Implementation Status:
TGA COVID-19 Vaccine Safety Monitoring Plan

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1. Executive Summary

1.1 Background

In February 2021, the Therapeutic Goods Administration published a COVID-19 Vaccine Safety Monitoring Plan (Version 1.0) outlining an enhanced pharmacovigilance framework to strengthen vaccine safety surveillance during the national immunisation programme. The plan specified five key objectives supported by 24 specific outputs across five strategic areas: enhanced adverse event reporting, proactive signal detection, regulatory response capability, communications, and stakeholder collaboration.

The plan was published in the context of provisional approval pathways for COVID-19 vaccines, where enhanced post-market surveillance was a regulatory condition to address uncertainties inherent in accelerated development timelines. Between February 2021 and October 2024, approximately 63.8 million COVID-19 vaccine doses were administered under this framework.

This assessment examines the documented implementation of the February 2021 plan through analysis of: (1) OAIC review submissions and internal audit findings; (2) FOI request responses and document searches; (3) Senate Estimates testimony under oath; and (4) official statements regarding implementation tracking. The review period covers February 2021 through November 2024.

1.2 Scope and Methodology

This assessment evaluates the entity's ability to demonstrate, through documentary evidence, that the 24 specific outputs outlined in the February 2021 plan were implemented as described. The assessment does not evaluate: (1) the quality of adverse event data collected; (2) the clinical appropriateness of safety decisions made; or (3) operational activities conducted outside the documented plan framework.

The methodology assessed each output against three implementation categories: Fully Implemented (documented evidence of complete implementation), Partially/Undocumented (activity occurred but systematic processes not documented), and Not Documented (no documentation identified). The assessment relied on the entity's own document searches, audit findings, and official statements regarding document existence.

1.3 Context: Monitoring Activity vs Enhanced Implementation

TGA conducted substantial safety monitoring activities during 2021-2024, including investigation of 148 safety signals and 57 regulatory actions (Senate Estimates testimony, October 2024). This assessment does not question whether monitoring activities occurred.

This assessment examines whether those activities constituted the enhanced monitoring beyond routine pharmacovigilance required as a condition of provisional approval, and whether implementation of the February 2021 Safety Plan was systematically documented and tracked.

1.4 Safety Plan Output Findings

Of 24 Enhanced Pharmacovigilance Plan outputs:

- 21% fully documented as implemented
- 54% partial or undocumented status
- 25% no evidence after four years

1.5 Key Findings

Finding 1: Absence of Enhanced Framework Documentation

While the TGA processed adverse event reports and published data, we identified no documented frameworks or protocols that would demonstrate enhanced monitoring capabilities beyond business-as-usual processes. This represents a material gap between stated commitments and verifiable implementation.

Finding 2: Critical Control Deficiencies in Signal Detection and Governance

Objective 2 (Signal Detection) and Governance functions show 0% documented implementation of plan-specified enhancements. While signal investigations occurred (148 signals investigated per Senate testimony, October 2024), no documented investigation protocols specific to COVID-19 vaccines, enhanced data analysis methodologies, or systematic oversight mechanisms were identified during the review period.

Under international pharmacovigilance standards adopted by TGA (ICH E2E) and internationally recognised best practice (CIOMS), robust signal management must leave a traceable audit trail from signal detection through assessment to decision. The absence of such documentation represents a complete failure to implement the enhanced process controls required for provisional approval, preventing independent verification of whether the enhanced monitoring framework was systematically applied.

Furthermore, while TGA reports 57 regulatory actions resulting from signal investigations, no public or FOI-accessible documentation links specific signals to specific actions, describes the decision-making criteria applied, or explains the disposition of the remaining investigated signals (148 signals investigated, 57 actions documented). International pharmacovigilance standards require complete traceability from signal identification through assessment to regulatory response, enabling verification that safety concerns were systematically evaluated and decisions were consistently applied. The absence of such documentation prevents independent verification of the regulatory decision-making process.

Verification Impossibility Without Documentation

Across approximately 63.8 million COVID-19 vaccine doses, TGA reports investigating 148 safety signals—around one signal per 431,000 doses. Whether this detection rate reflects appropriate sensitivity, intensive-surveillance success, under-detection, or performance comparable to international benchmarks cannot be assessed without access to the investigation protocols, causality assessment frameworks and decision-making criteria that international pharmacovigilance standards require, but which TGA has not published. This verification impossibility is precisely why those standards emphasise comprehensive documentation and audit trails: not just to show that signals were investigated, but to allow independent assessment of whether the pharmacovigilance system functioned with adequate sensitivity and rigour. The figures of 148 signals and 57 resulting actions describe

outputs only; the missing documentation concerns the processes that produced those outputs and whether they met the promised enhanced monitoring commitments.

Finding 3: Insufficient Evidence of Process Design and Operating Effectiveness

The entity is unable to provide documented evidence that processes were designed, implemented, and operated in accordance with the February 2021 Safety Plan. Operational activity alone does not constitute evidence of systematic, enhanced monitoring as specified in plan documentation.

1.6 Overall Assessment

Our analysis identified a significant variance between commitments outlined in the February 2021 plan documentation and verifiable evidence of implementation obtained through four years of investigation and FOI requests.

The Audit Trail Gap

International pharmacovigilance standards adopted by TGA (ICH E2E) and internationally recognised best practice (CIOMS) explicitly require that signal management activities produce traceable audit trails from detection through assessment to decision.

This documentation standard exists to enable independent verification, regulatory oversight, and continuous improvement of safety monitoring systems. For provisionally approved products where enhanced monitoring is a condition of approval, such documentation is not optional - it is a fundamental regulatory requirement. The inability to produce these audit trails four years after plan publication represents a systemic control deficiency that prevents verification of whether the enhanced monitoring framework was implemented as designed.

Moreover, the audit trail gap extends beyond signal detection to regulatory action: while 57 regulatory actions are reported, no documentation links specific signals to specific regulatory responses, no decision criteria are documented, and the disposition of investigated signals that did not result in regulatory action remains unexplained. This prevents verification that the enhanced monitoring framework produced systematic, evidence-based regulatory decisions as required.

2. Detailed Implementation Assessment

Table 1: Implementation Status Assessment by Output*

Plan Objective & Specific Output	What Was Promised (From Feb 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
OBJECTIVE 1: Timely collection and management of AEFI		**Status: 40% Implemented**
1.1 Enhanced reporting of AEFI	**Information on how to report published; communication activities to raise awareness.**	**✓ Fully Implemented. Evidenced by public website content, advertising, and weekly safety reports.**
1.2 Enhanced AEFI reporting forms	Updated TGA AEFI forms to capture COVID-19 specific info and need for follow-up on AESI.	✓ Fully Implemented. Forms were updated and are publicly available.
1.3 Enhanced AEFI report sharing	Criteria and processes for timely sharing of reports with state/territory jurisdictions.	◐ Partially/Undocumented. Automated data flows likely existed, but no documented criteria/processes for sharing were identified in TGA searches.
1.4 Enhanced AEFI data capabilities	TGA database and team prepared for increased data entry and management.	◐ Partially/Undocumented. Activity occurred (processing 150k+ reports), but no documentation of enhanced preparation (e.g., new system protocols) was found.
1.5 Enhanced AEFI report escalation	Criteria for COVID-19 vaccine report escalation and clinical review incorporated into procedures.	◐ Partially/Undocumented. Clinical reviews happened, but the audit found no documented, COVID-specific escalation criteria or updated SOPs.
OBJECTIVE 2: Proactive signal identification and assessment		**Status: 0% Implemented**
2.1 Understanding safety profiles	Establish expected AEFI rates, background rates, and a list of AESI.	◐ Partially/Undocumented. A list of AESI was used, but no documentation of established expected rates or calculated background rates was found.
2.2 Protocols for investigating AEFI	Specific protocols for investigating COVID-19 AEFI reports.	✗ Not Documented. The audit found zero documentation of specific investigation protocols for COVID-19 vaccines.

* Note: This assessment evaluates documented implementation of the February 2021 Safety Plan's specific outputs. While TGA investigated 148 safety signals and took 57 regulatory actions during this period (Senate Estimates testimony, October 2024), no public documentation links specific signals to specific regulatory actions, explains the decision-making criteria applied, or describes the disposition of investigated signals. The question is whether enhanced monitoring frameworks beyond routine pharmacovigilance were systematically documented as specified in the plan.

Plan Objective & Specific Output	What Was Promised (From Feb 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
2.3 Enhanced cumulative data reviews	Refined processes/statistical methods for signal detection; subpopulation analysis.	✗ Not Documented. The audit found zero documentation of refined processes, statistical methodologies, or subpopulation analysis frameworks.
2.4 Active surveillance	Collaborate with AusVaxSafety and coordinate safety signal detection.	◐ Partially/Undocumented. Collaboration occurred, but no documentation of coordinated signal detection between TGA and AusVaxSafety was found.
2.5 Clinical studies and reports	New processes to analyse post-market safety studies and monthly summary reports.	✗ Not Documented. The audit found zero documentation of new processes for analysing these sponsor-submitted reports. FOI 5275 also found no docs.
2.6 Environmental scanning	Processes for monitoring COVID-19 vaccine safety alerts from overseas regulators, medical literature, and other sources.	✗ Not Documented. No documented processes for systematic environmental scanning activities were identified.
2.7 International safety signals	Mechanisms for sharing COVID-19 safety information through ICMRA.	◐ Partially/Undocumented. TGA co-chaired ICMRA working group, but no documented processes for systematic information sharing were found.
2.8 Expert advice	Standing COVID-19 expert advisory committee established.	◐ Partially/Undocumented. Expert committees existed, but no documentation of a standing COVID-19-specific advisory committee was found.
OBJECTIVE 3: Clear communication		**Status: 60% Implemented**
3.1 Communications and media	Key messages; regular safety reports on website; enhanced media scanning.	✓ Fully Implemented. Evidenced by 150+ weekly safety reports, published statements, and media engagement.
OBJECTIVE 4: Integration of data from multiple sources		**Status: 0% Implemented**
4.1 Data Integration	(Implied by objective) Systematic integration of AEFI, AIR, and other data for analysis.	◐ Partially/Undocumented. Data was accessed, but the audit found no documented framework or protocol for the systematic integration of data sources.

Plan Objective & Specific Output	What Was Promised (From Feb 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
OBJECTIVE 5: Contribution to evidence base through research		**Status: 0% Implemented**
5.1 Contribution to Research	(Implied by objective) Using collected data for research and contributing to the scientific evidence base.	◐ Partially/Undocumented. While TGA officials may have engaged in research, the audit found no documented research plan, protocols, or outputs linked to the Safety Plan's objectives.
CROSS-CUTTING: Collaborations		**Status: 0% Implemented**
COLLAB.1 National collaborations	Coordinate with state/territory health departments, ATAGI, ACV, NCIRS, SAEFVIC, AEFI-CAN on COVID-19 vaccine safety.	◐ Partially/Undocumented. Meetings occurred, but no documented frameworks for systematic coordination were identified.
COLLAB.2 International collaborations	Information sharing with international regulators and WHO on COVID-19 vaccine safety.	◐ Partially/Undocumented. International engagement occurred, but no documented processes for systematic information sharing were found.
CROSS-CUTTING: Governance & Performance Measurement		**Status: 0% Implemented**
GOV.1 Implementation Oversight	(Implicit requirement) Oversight, tracking, and review of the Plan's implementation.	✗ Not Documented. The audit found zero governance documentation—no oversight committees, no progress reports, no performance metrics against the Plan.
GOV.2 Performance Measurement	(Implicit requirement) Measuring performance against the stated objectives and outputs.	✗ Not Documented. The admission that implementation was "never systematically tracked" confirms a total absence of performance measurement.

3. Detailed Observations

3.1 Documentation and Records Management

Observation:

- No systematic tracking of plan implementation identified
- No governance frameworks documented
- No enhanced signal detection protocols located
- No performance measurement mechanisms evidenced

Risk: Inability to demonstrate compliance with plan commitments or regulatory requirements.

3.2 Information Access and Transparency Controls

Observation:

- Entity demonstrated document classification capability to regulatory body (OAIC)
- Entity claimed technical impossibility for identical request from public (FOI)
- Differential treatment of substantively identical information requests

Risk: Inconsistent application of information management policies may indicate control deficiencies.

3.3 Regulatory Compliance

Observation:

- Provisional approval conditions specified enhanced monitoring requirements
- Entity delivered standard operational processes
- Gap between regulatory requirement and documented implementation

Risk: Potential non-compliance with approval conditions. Regulatory and legal exposure.

3.4 Stakeholder Communication and Assurance

Observation:

- 63.8 million vaccine doses administered under this framework
- Public communications stated rigorous and enhanced safety monitoring
- Unable to verify assurances through documentation review

Risk: Reputational damage. Erosion of public trust, particularly for future emergency and provisional approvals. Potential liability exposure.

4. Root Cause Analysis

The 0% implementation rate for Signal Detection, Data Integration, Research, and Governance functions indicates systematic process failures rather than isolated incidents. Four potential root causes have been identified:

Scenario 1: Records Never Created

Implication: Records management control failure. Non-compliance with PGPA Act s15 and Public Governance, Performance and Accountability Rule 2014.

Scenario 2: Records Created But Not Retrievable

Implication: Information management system deficiency. Operational ineffectiveness of document management controls.

Scenario 3: Records Created and Subsequently Destroyed

Implication: Archives Act 1983 non-compliance. Unauthorised destruction of Commonwealth records. Legal and regulatory breach.

Scenario 4: Enhanced Monitoring Never Implemented

Implication: Provisional approval condition not satisfied. Potential regulatory non-compliance. Gap between public commitments and operational reality.

Note: *Each scenario represents a material control deficiency. The root cause determination does not alter the finding that enhanced monitoring implementation cannot be verified through available documentation.*

5. Priority Reform Areas

Urgent reform is needed across five key areas: documentation and records management, governance and verification systems, risk assessment practices, transparency and accountability, and emergency preparedness. These recommendations are designed to address critical gaps, restore compliance with national and international safety standards, and ensure future vaccine safety oversight is credible and trustworthy. Immediate action in these areas is essential to rebuild public confidence and regulatory integrity for all Australians.

6. Conclusion

The available evidence indicates a material variance between the enhanced monitoring framework outlined in February 2021 plan documentation and verifiable implementation. Key process controls for signal detection, governance, and performance measurement were not evidenced during our review. The entity is unable to provide documentation supporting claims of systematic, enhanced monitoring beyond standard operational processes. Further work is required to investigate systemic administrative failures and potential breaches of Commonwealth legislation and international pharmacovigilance standards.

7. Evidence Base

This assessment is based on:

- TGA COVID-19 Vaccine Safety Monitoring Plan (February 2021)
- Testimony under oath in Senate Estimates hearings
- Analysis of official statements across multiple years revealing material inconsistencies
- Freedom of Information request responses and associated documentation
- Entity's own document search results demonstrating absence of verification mechanisms
- OAIC review submissions (MR22/00538 and MR25/01153) containing contradictory positions on document classification capabilities

8. Research Methodology

This assessment employs ISO 19011 audit principles and pharmacovigilance standards (ARGPM, ICH E2E, EMA GVP Module I) to systematically evaluate all 24 Plan outputs against TGA's public statements, FOI responses, Senate testimony, and OAIC submissions. Each output was classified as fully implemented, partially documented, or no evidence, benchmarked against TGA's own commitments and Commonwealth legislative requirements.

8.1 Audit Framework

The methodology applies systematic, evidence-based principles consistent with:

- ISO 19011 (management systems auditing)
- ISO 15489 (records management)
- Australian National Audit Office Better Practice Guide standards

8.2 Key Methodological Principles

Evidence-Based Analysis: All findings rely exclusively on TGA's own documents and official statements rather than speculation or third-party sources

Falsifiability: Every finding can be disproved through production of contradicting evidence by the TGA.

Temporal Analysis: Tracking statements across four years (2021-2024) reveals systematic patterns rather than isolated issues.

Replicability: Independent researchers using identical sources and framework would reach consistent findings.

Source Quality: All evidence derives from official TGA documents, FOI decisions, OAIC submissions, or parliamentary testimony under oath.

8.3 Independent Verification

Every finding in this assessment can be independently verified from publicly available sources, ensuring transparency and accountability of the analysis.

9. References

9.1 TGA Published Documents

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14. Ombudsman Act 1976 (Cth). Available at: https://www.legislation.gov.au/C2004A01611/latest/text

9.4 TGA FOI Responses and OAIC Submissions

15. Therapeutic Goods Administration (2024). TGA OAIC Submission MR22/00538 (24 September 2024) - pages 11-17.
16. Therapeutic Goods Administration (2022). FOI Request 2022 - COVID-19 Vaccine Safety Monitoring Plan implementation (Decision dated February 2022).
17. Therapeutic Goods Administration (2024). FOI Request - Documents related to COVID-19 Vaccine Safety Monitoring Plan objectives (OAIC-directed search, September 2024).

9.5 Parliamentary Records

18. Senate Community Affairs Legislation Committee (2024). Estimates Hansard (9 October 2024). Testimony of Dr Michelle Dascombe and Professor Tony Lawler. Available at: https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=committees/estimate/29000/&sid=0003

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