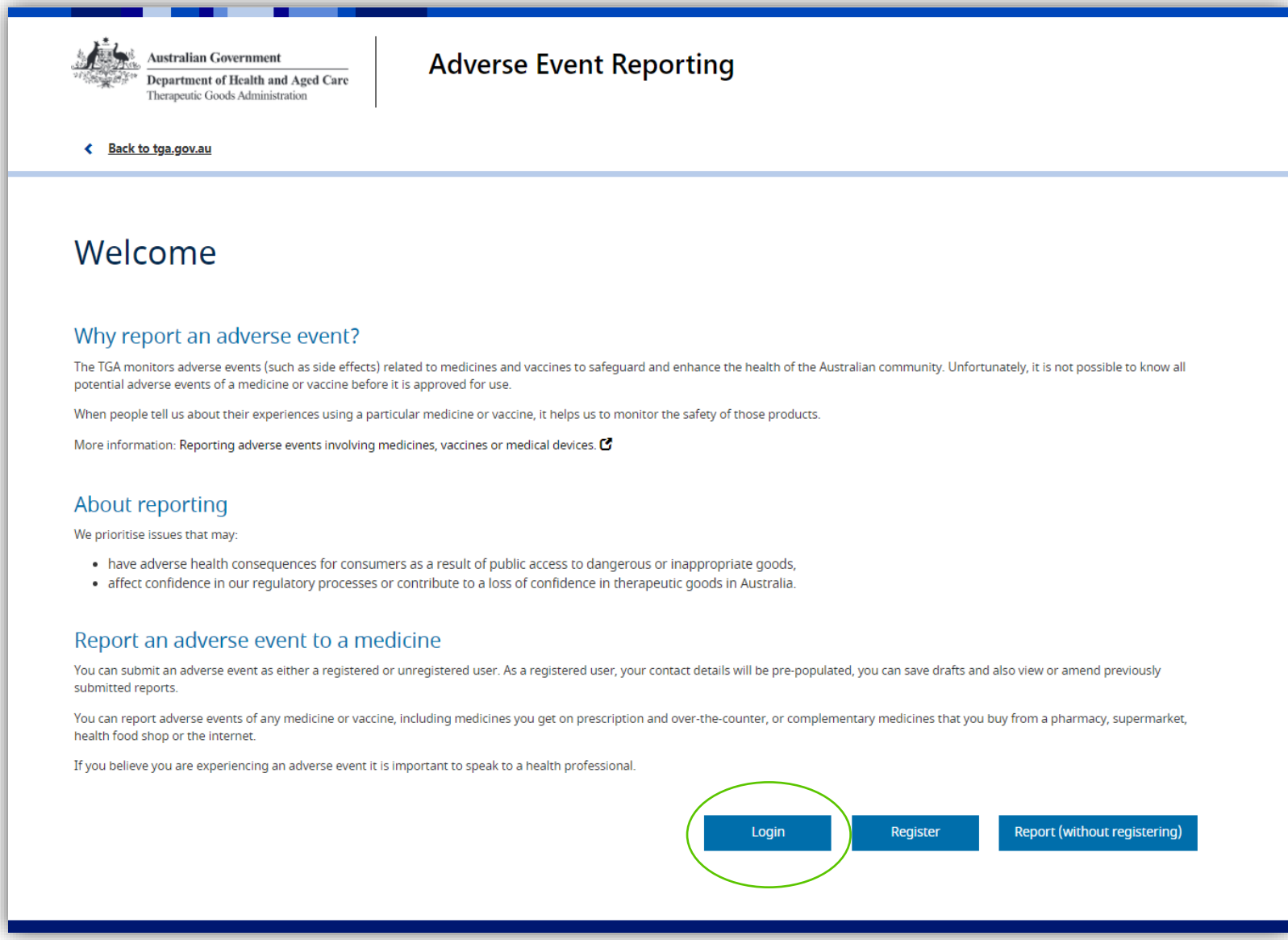


How does it work?

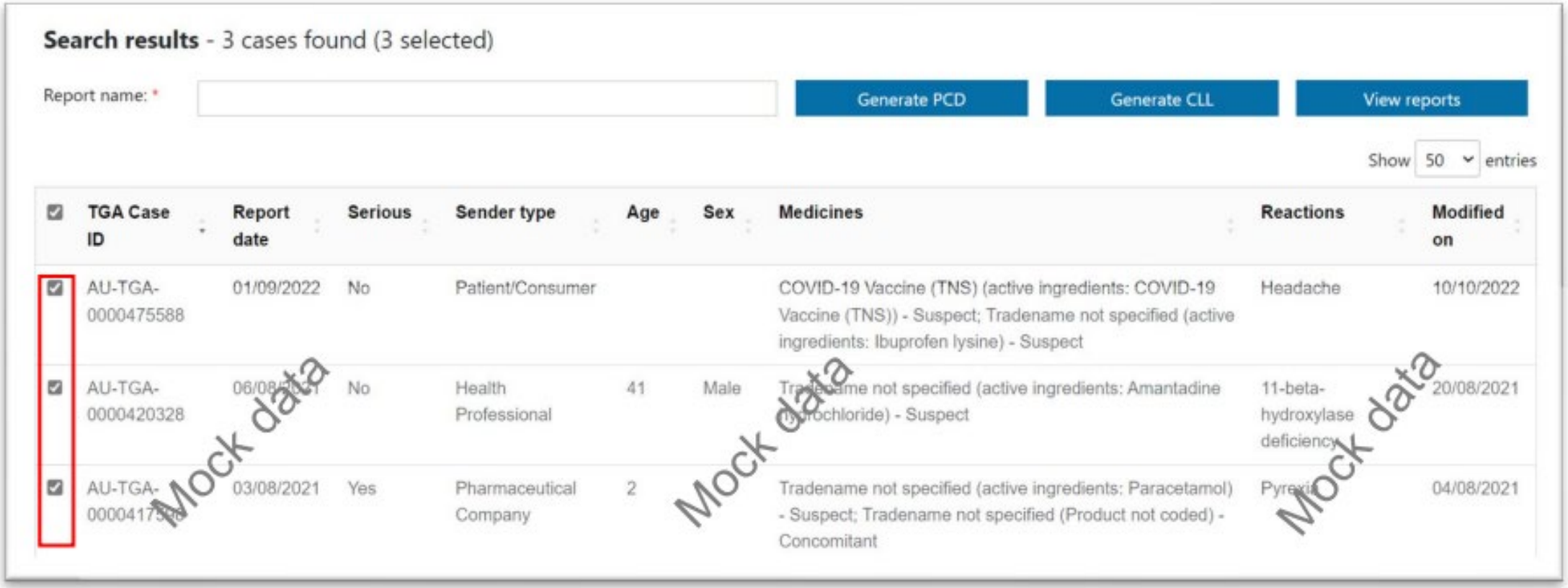
Accessed via TGA online

Use eBS credentials to login.

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



Download CLLs and PCDs



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.

Australian Prescriber

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


Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration
Every report helps to keep others safe.
You don't need to be certain, just suspicious.


Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration
Report adverse events to help keep other Australians safe.


Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration
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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Therapeutic Goods Administration