

REGULATORY COMPLIANCE ANALYSIS

# TGA COVID-19 Vaccine Safety Monitoring Implementation Audit & Gap Analysis

Comprehensive assessment of the February 2021 Safety Monitoring Plan  
Evidence-based evaluation across 24 specific outputs  
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# Executive Summary

## Audit Scope & Methodology

Comprehensive evidence-based assessment of TGA's February 2021 COVID-19 Vaccine Safety Monitoring Plan implementation across 24 specific measurable outputs. Analysis based on TGA's own systematic searches conducted September 2024 under OAIC direction (FOI Act s55V(2)), Senate testimony, FOI responses, and public documentation spanning four years (2021-2025).

5

Fully Implemented (21%)

13

Partial/Undocumented (54%)

6

Not Documented (25%)

**Key Finding:** While many monitoring activities occurred (evidenced through 150+ weekly safety reports), systematic documentation of how enhanced monitoring was conducted is largely absent. This creates an accountability gap: activity ≠ systematic implementation.

## Implementation Breakdown by Objective:

- Objective 1 (AEFI Collection): 40% implemented
- Objective 2 (Signal Detection): 0% publicly documented as enhanced - most problematic
- Objective 3 (Communication): 60% implemented - best performance
- Objective 4 (Data Integration): 0% implemented
- Objective 5 (Research): 0% implemented
- Governance: 0% implemented - critical gap

# Audit Methodology Framework

## Evidence-Based Approach

- Gap analysis comparing Feb 2021 Plan commitments against documented implementation
- Assessment against 24 specific measurable outputs
- Evidence hierarchy: TGA's own searches against 12 document categories > Senate testimony > FOI responses > public documents and official statements
- Objective evaluation: What can be demonstrated vs what cannot through temporal analysis over four years
- Falsifiable and replicable research framework

## Primary Evidence Sources

- TGA OAIC Submission MR22/00538 (Sept 2024): Systematic searches organised by implementation plan objectives under legal obligation FOI Act s55V(2)
- Senate Estimates testimony (9 Oct 2025): Official statements under parliamentary privilege
- FOI responses (2022-2025): Formal government records spanning 4 years
- TGA public documentation: 150+ weekly safety reports, regulatory decisions, annual reports

Audit methodology applied systematic, evidence-based principles consistent with ISO 19011 (management systems auditing), ISO 15489 (records management), and Australian National Audit Office compliance audit standards

## Implementation Status Classification Criteria

- ✓ Fully Implemented: Multiple forms of evidence, publicly accessible, systematic documentation exists, can be independently verified
- ⚠ Partially Implemented/Undocumented: Activities occurred (demonstrated through outputs) but implementation documentation absent, cannot verify systematic vs ad hoc approach
- ✗ Not Documented: No evidence of systematic implementation or documentation, no documents found in TGA searches despite claimed activities

# Evidence Hierarchy & Quality Assessment

## **TIER 1: TGA's Own Systematic Searches**

September 2024 OAIC-directed searches (s55V(2)). TGA senior medical officers searched internal systems using TGA's own classification framework. Legally obligated searches.

## **TIER 2: Senate Testimony Under Privilege**

October 2024 Senate Estimates. Official statements by TGA senior officials under parliamentary privilege. Dr Dascombe's characterisation of monitoring as 'day-to-day processes' and 'some difficulty' producing documents confirms record-keeping failure.

## **TIER 3: FOI Responses (Formal Records)**

2022-2025 FOI decisions. Formal government records with legal obligations. Including Kay email Feb 2022: 'no implementation report... entering phase of reviewing'.

## **TIER 4: Public Documentation**

150+ weekly safety reports, regulatory decisions, public statements, senate testimony (148 safety signals and resulting in 57 regulatory actions). Demonstrates activities occurred but not systematic implementation methodology.

# Key Assumptions & Limitations

## Key Assumptions

1. Good Faith Searches: TGA's September 2024 searches under OAIC direction conducted in good faith using appropriate search terms
2. System Coverage: TRIM and Promap document management systems contain implementation documentation if it exists
3. Classification Framework: TGA's own plan objective classification (used Sept 2024) is appropriate framework
4. Absence Significance: Zero search results indicates absence of systematic documentation, not mere difficulty locating\*
5. Search Comprehensiveness: Given systematic searches under legal obligation over four years reviewing 1,674 documents, probability that comprehensive documentation exists but remains unlocated is negligible
6. Activity vs Documentation: Absence of documentation doesn't mean activities didn't occur, but does mean implementation cannot be verified
7. Temporal Validity: Evidence from 2021-2025 remains valid indicator of implementation patterns

## Limitations

1. Search Completeness: Reliant on TGA's own searches; cannot independently verify all TGA systems were searched
2. Document Sampling: Analysis based on documents TGA identified; search categories, additional documents may exist but not located
3. Informal Documentation: Assessment focuses on systematic documentation; informal records or institutional knowledge not captured
4. Verification Constraints: Cannot independently audit TGA's internal document management practices
5. Temporal Gaps: Analysis covers 2021-2025; implementation activities may have been documented after September 2024 searches
6. Legal Interpretation: Assessment identifies patterns and contradictions; does not constitute legal determination of statutory breach (requires judicial assessment)

\*No documentation identified in TGA systematic searches, FOI responses, or public records

# TGA's Own Regulatory Guidance - Provisional Approval

## Australian Regulatory Guidelines for Prescription Medicines (ARGPM) - Provisional Registration Pathway

TGA's own published guidance establishes requirements for provisional approval pathway

### TGA Provisional Approval Requirements

#### Enhanced Monitoring Obligation

Provisional approval granted where further data needed. Enhanced post-market monitoring required as condition of approval. Sponsors must demonstrate comprehensive safety surveillance beyond routine monitoring.

#### Risk Management Plans

Sponsors must submit detailed risk management plans outlining specific monitoring activities, timelines, and deliverables. Plans must address uncertainties in preliminary clinical data.

#### Additional Studies Required

TGA may require sponsors to conduct additional studies during provisional period to address data gaps. Confirmatory data must confirm relationship between preliminary outcomes and clinical benefit.

#### Performance Conditions

Approval subject to conditions that must be satisfied. Transition to full approval requires demonstration that conditions met. Time-limited provisional registration on ARTG.

#### Regular Reporting

Sponsors must provide regular safety and efficacy updates to TGA throughout provisional period. Closer coordination between clinical, nonclinical, quality and RMP evaluation areas.

#### TGA Oversight Obligation

TGA must actively monitor compliance with provisional conditions. TGA may seek external expert advice more frequently during provisional period. Verify enhanced monitoring implemented and confirmatory studies completed.

### TGA's Accountability Gap

#### No Enhanced Monitoring Evidence

TGA published COVID-19 Vaccine Safety Monitoring Plan (Feb 2021) promising 'enhanced' protocols. While TGA investigated 148 safety signals and took 57 regulatory actions (Senate Estimates, October 2024), officials characterised this work as 'day-to-day processes' rather than enhanced monitoring. No documentation demonstrates activities were 'enhanced' beyond standard pharmacovigilance, and no audit trails link specific signals to specific actions as required by international standards (ICH E2E, CIOMS).

#### No Performance Verification

ARGPM requires verification that provisional conditions satisfied before full approval. No documented verification process. Comirnaty (July 2023) and Spikevax (April 2023) transitioned without documented verification.

#### Contradictory Characterisation

ARGPM: 'enhanced monitoring required'. Senate testimony (Oct 2025): 'day-to-day processes'. These characterisations irreconcilable. If day-to-day = enhanced, provisional framework meaningless.

#### No Oversight Documentation

ARGPM establishes TGA oversight obligation. Zero documentation of TGA's active monitoring of whether sponsors satisfied provisional conditions. Oversight vacuum.

#### Systemic Framework Failure

TGA's own guidance establishes verification requirements. TGA cannot demonstrate compliance with its own guidance. Framework integrity compromised when regulator fails own standards.

# International Comparison - Regulatory Transparency Standards

*TGA's opacity regarding provisional-to-full-approval transitions contrasts sharply with international regulatory practice*

## FDA Practice (US)

- Approval letters detailing basis for decision
- Comprehensive review memoranda from FDA medical officers
- Clinical study data summaries
- Post-authorisation safety monitoring reports
- Briefing documents for advisory committee meetings
- Public advisory committee proceedings (VRBPAC)
- Example: Comirnaty approval (Aug 2021) = 30-page approval letter + hundreds of pages of supporting documentation

## EMA Practice (EU)

- European Public Assessment Reports (EPARs) for each transition
- Pharmacovigilance Risk Assessment Committee (PRAC) recommendations
- Periodic safety update reports
- Committee for Medicinal Products for Human Use (CHMP) assessment reports
- Comprehensive safety monitoring results
- Independent expert committee review documentation

## TGA Practice (Australia)

### **Published Documentation:**

- Australian Public Assessment Reports (AusPARs) - clinical trial data submitted by sponsors
- Media releases announcing transitions

### **Notably Absent:**

- ✗ TGA's own post-market monitoring results and analysis
- ✗ Systematic evaluation of provisional approval compliance
- ✗ Safety Monitoring Plan implementation assessment
- ✗ Independent expert committee review of transition decisions
- ✗ Documentation of how enhanced monitoring conditions were verified

# Implementation Status by Safety Plan Objective and Output

| Objective   | Total outputs | Implemented | Partial  | Not Documented |
|---|---------------|-------------|----------|----------------|
| 1: Timely collection and management of AEFI           | 5             | 2 (40%)     | 3 (60%)  | 0 (0%)         |
| 2: Proactive signal identification and assessment     | 5             | 0 (0%)      | 2 (40%)  | 3 (60%)        |
| 3: Clear communication to consumers and providers     | 5             | 3 (60%)     | 2 (40%)  | 0 (0%)         |
| 4: Integration of data from multiple sources          | 4             | 0 (0%)      | 3 (75%)  | 1 (25%)        |
| 5: Contribution to evidence base through research     | 3             | 0 (0%)      | 3 (100%) | 0 (0%)         |
| Cross-cutting: Governance and performance measurement | 2             | 0 (0%)      | 0 (0%)   | 2 (100%)       |

Implemented: fully evidenced in official documentation, Partial: some activity, but incomplete documentation; Not Documented: no evidence found



# Accountability Implications of Documentation Gaps

*Absence of verifiable documentation creates profound accountability deficits across multiple dimensions*

## Legal Basis Questioned

TG Act s23 permits provisional approval as exception to normal evidentiary requirements, predicated on enhanced monitoring compensating for incomplete data. If enhanced monitoring cannot be demonstrated: Legal basis for 2021 provisional approvals undermined; Legal basis for 2023 transitions lacks evidentiary foundation; Integrity of provisional approval pathway itself compromised.

## Public Trust Implications

Australians received COVID-19 vaccines under provisional framework explicitly promising enhanced safety monitoring. TGA public communications emphasise rigorous oversight. Without documentation demonstrating oversight occurred: Public assurances unverifiable; Trust in regulatory commitments undermined; Future provisional approval claims lack credibility.

## Ministerial Accountability Deficit

Minister for Health accountable to Parliament for TGA decisions. Without documentation showing: What evidence supported transition decisions; How provisional conditions verified; Whether promised enhanced monitoring occurred. Minister cannot assure Parliament statutory requirements satisfied. Fundamental breakdown in ministerial accountability. Dr Dascombe's 'some difficulty' in producing documents admission to Senate (Oct 2025) confirms this deficit.

## Provisional Approval Framework Integrity

Framework integrity depends on: Verifiable evidence enhanced monitoring occurs; Demonstrated compliance with provisional conditions; Documented evaluation before transition. COVID-19 vaccine experience suggests framework operates as 'fast track to approval' without rigorous oversight justifying reduced evidentiary requirements. Undermines framework legitimacy for future products.

# Accountability Implications of Documentation Gaps

*Absence of verifiable documentation creates profound accountability deficits across multiple dimensions*

## Parliamentary Oversight Impossible

Senate Estimates revealed TGA's inability to demonstrate implementation: Dr Dascombe characterised monitoring as 'day-to-day' and 'some difficulty' in producing documents (contradicting 'enhanced' requirement); Prof Lawler welcomed FOI requests but no implementation documentation produced; No reference to completed implementation review despite Kay's 2022 promise. Parliament cannot exercise meaningful oversight.

## International Standing

Australia's regulatory standing depends on demonstrated compliance with international pharmacovigilance standards (ICH E2E, EMA GVP) and transparency comparable to peer regulators. Inability to produce documentation meeting these standards: Questions Australia's compliance with adopted international commitments; Positions Australia as less transparent than comparable jurisdictions; Potentially affects mutual recognition arrangements and international cooperation.

# Legislative Breaches - Commonwealth Framework

| Statute                       | Provision                | Requirement  | TGA Breach Pattern   |
|-------------------------------|--------------------------|--|--|
| PGPA Act 2013                 | s37(1)                   | Records must properly record and explain entity's performance in achieving objectives      | Cannot 'explain performance' - monitoring never tracked by objectives. Severity: ★★★★★   |
| Commonwealth Risk Mgmt Policy | Mandatory under PGPA s16 | Risk management framework required. Performance monitoring mandatory component             | No documented risk framework for Plan implementation. No performance monitoring documented. Severity: ★★★★★                          |
| Archives Act 1983             | s24(1)                   | Commonwealth records must not be destroyed except in accordance with normal admin practice | If implementation docs existed then destroyed - Archives Act breach. If never created - records management failure. Severity: ★★★★★  |
| Therapeutic Goods Act 1989    | ss22C, 23AA              | Provisional approval requires enhanced monitoring as condition                             | Cannot demonstrate 'enhanced' vs standard. Full approval granted without verification. Severity: ★★★★★                               |
| FOI Act 1982                  | s24AA                    | Must take reasonable steps to identify documents within scope                              | Sept 2024: organised docs by objectives (3 hrs). June 2025: claimed 'too subjective'. Capability then impossibility. Severity: ★★★★★ |
| FOI Act 1982                  | s24AA(1)(a) vs (1)(b)    | Practical refusal must cite correct statutory ground                                       | June 2025: cited (1)(b) but 3 hrs identification vs 177 hrs decision-making proves (1)(a). Wrong test applied. Severity: ★★★★★       |

# International Pharmacovigilance Standards - Context

**IMPORTANT: These are NOT legally binding requirements but provide context for assessing TGA's practices against international norms and TGA's stated commitments to align with these standards**

| Standard                           | Binding Status   | Key Requirement  | TGA Gap   |
|------------------------------------|--|--|---|
| ICH E2E Pharmacovigilance Planning | TGA formally adopted 2013                                  | Requires structured action plans with: safety issue, objective, actions, rationale, monitoring, milestones                     | Zero documentation of structured action plans per ICH E2E requirements. No milestone tracking documented.                           |
| CIOMS WG VIII                      | Internationally recognised best practice                   | Traceable audit trails from signal detection to decision. Documented signal investigation protocols and assessment procedures. | No audit trails linking 148 investigated signals to 57 regulatory actions. No documented signal investigation protocols identified. |
| EMA GVP Module I                   | Reference standard adopted in TGA guidelines (August 2025) | Mandatory requirements for quality system documentation, training records, performance monitoring                              | Zero documentation meeting EMA GVP Module I quality system requirements for COVID-19 monitoring.                                    |
| PIC/S Good Vigilance Practices     | TGA is PIC/S member (binding obligations)                  | Comprehensive pharmacovigilance system documentation, quality management, performance indicators                               | Cannot demonstrate PIC/S GVP compliance - no systematic documentation of quality management.  |
| WHO Pharmacovigilance Framework    | Voluntary participation                                    | National pharmacovigilance plans should include objectives, activities, timelines, performance measurement                     | No documented performance measurement against plan objectives. No timeline documentation.   |

# Systemic Issues Identified - Pattern Analysis

1

## Documentation vs Activity Gap

Activities occurred (150+ weekly reports, 148 safety signals investigated, 57 regulatory actions taken) but systematic documentation of HOW activities were conducted is absent. Creates verification impossibility: outputs visible, processes invisible.

2

## Enhanced vs Standard Monitoring

Senate testimony: 'day-to-day processes'. Plan commitment: 'enhanced monitoring'. Cannot reconcile these characterisations. If day-to-day = enhanced, provisional approval framework meaningless.

3

## Governance Vacuum

Zero governance documentation: no implementation oversight, no performance review, no accountability framework. Feb 2022 review promise never materialized. Four-year accountability gap.\*. Senate testimony (Oct 2025): Dr Dascombe admitted 'some difficulty' producing documents demonstrating Safety Plan implementation - confirming records were never systematically organised by objective.

4

## Records Management Failure

Systematic absence of implementation documentation potentially indicates either: (a) never created = PGPA/Archives failure, or (b) created then destroyed = Archives Act breach. Either way, systemic records management failure.

5

## Temporal Contradictions in FOI

TGA demonstrated capability (Sept 2024: 3 hours to organise 1,674 docs by objectives) then claimed impossibility (June 2025: 'too subjective'). Pattern suggests FOI manipulation not genuine difficulty.

6

## Provisional Approval Integrity

Cannot verify enhanced monitoring conditions satisfied before full approval granted. Framework requires verification; verification requires documentation; documentation absent. Framework integrity compromised.

\*Cannot demonstrate on public record

# Key Findings - Critical Oversight Failures Uncovered

While monitoring activities produced 150+ weekly safety reports demonstrating surveillance occurred, our analysis reveals systematic documentation of HOW enhanced monitoring was conducted is absent, undermining provisional approval framework integrity and public trust.

## 1. No Evidence of Systematic Enhanced Monitoring

TGA promised enhanced surveillance beyond routine processes as provisional approval condition. **No documented evidence** verifying enhanced monitoring occurred despite TGA reviewing **1,674 documents** in Sept 2024 systematic searches. Officials admitted monitoring treated as '**day-to-day processes**' without systematic tracking, leaving legal compliance unproven. (Outputs 1.2, 2.1; Senate testimony Oct 2024)

## 2. Complete Absence of Governance and Accountability Frameworks

No documented oversight, performance measurement, or governance mechanisms exist for Safety Monitoring Plan. **No governance documents** identified in TGA searches. **Over 3 years** since Feb 2022 review promise, yet no formal reviews, evaluations, or audit trails produced, creating profound accountability gap. (Outputs 5.4, 5.5; FOI responses 2022-2025)

## 3. No Documented Risk-Based Signal Detection Systems

While TGA investigated 148 safety signals and took 57 regulatory actions (Senate Estimates, October 2024), TGA cannot produce documented frameworks, protocols, or methodological standards for risk prioritisation, signal investigation, or causality assessment. No documentation links specific signals to specific actions or provides audit trails required by international standards (ICH E2E, CIOMS). TGA searches found 0 documents for outputs 2.4, 2.5, 4.4 combined. (Outputs 2.4, 2.5, 4.4)

## 4. Transparency Failures Undermine Public and Parliamentary Oversight

Despite holding **over 4,000 pages** of relevant documents, TGA consistently refused information release citing 'subjectivity' and resource constraints. Contradictory public statements erode trust and impede parliamentary scrutiny. FOI delays exceeded **1,400 days**. (OAIC reviews; Senate Estimates 2024-2025)

**In plain terms: Australians have no way to verify that COVID-19 vaccine safety monitoring met the enhanced standards promised as condition for provisional approval. As a result, safety risks could have gone undetected, and trust in regulatory commitments is fundamentally undermined.**

# Required Reforms - Restoring Framework Integrity

While public communication outputs (Objective 3) performed relatively well with 60% implementation, detailed analysis reveals comprehensive regulatory reform required across documentation standards, governance frameworks, and transparency mechanisms to restore provisional approval pathway integrity.

**These same documentation and governance failures will recur in the next pandemic unless addressed. Provisional approval framework integrity depends on learning from COVID-19 experience and implementing reforms for future emergency approvals to ensure public trust.**

## 1. Governance & Accountability

Oversight mechanisms should be strengthened to ensure emergency response frameworks have clear performance measurement and accountability pathways for vaccine safety monitoring. Independent audit and verification processes should underpin regulatory transitions and approvals to demonstrate that enhanced monitoring standards have been satisfied.

## 2. Documentation & Records Management

Documentation standards should demonstrate how enhanced monitoring differs from standard practice, with protocols, criteria, and key decisions systematically recorded and published. Compliance with mandatory creation, retention, and archiving obligations should be maintained, including during emergencies.

## 3. Systems for Risk Assessment & Verification

Robust frameworks should be developed for risk-based signal detection, prioritisation, investigation, and causality assessment, with regular scientific reviews and transparent methodologies to support decision-making.

## 4. Transparency & Public Engagement

Provisional approval compliance should be supported by public access to monitoring data, processes, and methodologies, alongside timely responses to FOI and parliamentary requests. Leadership should be accountable for upholding transparency, documentation and compliance obligations throughout regulatory processes.

## 5. Emergency Preparedness

Emergency preparedness should include scalable systems for rapid safety monitoring, strong data handling, and requirements for ongoing system improvement for future health emergencies when public trust is most critical.