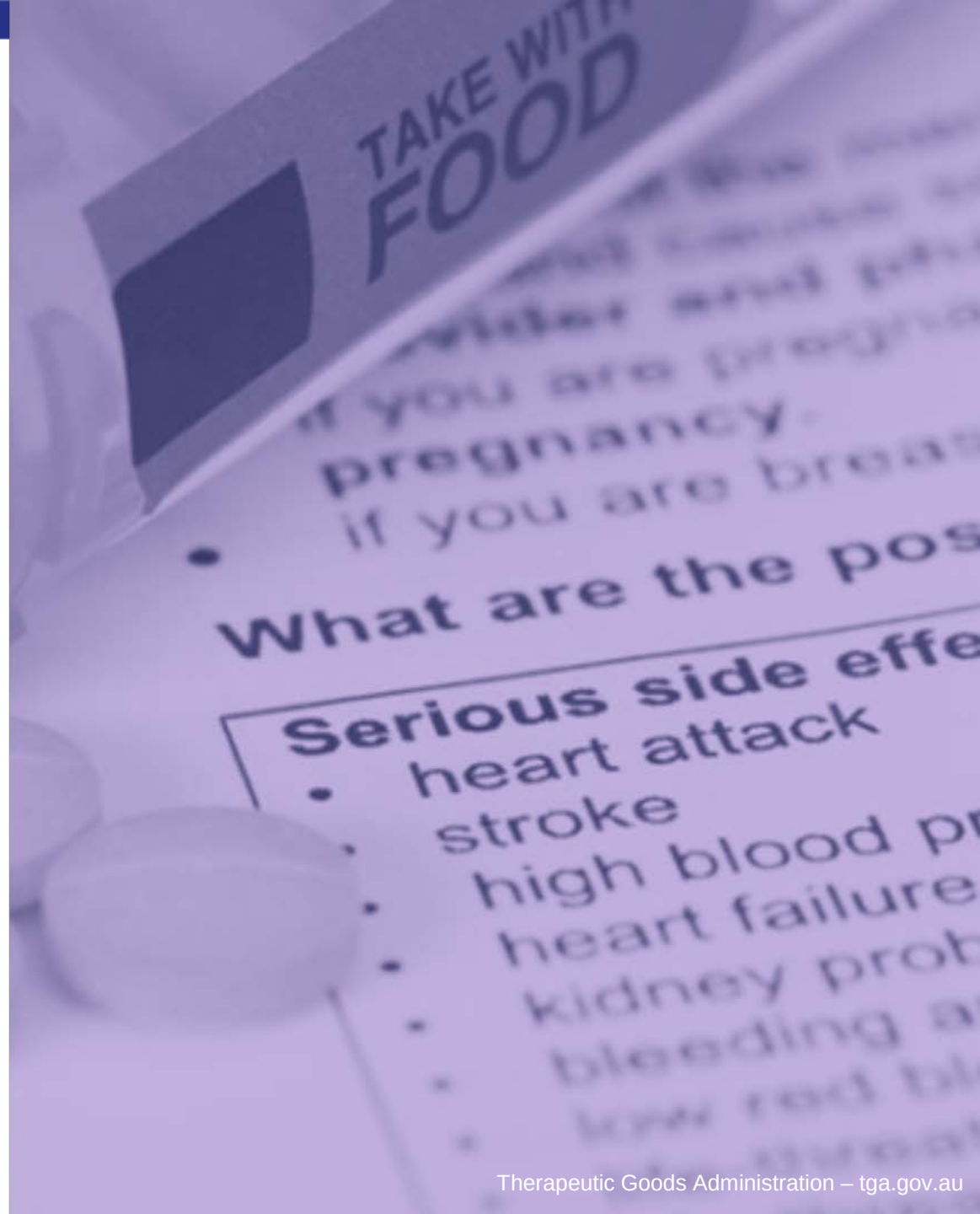
Update from TGA's Pharmacovigilance Branch – June 2025

Dr Alison Stubbs
Pharmacovigilance Branch
Department of Health, Disability and Ageing, TGA

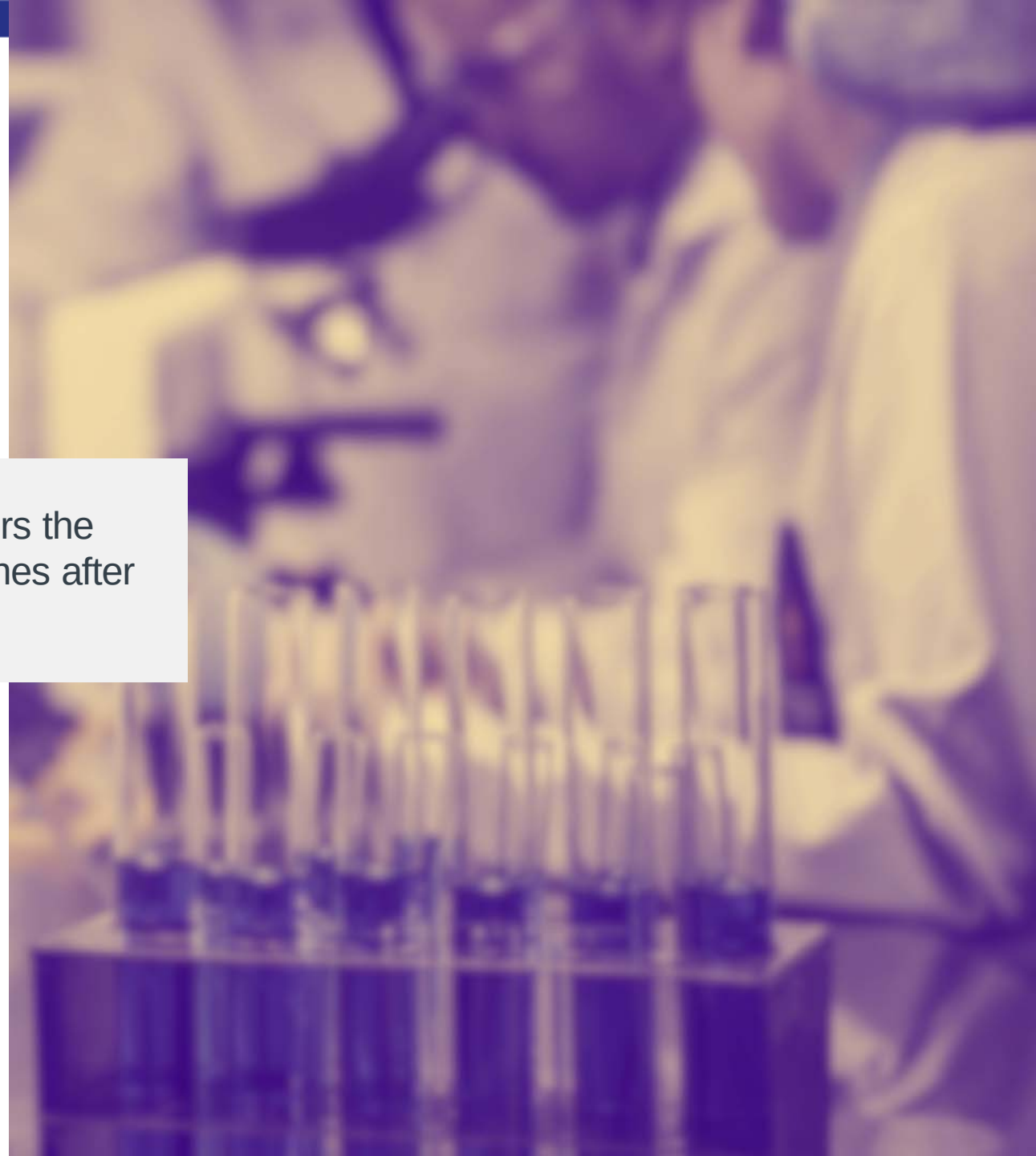
Session overview

- Reporting adverse events to the TGA
- PI updates from international regulators
- TGA safety communication
- Medicine shortages
- Pharmacovigilance inspection program



What we do

The Pharmacovigilance Branch of the TGA monitors the quality, safety and efficacy of medicines and vaccines after they have entered the Australian marketplace.



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

Reporting adverse events to the TGA

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

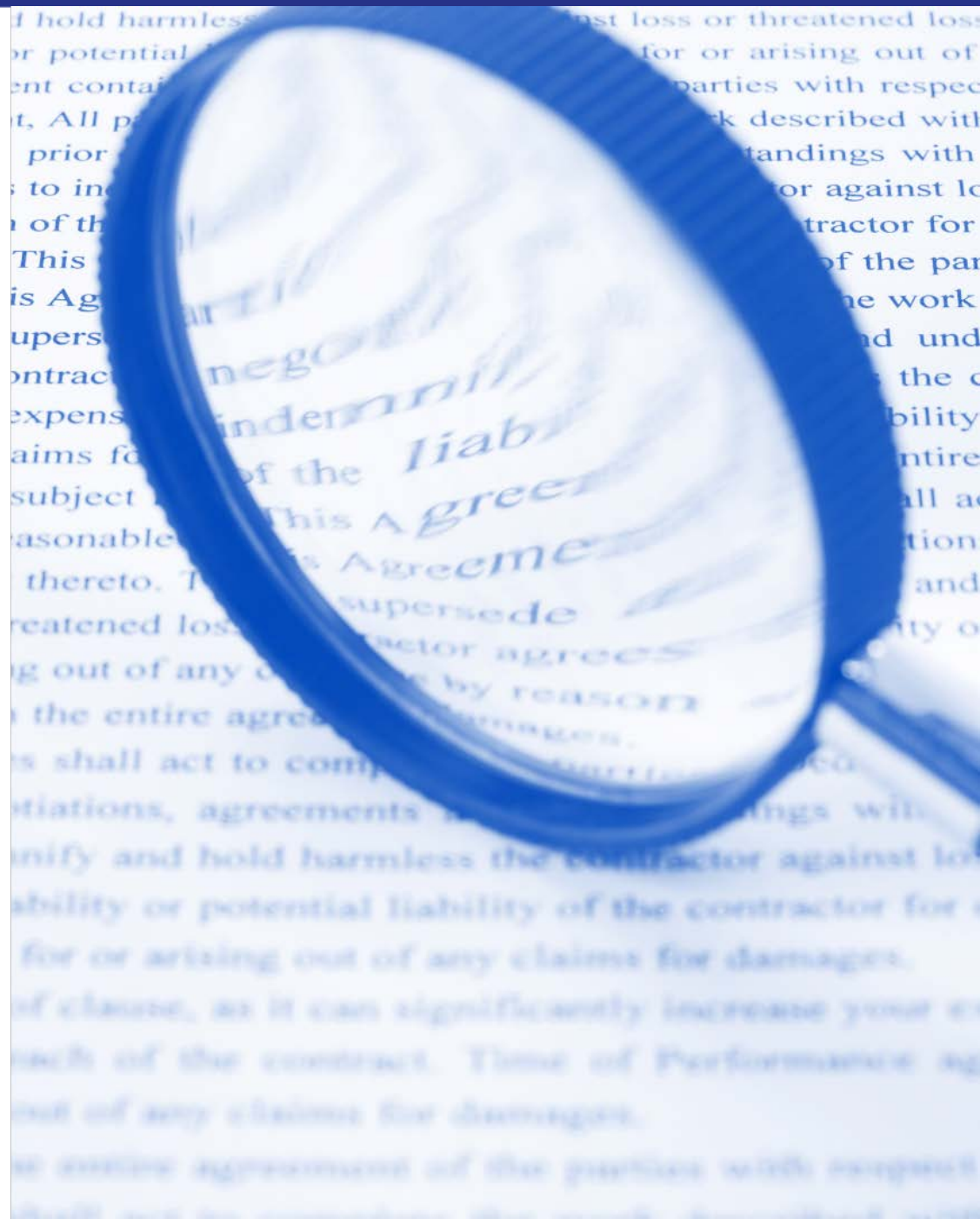
Other safety issues

- 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

Problem

- ICSR E2B(R2) format has no set rules about spacing
- long and hard to read



Full Case Details

Case ID: AU-TGA-0000777586

Case narrative:

Event Description ---------- Spontaneous report from Australia by a physician of a 33.000 years old female with events of refractory takayasu arteritis Disease Activity, and non-serious Progressive Vascular Stenosis, patient had tried and failed methotrexate, patient had tried and failed leflunomide, patient had tried and failed azathioprine, patient had tried and failed adalimumab, patient had tried and failed infliximab, and patient had tried and failed tocilizumab with Adalimumab Solution for Injection, Single Dose Pen. There was no reported medical history. On unknown date(s), the patient experienced patient had tried and failed tocilizumab, patient had tried and failed infliximab, patient had tried and failed adalimumab, patient had tried and failed azathioprine, patient had tried and failed leflunomide, patient had tried and failed methotrexate, refractory takayasu arteritis Disease Activity, Progressive Vascular Stenosis, Leflunomide, Methotrexate, tocilizumab, infliximab, azathioprine were also considered suspect. The patient had tried and failed methotrexate, leflunomide, azathioprine, adalimumab, infliximab and tocilizumab as steroid sparing agents. Her Current Treatment was prednisolone 25mg daily. Her tocilizumab was ceased due to ongoing aortic inflammation on Magnetic resonance angiography, and ongoing symptoms as of 30 Jun 2023 as there was emerging evidence showing potential efficacy of JAK inhibitors in Takayasu arteritis. She was a young women with small children and was at high risk of significant risk of morbidity and even mortality from excessive steroid exposure and ongoing disease activity. Tofacitinib had an acceptable side effect profile in this age group to which she was at low risk of cardiac events/malignancy due to her young age. Causalities ---------- The reporter's causality for the event(s) of Progressive Vascular Stenosis, patient had tried and failed adalimumab, patient had tried and failed azathioprine, patient had tried and failed infliximab, patient had tried and failed leflunomide, patient had tried and failed methotrexate, patient had tried and failed tocilizumab and refractory takayasu arteritis Disease Activity with Leflunomide (Leflunomide) was Not Provided The reporter's causality for the event(s) of Progressive Vascular Stenosis, patient had tried and failed adalimumab, patient had tried and failed azathioprine, patient had tried and failed infliximab, patient had tried and failed leflunomide, patient had tried and failed methotrexate, patient had tried and failed tocilizumab and refractory takayasu arteritis Disease Activity with Tocilizumab (Tocilizumab) was Not Provided The reporter's causality for the event(s) of Progressive Vascular Stenosis, patient had tried and failed adalimumab, patient 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Reactions:

Preferred term	Start date	End date	Management of event	Outcome
Drug ineffective				Unknown
Drug ineffective				Unknown
Drug ineffective				Unknown
Drug ineffective				Unknown
Drug ineffective				Unknown
Drug ineffective				Unknown
Takayasu's arteritis				Not recovered/not resolved/ongoing
Vascular stenosis				Unknown

Drug information:

1) ADALIMUMAB (adalimumab) - Suspect	
Dosage information	Route of administration: Subcutaneous
Treatment details	
Indication	Takayasu's arteritis
Action Taken	Unknown

2) AZATHIOPRINE (azathioprine) - Suspect	
Dosage information	Route of administration: Information Not Provided By Sponsor
Treatment details	
Indication	Drug use for unknown indication
Action Taken	Unknown

3) INFLIXIMAB (infliximab) - Suspect	
Dosage information	Route of administration: Information Not Provided By Sponsor
Treatment details	
Indication	Drug use for unknown indication
Action Taken	Unknown

4) LEFLUNOMIDE (leflunomide) - Suspect	
Dosage information	Route of administration: Information Not Provided By Sponsor
Treatment details	
Indication	Drug use for unknown indication
Action Taken	Unknown

5) METHOTREXATE (methotrexate) - Suspect	
Dosage information	Route of administration: Information Not Provided By Sponsor
Treatment details	
Indication	Drug use for unknown indication
Action Taken	Unknown

6) TOCILIZUMAB (tocilizumab) - Suspect	
Dosage information	Route of administration: Information not provided by sponsor
Treatment details	
Indication	Drug use for unknown indication
Action Taken	Unknown

Improving readability of case narratives

Solution

- spacing
- subheadings

Required evidence base

Boxed warnings should generally be based on observed data from clinical and sometimes non-clinical sources.

Clinical data may be from:

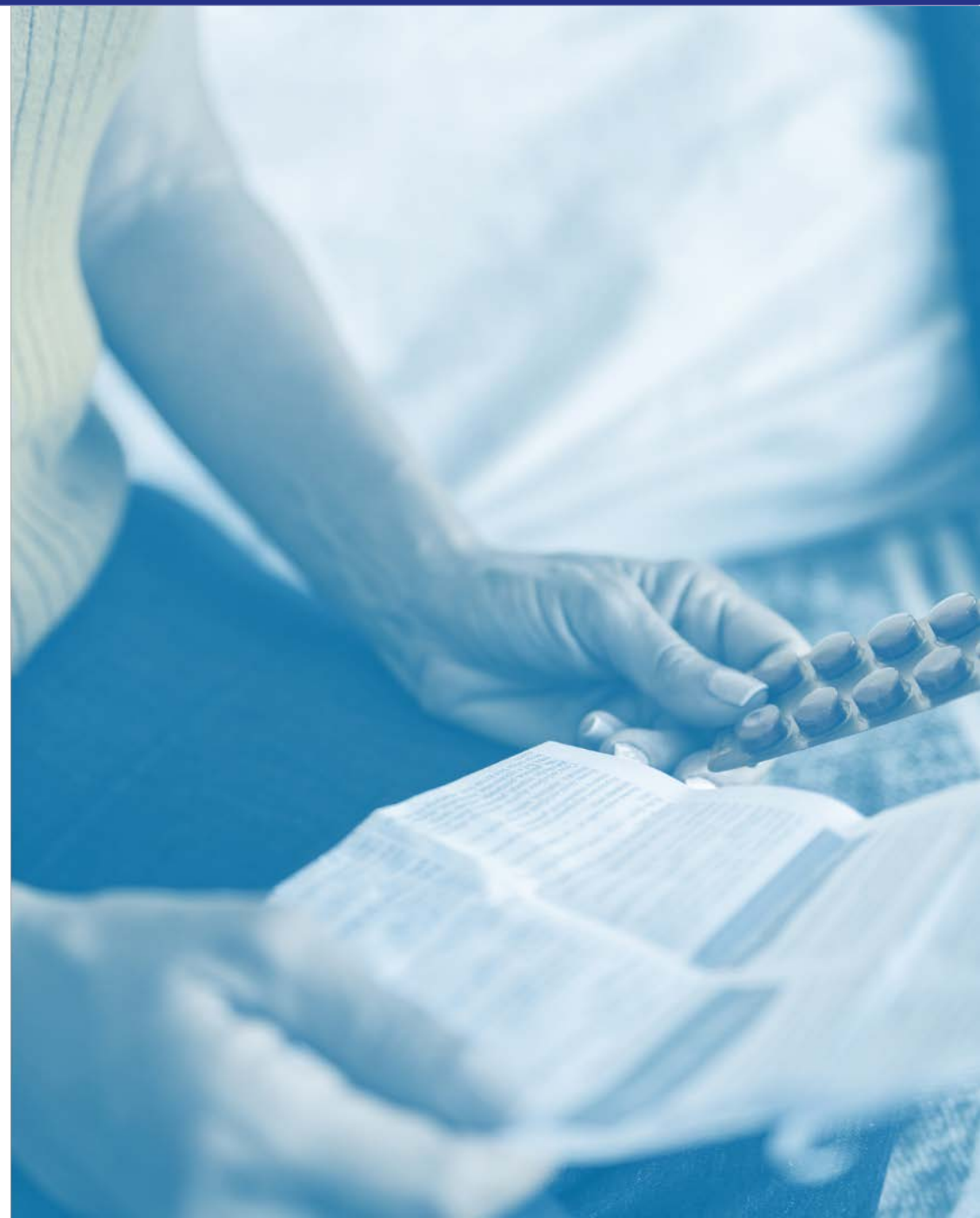
- market authorisation studies
- post-market sources including post-market studies (either sponsor initiated or investigator initiated) and literature or pharmacovigilance activities
- additional analyses of data
- off-label use of the medicine (in exceptional circumstances).

Generally, a boxed warning will be required on the basis of direct evidence from the particular medicine. Sometimes a boxed warning may also be required:

- on the basis of indirect evidence or an anticipated effect
- if a particular safety signal occurs for one medicine within a class, but not others.

Updates by comparable overseas regulators

When an overseas regulator adds safety information to their PI/CMI, the TGA expects you to update the Australian PI and CMI accordingly.



TGA safety communication

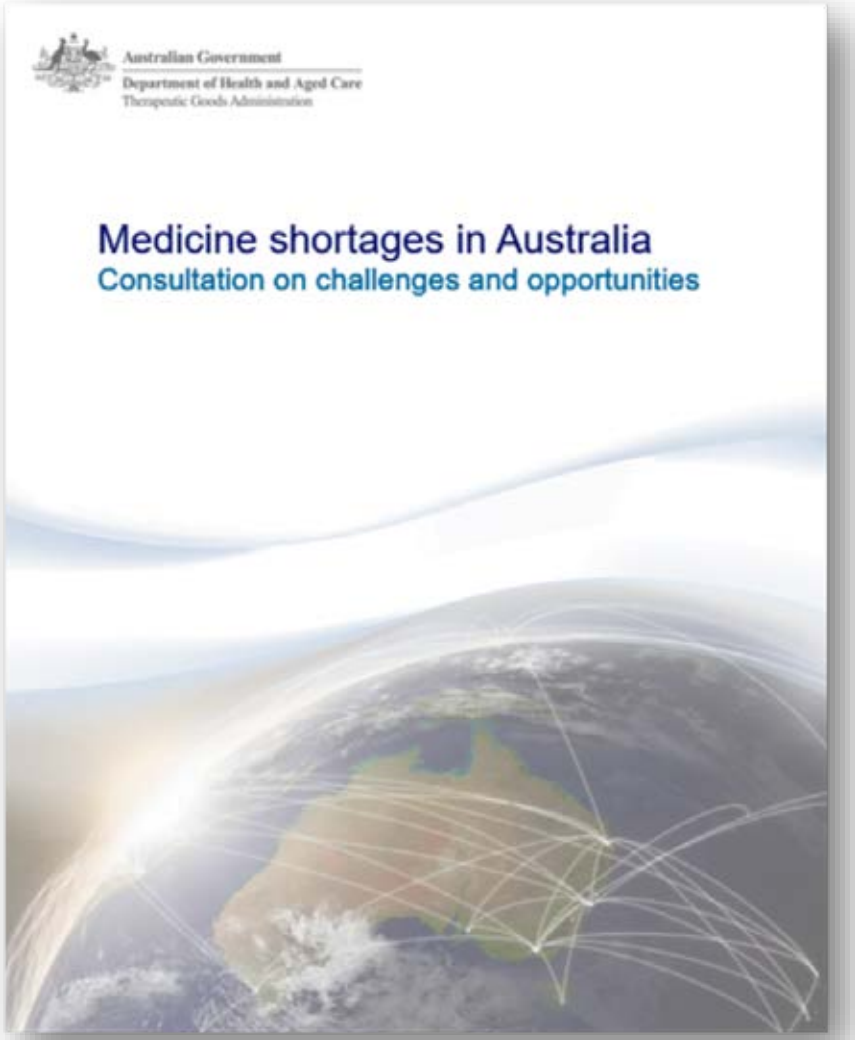
- Product Information updates are listed monthly on the TGA website
- Medicine Safety Update articles are published on the TGA website when the information is clinically important or of special interest
- Summaries and links to Medicine Safety Update articles appear in *Australian Prescriber* and are disseminated via the Primary Health Network

TGA Medicine Safety Updates

- More prominent warnings about serious side effects for fluoroquinolone antibiotics
- Azithromycin and rare risk of cardiovascular death
- Promethazine hydrochloride (Phenergan) not to be used in children under 6
- New safety warnings for isotretinoin (Roaccutane)
- Avoiding paediatric dosing errors with risperidone
- Updated warnings for Respiratory Syncytial Virus vaccines Arexvy and Abrysvo

Update on TGA's Medicine Shortage Reforms

Understanding the impact of shortages and discontinuations



Public consultation in 2024

217 respondents

Organisations

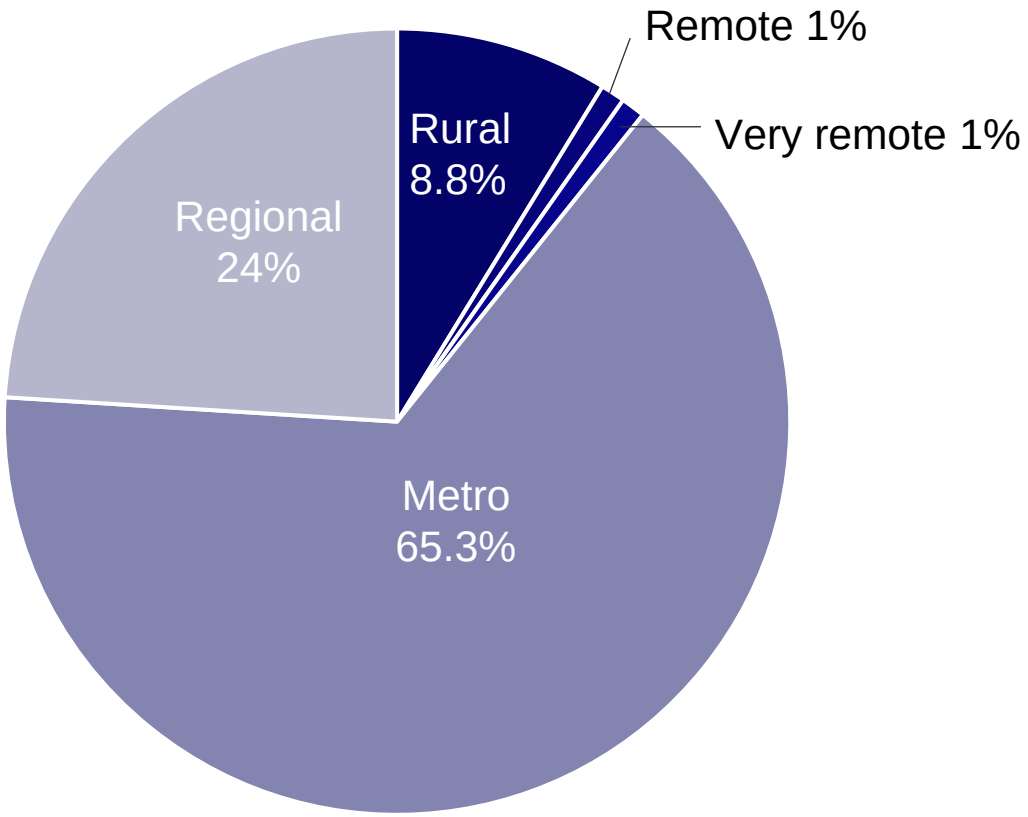
- 32 health professional
- 26 medicine industry
- 6 consumer
- 7 government

Individuals

- 116 consumers
- 19 prescribers
- 9 pharmacists
- 2 other health professionals

Understanding the impact of shortages and discontinuations

Market research in 2024



800 survey respondents + 17 one-to-one interviews

- 207 prescribers
- 197 pharmacists
- 295 impacted consumers
- 101 non-impacted consumers

Challenge themes

That people experienced relating to medicine shortages and discontinuations

1		Inconsistent, inaccurate or not timely information about medicine availability
2		Lack of reporting requirements for shortages of specific medicines of public interest that are not currently captured by mandatory reporting framework
3		Low confidence in medicine supply leading to stockpiling and reduced demand predictability

Challenge themes

4		Limited therapeutic alternatives for niche treatments
5		Time-consuming manual administrative and regulatory processes, leading to delays and barriers to patients accessing alternatives
6		Perceived inequitable distribution of and access to limited stock (*outside of TGA remit)*

TGA Medicine Shortages and Discontinuations improvements roadmap

Priority Outcome 1
Updated legislative framework to better meet public 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

1 2 3 4

Priorities announced

November 2024

Priority Outcome 1

Updated legislative framework

1.1 Reportable medicines: Include more critical non-prescription medicines in the mandatory reporting framework. − Completed March 2025

1.2 TGA access to medicine supply data: Include
a provision in the *Therapeutic Goods Act 1989* to require sponsors of any approved medicine to provide the TGA with detailed supply information on request.

1.3 Earlier notice of discontinuations: Require sponsors to provide 12 months' notice to the TGA of a decision to permanently discontinue a reportable medicine in Australia.

AUSTRALIA

Therapeutic Goods (Reportable Medicines) Determination 2025

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 5 March 2025

5 Reportable medicines

The medicines set out in Schedule 1, being medicines that are registered goods, are determined to be reportable medicines for the purposes of subparagraph 30EH(1)(b)(ii) of the Act.

- Public consultation closed on 13 January 2025
- **25** additional non-prescription medicines were added to the reportable medicines legislative instrument
- New medicines include sodium chloride 0.9% IV fluids, permethrin for scabies and hydroxocobalamin injections
- This new legislative instrument is now in effect

Feedback on proposals to update the *Therapeutic Goods Act 1989*

TGA access to supply data of any approved medicine on request

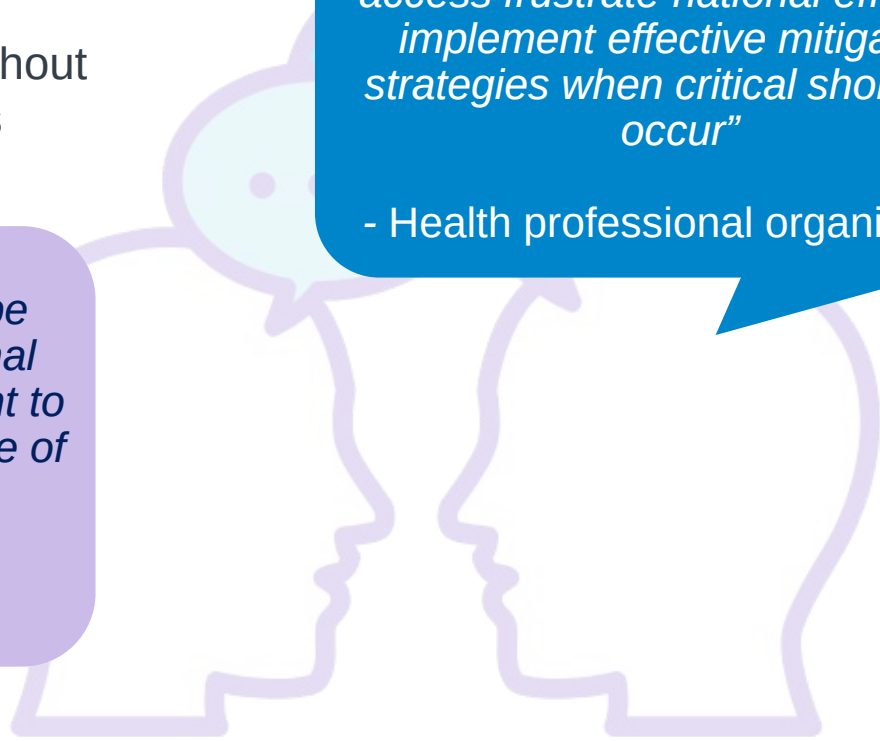
- Shortages of non-reportable medicines can have significant impacts on Australians
- Balanced approach to improving TGA monitoring without significant increase in regulatory burden to sponsors

"Products excluded from regulatory access frustrate national efforts to implement effective mitigation strategies when critical shortages occur"

- Health professional organisation

"…allows for proactive steps to be taken where local and international signposts on shortages are brought to the attention of TGA in the absence of formal notice from sponsors"

- Government respondent



Feedback on proposals to update the *Therapeutic Goods Act 1989*

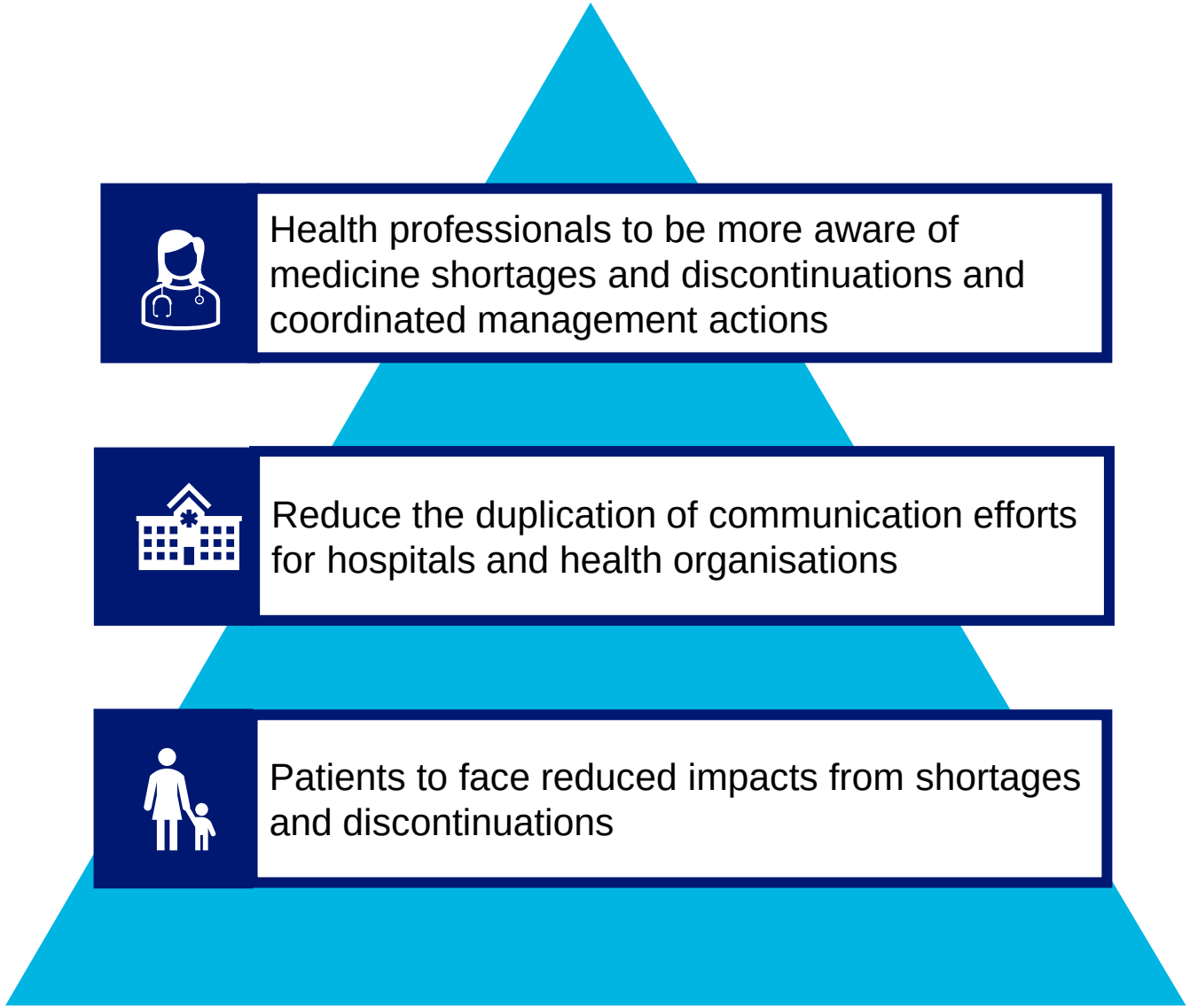
Earlier notice of discontinuations – uniform 12-month notice period

- Most support from government, health professional and consumer organisations
- Clearer reporting requirements
- Importance of maintaining the existing clause ‘or as soon as practicable after the decision is made’
- Need for flexibility in timing of TGA publication of discontinuations – *risks of stockpiling and wastage*
- Variation from discontinuation reporting requirements in other countries

Priority Outcome 3

Better access to shortages information for health professionals

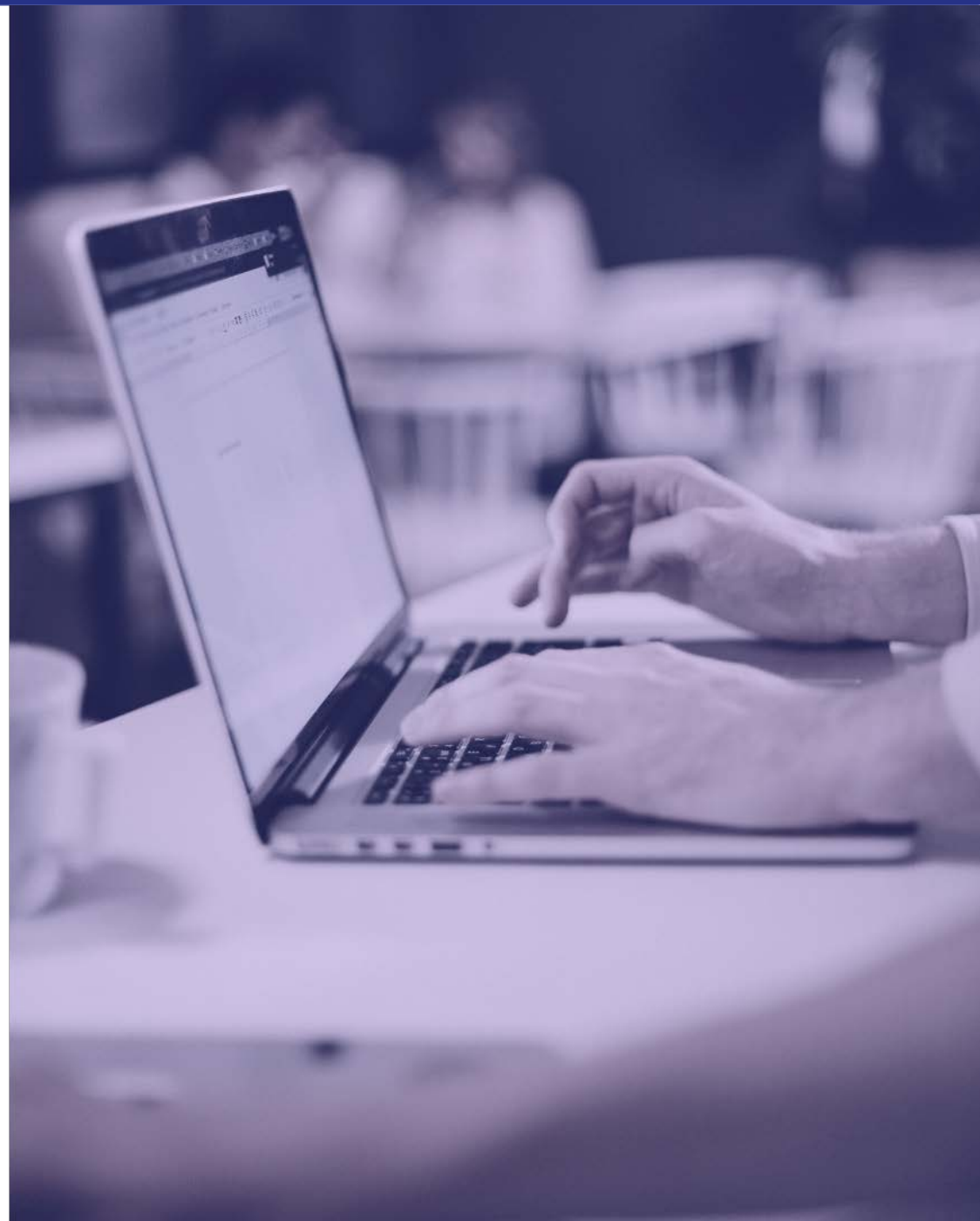
National coordination and communication framework for communicating about medicine shortages and discontinuations and coordinating mitigating actions



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



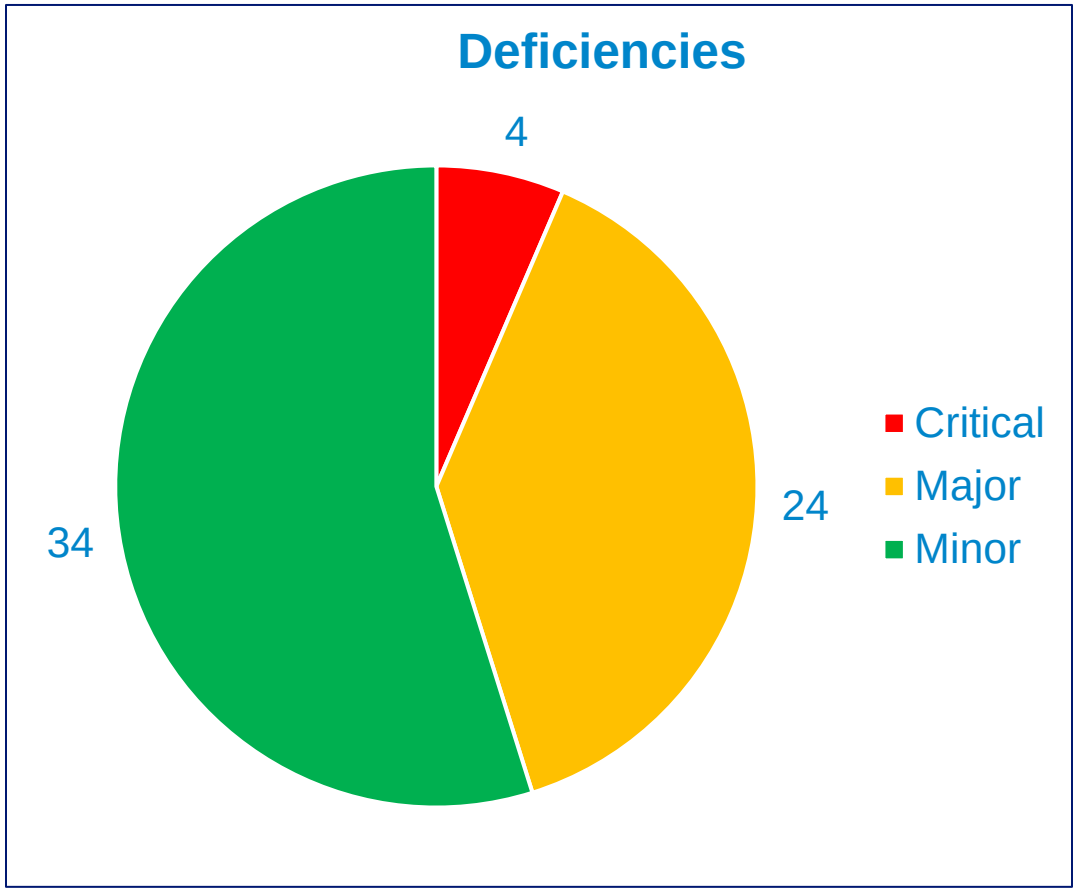
Update on TGA's Pharmacovigilance Inspection Program

Findings & changes

Amanda Chan
Senior Pharmacovigilance Inspector
Department of Health, Disability and Ageing, TGA

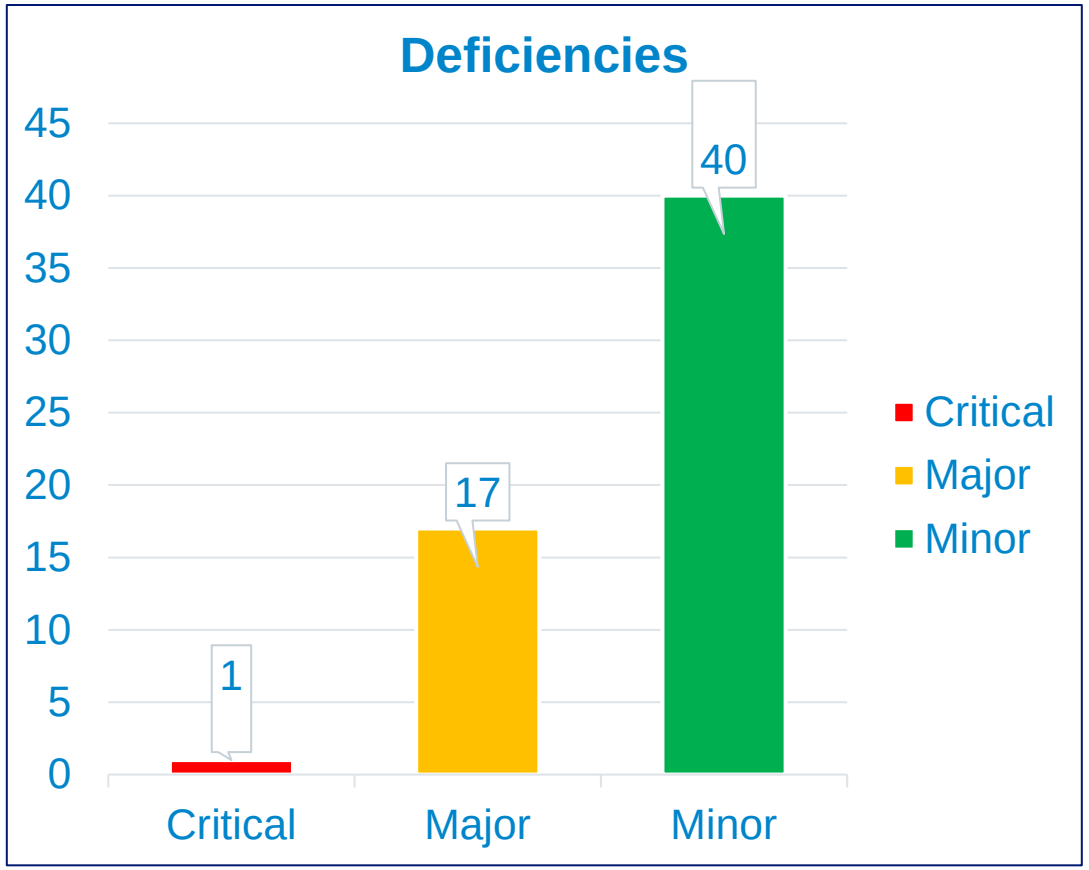
Pharmacovigilance inspections in 2022

- 9 pharmacovigilance inspections conducted
- Average 6.9 deficiencies per inspection



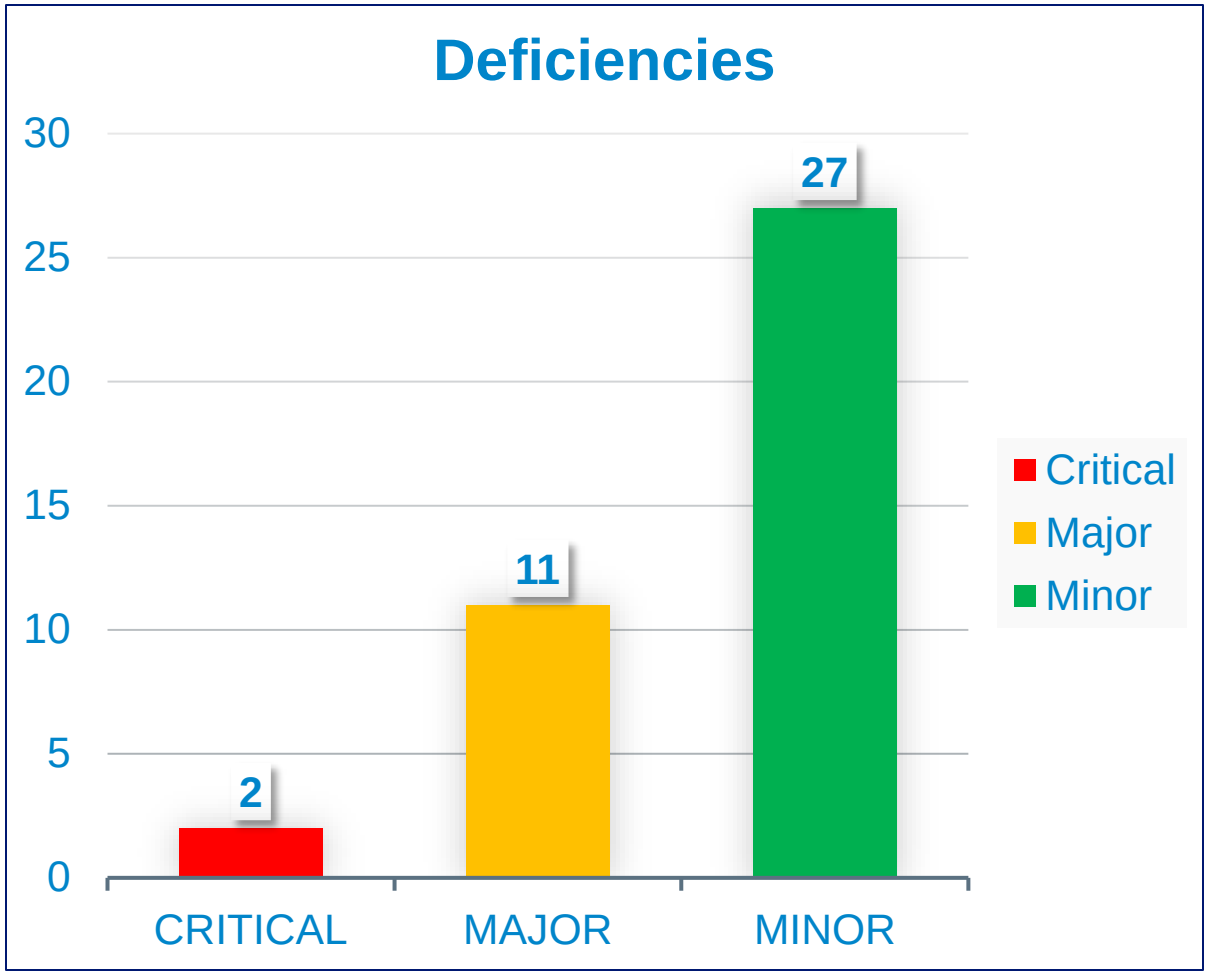
Pharmacovigilance inspections in 2023

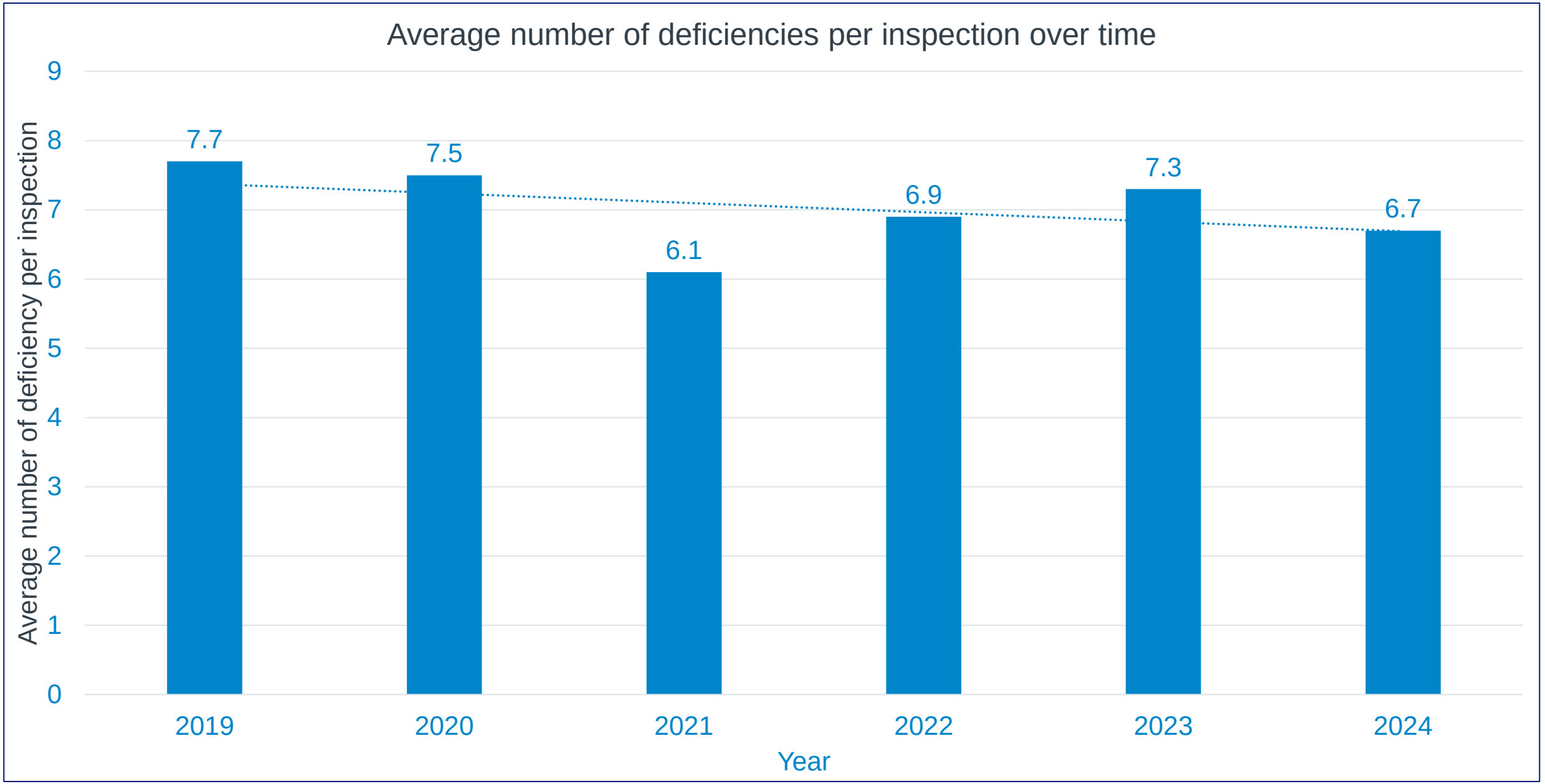
- 8 pharmacovigilance inspections conducted
- Average 7.3 deficiencies per inspection



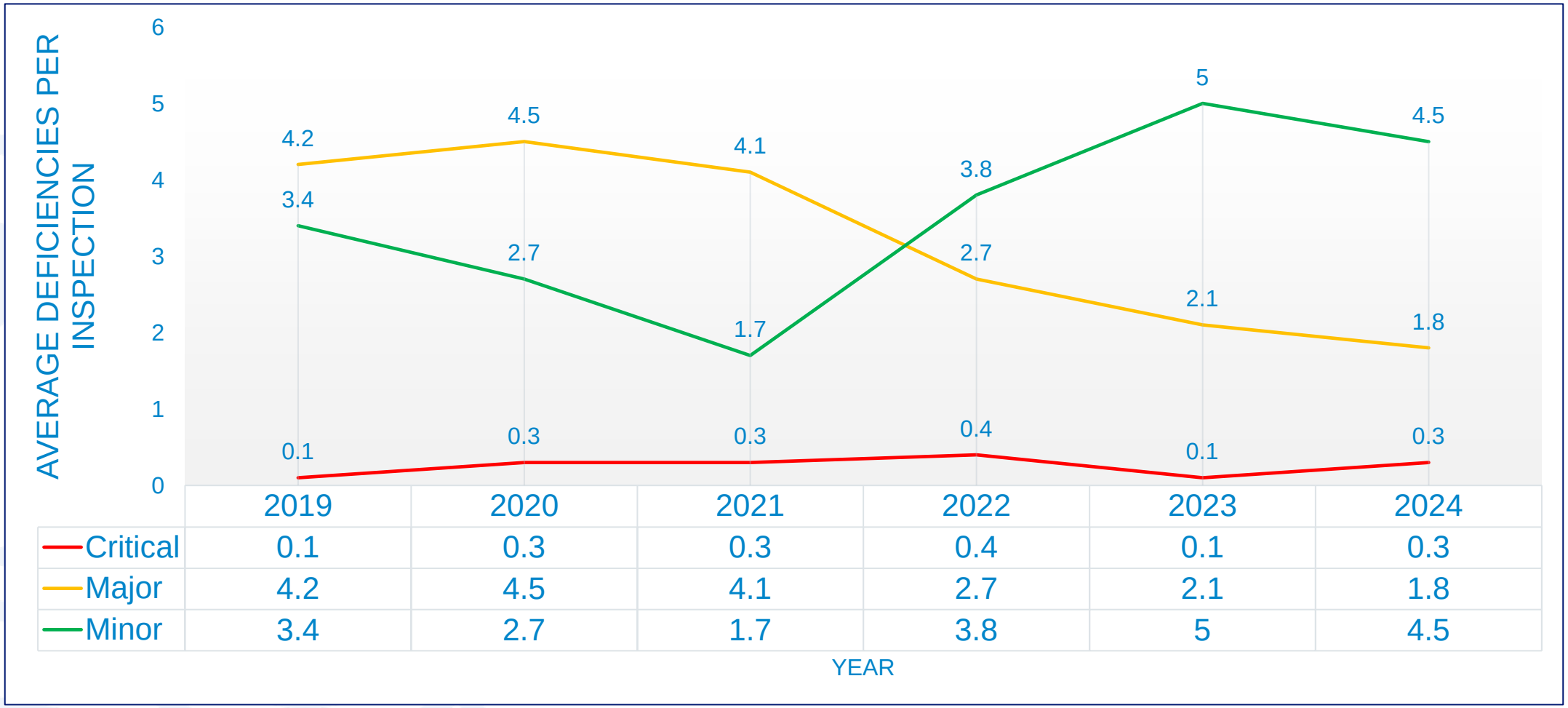
Pharmacovigilance inspections in 2024

- 6 pharmacovigilance inspections conducted
- Average 6.7 deficiencies per inspection

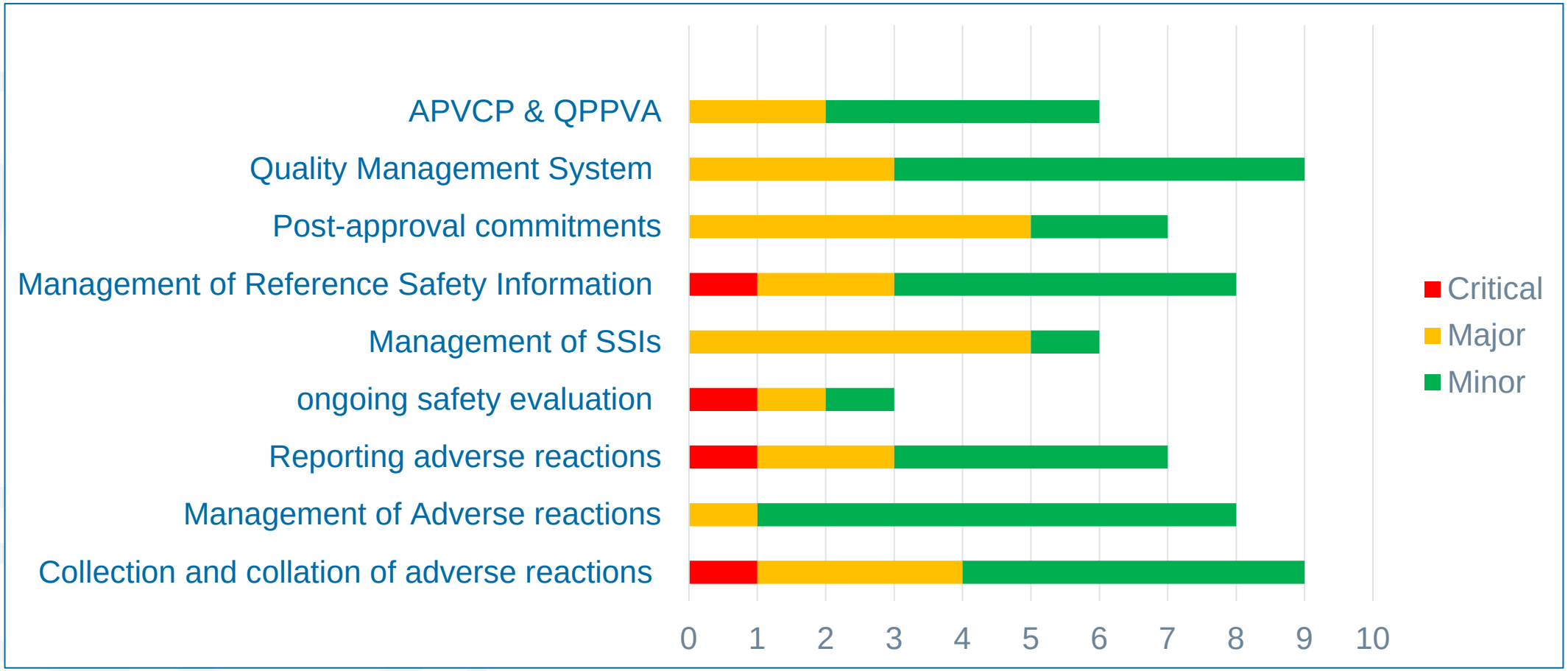



Average number of deficiencies per inspection over time
Average number of deficiency per inspection
9
8
7
6
5
4
3
2
1
0
7.7
7.5
6.1
6.9
7.3
6.7
2019
2020
2021
2022
2023
2024
Year

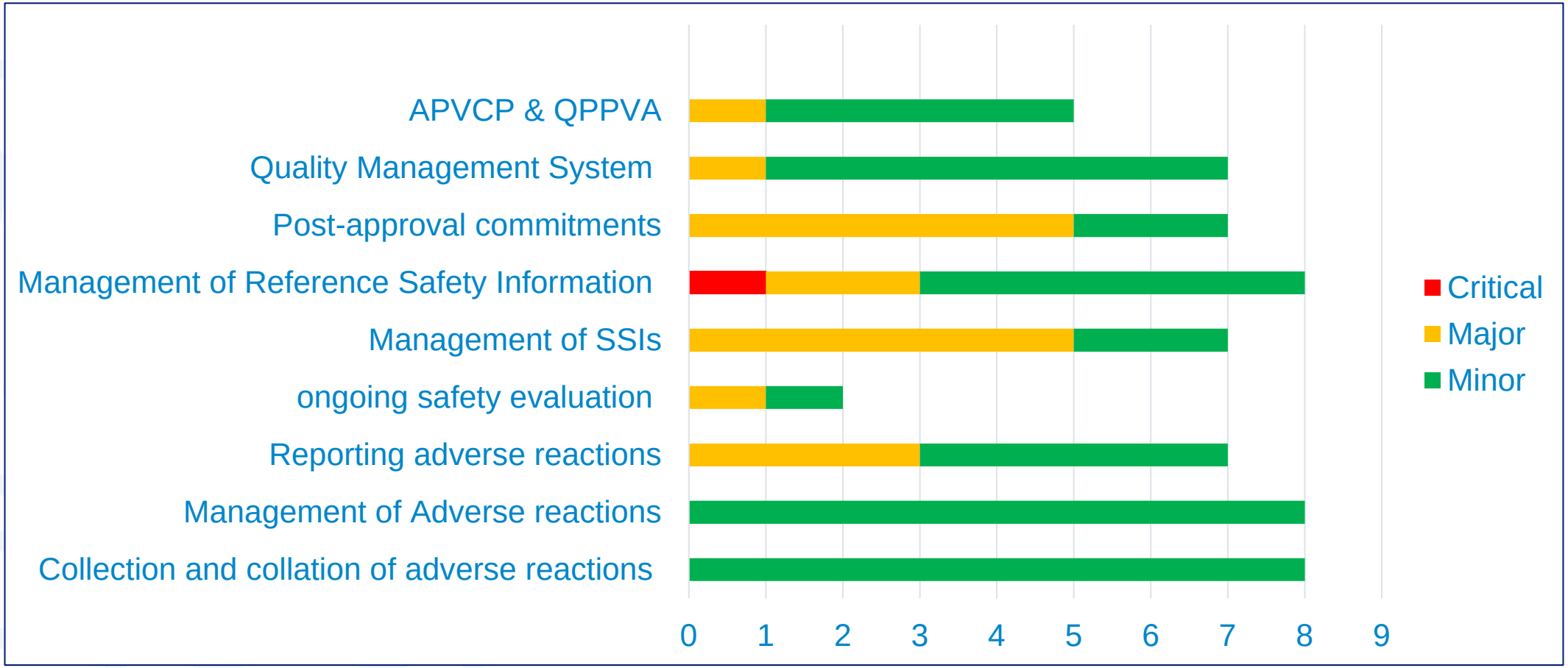
Average deficiencies per inspection by grade



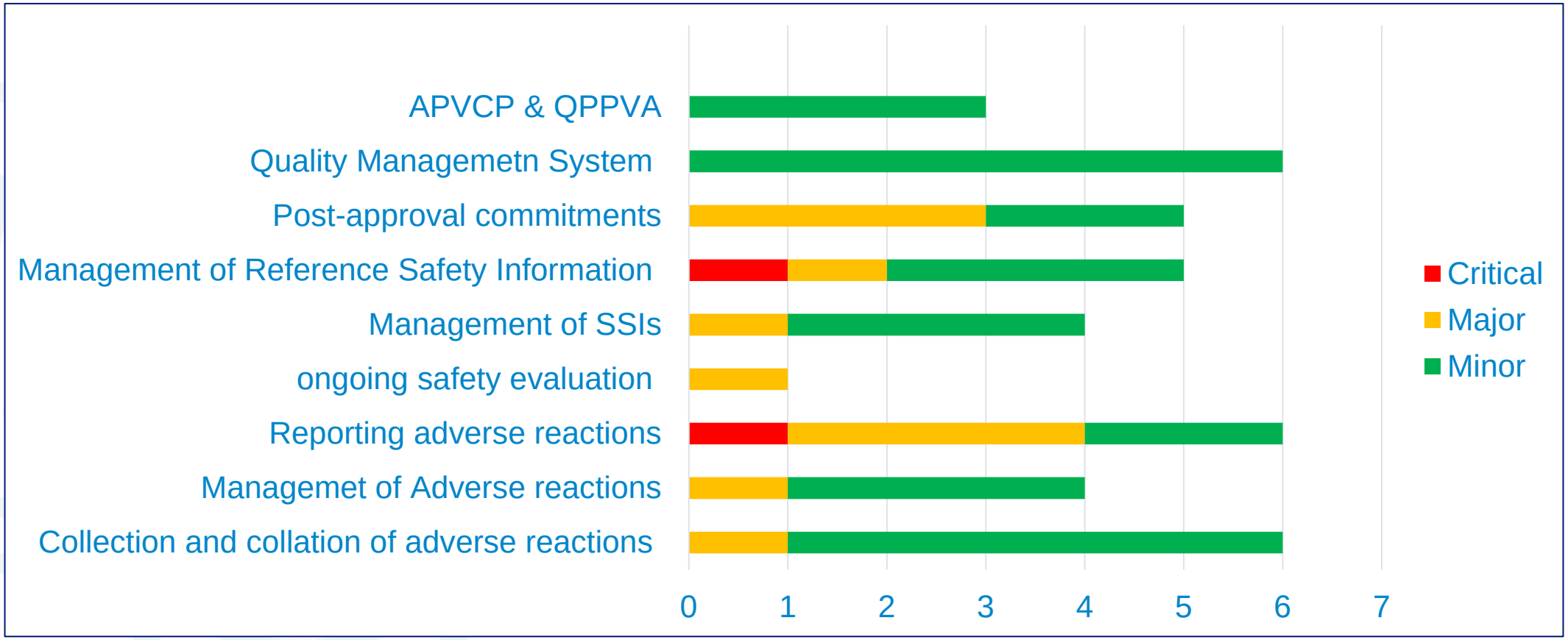
Number and grading of deficiencies in 2022



Number and grading of deficiencies in 2023



Number and grading of deficiencies in 2024



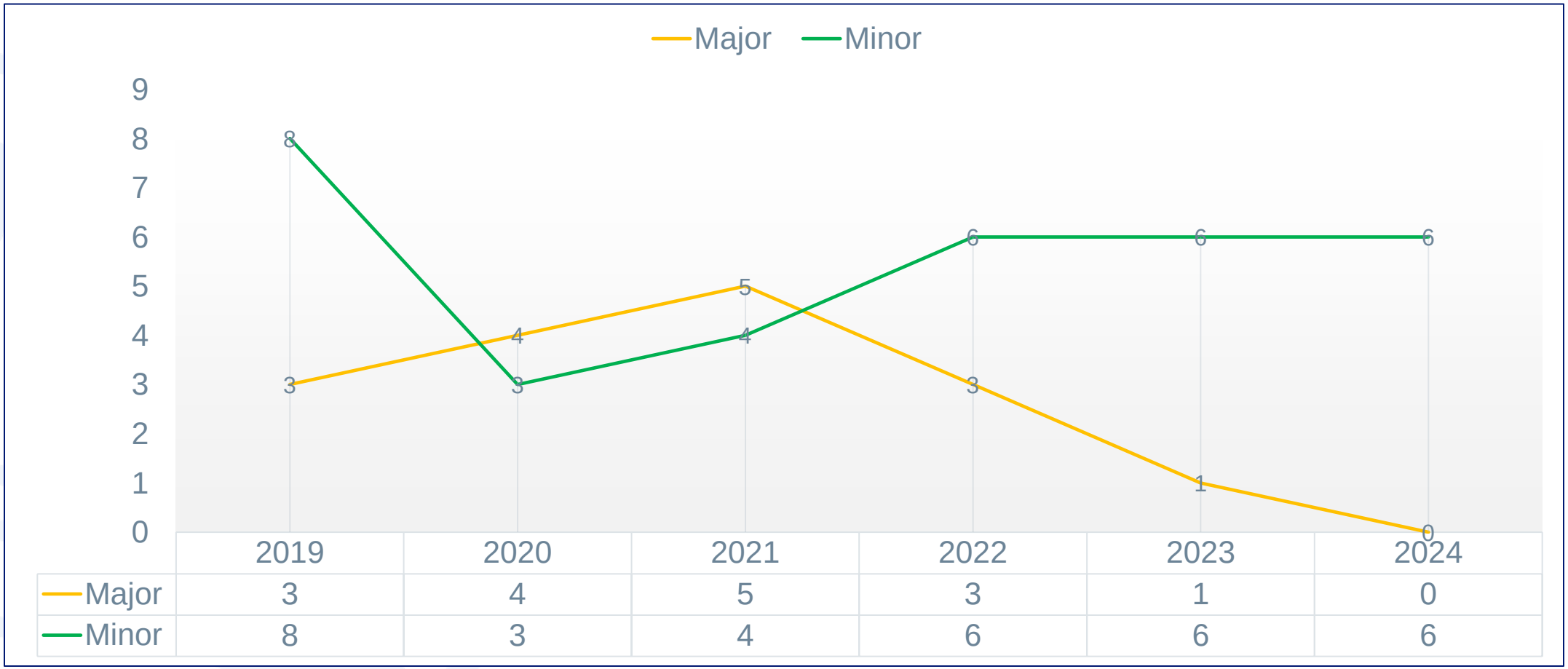
Improvement in deficiency findings over the years

- Case management
- Quality management system

Total number of deficiencies in case management over time

	2019	2020	2021	2022	2023	2024
Major	3	3	1	1	0	1
Minor	6	3	4	7	8	3

Total number of deficiencies in QMS over time



	2019	2020	2021	2022	2023	2024
Major	3	4	5	3	1	0
Minor	8	3	4	6	6	6

Limited changes in deficiency findings over the years

- Reference Safety Information
- Management of SSIs
- Post-approval commitment
- A-PVCP and QPPVA

Evolution of PVIP & next steps

Ongoing improvement

- Regular review to fine-tune processes
- Embracing new technologies and methodologies to improve inspection process
- Align with global trends

Work collaboratively with stakeholders

- Encourage feedback to identify areas for enhancement

Common feedback

Inspections are:

- too long
- rigorous
- too detailed
- too onerous
- not fit for purpose

But also …

Inspections have:

- been an excellent educational tool
- identified gaps in processes
- allowed for an open dialogue with the TGA
- identified the need for extra resourcing
- flagged common misconceptions across the sector and provided clarity
- allowed the ability to work with the TGA to ensure there is clear understanding of the requirements

Our aims

- Limit and revise inspection timeframes
- Formulate more focused document requests
- Review the scope of the inspection
- Use technological advances to gather information and documents

We are also aiming to:

- increase the number of inspections per year
- re-inspect where appropriate
- empower sponsors with the responsibility of CAPAs with limited regulatory involvement
- identify areas of specific need and provide targeted education
- publish more concise biannual PVIP reports

Therapeutic Goods Administration (TGA)

Exhibition booth **No.60**

Want to chat with me further? Come visit us.

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