

# Frequently Asked Questions: TGA COVID-19 Vaccine Safety Monitoring Audit

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**FAQ Version:** 1.1

**Audit Report Version:** 1.5.1

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## At a Glance

### The Promise

#### **Cabinet Commitment (November 2020)**

National Cabinet endorsed "active and comprehensive" COVID-19 vaccine safety monitoring, to be delivered through TGA's COVID-19 Vaccine Pharmacovigilance Plan.

#### **Why It Mattered**

Enhanced post-market monitoring was the regulatory safeguard that justified provisional, rather than standard, approval (less pre-market evidence, faster access) and underpinned government mandates affecting employment, travel and social participation.

#### **Regulatory Requirement**

Enhanced monitoring was a legal condition for provisional approval at population scale – the explicit trade-off for accelerated approval under greater uncertainty.

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## The Plan

#### **TGA's Safety Monitoring Plan (February 2021)**

TGA published a COVID-19 Vaccine Safety Monitoring Plan with 20 specific outputs to operationalise the Cabinet commitment.

#### **Deployment Scale**

Around 26 million Australians received 68 million doses under this framework, with mandates and significant consequences for non-compliance.

#### **AusVaxSafety Implementation**

Government-funded active surveillance delivered 6.8 million SMS surveys, around 3 million adverse events and about 62,000 self-reported medical visits.

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## The Gap – Four Missing Documentation Streams

### **Signal Management**

No audit trail showing how individual safety signals were evaluated or linked to specific regulatory decisions.

### **Provisional Approval Verification**

No records demonstrating that enhanced monitoring conditions were assessed and met for quarterly extensions and eventual full registration.

### **AusVaxSafety–TGA Integration**

No systematic documentation of how 6.8 million surveys and ~3 million adverse events were integrated into TGA pharmacovigilance workflows.

### **Governance and Performance Reporting**

Only 3 of 20 plan outputs (15%) fully documented; no evidence of systematic tracking against plan objectives.

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## What TGA Cannot Demonstrate

### **Regulatory Obligations**

TGA cannot produce documentation showing it met provisional-approval monitoring requirements under Cabinet-endorsed policy, Australian law and the international pharmacovigilance standards it cites (ICH E2E, CIOMS).

### **Official Confirmation**

The Information Commissioner confirmed that implementation records for the Plan could not be found after searches of 531 TRIM folders and more than 2,200 pages.

### **Senate Admission**

TGA officials admitted monitoring was "never systematically tracked" against Plan objectives and characterised it as "day-to-day processes".

### **Legal Commentary**

The OAIC decision has been noted in independent legal commentary (Sparke Helmore) and cited in parliamentary proceedings.

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## The Core Problem

### **Regulatory Justification**

Enhanced monitoring was both the regulatory justification for provisional approval

and the public-health justification for mandates – yet it cannot be verified through documentation.

### **Why It Matters**

If the enhanced monitoring promised to Cabinet, Parliament and the public cannot be evidenced, the regulatory and policy framework for Australia's largest deployment of provisionally approved medicines rested on an unverifiable assurance, despite Australia formally adopting international pharmacovigilance standards.

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## **Oversight and Evidence**

### **Current Status**

The matter is now before the OAIC, the Commonwealth Ombudsman, the Australian National Audit Office and a Senate committee.

### **Evidence Base**

All audit reports, timelines and source documents are fully public and permanently archived at DOI: [10.5281/zenodo.17731054](https://doi.org/10.5281/zenodo.17731054)

### **Read Time**

Around 15 minutes is sufficient to grasp the main findings and their implications.

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## **Part 1: Understanding the Issue**

### **Q1: What is this audit about?**

This audit assesses whether Australia's Therapeutic Goods Administration (TGA) systematically implemented the COVID-19 Vaccine Safety Monitoring Plan it published in February 2021. This Plan operationalised a National Cabinet-endorsed policy commitment requiring "active and comprehensive" post-market safety monitoring for COVID-19 vaccines administered under provisional approval.

### **Q2: What did I find?**

Only 15% of the Plan's 20 specified outputs are fully documented after four years. The Australian Information Commissioner confirmed after extensive searches covering 531 TRIM containers and 2,218+ pages that TGA implementation records for the Plan do not exist. TGA senior officials told a Senate committee that enhanced monitoring was conducted as "day-to-day processes" that were "never systematically tracked" against Plan objectives.

### Q3: Why does this matter?

68 million doses were administered under provisional approval, where enhanced monitoring beyond routine surveillance was the legal condition for approval. If this enhanced monitoring cannot be verified through documentation, the provisional approval verification framework has failed during Australia's largest deployment of provisionally approved medicines. The gap exists between a formal Cabinet-endorsed commitment and demonstrable delivery.

### Q3A: Why is accountability for this monitoring framework so critical?

#### Scale and Stakes:

- **26 million Australians** received COVID-19 vaccines
- **73 million doses** administered in total (68 million under provisional approval)
- This was Australia's **largest and fastest vaccine deployment in history**

#### Government Mandates:

- Federal and state governments imposed vaccine mandates across multiple sectors
- Many Australians faced job loss, professional deregistration, or exclusion from society without vaccination
- International travel was restricted for unvaccinated citizens
- Access to workplaces, venues, and services was conditional on vaccination status
- These measures were justified based on assurances of robust safety monitoring

#### The Regulatory Trade-Off:

Provisional approval is specifically designed for situations where products are approved faster with less complete evidence. **In exchange for faster approval, enhanced safety monitoring is mandatory.** This monitoring is the regulatory safeguard that compensates for abbreviated pre-approval evidence. It's not optional—it's the legal condition that makes provisional approval acceptable.

#### The Social Contract:

When government tells 26 million citizens:

1. "These vaccines are provisionally approved"
2. "We are conducting enhanced safety monitoring"
3. "You must take these vaccines to participate in society"

**Then government must be able to demonstrate:**

- The enhanced monitoring actually occurred as promised
- It was systematic and verifiable, not just routine processes
- The safety monitoring framework that justified provisional approval and mandates was actually implemented

If TGA cannot verify the enhanced monitoring framework was systematically implemented, then the regulatory safeguard for provisional approval cannot be proven, and the assurances given to justify mandates cannot be demonstrated through documentation.

**The stakes were extraordinary. The accountability must match.**

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## **Part 2: The Commitments Made**

### **Q4: What was the Cabinet policy commitment?**

On 13 November 2020, National Cabinet endorsed the Australian COVID-19 Vaccination Policy, which formally committed the Commonwealth Government to "active and comprehensive" post-market safety monitoring of COVID-19 vaccines. Page 13 of this policy document specified delivery via the TGA's COVID-19 Vaccine Pharmacovigilance Plan. This was not guidance—it was Cabinet-endorsed policy requiring operational implementation.

### **Q5: What was TGA's operational plan?**

In February 2021, TGA published the COVID-19 Vaccine Safety Monitoring Plan as the operational implementation of the Cabinet commitment. It specified 20 outputs across 5 strategic areas with 17 numbered sub-activities, defining the enhanced monitoring framework required for provisionally approved vaccines. This was published as a formal plan, not internal guidance.

### **Q6: What was AusVaxSafety's role?**

AusVaxSafety publicly positioned itself as operating "as part of the national COVID-19 Vaccine Pharmacovigilance Plan, led by the TGA." This government-funded programme (via NCIRS) conducted 6.8 million SMS surveys, reported approximately 3 million adverse events, and documented 62,000 medical visits. Active surveillance through AusVaxSafety was intended to be the "enhanced" component distinguishing this monitoring from routine pharmacovigilance.

## **Q7: How many doses were affected?**

68 million doses were administered during the provisional approval period when this three-tier monitoring framework (Cabinet policy → TGA Plan → AusVaxSafety delivery) was supposed to be operating. This represents approximately 94% of Australia's COVID-19 vaccine rollout.

## **Q8: What was the context for this vaccine deployment?**

### **Unprecedented Scale:**

- **26 million Australians** vaccinated (approximately 96% of eligible population)
- **73 million total doses** administered
- **68 million doses** under provisional approval
- Fastest mass vaccination programme in Australian history

### **Government Mandates and Restrictions:**

#### **Federal mandates:**

- Aged care workers
- Healthcare workers
- Disability care workers
- Commonwealth employees in certain roles

#### **State and territory mandates (varied by jurisdiction):**

- Broader healthcare and education sectors
- Hospitality and entertainment workers
- Construction workers
- Emergency services
- Public-facing government employees

#### **Public health orders:**

- Unvaccinated citizens excluded from venues, restaurants, gyms
- Interstate travel restrictions
- International border closures for unvaccinated
- Quarantine requirements differentiated by vaccination status

### **Consequences for Non-Compliance:**

- Immediate job termination across multiple industries
- Professional deregistration (doctors, nurses, teachers, allied health)

- Loss of income and career disruption
- Inability to work in mandated sectors
- Restricted access to social, cultural, and economic participation
- Inability to visit family members in aged care or hospitals
- Exclusion from major life events (weddings, funerals)

### **Provisional Approval Framework Context:**

These vaccines were approved via provisional approval pathway, which:

- Allows faster approval with abbreviated pre-market evidence requirements
- **Requires enhanced post-market safety monitoring as the compensating regulatory safeguard**
- Makes systematic safety surveillance the key regulatory control for provisionally approved medicines
- Legally conditions approval on demonstrable enhanced monitoring beyond routine surveillance

### **The Assurances Given to Australians:**

Government and health authorities repeatedly stated:

- "These vaccines have undergone rigorous safety assessment"
- "The TGA is conducting enhanced safety monitoring"
- "Active surveillance through AusVaxSafety provides real-time safety data"
- "We have robust pharmacovigilance systems in place"
- "Post-market monitoring will detect any safety signals"

### **Why Documentation and Verification Matter:**

When government:

1. Deploys provisionally approved products to 26 million people
2. Mandates these products with severe personal and professional consequences for refusal
3. Restricts citizens' fundamental freedoms based on vaccination status
4. Justifies these extraordinary measures with assurances of enhanced safety monitoring

### **Then government must demonstrate:**

- The promised enhanced monitoring actually occurred systematically
- It met the enhanced standard required for provisional approval (not just routine surveillance)
- It functioned as the regulatory safeguard it was represented to be
- The monitoring framework that justified both provisional approval and coercive mandates was implemented as designed

## **The Accountability Question:**

If 26 million Australians:

- Received provisionally approved vaccines
- Under government mandates with severe consequences for refusal
- Based on assurances of enhanced safety monitoring
- During the most significant public health intervention in Australian history

**But that enhanced monitoring cannot be verified through documentation, cannot be demonstrated to have been systematically tracked, and officials confirm it was never measured against Plan objectives...**

**Then this represents a fundamental failure of regulatory accountability, transparency, and the provisional approval verification framework at the exact moment when such accountability mattered most.**

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## **Part 3: What's Missing**

### **Q9: What records are missing?**

Four critical categories of documentation cannot be located:

#### **Signal Management:**

- Audit trails linking 91 of 148 investigated safety signals to disposition decisions
- Documented decision criteria for signal evaluation
- Systematic protocols for signal prioritisation

#### **AusVaxSafety Integration:**

- Coordination protocols between TGA and AusVaxSafety
- Data integration frameworks showing how 3 million adverse events informed regulatory decisions
- Systematic incorporation of active surveillance into signal detection

#### **Provisional Approval Verification:**

- Documentation verifying enhanced monitoring conditions were met before provisional approval extensions
- Records demonstrating enhanced monitoring continued through transitions to full registration



### **Governance and Oversight:**

- Performance measurement against Plan objectives
- Oversight mechanisms for monitoring framework
- Systematic tracking of Plan implementation

### **Q10: How extensive is the documentation gap?**

Assessment of the Plan's 20 specified outputs shows:

- **15% fully documented** (3 of 20 outputs)
- **55% partially implemented or undocumented** (11 of 20 outputs)
- **30% not documented at all** (6 of 20 outputs)

Critical gaps exist in signal detection protocols, multi-source data integration frameworks, governance oversight, and verification documentation for provisional approval conditions.

### **Q11: What should exist if implementation occurred as designed?**

International pharmacovigilance standards (ICH E2E, CIOMS) that TGA formally adopted require:

- **Signal management protocols** with documented decision criteria
- **Audit trails** from signal detection through regulatory action
- **Data source integration frameworks** for multi-source surveillance systems
- **Governance oversight** with performance measurement against objectives
- **Verification records** demonstrating regulatory conditions were met

For provisional approval specifically, enhanced monitoring must be demonstrable and verifiable—not merely asserted—to prove regulatory conditions are being met.

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## **Part 4: Independent Verification**

### **Q12: How do you know records are missing (not just withheld)?**

The Australian Information Commissioner conducted extensive searches in response to FOI requests and issued a formal decision ([2025] AICmr 54) confirming that TGA implementation records for the Plan do not exist. This finding resulted from OAIC-directed searches conducted by two senior TGA officers covering 531 TRIM containers and reviewing 2,218+ pages. This is not FOI obstruction—the

Commissioner independently verified through departmental searches that the records are genuinely absent.

### **Q13: What did the Information Commissioner find?**

In decision [2025] AICmr 54 (March 2025), the Australian Information Commissioner:

- Directed extensive TGA searches covering 531 TRIM containers
- Reviewed 2,218+ pages of potentially relevant material
- Confirmed no TGA implementation records for the Plan exist
- Found no systematic tracking of Plan objectives
- Validated that requested records are genuinely absent, not merely withheld

### **Q14: What did TGA tell the Senate?**

In testimony to the Senate Community Affairs Legislation Committee on 9 October 2025, TGA senior officials stated:

- Implementation was conducted as "day-to-day processes"
- Monitoring was "never systematically tracked" against Plan objectives
- A "vast volume" of documents exists but cannot demonstrate the Plan was delivered as designed
- They are "very happy to receive FOI requests" whilst simultaneously defending refusal to release implementation documentation
- Producing organised documentation would be difficult because activities were not tracked by Plan objectives

### **Q15: Has this been independently verified by others?**

Yes. Sparke Helmore Lawyers, a major Australian law firm, published independent legal analysis of the OAIC case (AUQ and Department of Health and Aged Care). The case has been cited in legal, parliamentary, and media contexts. The matter is currently before multiple oversight bodies: the Australian Information Commissioner (review MR25/01153), Commonwealth Ombudsman (complaint submitted), Australian National Audit Office (audit requested), and Senate Community Affairs Legislation Committee (parliamentary referral).

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## **Part 5: The Details**

### **Q16: How many safety signals were investigated?**

TGA investigated 148 COVID-19 vaccine safety signals and took 57 regulatory actions. However, 91 signals (62%) have no documented disposition or decision criteria. Zero audit trails linking signals to specific regulatory actions have been

identified through systematic searches. This absence of audit trails contradicts ICH E2E and CIOMS international pharmacovigilance standards that TGA formally adopted.

### **Q17: What's the AusVaxSafety integration gap?**

Despite AusVaxSafety's public positioning as operating "as part of" the TGA-led national pharmacovigilance plan:

- Zero documentation of systematic integration into TGA signal detection exists
- No coordination protocols found in OAIC-directed searches
- TGA omitted the term "AusVaxSafety" from its classification system for OAIC searches
- No audit trails showing how 3 million adverse events informed TGA decisions
- Cannot verify the "enhanced" (active surveillance) component was systematically used

Active surveillance was supposed to distinguish this monitoring from routine pharmacovigilance, but systematic integration cannot be demonstrated through documentation.

### **Q18: What international standards weren't met?**

TGA formally adopted ICH E2E (Pharmacovigilance Planning) and CIOMS (signal management) standards but cannot demonstrate compliance:

#### **ICH E2E requires:**

- Documented pharmacovigilance plans with measurable objectives
- Systematic tracking of plan implementation
- Verification that planned activities occurred

#### **CIOMS requires:**

- Audit trails from signal detection through evaluation to decision
- Documented decision criteria for signal prioritisation
- Transparent signal management processes

The absence of implementation records, audit trails, and systematic tracking indicates non-compliance with these internationally recognised standards that Australia formally adopted.

### **Q19: What percentage of Plan outputs are documented?**

Of the Plan's 20 specified outputs assessed:

**Fully documented (15%):** 3 outputs

- Regular safety updates published
- DAEN database maintained
- Some public communications delivered

**Partially implemented or undocumented (55%): 11 outputs**

- Activities may have occurred but systematic tracking absent
- Incomplete audit trails
- Cannot verify against Plan specifications

**Not documented (30%): 6 outputs**

- No evidence located after four years
- Include critical integration and governance elements
- Systematic verification impossible

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## **Part 6: Addressing Objections**

### **Q20: Couldn't TGA have done the monitoring without formal tracking?**

No. Provisional approval legally requires enhanced monitoring **beyond** routine surveillance with demonstrable verification. The term "enhanced" implies something additional to standard processes. Describing this as "day-to-day processes" that were "never systematically tracked" contradicts the enhanced monitoring requirement.

Without separate tracking, audit trails, and verification documentation, compliance with provisional approval conditions cannot be proven. The absence of systematic tracking means there's no way to distinguish between routine surveillance (which exists for all medicines) and the enhanced monitoring that was the specific condition for provisional approval of these vaccines.

### **Q21: Isn't this just a documentation problem, not a safety problem?**

The audit assesses whether TGA can demonstrate through documentation that promised enhanced monitoring was systematically implemented. Documentation is how regulatory compliance is verified—it's not optional or separate from the substantive work.

The absence of implementation records, combined with official confirmation that monitoring was "never systematically tracked," means the verification framework for provisional approval conditions has failed. If enhanced monitoring cannot be

documented, it cannot be verified. If it cannot be verified, regulatory compliance cannot be proven.

This is a fundamental governance and accountability failure, not merely poor record-keeping.

## **Q22: Why does it matter if vaccines were approved elsewhere?**

Australian provisional approval is a distinct regulatory pathway with its own legal requirements. The specific condition was that TGA would conduct enhanced monitoring beyond routine surveillance as outlined in the Cabinet-endorsed policy and published Plan.

Whether other countries approved these vaccines under their own regulatory frameworks is irrelevant to whether TGA met its own regulatory obligations, followed its published plan, and delivered on Cabinet-endorsed commitments for the Australian deployment.

International approvals cannot substitute for demonstrable compliance with Australia's own provisional approval conditions.

## **Q23: Maybe TGA just has poor record-keeping?**

Poor record-keeping would be a serious regulatory failure in itself, but the evidence suggests something more systemic:

- **Records management is a legal requirement** under the Archives Act 1983 and Public Governance, Performance and Accountability Act 2013
- **TGA demonstrated capability** to organise hundreds of documents by category for the Information Commissioner
- **Same classification system was deemed "too subjective"** when citizen requested documents using it
- **Officials confirmed** monitoring was "never systematically tracked" against Plan objectives

This pattern indicates not poor record-keeping, but an absence of the systematic implementation framework itself. If activities were never tracked against Plan objectives, then records of that tracking cannot exist—because the tracking never occurred.

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## **Part 7: What Happens Next?**

### **Q24: What oversight processes are underway?**

**Australian Information Commissioner:**

- Review MR25/01153 ongoing
- Examining FOI handling and documentation practices

#### **Commonwealth Ombudsman:**

- Complaint submitted regarding TGA pharmacovigilance practices
- Case not yet assigned for investigation

#### **Australian National Audit Office:**

- Performance audit requested of Safety Plan commitment and provisional approval verification
- Submission provided with complete evidence base

#### **Parliamentary Oversight:**

- Matter referred to Senate Community Affairs Legislation Committee
- Senate testimony on record regarding implementation gaps

All oversight bodies have access to the complete audit evidence through public GitHub repository and permanent Zenodo archive.

### **Q25: What would close this audit gap?**

TGA could refute these findings by producing the implementation documentation that the Information Commissioner's extensive searches could not locate:

- Systematic tracking records showing Plan outputs were delivered as designed
- Audit trails linking safety signals to disposition decisions with documented criteria
- Coordination protocols and data integration frameworks for AusVaxSafety
- Governance oversight documentation with performance measurement against Plan objectives
- Verification records demonstrating enhanced monitoring conditions were met before provisional approval extensions and transitions to full registration

If these records exist, producing them would immediately resolve the documented gap. The audit methodology is fully falsifiable—the findings can be refuted if TGA provides the implementation documentation.

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## **Evidence Access and Verification**

### **Q26: How can people access the evidence?**

All evidence, methodology, and findings are open source and permanently archived:

**GitHub Repository:**

<https://github.com/paulrekaris/TGA-COVID19-Vaccine-Safety-Monitoring-Audit>

**Permanent DOI:**

<https://doi.org/10.5281/zenodo.17731054>

**Methodology:**

Fully replicable and falsifiable using publicly available documents, FOI records, TGA correspondence, OAIC submissions, Senate testimony, and TGA publications. Not peer reviewed; open to corrections and new information.

**Citation:**

Rekaris, P. (2025). Documentation Gap Analysis: Implementation Audit of TGA COVID-19 Vaccine Safety Monitoring Plan (Version 1.5.1).

Zenodo. <https://doi.org/10.5281/zenodo.17731054>

## Research Methodology

**Q27: What methodology did I use?**

My investigation follows scientific principles of falsification and replication. The methodology is fully documented in the [GitHub repository](#) and includes:

- Systematic FOI requests (2021–2025)
- OAIC review materials and decisions
- Senate Hansard testimony
- Systematic review of all publicly available TGA safety monitoring documents, reports and publications (2020–2025)
- Australian Government COVID-19 policy documents
- Timeline reconstruction from official sources
- Documentation of contradictions across multiple sources
- Permanent archiving ([Zenodo DOI: 10.5281/zenodo.17731054](#))

All evidence is primary-source and publicly verifiable. The repository contains complete documentation allowing independent replication of my findings.

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## Limitations and Peer Review

**Q28: What are the limitations of this research?**

Several important limitations:

1. **Not yet peer-reviewed:** My research has been submitted to public health policy journals but has not completed formal peer review

2. **Individual researcher:** Conducted in my personal capacity, not institutional research
3. **Document-dependent:** Analysis based on publicly available documents and materials TGA released (or confirmed don't exist) through FOI
4. **Cannot assess undocumented activity:** My findings address what can be demonstrated through documentation, not what may have occurred without records

**Crucially:** TGA can refute these findings at any time by producing implementation records for the COVID-19 Vaccine Safety Monitoring Plan. The absence of such records, confirmed by the [Information Commissioner](#), is the central finding.

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## Purpose and Accountability

### Q29: Why am I doing this?

Multiple reasons:

**Public accountability:** Cabinet endorsed a comprehensive safety monitoring framework for medicines deployed at population scale under provisional approval. Whether that framework was systematically implemented, as documented, matters for regulatory accountability.

**Test my findings:** By publishing openly, I invite correction. If my analysis is flawed, expert scrutiny will reveal that.

**Historical record:** Australia's largest deployment of provisionally approved medicines requires proper documentation. This investigation creates a permanent record.

**Professional obligation:** With 30 years' experience in public policy, regulation and risk management, I have relevant expertise to conduct this type of accountability research.

**Transparency matters:** Particularly for regulatory frameworks governing critical health interventions at population scale, accountability and transparency aren't optional.

### Q30: Do I welcome feedback and correction?

Yes, absolutely. I've published this investigation openly specifically to invite scrutiny and correction.

If errors are identified in my analysis, I will correct them and document the corrections in the repository. If TGA or others can provide evidence that implementation records exist, or that my interpretation of the documentary record is flawed, I welcome that information.



The research is archived permanently ([DOI: 10.5281/zenodo.17731054](https://doi.org/10.5281/zenodo.17731054)), but the [GitHub repository](#) remains open for updates and corrections based on new evidence or valid criticism.

### How to provide feedback:

- [GitHub issues](#)
- Email: [prekas23@gmail.com](mailto:prekas23@gmail.com)
- All substantive corrections will be acknowledged and documented

The goal is accuracy and accountability, not advocacy. Correction improves both.

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## About the Researcher

### Q31: Who am I?

I'm a policy analyst and consultant with 30 years' professional experience across government, higher education and banking sectors. My background includes:

- Public policy development and analysis
- Regulatory frameworks and compliance
- Risk management and governance
- FOI processes and administrative law

I've worked across multiple Victorian government departments (Government Services, Education, School Building Authority, Parliamentary Budget Office) and have relevant expertise for this type of regulatory accountability research.

I'm conducting this investigation in my personal capacity as a private citizen, not on behalf of any organisation or political group.

1. FOI
2. **Cannot assess undocumented activity:** My findings address what can be demonstrated through documentation, not what may have occurred without records

**Crucially:** TGA can refute these findings at any time by producing implementation records for the COVID-19 Vaccine Safety Monitoring Plan. The absence of such records, confirmed by the [Information Commissioner](#), is the central finding.

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# Additional Resources

## Related Publications:

- Rekaris, P. & Sladden, J (2025). "TGA's vaccine safety black hole - a battle for transparency." *Science, Public Health Policy and the Law*, May 2025.
- Rekaris, P. & Sladden, J (2025). "Stairs to Nowhere: TGA's vanishing promise of safety monitoring." *Science, Public Health Policy and the Law*, November 2025.

## Independent Legal Analysis:

- Sparke Helmore Lawyers. (2025). "Case note: AUQ and Department of Health and Aged Care (Freedom of information)." <https://www.sparke.com.au/insights/case-note-auq-and-department-of-health-and-aged-care-freedom-of-information/>

## Official Documents:

- Australian COVID-19 Vaccination Policy (November 2020): <https://www.health.gov.au/sites/default/files/documents/2020/12/covid-19-vaccination-australian-covid-19-vaccination-policy.pdf>
- TGA COVID-19 Vaccine Safety Monitoring Plan (February 2021): <https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf>
- OAIC Decision [2025] AICmr 54: Available through OAIC public register: <https://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/AICmr/2025/54.html>

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**For queries or corrections:** Contact via GitHub repository issues or email provided in repository documentation.