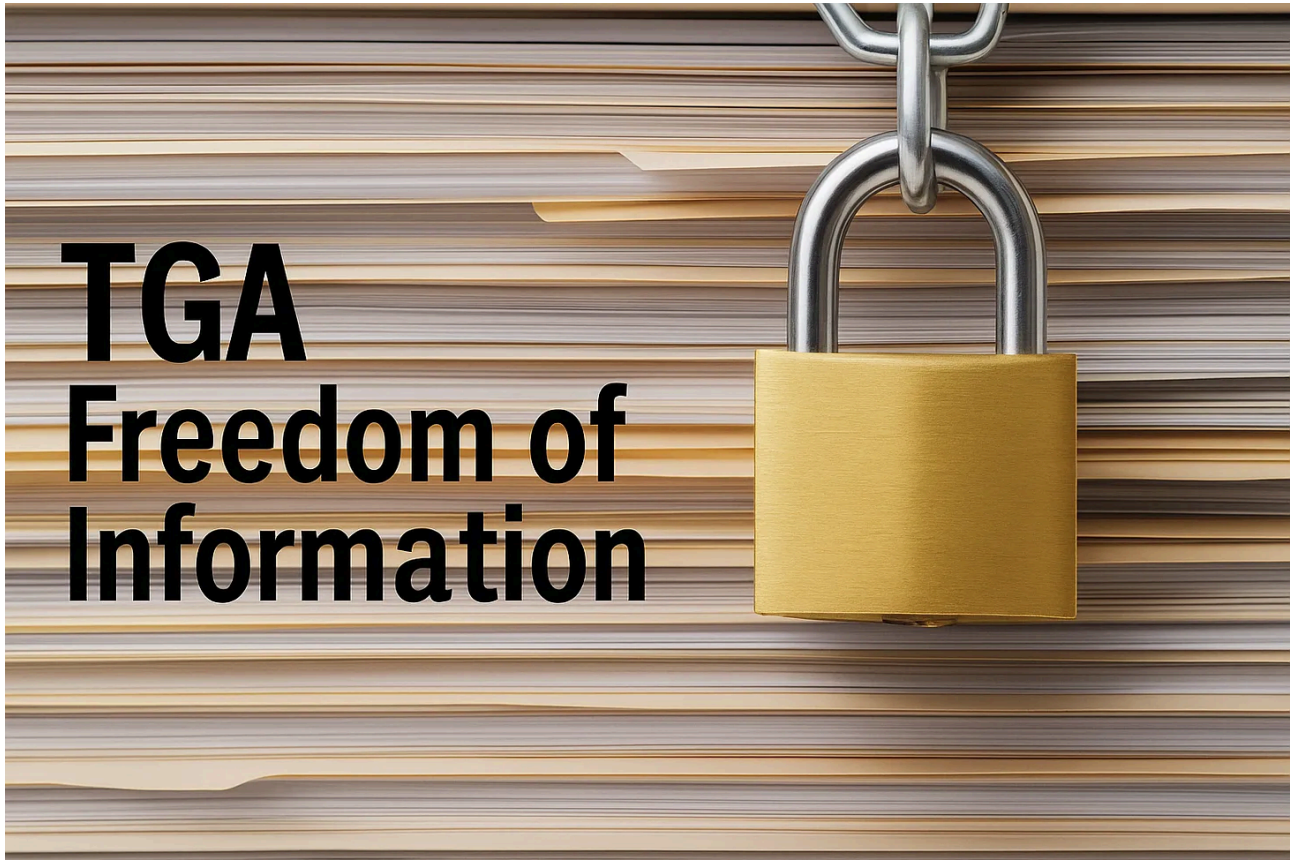
TGA's vaccine safety black hole - a battle for transparency

For 3yrs, P. Rekaris & Dr Julie Sladden have fought to expose the truth behind Australia's vaccine safety oversight. The TGA denied the documents existed—until they didn't. The battle is ongoing.

MARYANNE DEMASI, PHD

MAY 25, 2025



GUEST POST

by

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sectors. He specialises in regulatory transparency.

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passion for transparency in healthcare, politics and re

A three-year Freedom of Information (FOI) battle has exposed a
contradiction at the heart of Australia's pharmaceutical regulat

The Therapeutic Goods Administration (TGA) claims it both do
documentation detailing how Covid-19 vaccine safety was imple

This paradoxical stance raises profound concerns about transpa
accountability in our public health system.

Provisional approval and the safety promis

When Covid-19 vaccines were granted “provisional” approval in
conditions were required.

Unlike standard approvals, provisional approval is based on limited data – so the TGA was legally required to conduct enhanced safety monitoring.

This included mandatory pharmacovigilance activities beyond routine surveillance, i.e. detailed ongoing safety reporting, active monitoring for specific adverse events, and immediate investigation of emerging safety signals – all essential safeguards given the

expedited nature of the approval process.

In February 2021, the TGA released its *Covid-19 Vaccine Safety Monitoring Plan* committing to timely collection of adverse event reports, surveillance for safety signals, and regular public communications.

These safeguards were meant to earn public trust during a time of a global health emergency.

The startling contradiction

In light of these legal and regulatory requirements, one would reasonably expect the TGA would have ready access to documentation showing how it monitored vaccine safety.

But that wasn't the case.

In February 2022, we submitted a seemingly straightforward FOI request 3643, seeking documentation that showed how this critical Safety Monitoring Plan was being put into practise.

The TGA replied that the document "does not exist."

Then, in a baffling contradiction, the TGA later admitted it held "ample documentation demonstrating compliance" with the Plan.

Under Section 24A of the FOI Act, a request can only be refused if the documents cannot be found or genuinely do not exist - not because they are inconvenient to produce.

The TGA's position was not just contradictory – it was untenable.

Failure of statutory obligations

The TGA is legally bound to maintain safety plan implementation records under several laws and guidelines, including the Public Governance, Performance and Accountability Act, international pharmacovigilance standards, and the Commonwealth Risk Management Framework.

The TGA's own adopted 'Guideline on Good Pharmacovigilance Practices' explicitly requires structured documentation and periodic safety update reports - the very documentation the agency initially claimed did not exist.

These standards ensure that regulators can verify their actions, especially when fast-tracking products during a public health emergency.

The TGA's contradictory positions highlighted in its FOI responses suggest the agency may fundamentally misunderstand its statutory obligations for transparency and accountability under both FOI legislation and the pharmaceutical regulatory framework.

Without proper documentation and verification pathways, these commitments are just wishful thinking - undermining the entire regulatory system and potentially putting

public health at risk.

This gap between policy and documented practice means millions of Australians may have been vaccinated without confirmation that key safety measures were followed as promised under its own Safety Plan.

Under legal pressure, documents emerge

It wasn't until the Office of the Australian Information Commissioner (OAIC) intervened that the TGA finally disclosed over 2,200 pages of related documentation, including:

- 303+ pages on adverse event processing
- 679+ pages on safety signal detection
- 406+ pages on regulatory actions
- 250+ pages on public communications
- 274+ pages on stakeholder collaboration

These were precisely the implementation documents the TGA had acknowledged possessing while simultaneously refusing access by claiming no single implementation report existed.

The TGA's failure to provide these materials earlier not only violates the core tenets of the FOI Act, but also raises questions about procedural fairness and transparency in public health governance.

Information management in disarray

Given Australia was involved in the 'largest global vaccination trial ever,' the TGA is obligated to have this information readily available. After all, the progression from provisional to full approval explicitly required the rigorous collection and analysis of medium- and long-term safety and efficacy data.

If the TGA couldn't even search for key safety documents, how could it detect safety signals in real time?

According to its own submission made to the OAIC, the TGA:

- Only searched records from February 2022, completely missing the critical first year of vaccine safety monitoring
- Assessed Safety Plan objectives in isolation rather than examining the system holistically
- Failed to locate WHO/ICMRA collaboration records cited in its own Safety Plan, despite daily meetings noted in TGA logs

This is not an isolated incident.

In a separate FOI (5275) concerning Pfizer's post-market safety data, the TGA again claimed the documents "do not exist." This, despite their own Safety Monitoring Plan explicitly requiring 'timely submission of post market safety studies and monthly safety summaries' as a condition of registration.

These admissions point to a systemic failure to uphold key pharmacovigilance responsibilities.

A failure of timeliness, transparency and oversight?

Our FOI request for the Covid-19 Vaccine Safety Monitoring Plan dragged on for a staggering 1,133 days. This spanned the entire mass vaccination period, rendering the information effectively useless and nullifying any practical value to the public.

But this case transcends paperwork. It potentially exposes critical gaps in safety oversight during Australia's largest-ever medical emergency and raises critical questions about the TGA's provisional approval process:

1. Was the Safety Monitoring Plan ever intended to be operational, or was it just rubber stamped for provisional approval?
2. How can the TGA claim both "ample documentation" and "no records" without accountability?
3. If the regulator can't search its own safety records, how can it detect and investigate vaccine-related events in a timely manner?
4. How can Australians trust the safety of provisionally approved products if the conditions of that approval were not properly verified?

After three years of chasing answers, we have submitted a new, more narrowly focused FOI request last month, seeking documents directly related to the plan's implementation.

The TGA identified 399 documents - totalling nearly 4,000 pages - but promptly initiated a "practical refusal" process, again citing resource constraints. Discussions to access these documents are ongoing.

Three years after our initial request, Australians *still* cannot verify whether enhanced monitoring of safety signals ever occurred.

These regulatory behaviours and lack of transparency have contributed to the significant erosion of public trust in health governance.

In our opinion, this inability to document and verify critical safety monitoring is alarming and poses significant public health risks.

The Covid-19 vaccine rollout was unprecedented: provisional approvals, novel technologies and rapid mass deployment. Regardless of one's stance on vaccines, unverified safety monitoring should concern everyone.

And so, one final question remains: If the TGA cannot confirm whether it implemented its own safety monitoring plan - then what exactly is it regulating?

Note: This article is based on documented FOI correspondence, TGA submissions to the Information Commissioner, and official review decisions spanning 2022-2025. A complaint is currently pending with the Commonwealth Ombudsman.

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Discussion about this post

Comments Restacks

Write a comment...

Julian Gillespie 25 May

Liked by Maryanne Demasi, PhD

thank you Dr Sladden & Paul Rekaris,

.. I have said it before

TGA: The Gaslighting Agency

had they implemented the Plan, the signals would have screamed "STOP"

.. so they did not implement the Plan

as presently staffed, with its culture of deception and meeting the needs of its pharmaceutical stakeholders .. and dare I say it .. the TGA's 5 Eyes capture .. well .. the entire administration needs to be gutted and entirely new legislation drawn for preventing a re-occurrence of what has been a diabolical betrayal of the department's core mission - to "provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods"

.. they got the "timely availability" part right .. but of goods that immediately maimed and killed

and they knew this .. so no reliable paperwork was allowed to be generated

a quick history reminder .. the Nazi leadership also had a policy of "plausible deniability" - deliberately keeping the most incriminating directives oral or unwritten to avoid accountability

here a Plan was announced .. then .. I think we can all surmise .. senior persons issued incriminating directives .. given orally and not in writing .. to not implement the Plan

the theater we see detailed above is meant to be the closing Act .. a show of apparent bureaucratic bumbling, by officials paid millions in their positions, who just somehow forgot to do what they said they would do

.. they spat the 'fog of bureaucracy' cliche in everyone's face

it's a show .. it's a sham

as the hip-hoppers Public Enemy would remind you: Don't believe the hype

thank you again Dr Sladden and Paul Rekaris for enduring their lies and documenting the betrayal .. the complicity .. and the corruption

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3 replies by Maryanne Demasi, PhD and others

Helena Rose 25 May

Liked by Maryanne Demasi, PhD

The Fox (TGA) should not be allowed to guard the Chicken Coop. They cannot Monitor for Safety while at the same time 96% to 98% of their funding comes from the Approval of Drugs and Vaccines. Total Conflict of Interest. Why was this ever allowed and is still continuing?

LIKE (20) REPLY SHARE

3 replies

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