TGA Provisional Approval COVID -19 Vaccine Safety Records

An Evidence-Based Review of Australia's COVID-19 Vaccine Safety Regulatory Oversight

November 2025

⚠ THE PROBLEM

The TGA published a comprehensive COVID-19 Vaccine Safety Monitoring Plan in **February 2021**. Nearly four years later, it admits it **never systematically tracked whether this monitoring was actually done**.

3+

Years of FOI battles

Two separate FOI requests and OAIC processes

4,000+

Pages TGA admits exist but refuses to release (FOI 25-0166)

3

Section 24AB consultations and multiple exchanges (Sept 2022 – May 2025)

1,360+ Days*

FOI refused despite consultations

*As at 9/11/25

✓ WHAT TGA CAN DO

September 2024

Reporting to Information Commissioner (MR22/00538)

- **Systematically classify** hundreds of documents by type (SOPs, protocols, workflows, electronic briefings)
- **Create detailed tables** organising documents (pages 7-17)
- **Demonstrate sophisticated** document management capability using 12 document categories

✗ WHAT TGA CLAIMS IT CAN'T DO

June 2025

Responding to citizen FOI request (FOI 25-0166)

- Use **the same classifications** (claims they're "too subjective")
- **Identify documents** related to safety plan objectives
- Admit documents were **never systematically tracked**

> *"these have not been previously identified or related to that objective and would therefore require subjective interpretation."*
>
> Source: FOI 25-0166 Decision, June 2025

Section 24AB Consultation Details:

After two section 24AB consultations, we narrowed our scope to just 30 documents.

TGA calculated burden on 399 documents - a 13x scope inflation beyond what was actually requested or 7.5% of total documents discovered.

FOI 25-0166 had two parts:

Point 1: Find 5 documents **by their specific names** (listed in the Safety Plan)

→ TGA Decision: ✅ **Accepted** - "clear and reasonable"

Point 2: Find 30 documents **by document type and objective** (using TGA's own classifications from September 2024)

→ TGA Decision: ❌ **Refused** - "too subjective," "would unreasonably divert resources"

Section 24AB Consultation Details cont.

Both parts used:

- ✅ Same timeframe (Feb 2021 - Feb 2025)
- ✅ Same selection method (most recent versions)
- ✅ Same document categories (TGA's own classifications from Sep 2024 OAIC)
- ✅ Same scope (Safety Plan related)

If the exact same criteria are clear enough for 5 documents, why aren't they clear enough for 30?

≠ THE TIMELINE OF CONTRADICTIONS ≠

FEB 2022	JUL 2022	SEP 2024	JUN 2025	OCT 2025
Records don't exist (FOI 3643)	"Ample documentation" (OAIC submission) (MR22/00538)	Demonstrates capability (MR22/00538)	TGA refuses. Claims FOI "subjective" (FOI 25-0166)	“There would be some difficulty” in producing documents (Dr Dascombe) “Very happy" to receive FOI (Prof. Lawler) as TGA simultaneously defends refusal

From an internal TGA email in the same submission:
"We would of course have ample documents demonstrating things we have done that correspond to each of the objectives of the plan" **— Elspeth Kay, Assistant Secretary, Pharmacovigilance Branch, 23 Feb 2022**

9 October 2025: When Senator Alex Antic specifically questioned TGA officials about the COVID-19 Vaccine Safety Monitoring Plan, asking whether it was used and whether documents were collected, Professor Lawler responded: "very happy to receive any requests for freedom of information" while Dr Dascombe confirmed "high volume" of documents exist relating to "day-to-day processes" (Senate Community Affairs Legislation Committee, 9 October 2025)

TGA'S PATTERN OF BEHAVIOUR

DENIAL → ADMISSION → ENCOURAGEMENT → REFUSAL

DENIAL

February 2022

"Documents do not exist"

ADMISSION

July 2022 - September 2024

MR22/00538: "Ample documentation" exists and asked to make new FOI request

ENCOURAGEMENT

Senate Estimates Community Affairs Legislation Committee, October 2025

"Very happy to receive requests for Freedom of Information"

REFUSAL

June 2025

FOI 25-0166: Request "too subjective", despite using TGA's own classification system and limiting scope to just 30 documents

Dr. Dascombe's Senate Testimony: The Admission

- Day-to-day processes" and "standard sort of process" — Provisional approval requires enhanced monitoring BEYOND routine surveillance.
- If monitoring was 'standard,' **were provisional approval conditions legally met?**
- **Documents were never systematically tracked.** Admission of "some difficulty" because documents "relate to day-to-day work" confirms no tracking by Safety Plan objectives occurred.

Senate Community Affairs Legislation Committee, 9 October 2025

As systematic implementation tracking never occurred, enhanced monitoring required for provisional approval cannot be verified.

⚠ WHY THIS MATTERS

Breach of Provisional Approval Framework

Provisional approval legally requires enhanced monitoring beyond routine surveillance. Dr Dascombe's characterisation of monitoring as "day-to-day processes" and "standard sort of process" is fundamentally inconsistent with these requirements, raising serious questions about whether provisional approval conditions were actually met.

Accountability Failure

The TGA made a public commitment to robust safety oversight but now admits it "never systematically tracked" implementation, creating a verifiable gap between promise and practice.

A Two-Tiered Transparency System

The TGA demonstrates sophisticated document retrieval for the Information Commissioner but claims the same task is "too subjective" for a citizen, applying one standard for regulators and another for the public.

A SIMPLE ANALOGY 

Imagine a hospital after a serious infection outbreak.

After an investigation, they develop and publish a detailed infection control plan to prevent future outbreaks.

Four years later, when asked for records proving the plan was implemented, hospital leadership responds:

”Infection control is part of hospital day-to-day processes now. We don't track or monitor it separately".

Would you accept that answer?

Of course not - because:

Enhanced protocols exist to be verified

"Day-to-day" contradicts "enhanced plan"

⚠ Without separate tracking and reporting, the hospital can't prove compliance

THE CRITICAL QUESTION

If enhanced monitoring was conducted as legally required for provisionally approved products, why can't TGA produce consolidated documentation after four years?

➡ Monitoring wasn’t conducted as a structured program, OR
➡ Records are too disorganised to retrieve, OR
➡ Documents were never consolidated as the law requires

Conclusion: ➡ Every possible explanation reveals a regulatory failure

THIS ISN’T AN ADMINISTRATIVE PROBLEM.

IT’S A TRANSPARENCY PROBLEM!

How can the same agency use document classifications systematically when reporting to the Information Commissioner, but claim those same classifications are "too subjective" for a citizen’s FOI request?

The TGA has provided no explanation

STATUTORY OBLIGATIONS POTENTIALLY BREACHED

Freedom of Information Act 1982

Documents claimed "do not exist" then "ample documentation" acknowledged. 1,133-day delay far exceeds statutory timeframes

Therapeutic Goods Act 1989

Unable to provide documentation demonstrating how provisional approval conditions requiring enhanced pharmacovigilance were implemented

International Pharmacovigilance Standards

Failed to locate ICH E2E, WHO/ICMRA collaboration records. Assessed objectives "in isolation rather than examining the system holistically"

Public Governance, Performance and Accountability Act 2013

Unable to systematically verify Safety Monitoring Plan implementation raises concerns about risk oversight and performance record duties

Archives Act 1983

Unable to systematically verify Safety Monitoring Plan implementation signals a breach of duties to create, maintain, and organise full and accurate records of regulatory actions as required by the Act

THE KEY CONTRADICTION

Senator Antic: “Can you produce documents showing Safety Plan implementation?”

Dr Dascombe (9 Oct 2025): "There would be some difficulty in doing that... the five key themes... essentially describe our day-to-day processes... vast volume of documents relate to our day-to-day work.”

But in July 2022, TGA officially submitted to the OAIC an email from Elspeth Kay, Assistant Secretary, Pharmacovigilance Branch (Attachment B, p.5, MR22/00538) 23 Feb 2022 stating:

“We would of course have ample documents demonstrating things we have done that correspond to each of the objectives of the plan”.

THE DOCUMENTATION PROBLEM

- Kay (2022): "Of course" have documents by objective
- TGA presented this as official evidence to OAIC
- Dascombe (2025): "Some difficulty" producing same documents
- Monitoring was "day-to-day" work - not systematically tracked by Plan objective
- "Vast volume" exists but "difficulty" retrieving it
- Documents "never previously identified" by objective (TGA admission, June 2025)

After 4 years: The TGA still can't provide consolidated documentation for enhanced safety plan implementation for the biggest vaccine rollout in Australian history

THE UNDELYING PROBLEM: A SYSTEM FAILURE?

Potential issues:

Dr. Dascombe's senate testimony and Kay's FOI responses raises fundamental questions about TGA's provisional approval compliance and its:

➤ **Information systems** - Lack capability to track by safety plan objective?

➤ **Resourcing** - Insufficient capacity for systematic documentation?

➤ **Organisational processes** - Disconnect between what was known in 2022 (Kay: documents "of course" exist) and what can be delivered in 2025 (Dascombe: "some difficulty")

The key question for investigation: how do you verify what you don't monitor?

- Does the TGA have adequate systems, resources, and organisational capability to verify provisional approval monitoring?

This potentially affects all provisional approvals - not just COVID-19 vaccines

THE CORE REGULATORY ISSUE

Monitoring was "day-to-day" and "standard" — D

∴

It was NOT "enhanced" — ¬E

∴

Provisional approval conditions were NOT met — ¬P

∴

Legal basis for approval is QUESTIONABLE — ¬L

63.8 million doses

administered under conditions that may not have been satisfied

Source: TGA Chief Medical Officer testimony, Senate Estimates, 9 October 2025

CURRENT STATUS

Legal and Regulatory Analysis

September 2024 OAIC submission proves contradiction

Information Commissioner Review

MR25/01153 - Evidence submitted October 2025

Senate Community Affairs Legislation Committee

Senate hearing 9 October 2025

Commonwealth Ombudsman

Complaint lodged April 2025 (awaiting formal commencement)

Matter: MR25/01153 (FOI 25-0166)

Key Evidence: TGA OAIC Submission MR22/00538 (24 September 2024) | FOI 25-0166 Decision (3 June 2025)

🔍 RESEARCH METHODOLOGY

Four-Year Evidence-Based Investigation (2022-2025)

FOI Requests

Two separate requests (FOI 3643, FOI 25-0166) iteratively refined using TGA's own document classification systems

OAIC Reviews

Two OAIC reviews (MR22/00538, MR25/01153). TGA admits holding 399 documents (3,926 pages) in 12 categories but refuses release (FOI 25-0166)

Comprehensive Document and Data Analysis

Analysis of TGA administrative responses, document categories, and classification systems revealing contradictory practices, statements made by executive officers and systemic recording failures

Cross-Referencing

Systematic comparison of TGA public statements, FOI responses, OAIC submissions, and parliamentary testimony

Statutory Analysis

Analysis of obligations under TGA Act 1989, PGPA Act 2013, FOI Act 1982, and pharmacovigilance standards

Parliamentary Evidence

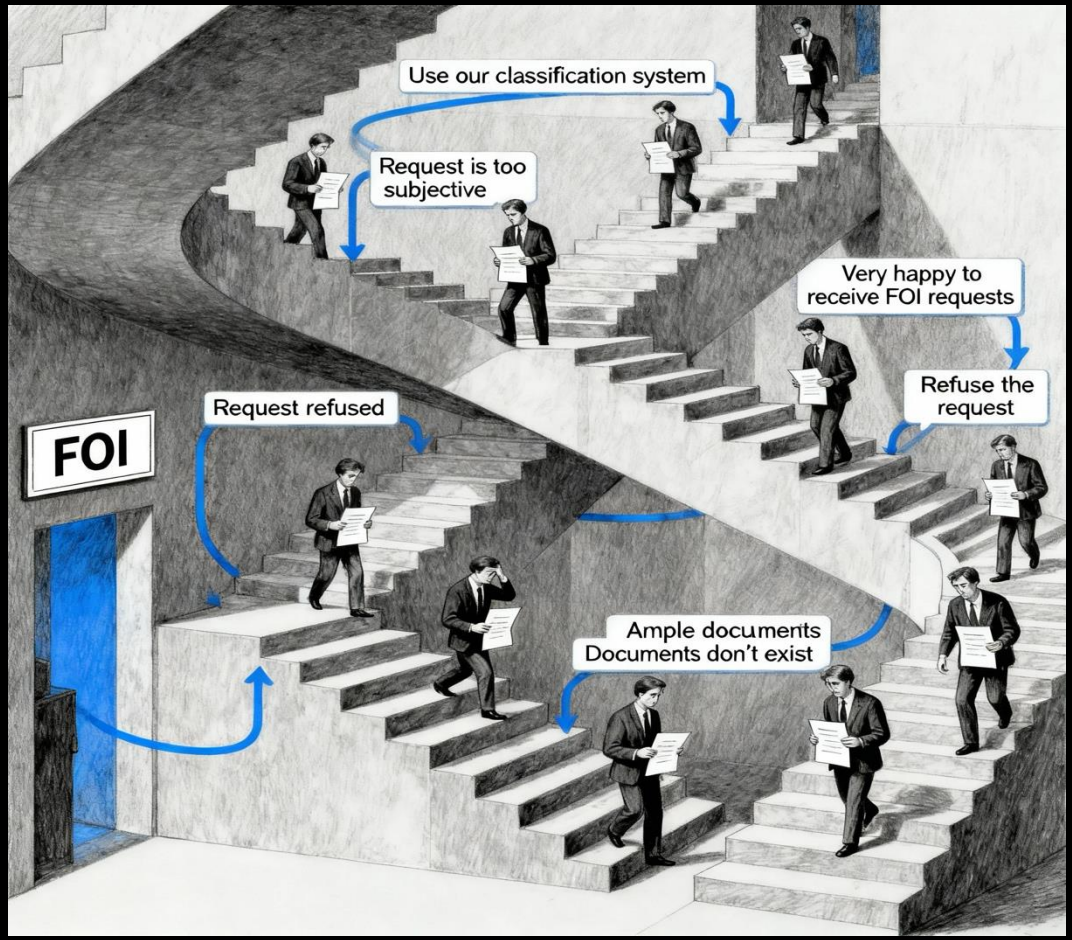
Integration of Senate Community Affairs Legislation Committee testimony (9 October 2025) demonstrating real-time contradictions

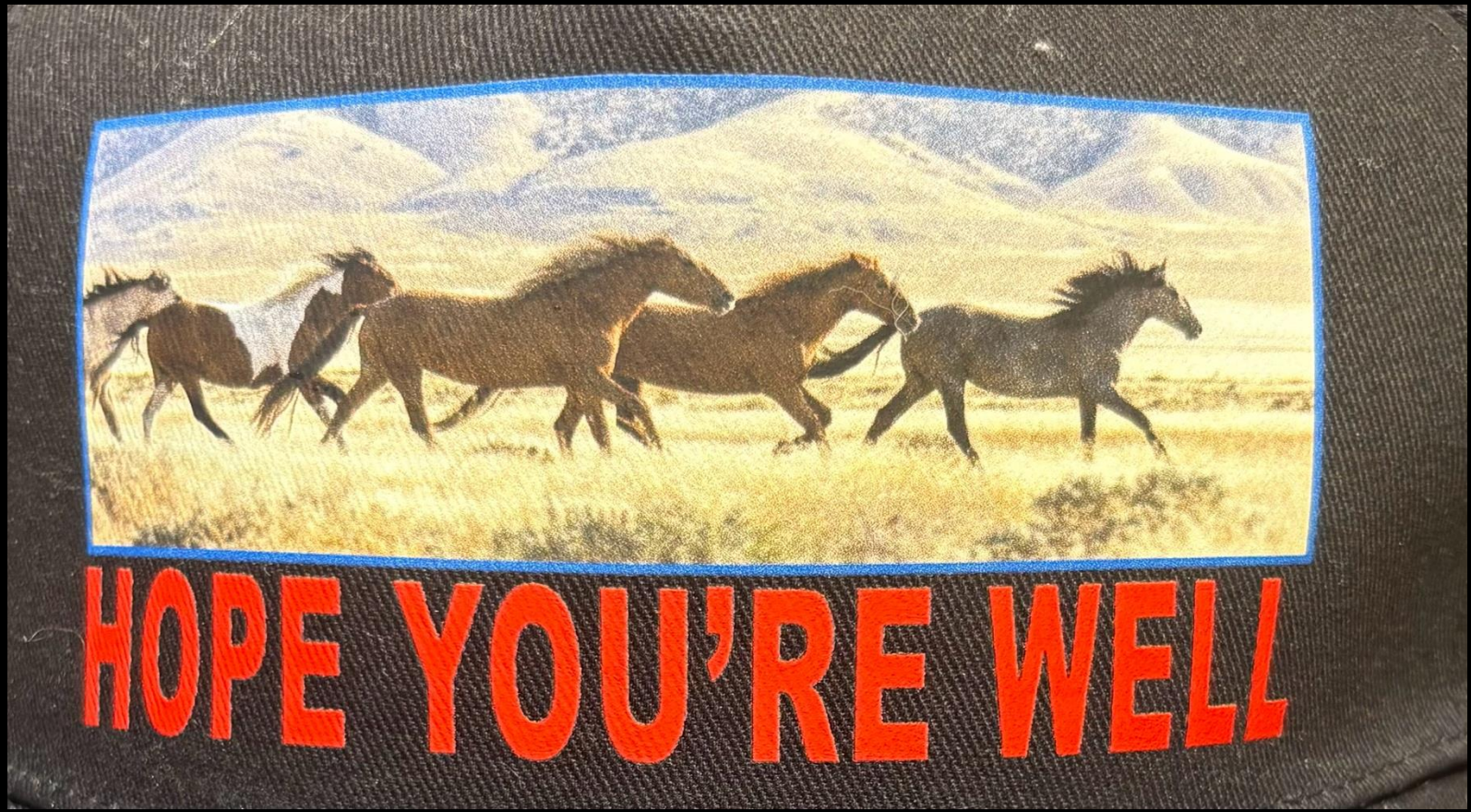
Independent Review: Research reviewed by medical doctor and medical research scientist with expertise in health policy and regulatory transparency

This multi-layered approach combines legal recourse, administrative challenge, and comprehensive analysis to establish patterns of dysfunction affecting Australia's medicines regulator.

"A true democracy is a place of many voices, including discordant voices."
— Justice Michael Kirby

FOI Stairs: ≈ 1,400 days to no where




HOPE YOU'RE WELL