Documentation Gap Analysis: Independent Audit of TGA COVID-19 Vaccine Safety Monitoring Plan

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Version History

This is Version 1.5.1 (December 2025).

For detailed version history and changes from Version 1.0, see Appendix E.

Table of contents

Executive Summary

Background

On 13 November 2020, National Cabinet endorsed the Australian COVID-19 Vaccination Policy, which committed the Commonwealth to ongoing post-market safety monitoring of COVID-19 vaccines through the TGA's COVID-19 Vaccine Pharmacovigilance Plan. The policy identified active surveillance as a core pillar of TGA-led pharmacovigilance and assigned responsibility for monitoring adverse events following immunisation to the TGA.

In February 2021, the TGA published its COVID-19 Vaccine Safety Monitoring Plan, operationalising this policy commitment into a structured national pharmacovigilance framework. Described as building on existing pharmacovigilance systems, the Plan specified 20 outputs across 17 numbered strategies spanning adverse events following immunisation (AEFI) collection, signal detection, data integration, regulatory action, communication, and collaboration. This Plan represented TGA's operational implementation of the enhanced-monitoring expectation for provisionally approved COVID-19 vaccines.

Within this framework, AusVaxSafety—coordinated by the National Centre for Immunisation Research and Surveillance (NCIRS) and funded by the Australian Government—described its large-scale active surveillance program for COVID-19 vaccines as operating "as part of the national COVID-19 Vaccine Pharmacovigilance Plan, led by the TGA and the Australian Government". This positioning established AusVaxSafety as the delivery mechanism for the active surveillance pillar within the TGA-led safety-monitoring framework.

As part of the government's commitment to active and enhanced vaccine safety surveillance for COVID-19 vaccines, AusVaxSafety operated large-scale active surveillance throughout the rollout, completing around 6.8 million SMS-based surveys and reporting approximately 3 million adverse events and 62,000 medical visits by April 2025. However, OAIC-directed searches and FOI processes identified no coordination protocols, integration frameworks or audit trails showing how AusVaxSafety data were systematically incorporated into TGA's signal detection, cumulative reviews or regulatory decisions, so any linkage between the two systems cannot be independently verified.

Operationally, TGA continued to rely on day-to-day pharmacovigilance processes, including spontaneous reporting to DAEN, sponsor and jurisdictional reports, routine signal-assessment meetings and publication of COVID-19 vaccine safety reports. When an FOI applicant sought an “implementation report” for the Plan (FOI 3643), TGA refused access under section 24A on the basis that no such document existed and directed the applicant to generic vaccine-safety webpages instead. In March 2025,

following an Information Commissioner review, decision AICmr54 accepted TGA's September 2024 MR22/00538 search evidence and upheld the "no documents" finding, confirming that no discrete implementation report could be located.

The pattern of TGA responses to implementation inquiries—from initial email requests through FOI decisions to OAIC review—is documented in Appendix B and demonstrates consistent institutional position that Plan implementation was not systematically tracked.

The Australian National Audit Office's performance audit of the COVID-19 vaccine rollout published in August 2022 examined planning, logistics, governance structures and achievement of vaccination targets, but did not assess vaccine safety monitoring, implementation of the Safety Monitoring Plan or compliance with provisional-approval pharmacovigilance conditions. There has therefore been no independent performance audit of TGA's COVID-19 vaccine pharmacovigilance system or of documented implementation of the Safety Monitoring Plan.

Purpose

This assessment examines whether TGA's COVID-19 vaccine pharmacovigilance system can demonstrate, on the available record, that the February 2021 Safety Monitoring Plan was implemented, governed and evaluated as intended. It focuses on:

- the existence (or absence) of a verifiable implementation trail for the Plan's objectives and strategies for enhanced COVID-19 vaccine safety monitoring
- evidence of integration between AusVaxSafety and TGA signal-management processes
- the adequacy of signal-detection and decision-making governance and auditability
- the effectiveness of FOI and OAIC processes in making Plan-level implementation evidence available.

The review period is February 2021 to November 2025 and draws on public TGA and partner-agency documents, FOI decisions and OAIC submissions (including MR22/00538 and AICmr54), Senate testimony by senior TGA officials, and targeted online searches.

The audit benchmarks documented implementation of TGA's COVID-19 Vaccine Safety Monitoring Plan against the provisional approval framework for early-data COVID-19 vaccines and against international pharmacovigilance standards adopted by TGA (ICH E2E, CIOMS, EMA GVP Module IX, and TGA pharmacovigilance guidance).[1]

[1] Core framework documents: TGA Consultation: Provisional Approval pathway for prescription medicines (2017); TGA Provisional registration extension and transition to full registration; Explanatory Memorandum, Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017; TGA COVID-19

Key Findings

Overall finding: Enhanced post-market monitoring required under these frameworks was not supported by documented implementation, governance or performance-measurement arrangements; records show routine pharmacovigilance activity but no traceable plan-level framework linking safety signals to regulatory actions or demonstrating compliance with Safety Plan commitments and provisional-approval conditions requiring enhanced post-market safety monitoring.

The transition of vaccines from provisional to full registration in 2023 leaves unresolved whether enhanced monitoring commitments were discontinued, continued under different arrangements, or—as the characterisation of work as “day-to-day processes” suggests—were never systematically implemented; this transition gap is examined in section 4.2.1.

Finding 1: No enhanced framework documentation

While TGA processed adverse event reports and published safety data, this assessment found no documented frameworks or protocols demonstrating enhanced post-market safety monitoring beyond business-as-usual processes. Systematic review of TGA’s public material identified no Plan specific implementation, governance or integration documents, and OAIC-directed MR22/00538 searches across more than 531 TRIM containers and 2,200+ pages located no records documenting implementation, governance or AusVaxSafety integration for any Plan objective.

FOI 25-0166 demonstrates that relevant documentation nevertheless exists: TGA successfully identified 399 Plan-aligned records using standard document types (SOPs, protocols, workflows, implementation guidelines), but refused to process any of them under s 24(1)(b), citing resource constraints. Identifying documents and then declining access undermines claims that Plan implementation documentation cannot be located due to search limitations or records management difficulties, and indicates an institutional choice not to facilitate scrutiny rather than an inability to find records.

TGA’s 2022-23 and 2023-24 Performance Report contains no references to the COVID -19 Vaccine Safety Monitoring Plan, no output tracking and no performance metrics for Plan implementation, confirming that enhanced monitoring commitments were not tracked at an institutional level.

TGA subsequently published an Australian Public Assessment Report (AusPAR) documenting the conversion of Pfizer’s Comirnaty from provisional to full registration in July 2023, but this assessment contains no evidence that the February 2021 COVID-19

Vaccine Safety Monitoring Plan (Feb 2021); ICH E2E Pharmacovigilance Planning; CIOMS Signal Detection in Pharmacovigilance; EMA GVP Module IX: Signal management; TGA Pharmacovigilance responsibilities of medicine sponsors.

Vaccine Safety Monitoring Plan was implemented or used as a verification framework for the transition. As outlined in detail in Section 4.4, even at this definitive decision point, there is no checklist of provisional conditions, no Plan-level governance or performance metrics, and no documented confirmation that “enhanced monitoring” obligations were satisfied.

While TGA guidance and AusPARs describe post-approval commitments, risk-management plans and ongoing safety reporting, the public and FOI record reviewed for this audit does not contain a consolidated, auditable trail showing that each sponsor’s provisional-approval conditions were tracked and verified as completed before extension or transition to full registration; this is presented as a documentation gap rather than a definitive conclusion about whether underlying activities occurred.

Finding 2: “Day-to-day processes” vs enhanced monitoring

In Senate Community Affairs Legislation Committee testimony (9 October 2025), TGA’s Dr Marcus Dascombe characterised COVID-19 vaccine safety monitoring as managed through TGA’s “day-to-day processes” of pharmacovigilance, a description fundamentally inconsistent with the February 2021 Plan’s commitment to “enhanced” monitoring as a condition of provisional approval. The Plan explicitly frames its approach as enhanced pharmacovigilance, requiring systematic processes, documented frameworks and coordinated surveillance mechanisms beyond routine operations, reflecting the higher uncertainty attaching to provisionally approved products under the Therapeutic Goods Act 1989.

This characterisation, combined with TGA’s direct communications pattern (generic pharmacovigilance links and FOI 3643’s confirmation that no implementation report exists), points to three possibilities: routine pharmacovigilance was treated as sufficient; enhanced processes were implemented but not distinguished or documented; or the enhanced framework remained aspirational while routine processes continued. Each scenario represents failure to implement the Plan as specified and prevents TGA from demonstrating compliance with provisional approval conditions requiring enhanced surveillance.

Finding 3: Critical control gaps in signal detection and governance

Objective 2 (signal detection) shows 0 per cent documented implementation of the Plan’s specified enhancements in the records identified to date. Although TGA investigated 148 signals and reports 57 regulatory actions, no COVID-19 specific signal investigation protocols, enhanced quantitative methodologies or systematic oversight mechanisms linked to the Plan were identified, and OAIC-directed TRIM searches found no AusVaxSafety–TGA coordination protocols, multi-source integration procedures or Plan specific guidelines for signal detection.

International pharmacovigilance standards referenced by TGA (ICH E2E) and widely recognised best practice (CIOMS) expect signal management to produce traceable audit trails from detection through assessment to regulatory decision. The absence of such documentation prevents independent verification that the Plan's enhanced monitoring framework was systematically applied and indicates failure to implement the enhanced process controls expected under provisional approval safety monitoring conditions.

Finding 4: Signal–action transparency gap

TGA reports 57 regulatory actions arising from 148 signal investigations, yet no public or FOI accessible documentation links specific signals to specific actions, describes the decision criteria applied or explains the disposition of the 91 signals that did not lead to documented regulatory action. Nor is there documented evidence of how AusVaxSafety data fed into these investigations or actions, leaving the triage and closure of non-actioned signals opaque.

Across approximately 73 million doses administered, TGA investigated around one signal per 431,000 doses, but whether this reflects appropriate sensitivity, under detection or performance comparable with international benchmarks cannot be assessed without access to investigation protocols, causality assessment frameworks and prioritisation criteria. Without documented decision criteria, investigation notes, or risk assessments, it's impossible to verify whether these 91 closures represented appropriate safety judgments or system failures to detect problems. International standards emphasise such documentation precisely so that systems can be assessed for rigour and sensitivity, not just counted by outputs.

Finding 5: Governance and performance measurement deficiency

FOI processes, OAIC-directed searches and systematic documentary review identified no governance oversight or performance measurement documentation for Plan implementation, and TGA confirmed in FOI 3643 that implementation was "never systematically tracked" against the Plan's objectives. This appears inconsistent with PGPA Act 2013 section 37, which requires entities to keep records that properly record and explain performance, and with ISO based principles that require systematic monitoring, measurement and documented evaluation against defined objectives.

For a plan tied to provisional approval conditions, the absence of implementation governance or performance tracking represents a fundamental control deficiency that prevents TGA from demonstrating whether enhanced monitoring was delivered as specified; the omission of any Plan related outputs or metrics from either TGA's 2022-23 and 2023-24 Performance Reports reinforces this institutional accountability gap.

Finding 6: Insufficient evidence of process design and operating effectiveness

TGA cannot 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. While adverse event reports were processed, signals investigated and weekly safety reports published, these outputs do not demonstrate that the enhanced framework was designed, documented and governed as a system.

International pharmacovigilance standards adopted or referenced by TGA (including ICH E2E and CIOMS guidance) require signal management activities to produce traceable audit trails from detection through assessment to decision, so that regulators and independent parties can verify performance and improve systems over time. For provisionally approved products where enhanced monitoring is a condition of approval, the inability to produce such 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.

AusVaxSafety: active surveillance without documented integration

AusVaxSafety operated SMS based active surveillance throughout the rollout, completing 6.8 million surveys by April 2025, recording around 3 million adverse events (43.5 per cent of respondents) and 62,000 reports of medical attention (0.9 per cent), while TGA reports 148 signals and 57 regulatory actions. Yet OAIC-directed searches and multiple FOI processes identified no coordination protocols, integration frameworks or audit trails showing how AusVaxSafety data were systematically incorporated into TGA signal detection, cumulative reviews or regulatory decisions.

Without documented integration frameworks, independent parties cannot verify how population level active surveillance data informed TGA signal prioritisation, whether AusVaxSafety findings were reconciled with passive surveillance, or what criteria determined when AusVaxSafety results would trigger TGA investigations. This aligns with the 0 per cent implementation rating for Objective 4 (data integration) and indicates that active and passive systems appear to have operated largely in parallel rather than as a coordinated pharmacovigilance system. The requirement for documented coordination protocols is not bureaucratic formalism but a fundamental accountability mechanism: without them, independent parties cannot verify whether AusVaxSafety's 62,000 medical attention reports and 3 million adverse event reports were systematically considered in TGA's signal prioritisation

Expert committees distinguished from Plan implementation

Expert advisory committees such as ATAGI, ACV and AEFI CAN clearly existed and provided clinical and technical advice on COVID-19 vaccines, as documented in ANAO

findings and public meeting statements. However, the presence of advisory structures does not substitute for documented Plan implementation, governance oversight or performance measurement.

No committee terms of reference, standing agendas or decision records were identified that demonstrate how these committees systematically fed safety advice into TGA's signal management workflows, regulatory actions or Plan level implementation tracking. Advisory functions address what decisions should be made; the Safety Plan and provisional approval framework require evidence that enhanced monitoring processes were systematically implemented, integrated and measured—requirements that advisory committees alone do not fulfil.

Overall significance

These findings are significant because enhanced post-market monitoring was not discretionary but a regulatory condition of provisional approval under the Therapeutic Goods Act 1989, and approximately 68 million of 72.3 million COVID-19 vaccine doses (94 per cent) were administered while vaccines remained provisionally approved.

The inability to demonstrate systematic implementation of enhanced monitoring commitments represents a fundamental accountability gap in Australia's regulation of provisionally approved medicines, and a potential non-compliance with provisional approval conditions that permitted early market access for products with incomplete safety data.

Conclusion

The evidence assembled for this assessment indicates that, despite ongoing day-to-day pharmacovigilance activity and extensive public safety reporting during the largest vaccination rollout in Australia's history, there is no verifiable documentary trail showing that the COVID-19 Vaccine Safety Monitoring Plan's enhanced monitoring, integration and governance requirements were implemented in practice. The fact that the FOI "reasonable search" process required two senior TGA officers (a Senior Medical Officer and an Assistant Director in the Vaccines Surveillance Section) to conduct manual searches for such a critical implementation document itself suggests the absence of routine governance or records-management systems that would ordinarily track and surface Plan-level implementation documentation.

Australia's COVID-19 vaccine rollout represents the nation's largest deployment of provisionally approved medicines: around 68 million doses, 94 per cent of the total rollout, were administered under conditions requiring enhanced monitoring that cannot be verified through documented evidence. TGA can resolve this either by producing the missing documentation or, if documentation cannot be produced, by accepting

independent investigation by the Australian National Audit Office, the Commonwealth Ombudsman or relevant parliamentary oversight committees.

After identifying 399 relevant documents but refusing to process them (FOI 25-0166), after comprehensive OAIC-directed searches finding zero Plan implementation records (MR22/00538), and after four years of consistent institutional inability to demonstrate enhanced monitoring beyond routine processes, only two possibilities remain: either the enhanced monitoring framework was never systematically implemented, or it was implemented but TGA failed to document it. Both scenarios represent regulatory failure and potential non-compliance with Commonwealth accountability frameworks, and neither is acceptable for 68 million doses administered under provisional approval.

Taken together, the absence of Plan-specific implementation and governance records in public sources, the negative results of OAIC-directed internal searches, and the refusal to process the identified corpus of 399 Plan-aligned documents suggest that the probability of locating the required documentation is low and may reasonably be regarded as negligible. This in turn strongly indicates that key conditions attached to provisional approval of COVID-19 vaccines—enhanced and documented post-market safety monitoring—were not demonstrably met, and that there has been a significant shortfall in TGA's pharmacovigilance governance and record-keeping obligations under Australian law.

On the available record, there has been a serious regulatory failure in the design, documentation and demonstrability of COVID-19 vaccine safety monitoring; whether this reflects implementation failure or documentation failure, both scenarios constitute material non-compliance with provisional-approval conditions, Commonwealth accountability frameworks and international pharmacovigilance standards, and the scale of deployment under these conditions warrants independent investigation.

1. Background and Context

1.1 Regulatory and policy setting

On 13 November 2020, National Cabinet endorsed the Australian COVID-19 Vaccination Policy, which committed the Commonwealth to active and comprehensive post-market safety monitoring of COVID-19 vaccines by the TGA, including appropriate adverse-event monitoring arrangements as vaccination scaled up.[2] In February 2021, the TGA published its COVID-19 Vaccine Safety Monitoring Plan (Version 1.0) as the operational implementation of this commitment, stating that it builds on existing vaccine pharmacovigilance systems to strengthen safety surveillance for COVID-19 vaccines and setting out five strategic areas, supported by 17 numbered strategies, covering enhanced adverse-event reporting, proactive signal detection, regulatory response capability, communications and stakeholder collaboration.[3] External partners such as AusVaxSafety subsequently described their active surveillance program as operating as part of a national COVID-19 Vaccine Pharmacovigilance Plan led by the TGA and the Australian Government, positioning active surveillance as a core component of the Commonwealth's enhanced-monitoring framework.[4]

Provisional Approval and Enhanced Monitoring

Under the provisional-approval pathway, medicines may be registered for a time-limited period on the basis of preliminary clinical data where there is an unmet medical need. Because pre-market evidence is incomplete, TGA guidance requires provisionally registered medicines to be subject to enhanced post-market monitoring as a condition of registration, including rigorous safety surveillance, submission of confirmatory clinical data and active risk-management measures, with sponsors required to demonstrate compliance before any extension of provisional registration or transition to full registration is granted.[5]

This report therefore treats the Therapeutic Goods Act 1989, TGA's provisional-registration guidance and the National-Cabinet-endorsed vaccination policy as establishing a provisional-approval pathway that depends on enhanced post-market

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[2] Australian Government Department of Health. *Australian COVID-19 Vaccination Policy*. Canberra: Australian Government; 2020. Available at: https://www.health.gov.au/sites/default/files/documents/2020/11/australian-covid-19-vaccination-policy.docx.

[3] In this report, the term 'enhanced post-market safety monitoring' (or 'enhanced monitoring') is used to summarise the strengthened post-approval monitoring requirements described in TGA's provisional registration guidance, and 'enhanced COVID-19 vaccine safety monitoring' refers to the enhanced monitoring commitments in TGA's February 2021 COVID-19 Vaccine Safety Monitoring Plan.

[4] AusVaxSafety (NCIRS). *Active and enhanced vaccine safety surveillance for COVID-19 vaccines in Australia*. Sydney: National Centre for Immunisation Research and Surveillance; 2024. Available at: https://www.ausvaxsafety.org.au/active-and-enhanced-vaccine-safety-surveillance-covid-19-vaccines-australia.

[5] https://www.tga.gov.au/sites/default/files/consultation-provisional-approval-pathway-for-prescription-medicines.pdf

safety monitoring, with the February 2021 COVID-19 Vaccine Safety Monitoring Plan providing TGA's operational implementation of those expectations for COVID-19 vaccines; the audit question is whether TGA can demonstrate, through documentation, that this enhanced-monitoring framework was implemented and used to verify provisional-approval conditions before extensions and transitions to full registration were granted.

In practice, TGA's COVID-19 vaccine pharmacovigilance relied on familiar day-to-day processes: spontaneous adverse event reports to the DAEN database, sponsor and jurisdictional reporting obligations, periodic safety reports, and regular internal signal-assessment workflows, as described in Senate Community Affairs Legislation Committee testimony on 9 October 2025.[6] The Plan sat above these routine activities and was intended to provide an enhanced, documented framework linking multiple data sources, signal-management processes and governance arrangements for provisionally approved vaccines.

Freedom of Information (FOI) requests and an Office of the Australian Information Commissioner (OAIC) review outcomes confirm not only that no discrete "implementation report" or labelled Plan-implementation file can be located; they do not show whether the Plan's enhanced post market monitoring requirements were embedded in day-to-day processes or documented elsewhere.

In February 2022, TGA refused FOI request 3643 on the basis that no "implementation report" for the COVID-19 Vaccine Safety Monitoring Plan existed, while pointing to generic vaccine-safety webpages instead of Plan-specific documentation. The applicant sought an Information Commissioner review, and in March 2025 the Office of the Australian Information Commissioner (decision AICmr54) accepted TGA's September 2024 MR22/00538 search evidence and upheld the "no documents" decision, confirming at FOI/IC-review level that TGA could not identify any discrete Plan-implementation records.

Australia's COVID-19 vaccines were initially supplied under the TGA's provisional approval pathway, alongside substantial advance-purchase agreements for multiple vaccine platforms.[7]

[6] Senate Community Affairs Legislation Committee 2025, Official Committee Hansard – Estimates, 9 October 2025, Parliament of Australia, Canberra.
[7] For background on vaccine types, provisional approval dates and early purchase agreements, see Australian Parliamentary Library, *COVID-19 vaccines: a quick guide*, 2021–22.

Scale and Significance of Australia's COVID-19 vaccine rollout

Between February 2021 and July 2023, approximately 68 million COVID-19 vaccine doses were administered in Australia, representing 94% of the total rollout. The vast majority were given while vaccines remained under provisional approval.

Enhanced post-market monitoring was a regulatory condition of provisional approval under the Therapeutic Goods Act 1989. This assessment finds that TGA cannot demonstrate through documented evidence that this enhanced monitoring was systematically implemented as specified in the February 2021 Plan.

This represents Australia's largest deployment of provisionally approved medicines and the inability to verify enhanced monitoring implementation has implications for the integrity of the provisional approval framework.

This report therefore assesses the implementation of the Safety Monitoring Plan in a context where both TGA and the OAIC have formally acknowledged that no dedicated implementation report or Plan-specific governance and integration documents can be located.

TGA's day-to-day pharmacovigilance activities were conducted against the backdrop of specific regulatory conditions requiring "enhanced" post-market surveillance for provisionally approved vaccines. Enhanced post-market surveillance was a key requirement of the provisional-registration framework and associated TGA guidance under the Therapeutic Goods Act 1989, intended to address uncertainties inherent in accelerated vaccine development and rollout, and was operationalised through the COVID-19 Vaccine Safety Monitoring Plan.[8] Between February 2021 and October 2024, approximately 73 million COVID-19 vaccine doses were administered in Australia under the COVID-19 vaccine approval and rollout framework, the majority during the period when key vaccines were provisionally approved.[9]

The Australian National Audit Office's performance audit Australia's COVID-19 Vaccine Rollout (Auditor-General Report No. 3 2022–23) assessed the planning, governance and implementation of the national rollout by the Department of Health and Aged Care.[10] The audit examined issues such as rollout planning, logistics, governance arrangements, data quality, stakeholder engagement and achievement of vaccination

[8] See Therapeutic Goods Administration, provisional registration and transition guidance and COVID-19 vaccine approval process (enhanced post-market monitoring for provisionally registered medicines), and COVID-19 Vaccine Safety Monitoring Plan (February 2021).
[9] For example, Department of Health and Aged Care, COVID-19 vaccination – vaccination data – 10 October 2024; TGA, COVID-19 vaccine safety reports (cumulative doses since rollout).
[10] Auditor-General Report No. 3 2022–23, Australia's COVID-19 Vaccine Rollout, Australian National Audit Office, 17 August 2022. https://www.anao.gov.au/sites/default/files/2022-10/Auditor-General_Report_2022-23_3_0.pdf

targets, but did not examine vaccine safety monitoring, detailed coordination between vaccine stakeholders or implementation of the COVID-19 Vaccine Safety Monitoring Plan, or compliance with provisional-approval safety-monitoring conditions. The report also noted that the Commonwealth established expert committees, including ATAGI, ACV and SITAG, to provide clinical and technical advice on COVID-19 vaccines, risk–benefit assessment and rollout strategy. The audit therefore provides assurance about aspects of the rollout and governance structures, but it does not assess whether TGA's operational pharmacovigilance processes, systems and records collectively demonstrated implementation of the Safety Monitoring Plan; without such an assessment there is no independent assurance that safety signals were systematically traced through to regulatory decisions and actions during the rollout.

Accordingly, there has been no independent performance audit of TGA's COVID-19 vaccine pharmacovigilance system or of documented implementation of the COVID-19 Vaccine Safety Monitoring Plan; these issues fall outside the scope of Auditor-General Report No. 3 2022–23 and are the focus of this assessment.

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 online document searches; (3) Senate Community Affairs Legislation Committee testimony under oath; and (4) official statements regarding implementation tracking. The review period covers February 2021 through November 2025 and focuses on whether TGA's routine pharmacovigilance activities and documented records can be shown to implement the enhanced monitoring, integration and governance framework set out in the February 2021 Plan.[11]

1.2 Scope and Methodology Overview

Scope of Assessment

This assessment evaluates whether the Therapeutic Goods Administration can demonstrate, through publicly available documentation, implementation of the 17 specific outputs committed to in the February 2021 COVID-19 Vaccine Safety Monitoring Plan. Over 2,200 pages of routine pharmacovigilance documentation have been identified in this report. What it did not find was any documentation of Plan-specific governance, integration protocols, or performance measurement - the enhancements that distinguished this Plan from business-as-usual

In scope:

- Evidence of enhanced post-market pharmacovigilance processes beyond routine operations

[11] https://www.health.gov.au/sites/default/files/2024-10/covid-19-vaccination-vaccination-data-10-october-2024.xlsx

- Traceable audit trails from signal detection through investigation to regulatory action
- Governance arrangements, performance tracking, and oversight mechanisms
- Records management effectiveness as demonstrated through FOI responses, OAIC-directed searches, and Senate testimony

Out of scope:

- Clinical safety, efficacy, or risk-benefit evaluations of COVID-19 vaccines
- Appropriateness or quality of individual regulatory decisions
- Operational effectiveness of partner organisations (AusVaxSafety, NCIRS, state health agencies), which are separate entities outside TGA's direct accountability
- Internal communications between TGA and partners unless publicly released

Methodological Framework

This assessment applies ISO 19011:2018 audit principles to evaluate the Plan's 17 explicitly numbered strategies (1.1-1.5, 2.1-2.8, 3.1, 4.1, 5.1-5.2) plus governance and performance measurement processes required under Commonwealth accountability frameworks (PGPA Act 2013 s37, Archives Act 1983).

Each output was assessed against three implementation categories:

- Fully Implemented: Documented evidence of complete implementation
- Partially/Undocumented: Activity occurred but systematic processes not documented
- Not Documented: No documentation identified despite comprehensive searches

Evidence Base and Information Asymmetry

This assessment relies exclusively on publicly verifiable evidence:

- TGA's published Plan, official statements, and direct responses to information requests
- FOI-released materials 2022-2025 (FOI 3643, FOI 25-0166)
- OAIC internal review submissions (MR22/00538, MR25/01153)
- Senate testimony under oath from senior TGA officials
- Publicly accessible partner organisation reports (AusVaxSafety, NCIRS)

The assessment recognises an inherent information asymmetry: TGA holds internal operational knowledge that may not be publicly documented. However, for a regulatory framework tied to provisional approval conditions, the ability to demonstrate implementation through documentation is fundamental to public accountability and independent verification. The operational success of partner organisations cannot substitute for TGA's obligation to document fulfilment of its own Plan commitments.

Absence of documents after these rigorous, multi-modal searches constitutes strong evidence of significant implementation and governance gaps. If additional documentation exists but was not disclosed through FOI processes, OAIC reviews, or public channels, TGA may provide such documentation to address the findings identified.

Evidence Gathering Approach

This assessment's evidence base derives from two complementary sources, detailed in Appendices A and B:

Systematic Documentary Search (Appendix A): Structured online review of publicly available TGA documents, parliamentary testimony, and partner organisation reports conducted December 2024 – February 2025. Search methodology aligned with ANAO Better Practice Guides, using Plan-aligned search terms across TGA repositories, Senate Community Affairs Legislation Committee records, and regulatory partner publications.

Direct TGA Communications (Appendix B):

Analysis of artefacts including key escalating requests to TGA (January-February 2022) seeking Plan implementation documentation, including two formal FOI requests: 3643 and 25-0166. Appendix B4 included detailed statistical analysis of OAIC-directed search results (September 2024) involving TRIM searches using eight search terms across more than 531 containers, yielding 2,218 pages classified by Plan objectives across 12 document categories.

TGA responses establish baseline institutional position: identical generic pharmacovigilance links provided across all three responses, with FOI decision explicitly confirming "no implementation report exists" while claiming "ample documentation" exists elsewhere.

These parallel evidence streams—researcher-initiated requests establishing institutional position, followed by comprehensive public document review—provide triangulated verification of documentation gaps identified.

Replicability and Falsifiability

Every finding in this assessment is falsifiable through production of contradicting documentation. If TGA can provide:

- Documented protocols for coordinating AusVaxSafety data with signal investigations
- Documented signal investigation procedures specific to COVID-19 vaccines
- Documented decision-making criteria linking investigated signals to regulatory actions

- Documented plan implementation governance and performance measurement systems

...then the corresponding findings would be revised or withdrawn. The assessment methodology is designed to be correctable through provision of documentary evidence, consistent with scientific principles of falsifiability and audit standards requiring evidence-based conclusions.

Detailed methodological framework including evidence hierarchy, audit criteria, and standards applied is provided in Section 9.

1.3 Context: Monitoring Activity vs Enhanced Implementation

TGA conducted substantial safety monitoring activities during 2021-2023, documented in the November 2023 Safety Signals Report and confirmed in Senate testimony (October 2025). These activities included investigation of 148 safety signals, 57 regulatory actions, and publication of 150+ weekly safety reports demonstrating operational capability.

Similarly, AusVaxSafety—Australia's active surveillance platform—successfully operated throughout the vaccine rollout, completing over 6.8 million COVID-19 vaccine safety check surveys as at April 2025. Of survey respondents, 43.5% reported at least one adverse event and 0.9% reported seeking medical attention (AusVaxSafety website, 1 December 2025).[12] This demonstrates that active surveillance infrastructure was established, operational, and generating population-level safety data at scale.

This assessment does not question whether monitoring activities occurred.

It examines whether those activities constituted the enhanced monitoring beyond routine pharmacovigilance required under the Therapeutic Goods Act's provisional approval framework and associated guidance, and under TGA's adopted pharmacovigilance standards, and whether implementation of the February 2021 Safety Plan was systematically documented and tracked—particularly the coordination between active and passive surveillance systems that Strategy 2.4 explicitly promised.

Available material shows that large volumes of COVID-19 vaccine safety data were collected, analysed and reported in aggregate, but there is no documented, traceable audit trail showing what happened to individual safety signals—how they were evaluated, what criteria were applied, or how they translated into specific regulatory decisions and actions.[13]

[12] According to AusVaxSaftey, adverse events are self-reported, have not been clinically verified, and do not necessarily have a causal relationship with the vaccine.
[13] https://www.tga.gov.au/resources/guidance/pharmacovigilance-responsibilities-medicine-sponsors

In effect, the arrangements are analogous to operating an extensive network of security cameras without a recording and logging system: activity clearly occurred, but there is no verifiable record of how specific safety concerns were handled.

Under international pharmacovigilance standards adopted by TGA (ICH E2E) and internationally recognised best practice (CIOMS), enhanced post-market monitoring requires documented protocols, systematic processes, traceable audit trails, governance structures and performance-measurement systems. These framework elements enable verification that monitoring activities followed the enhanced processes specified in the Plan, rather than standard operational procedures. It is the documented enhanced framework—including the coordination of surveillance systems—not merely the occurrence of monitoring activities, that this assessment evaluates.

This research raises a simple question. If routine processes were sufficient, there would have been little reason to publish a dedicated COVID-19 Vaccine Safety Monitoring Plan; the Plan's emphasis on "strengthening" and "enhanced" monitoring indicates that TGA recognised the need for an augmented framework for provisionally approved COVID-19 vaccines, over and above day-to-day pharmacovigilance.

1.4 Limitations of This Assessment

This assessment is limited to documentary evidence available through:

- Publicly accessible TGA publications and reports
- FOI-released materials (2022-2025)
- OAIC internal review submissions (MR22/00538, MR25/01153)
- Senate Community Affairs Legislation Committee testimony under oath
- Partner organisation public reports (AusVaxSafety, NCIRS)

Operational activities that occurred but were not documented cannot be evaluated through this methodology. The assessment does not question the professional judgement or good faith of TGA staff conducting safety monitoring activities. Rather, it evaluates whether the enhanced monitoring framework specified in the February 2021 Plan was implemented with the systematic documentation, audit trails, and governance structures that:

- International pharmacovigilance standards require (ICH E2E, CIOMS VIII)
- ISO audit principles require (ISO 19011:2018)
- Commonwealth accountability frameworks require (PGPA Act 2013, Archives Act 1983)
- Provisional approval arrangements under the Therapeutic Goods Act 1989 require enhanced post-market monitoring and allow TGA to impose specific pharmacovigilance conditions.

TGA staff and partner-agency staff were not interviewed as part of this audit; the findings are based solely on documentary evidence and do not incorporate direct stakeholder testimony.

If TGA possesses additional documentation not disclosed through FOI, OAIC processes, or public channels that addresses the identified gaps, this assessment's findings may be revised accordingly upon provision of such evidence.

2. Implementation Status and Key Findings

2.1 Overall Assessment

This assessment 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.

Of 20 enhanced pharmacovigilance Plan outputs:

- 15% fully documented as implemented (3 outputs)
- 55% partial or undocumented status (11 outputs)
- 30% no evidence after four years (6 outputs)

The assessment confirms that substantial operational activity occurred: TGA published over 150 weekly safety reports, processed adverse event notifications through DAEN, investigated 148 safety signals, and documented 57 regulatory actions. Partner organisations, particularly AusVaxSafety, established and operated active surveillance infrastructure at significant scale (6.8+ million surveys completed).[14]

However, the enhanced monitoring framework specified in the Plan—systematic processes, documented protocols, coordinated surveillance integration, governance oversight, and performance measurement—cannot be verified through available documentation. This creates a fundamental accountability gap: operational pharmacovigilance activities demonstrably occurred, but the systematic frameworks that would enable independent verification of “enhanced” monitoring cannot be evidenced.

TGA has not produced any documentation showing how AusVaxSafety data fed into its 148 signal investigations or 57 regulatory actions, or any audit trail explaining triage decisions for the remaining 91 signals where no further regulatory action was taken. Across OAIC-directed TRIM searches using eight search terms and more than 531

[14] https://www.ausvaxsafety.org.au/vaccine-safety-data/covid-19-vaccines

containers, no AusVaxSafety–TGA coordination protocols, multi-source integration procedures, or Plan-specific implementation guidelines were identified.[15]

Three findings are particularly significant:

Documentation Pattern: Routine pharmacovigilance activities (weekly reports, DAEN database) are well documented, while enhanced elements specific to provisional approval conditions (dedicated teams, coordination frameworks, systematic integration) are not evidenced.

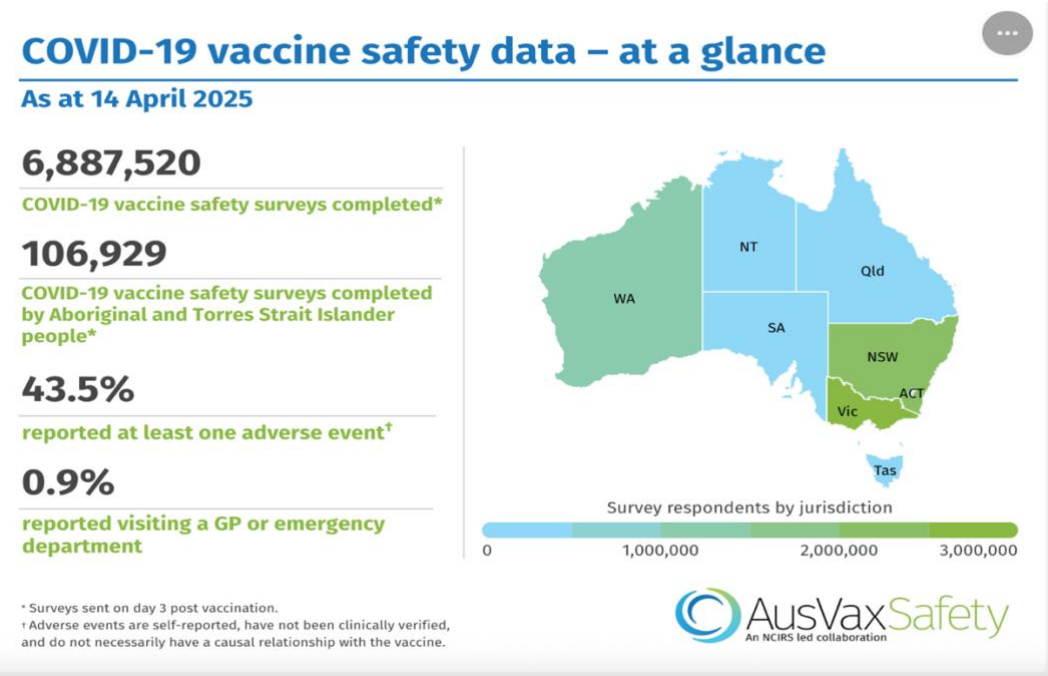
Characterisation Contradiction: Senior officials described COVID-19 vaccine safety work as "day-to-day processes," fundamentally inconsistent with the Plan's commitment to enhanced post-market monitoring as a provisional approval condition.

Verification Impossibility: The absence of documented protocols, decision criteria, and audit trails prevents independent assessment of whether the pharmacovigilance system functioned with adequate sensitivity, whether decisions were consistently applied, or whether provisional approval conditions requiring enhanced monitoring were satisfied.

For provisionally approved products where enhanced monitoring is a regulatory condition (Therapeutic Goods Act 1989), the ability to demonstrate implementation through systematic documentation is not optional—it is fundamental to regulatory accountability and public confidence.

The scale of provisional approval deployment (68 million doses), combined with the systematic absence of implementation documentation across four years of investigation, indicates this is not an isolated records management issue but a systematic failure in pharmaceutical governance with implications for future provisional approval frameworks.

[15] Therapeutic Goods Administration (2024). OAIC Submission MR22/00538 – Response to written notice and direction under ss 55V(2) and 55(2)(e)(ii) of the Freedom of Information Act 1982 (20 September 2024). Attachments A–B document TRIM/Promapp search methods and results, including searches across 531+ containers yielding zero Plan implementation documents.



2.2 Key Findings

Finding 1: Absence of Enhanced Framework Documentation

While the TGA processed adverse event reports and published data, this assessment found no documented frameworks or protocols that would demonstrate enhanced monitoring capabilities beyond business-as-usual processes. (Appendix A, Section A.5.1; Appendix B, FOI 3643 para 7). This represents a material gap between stated commitments and verifiable implementation.

TGA successfully identified 399 documents aligned with Plan objectives using standard document classifications (SOPs, protocols, workflows, implementation guidelines). This demonstrates institutional capability to locate relevant records. However, TGA refused to process any of these documents under s24(1)(b), citing resource constraints. This pattern—identifying that documents exist but refusing access—undermines claims that Plan implementation documentation cannot be located due to search limitations or records management challenges. It suggests a choice not to facilitate scrutiny rather than an inability to locate records.

Verification documentation absent at point of full registration:[16] For Comirnaty, the 2023 AusPAR records the provisional-to-full registration decision and summarises clinical and pharmacovigilance data, but does not identify any evaluation against the COVID-19 Vaccine Safety Monitoring Plan, any verification that enhanced monitoring requirements were met, or any Plan-specific governance or performance-measurement

[16] https://www.tga.gov.au/products/medicines/prescription-medicines/application-and-market-authorisation/covid-19-vaccine-information-sponsors-industry/covid-19-vaccines-regulatory-status

evidence. This is consistent with OAIC-directed TRIM searches and FOI outcomes, which located no implementation reports, Plan-specific SOPs, or decision records demonstrating how provisional approval conditions were verified before full registration.

This institutional response pattern is documented comprehensively in Appendix B, which establishes TGA's baseline position from February 2022 through OAIC-directed searches in September 2024, demonstrating consistency across four years of escalating requests.

Finding 2: "Day-to-Day Processes" Characterisation Contradicts Enhanced Monitoring Commitment

In Senate Community Affairs Legislation Committee testimony (9 October 2025), TGA's Dr Marcus Dascombe, characterised COVID-19 vaccine safety monitoring as managed through the agency's "day-to-day processes" of pharmacovigilance. This characterisation is fundamentally inconsistent with the February 2021 Plan's commitment to "enhanced" monitoring as a condition of provisional approval.

The February 2021 Plan explicitly frames its approach as enhanced pharmacovigilance, specifying systematic processes, documented frameworks, and coordinated surveillance mechanisms beyond routine operations. Under the Therapeutic Goods Act 1989, provisionally registered medicines are subject to conditions and enhanced post-market surveillance because they are approved on the basis of more limited, early clinical data than standard registrations, which creates greater uncertainty about their benefit–risk profile.[17]

This characterisation is reinforced by TGA's direct communications pattern documented in Appendix B: when explicitly requested to provide Plan implementation evidence in early 2022, TGA provided identical generic pharmacovigilance links across three responses, with FOI 3643 decision confirming no implementation report exists (Appendix B, Table 1).

Characterising this work as "day-to-day processes" suggests one of three scenarios:

- TGA's routine pharmacovigilance processes were considered sufficient (contradicting the enhanced framework commitment)
- Enhanced processes were implemented but not distinguished from routine operations (documentation and governance failure)
- The enhanced framework remained aspirational while routine processes continued (implementation failure)

[17] TGA 2017 Provisional Approval consultation paper, pp. 6, 11–14; TGA, *Provisional registration extension and transition to full registration*; Explanatory Memorandum, Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017, Sch 1. https://www.tga.gov.au/sites/default/files/consultation-provisional-approval-pathway-for-prescription-medicines.pdf

All three scenarios represent failure to implement the Plan as specified. Moreover, if enhanced monitoring activities were indistinguishable from routine "day-to-day" operations, TGA cannot demonstrate compliance with provisional approval conditions requiring enhanced surveillance.

This characterisation is reinforced by the documentation pattern: routine activities (weekly reports, DAEN database) are well documented, while enhanced elements (dedicated teams, coordination frameworks, systematic integration) cannot be evidenced.

Finding 3: Critical Control Deficiencies in Signal Detection and Governance

Objective 2 (signal detection) shows 0 per cent documented implementation of the Plan's specified enhancements. While signal investigations clearly occurred (148 signals investigated and 57 actions reported in TGA publications and Senate Community Affairs Legislation Committee testimony, October 2025), no COVID-19-specific signal-investigation protocols, enhanced quantitative analysis methodologies, or systematic oversight mechanisms linked to the Plan were identified.

Across OAIC-directed TRIM searches using eight search terms and more than 531 containers, TGA again identified no AusVaxSafety–TGA coordination protocols, no multi-source integration procedures, and no Plan-specific implementation guidelines for signal detection.

Under international pharmacovigilance standards referenced by TGA (including ICH E2E) and widely recognised best practice frameworks (such as CIOMS guidance), signal management is expected to generate traceable audit trails from detection through assessment to regulatory decision. The absence of such documentation prevents independent verification of whether the Plan's enhanced monitoring framework was systematically applied, and indicates failure to implement the enhanced process controls required under the provisional approval safety-monitoring conditions.

Finding 4: Signal Investigation and Regulatory Action Transparency Gap

TGA reports 57 regulatory actions resulting from 148 signal investigations. However, no public or FOI-accessible documentation links specific signals to specific actions, describes decision-making criteria applied, or explains the disposition of 91 signals that did not result in documented regulatory action.

Across approximately 73 million doses administered, TGA investigated one signal per 431,000 doses.[18] Whether this detection rate reflects appropriate sensitivity, under-detection, or performance comparable to international benchmarks cannot be assessed

[18] As of March 2025. https://www.health.gov.au/sites/default/files/2025-03/covid-19-vaccine-rollout-update-14-march-2025.pdf

without access to investigation protocols, causality assessment frameworks, and prioritisation criteria that international pharmacovigilance standards require.

International standards emphasise comprehensive documentation and audit trails not merely to show that signals were investigated, but to enable independent assessment of whether the pharmacovigilance system functioned with adequate sensitivity and rigour. The figures of 148 signals and 57 actions describe outputs only; the missing documentation concerns the processes that produced those outputs and whether they met enhanced monitoring commitments.

Systematic documentary searches (Appendix A, Section A.5.1) found TGA's 2022-23 and 2023-24 Performance Report contains zero references to the COVID-19 Vaccine Safety Monitoring Plan, zero output tracking, and zero performance metrics—supporting the finding that implementation was not tracked at institutional level. This omission means that implementation and verification of these commitments are invisible in the agency’s primary accountability documents.

Finding 5: Governance and Performance Measurement Control Deficiency

FOI processes, OAIC-directed searches, and systematic documentary review identified no governance oversight or performance measurement documentation for Plan implementation (Appendix B, FOI 3643 decision; Appendix A, Section A.5.1).

TGA confirmed in FOI 3643 responses that implementation was "never systematically tracked" against the plan’s objectives. This assessment identified zero documented governance oversight or performance measurement for Plan implementation (Appendix B, FOI 3643 decision; Appendix A, Section A.5.1) which appears inconsistent with the obligation in PGPA Act 2013 s37 for Commonwealth entities to keep records that properly record and explain their performance in achieving their purposes, and with ISO 9001:2015 and ISO 31000:2018 principles that require systematic monitoring, measurement and documented evaluation of implementation against defined objectives.

For a plan tied to provisional approval conditions, the absence of implementation governance or performance tracking represents a fundamental control deficiency preventing TGA from demonstrating whether enhanced post-market monitoring was delivered as specified.

AusVaxSafety: Active Surveillance Without Documented Signal Investigation

AusVaxSafety was established in 2014 and is led by the National Centre for Immunisation Research and Surveillance (NCIRS). The AusVaxSafety program exemplifies the documentation gaps identified across Plan implementation: it operated active SMS-based surveillance throughout the COVID-19 vaccine rollout

and published regular national safety summaries, yet no TGA documentation could be located showing how AusVaxSafety data were systematically integrated into TGA's signal-detection or decision-making processes. The February 2021 Plan committed to "collaborate with AusVaxSafety to receive active surveillance information and coordinate safety signal detection and investigation activities".

Despite OAIC-directed searches and multiple FOI processes specifically requesting implementation documents, TGA reported no coordination protocols, integration frameworks, workflows or audit trails could be located. TGA's September 2024 comprehensive search acknowledged AusVaxSafety within scope but omitted it as a search term and could not locate publicly accessible partner organisation reports (OAIC Submission MR22/00538, Tables 3-4, pp.18-21).

The documentation gap is evidenced by unintegrated surveillance at scale:

- AusVaxSafety: approximately 6.9 million surveys completed (April 2025), documenting 3 million adverse events (43.5% of respondents) and 62,000 medical visits (0.9%)
- TGA: 148 signals investigated, 57 regulatory actions documented
- No documented linkage between systems

Without coordination protocols, independent parties cannot verify:

- How population-level adverse event data informed TGA signal prioritisation
- Whether 3 million adverse events from active surveillance were reconciled with passive surveillance (DAEN)
- What criteria determined when AusVaxSafety findings would trigger TGA investigations
- How discrepancies between surveillance systems were resolved

This assessment found no documentation demonstrating systematic integration of AusVaxSafety data into TGA's signal detection, cumulative reviews, or regulatory decisions (Appendix A, Section A.5.3; Appendix B, Objective 5 collaboration claims lacking audit trails). The two systems appear to have functioned in parallel rather than as a coordinated pharmacovigilance system, consistent with 0% implementation for Objective 4 (data integration).

International pharmacovigilance standards (ICH E2E, CIOMS VIII) require documented audit trails from signal detection through assessment to regulatory action to enable verification that integration occurred systematically rather than ad hoc.

The requirement for documented coordination protocols is not bureaucratic formalism but a fundamental accountability mechanism: without documented integration frameworks, independent parties cannot verify whether AusVaxSafety's 62,000 medical attention reports and 3 million adverse event reports were systematically considered in TGA's signal prioritisation, or whether the two surveillance systems operated in parallel without systematic coordination

Expert Committees and Governance Framework

The existence of expert advisory committees (ATAGI, ACV, AEFI-CAN) that provided advice on COVID-19 vaccine safety is well-documented through ANAO audit findings and publicly available meeting statements. However, expert advisory structures do not substitute for documented Plan implementation, governance oversight, or performance measurement.

Advisory committees address *what decisions should be made* based on clinical and scientific evidence. Plan governance addresses *whether the enhanced monitoring framework was systematically implemented, operated, and measured* as specified. These are distinct accountability questions:

- Advisory function: Did expert committees review safety data and provide appropriate clinical recommendations? (Evidence: ACV meeting statements exist)
- Implementation function: Was the February 2021 Plan's enhanced monitoring framework—including multi-source integration, systematic coordination, and performance tracking—implemented as committed? (Evidence: no documentation located)

No committee terms of reference, standing agendas, or decision records were identified that demonstrate how ATAGI, ACV, or AEFI-CAN systematically fed COVID-19 vaccine safety advice into TGA's signal-management workflows, regulatory actions, or Plan-level implementation tracking. Available documentation shows committees existed and met, but not how their deliberations linked to Plan governance, AusVaxSafety coordination (Strategy 2.4), or the 17 explicitly numbered implementation strategies.

For provisionally approved medicines where enhanced monitoring is a regulatory condition, the question is not whether expert advice was available, but whether the enhanced monitoring framework specified in the Plan was systematically implemented with documented processes, integration protocols, and performance measurement—requirements that expert committees do not fulfil.

Finding 6: 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.

While TGA clearly conducted operational activities—processing adverse event reports, investigating signals, publishing weekly safety reports—these activities do not demonstrate that the enhanced monitoring framework specified in the Plan was systematically designed, documented, and governed. International standards (ISO 19011:2018, ICH E2E, CIOMS) distinguish between operational outputs and systematic process implementation:

- Operational output: 148 signals investigated (activity occurred)
- Systematic process: Documented investigation protocols, prioritisation criteria, causality frameworks (design and governance not evidenced)

The absence of process documentation means independent parties cannot verify whether enhanced monitoring occurred through systematic frameworks or through ad hoc application of routine pharmacovigilance processes. For provisionally approved products where enhanced monitoring is a regulatory condition, this distinction is fundamental.

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.[19]

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.

As shown by the OAIC-directed MR22/00538 TRIM searches, no AusVaxSafety–TGA coordination protocols, multi-source integration procedures or Plan-specific

[19] https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf

implementation guidelines were identified, and no documentation links AusVaxSafety data to TGA's 148 signals, 57 regulatory actions or the 91 signals closed with no further action.

Critical Unanswered Questions - AusVaxSafety Coordination:

- How were AusVaxSafety's 6.8+ million safety surveys analysed and integrated with TGA's signal detection processes?
- What protocols governed coordination between active surveillance (AusVaxSafety) and passive surveillance (DAEN) systems?
- How did approximately 3 million adverse events reported through AusVaxSafety relate to the 148 signals TGA investigated?
- What threshold determined when AusVaxSafety findings (including 62,000 individuals seeking medical attention) would trigger TGA signal investigations?
- How were discrepancies between surveillance systems reconciled (e.g., if AusVaxSafety identified patterns not visible in DAEN, or vice versa)?
- Why could TGA's September 2024 comprehensive search not locate AusVaxSafety's publicly accessible website and data despite acknowledging the collaboration within scope?
- What distinguished COVID-19 vaccine safety monitoring from TGA's routine pharmacovigilance operations?
- If enhanced monitoring was conducted through "day-to-day processes," how can TGA demonstrate it met provisional approval conditions requiring enhanced surveillance?
- Were additional resources, dedicated teams, or systematic processes allocated beyond routine operations?
- How did TGA verify that routine "day-to-day" processes provided the enhanced oversight provisional approval conditions required?

These questions cannot be answered without the documented protocols, coordination frameworks, and decision-making criteria that international pharmacovigilance standards require but which remain undocumented.

3. Detailed Plan Implementation Assessment

Table 1: Implementation Status Assessment by Output[20]

Plan Objective & Specific Output[21]	What Was Promised (From February 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 150+ weekly 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.

[20] Ratings reflect documented evidence available through public sources and FOI/OAIC processes. "Implemented" indicates documented operational delivery; "Partially Documented" indicates activity occurred but systematic documentation incomplete; "Not Documented" indicates no evidence found.
[21] Objectives 4 (Data integration) and 5 (Contribution to evidence base) are reconstructed from the narrative and cross cutting functions described in the February 2021 COVID-19 Vaccine Safety Monitoring Plan, rather than from a discrete numbered section, to ensure that all Plan commitments relating to integration, research and evidence generation are captured in this assessment.

Plan Objective & Specific Output[21]	What Was Promised (From February 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
2.2 Protocols for investigating AEFI	Specific protocols for investigating COVID-19 AEFI reports.	✗ No documents found. The audit found zero documentation of specific investigation protocols for COVID-19 vaccines.
2.3 Enhanced cumulative data reviews	Refined processes/statistical methods for signal detection; subpopulation analysis.	✗ No documents found. The audit found zero documentation of refined processes, statistical methodologies, or subpopulation analysis frameworks.
2.4 Active surveillance[22]	Collaborate with AusVaxSafety and coordinate safety signal detection.[23]	◐ Partially/Undocumented. AusVaxSafety infrastructure operated effectively throughout 2021-2025, completing 6,887,520 COVID-19 vaccine safety surveys as at April 2025. Of respondents, 43.5% reported at least one adverse event (approximately 3 million individuals) and 0.9% sought medical attention (approximately 62,000 individuals). Infrastructure capability is documented and not disputed. However, no documentation was identified showing systematic coordination of this active surveillance data with TGA's signal detection processes. TGA's September 2024 comprehensive search acknowledged AusVaxSafety within scope but omitted it as a search term and could not locate partner organisation reports

[4] *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 Community Affairs Legislation Committee Estimates testimony, October 2025), 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.

[23] Public TGA documents, FOI releases and OAIC-directed TRIM searches together show extensive routine pharmacovigilance documentation (AEFI workflows, signal-detection methods, regulatory actions) but no documented implementation of the COVID-19 Vaccine Safety Monitoring Plan's enhanced, multi-source integration requirements—particularly Strategy 2.4 on AusVaxSafety coordination.

Plan Objective & Specific Output[21]	What Was Promised (From February 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
		(OAIC Submission MR22/00538). The coordination component of Strategy 2.4's commitment cannot be verified despite demonstrated operational capability.
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 identified. FOI 5275 also found no document found.[24]
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. Despite expert committees advising on vaccine policy and safety, OAIC-directed searches and FOI processes have not identified documentation that maps these advisory processes to the Plan's enhanced monitoring requirements, or that demonstrates systematic implementation and performance measurement for each objective[25]

[24] In a separate FOI (5275) concerning Pfizer's post-market safety data, TGA stated that documents relating to the requested post-market safety studies and monthly safety summaries 'do not exist', despite the Safety Monitoring Plan listing 'timely submission of post-market safety studies and monthly safety summaries' as a condition of registration.

[25] For example, the Advisory Committee on Vaccines provides independent medical and scientific advice to the Minister for Health and the Therapeutic Goods Administration on the safety, quality and efficacy of

Plan Objective & Specific Output[21]	What Was Promised (From February 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
OBJECTIVE 3: Clear communication		**Status: 100% 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.
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

vaccines supplied in Australia, including pre-market assessment, post-market monitoring and safe use in national immunisation program. https://www.tga.gov.au/safety/safety-monitoring-and-information

Plan Objective & Specific Output[21]	What Was Promised (From February 2021 Plan)	Implementation Status & Evidence (From Audit & FOI Findings)
		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" FOI 3643; OAIC MR22/00538 confirms a total absence of performance measurement.

4. Detailed Observations

4.1 Implementation Documentation and Governance Gap

This audit identified a fundamental gap between the Safety Monitoring Plan's documented commitments and the TGA's documented implementation and governance commitments.

Observation:

- No systematic tracking of Plan implementation identified
- No governance frameworks documented
- No enhanced signal detection protocols located
- No performance measurement mechanisms evidenced
- AusPAR records show no evaluation against the COVID-19 Vaccine Safety[26] Monitoring Plan, no verification that enhanced monitoring requirements were met, and no Plan-specific governance or performance-measurement evidence[27]
- Provisional approval conditions specified enhanced monitoring; the entity delivered standard operational pharmacovigilance processes instead of documented "enhanced" arrangements[28] [29]

[26] Documentation for the provisional-to-full registration decision summarising clinical and pharmacovigilance data
[27] TGA 2023, Australian Public Assessment Report for Comirnaty: Provisional to full registration, Australian Government Department of Health and Aged Care, 7 August 2023, https://www.tga.gov.au/sites/default/files/2023-08/auspar-comirnaty-230807.pdf.auspar-comirnaty-230807.pdf
[28] https://www.tga.gov.au/products/medicines/prescription-medicines/application-and-market-authorisation/covid-19-vaccine-information-sponsors-industry/covid-19-vaccines-regulatory-status
[29] https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf

Key Risk Identified: Inability to demonstrate compliance with Plan commitments, regulatory requirements, and provisional approval conditions, creating regulatory and legal exposure.[30]

OAIC-directed TRIM searches in September 2024, using eight distinct search terms, document-type classifications (SOPs, protocols, workflows, implementation guidelines) and review of more than 531 containers, failed to identify any implementation reports, governance frameworks, performance measurement documents, or Plan-specific coordination protocols for the COVID-19 Vaccine Safety Monitoring Plan. This confirms under statutory oversight that the absence of Plan implementation documentation in 2022 was not a search limitation but a persistent governance and records-creation deficiency.[31]

The significance of FOI 25-0166 cannot be overstated. TGA's successful identification of 399 relevant documents using Plan-aligned terminology and standard document classifications demonstrates that: (1) relevant records exist in TGA's systems, (2) TGA possesses the institutional capability to locate them, and (3) the evidentiary gap represents an access barrier rather than an absence of records. The practical refusal decision, made after identifying a finite corpus of objectively defined documents, suggests a deliberate limitation on external scrutiny rather than a good-faith inability to process requests.

The Advisory Committee on Vaccines publishes detailed meeting statements summarising its advice on specific safety issues, such as transverse myelitis following mRNA COVID-19 vaccines (Meeting 53, June 2025) and herpes zoster ophthalmicus following Shingrix (Meeting 54, October 2025). These statements confirm that expert review of safety data occurred, but they do not provide a traceable implementation framework linking AusVaxSafety data, internal signal processes and regulatory actions back to the COVID-19 Vaccine Safety Monitoring Plan or to provisional-approval conditions.[32]

4.1.1 Expert Advisory Committees Distinguished from Plan Governance

ANAO's COVID-19 vaccine rollout audit confirms that expert committees including ATAGI, ACV, and SITAG provided clinical and technical advice on vaccine policy, safety assessment, and rollout strategy. These committees are documented through published meeting statements, public recommendations, and parliamentary references.

[30] https://www.tga.gov.au/products/medicines/prescription-medicines/overview/covid-19-vaccine-approval-process
[31] TGA-OAIC-Submission-MR22-00538-Sept-2024
[32] https://www.tga.gov.au/resources/publication/meeting-statements/acv-meeting-statement-meeting-53-4-june-2025

However, the existence of expert advisory committees does not demonstrate implementation of the February 2021 Safety Monitoring Plan's governance requirements. Advisory committees serve a distinct function:

Advisory committees provide: Expert clinical judgment on safety signals and risk-benefit assessment

Plan governance requires: Systematic implementation tracking, performance measurement, documented coordination protocols, and audit trails linking surveillance data to regulatory decisions

The assessment identified zero documentation demonstrating:

- How committee advice was operationalised into Plan-specific processes
- Whether committees were briefed on Plan implementation progress
- What coordination mechanisms existed between committee deliberations and Plan outputs
- How committee recommendations linked to the 148 signals, 57 actions, and 91 "no further action" closures

Advisory Committee on Vaccines meeting statements (such as Meeting 53, June 2025, on mRNA vaccines and transverse myelitis) demonstrate expert review occurred, but do not provide audit trails showing how AusVaxSafety's 6.8 million surveys, DAEN reports, and international signals were systematically integrated into committee briefings or how committee advice translated to documented regulatory decisions under the Plan framework.

4.2 Alignment with Provisional Approval Framework

Table 2: Key Framework Requirements vs Documented Implementation

Framework requirement	Source	What is required or promised	Evidence in TGA record set	Audit assessment
Enhanced post-market monitoring as a condition of provisional registration for early data COVID-19 vaccines	TGA provisional approval framework[33]	Provisional approvals are time limited, granted on early clinical data, and subject to enhanced post-market monitoring and additional	The February 2021 COVID-19 Vaccine Safety Monitoring Plan sets out “enhanced” monitoring objectives, but OAIC -directed searches and FOI processes found no governance	Gap: 'enhanced monitoring' requirement not supported by documented implementation.

[33] TGA provisional approval framework (2017 consultation paper; provisional registration extension guidance; EM 2017 Measures No. 1).

Framework requirement	Source	What is required or promised	Evidence in TGA record set	Audit assessment
		conditions to manage greater uncertainty.[34]	frameworks, implementation tracking or performance measurement demonstrating these enhanced arrangements.[35]	
Verification that enhanced monitoring requirements and other provisional-approval obligations are satisfied before extension or transition to full registration	TGA provisional approval framework; Provisional registration extension and transition to full registration guidance	Sponsors must provide data demonstrating fulfilment of provisional conditions, and TGA must assess this evidence before granting extensions or full registration, including confirmation including assessment of whether required enhanced monitoring has been implemented.	For Comirnaty and other COVID-19 vaccines, AusPARs recording provisional-to-full or extension decisions summarise clinical data, RMP and conditions but contain no verification checklist or evaluation of implementation against the February 2021 Safety Monitoring Plan or other enhanced-monitoring obligations	Gap: compliance with provisional-framework verification requirements has not been documented; no documented process identified showing how enhanced monitoring requirements were verified before full registration[36]
Pharmacovigilance Plan specifying safety issues, planned studies, milestones and reporting	ICH E2E Pharmacovigilance Planning[37]	A written Safety Specification and Pharmacovigilance Plan should identify important risks, specify post authorisation studies, and define milestones and reporting.	The Safety Monitoring Plan exists, but no implementation reports, study tracking documents or milestone records linked to its 20 outputs were identified.	Gap: plan exists; systematic implementation and tracking documentation absent.
Documented signal	CIOMS / GVP signal	Signal management	TGA officials reported	Gap: traceability requirement not

[34] TGA, COVID-19 Vaccine Safety Monitoring Plan, Feb 2021.
[35] TGA–OAIC submission MR22/00538 (Sept 2024 TRIM search description).
[36] https://www.tga.gov.au/sites/default/files/provisional-registration-extension-and-transition-full-registration.pdf
[37] ICH, *E2E Pharmacovigilance Planning*

Framework requirement	Source	What is required or promised	Evidence in TGA record set	Audit assessment
management from detection to decision and action	management guidance[5]	steps (detection, validation, analysis, prioritisation, decision, action, communication) should be documented and traceable.[38]	investigation of 148 safety signals and 57 resultant actions at Senate Estimates, but no public documentation links specific COVID-19 signals to specific regulatory decisions or describes the criteria applied.[39]	met; no end-to-end audit trails.
Pharmacovigilance record keeping ensuring retrievability and traceability of decisions	TGA pharmacovigilance responsibilities and related guidance[7]	PV systems must ensure records are maintained so that safety concerns, evaluations and resulting actions are fully retrievable and traceable over time.[40]	OAIC-directed TRIM searches (eight search terms, 531+ containers) did not locate implementation reports, Plan specific SOPs, or performance measurement documents for the Safety Monitoring Plan.	Gap: PV record keeping obligations not evidenced for the Plan's enhanced activities.
Systematic use of active surveillance and multi-source data integration	Safety Monitoring Plan and PV standards[24]	Active surveillance systems (e.g. AusVaxSafety) and multiple data sources should feed into an integrated signal detection and assessment framework, with roles, processes and data flows defined.	AusVaxSafety conducted more than 6.8 million COVID-19 vaccine safety surveys and produced detailed outputs, but no documented framework showing systematic integration of these data into TGA signal management processes was identified.[41]	Gap: operational capability present, but integration and coordination requirements not documented.

The February 2021 COVID-19 Vaccine Safety Monitoring Plan was intended to operationalise the enhanced post-market monitoring conditions attached to provisional approvals for early-data COVID-19 vaccines and to align with international

[38] CIOMS, Signal Detection in Pharmacovigilance; EMA, GVP Module IX: Signal management.
[39] Senate Community Affairs Legislation Committee, Estimates, 9–10 Oct 2025 (148 signals, 57 actions).
[40] TGA, Pharmacovigilance responsibilities of medicine sponsors (and related PV guidance).
[41] NCIRS/AusVaxSafety COVID-19 vaccine safety surveillance outputs

pharmacovigilance standards adopted by TGA. Table 2 compares these framework requirements with documentation identified through OAIC-directed TRIM searches and FOI processes.[42] Across the provisional-approval framework, ICH E2E pharmacovigilance planning, CIOMS/GVP signal-management guidance and TGA's own pharmacovigilance obligations, the common expectation is a traceable, documented chain from plan to signal to regulatory decision. The audit found routine pharmacovigilance activity but no corresponding documentation demonstrating systematic implementation of the Plan's enhanced requirements.

4.2.1 Post-Transition Monitoring Framework

Pfizer Comirnaty and Moderna Spikevax transitioned from provisional to full registration in mid-2023 (July 2023 and April 2023 respectively), after approximately 68 million doses had been administered under provisional approval. This transition raises a critical question: what happened to the enhanced monitoring commitments specified in the February 2021 Plan?

Three scenarios are possible:

- **Enhanced monitoring was discontinued** following transition to full registration, on the basis that the Plan's commitments were time-limited to the provisional approval period.
- **Enhanced monitoring continued under a different framework**, with new governance arrangements, documentation systems, or integration protocols established for the post-provisional period.
- **Enhanced monitoring was never systematically implemented**, meaning the transition from provisional to full registration changed nothing in operational practice—TGA's characterisation of COVID-19 vaccine safety work as "day-to-day processes" remained accurate throughout.

The available evidence cannot distinguish between these scenarios. No public documentation describes:

- Whether the Plan's enhanced monitoring framework was formally discontinued
- What governance arrangements replaced it (if any)
- How the transition affected coordination with AusVaxSafety and other surveillance systems

[42] Core framework documents: TGA Consultation: Provisional Approval pathway for prescription medicines (2017); TGA Provisional registration extension and transition to full registration; Explanatory Memorandum, Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017; TGA COVID-19 Vaccine Safety Monitoring Plan (Feb 2021); ICH E2E Pharmacovigilance Planning; CIOMS Signal Detection in Pharmacovigilance; EMA GVP Module IX: Signal management; TGA Pharmacovigilance responsibilities of medicine sponsors.

- Whether performance measurement or implementation tracking was conducted for the provisional approval period before transition

If Scenario 1 is correct, TGA should be able to produce an end-of-Plan evaluation or transition report documenting what was implemented during the provisional period and what monitoring arrangements succeeded it. If Scenario 2 is correct, post-transition monitoring frameworks should be documented and publicly available. If Scenario 3 is correct—that enhanced monitoring commitments were never systematically implemented beyond business-as-usual processes—this has significant implications for the integrity of Australia's provisional approval framework and public assurances given during the rollout.

The inability to determine which scenario occurred represents a fundamental accountability failure. For 68 million doses administered under provisional approval—Australia's largest deployment of medicines under this regulatory pathway—TGA cannot demonstrate through documented evidence what enhanced monitoring arrangements were in place, when they operated, whether provisional approval conditions were satisfied, or whether enhanced monitoring continues post-transition. This makes retrospective verification of regulatory compliance impossible.

4.3 Provisional Approval Lifecycle: Verification Gap

Australia's COVID-19 vaccine rollout represents the nation's largest deployment of provisionally approved medicines. Between February 2021 and July 2023, approximately 68 million doses (94% of the total rollout) were administered while key vaccines remained under provisional approval. This scale necessitates rigorous verification that provisional approval conditions were satisfied and enhanced monitoring requirements were met before transition to full registration[43]

Legislative Framework for Provisional Approval

The Therapeutic Goods Act 1989 establishes a structured provisional approval pathway with specific conditions and verification requirements:

Determination phase (s22C): TGA assesses whether a medicine qualifies for provisional approval based on preliminary data and development stage.[44]

Provisional registration (s23AA, s28(2A)(aa)): TGA converts the application to provisional registration and imposes conditions, which may include requirements for post-market monitoring.[45]

[43] Appendix C, Dose Count Summary; Senate Community Affairs Legislation Committee testimon
[44] Therapeutic Goods Act 1989 (Cth), s22C (Applications for provisional determination). AustLII. https://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s22c.html
[45] Therapeutic Goods Act 1989 (Cth), s23AA (Applications for provisional registration of medicine), s28(2A)(aa). AustLII. https://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s23aa.html

Time-limited approval (s29): Provisional registration operates for defined periods (typically 2 years) with mandatory review at each extension.[46]

Verification requirement (s29(3)-(6)): Extension of provisional approval and transition to full registration require TGA to assess that provisional conditions have been satisfied.[47]

TGA Guidance Requirements for Provisional Approval

Risk Management Plans (RMPs): Sponsors seeking provisional registration must submit a Risk Management Plan that sets out the safety specification, planned pharmacovigilance activities and risk-minimisation measures, including timelines and milestones for the provisional period. This requirement is set out in TGA's guidance on risk management plans and associated submission processes.[48] [49]

Transition to full approval (full registration): Transition from provisional to full registration requires sponsors to demonstrate, with documented evidence, that the conditions of provisional registration have been met, including completion (or adequate progress) of planned studies and delivery of updated safety and efficacy data. TGA's guidance on provisional registration extension and transition to full registration specifies the evidentiary requirements and decision framework for moving from provisional to full approval.[50] [51] [52]

Evidence Gap: Zero Verification Documentation

Systematic searches conducted in September 2024 under Office of the Australian Information Commissioner direction (OAIC reference MR22/00538) examined more

[46] Therapeutic Goods Act 1989 (Cth), s29 (Duration of registration or listing). AustLII https://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s29.html
[47] Therapeutic Goods Act 1989 (Cth), s29(3)–(6) (provisions governing the period for which registration or listing remains in force, including extensions on application).
[48] Therapeutic Goods Administration 2024, Risk management plans for medicines and biologicals, Australian Government Department of Health and Aged Care. https://www.tga.gov.au/sites/default/files/risk-management-plans-medicines-and-biologicals.pdf
[49] Therapeutic Goods Administration 2024, Submitting risk management plans for medicines and biologicals, Australian Government Department of Health and Aged Care. https://www.tga.gov.au/resources/guidance/submitting-risk-management-plans-medicines-and-biologicals
[50] Therapeutic Goods Administration 2024, Provisional registration extension and transition to full registration, Australian Government Department of Health and Aged Care. https://www.tga.gov.au/sites/default/files/provisional-registration-extension-and-transition-full-registration.pdf
[51] Therapeutic Goods Administration 2025, Applying for provisional registration extension or transition to full registration, Australian Government Department of Health and Aged Care. https://www.tga.gov.au/resources/guidance/applying-provisional-registration-extension-or-transition-full-registration
[52] Therapeutic Goods Administration 2025, Applying for provisional registration for a prescription medicine, Australian Government Department of Health and Aged Care. https://www.tga.gov.au/resources/guidance/applying-provisional-registration-prescription-medicine

than 531 TRIM document management containers using eight plan-aligned search terms. These searches found zero documents demonstrating:

- Verification that enhanced monitoring requirements were satisfied before Comirnaty (July 2023) or Spikevax (April 2023) transitioned to full approval
- TGA's documented assessment of whether provisional approval conditions were met
- Decision-making criteria or rationale for granting full approval

Additionally, FOI request 25-0166 (June 2025) identified 399 Plan-aligned documents across 12 document categories, yet TGA refused to process any of these documents under s24(1)(b) of the Freedom of Information Act 1982, citing practical refusal provisions.[53]

Australian Public Assessment Reports (AusPARs)

Australian Public Assessment Reports (AusPARs) are TGA's published summaries of its evaluation of sponsor submissions, including clinical data, benefit–risk reasoning and key conditions at the time of each regulatory decision. The 2023 AusPAR for Comirnaty records the conversion from provisional to full registration (TGA decision 13 July 2023, ARTG entry 14 July 2023) but does not identify any evaluation of implementation against the February 2021 COVID-19 Vaccine Safety Monitoring Plan or its enhanced monitoring outputs.[54] Similarly, TGA's media release announcing Spikevax's transition to full registration (21 April 2023) contains no reference to verification of Plan implementation.[55] Despite these being the definitive public assessments for provisional-to-full transitions, neither document contains Plan-implementation evidence, verification checklists showing that provisional-approval conditions were met, or Plan-level governance documentation. This absence is consistent with the broader finding of systematic documentation gaps across all verification mechanisms.

Implications for Provisional Approval Framework Integrity

The absence of documented verification creates three critical accountability gaps:

Legal Basis Questioned: Provisional approval under s23AA is predicated on enhanced monitoring compensating for incomplete safety data. Without documented verification that enhanced monitoring was implemented and conditions met, the basis

[53] FOI 25-0166 Decision, June 2025; OAIC Review MR25/01153 (pending).
[54] Therapeutic Goods Administration 2023, Australian Public Assessment Report for Comirnaty: Provisional to full registration, Australian Government Department of Health and Aged Care, 7 August 2023. https://www.tga.gov.au/sites/default/files/2023-08/auspar-comirnaty-230807.pdf
[55] TGA 2023, 'Moderna's COVID-19 vaccine Spikevax receives approval for full registration', media release, 21 April 2023, Australian Government Department of Health and Aged Care, https://www.tga.gov.au/news/media-releases/modernas-covid-19-vaccine-spikevax-receives-approval-full-registration.

for transitioning 68 million provisionally-approved doses to full approval remains unverified through available documentation.

Framework Integrity Compromised: If enhanced monitoring cannot be distinguished from routine pharmacovigilance (as Senate testimony suggests—TGA officials characterised monitoring as "day-to-day processes"[56]), then the provisional approval framework operates as a fast-track to approval without the rigorous oversight that justifies reduced evidentiary requirements.

Future Emergency Preparedness: These gaps will recur unless provisional approval frameworks are strengthened with mandatory verification documentation and published transparency mechanisms.

4.4 Stakeholder Communication and Assurance

Observation: By late July 2023, more than 68 million COVID-19 vaccine doses had been administered in Australia since roll-out commencement, the vast majority while primary vaccines were provisionally approved.[57] [58]

- Public communications stated rigorous and enhanced safety monitoring for provisionally approved vaccines, consistent with the COVID-19 vaccine approval framework.
- Assurances could not be verified through documentation review.

Key Risk Identified: Reputational damage and erosion of public trust, particularly for future emergency and provisional approvals, with potential liability exposure.[59]

4.5 Active Surveillance Infrastructure Without Documented Integration

Context

AusVaxSafety is Australia's national active surveillance system operated by NCIRS. The February 2021 TGA COVID-19 Vaccine Safety Monitoring Plan explicitly committed to "collaborate with AusVaxSafety to receive active surveillance information and coordinate safety signal detection and investigation activities" (Strategy 2.4, p.9).[60]

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[56] Senate Community Affairs Legislation Committee, Hearing 9 October 2025, Dr Marcus Dascombe, TGA: "There would be some difficulty in producing documents... the five key themes... essentially describe our day-to-day processes."

[57] https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-27-07-2023

[58] https://www.health.gov.au/resources/publications/covid-19-vaccination-vaccination-data-10-october-2024?language=en

[59] https://pmc.ncbi.nlm.nih.gov/articles/PMC9672672/

[60] https://ncirs.org.au/sites/default/files/2025-10/2023%20AEMS%20Annual%20Report.pdf

Operational performance:

- 6,887,520 COVID-19 vaccine safety surveys completed as at 14 April 2025.
- 43.5% reported at least one adverse event (approximately 3 million individuals).
- 0.9% reported seeking medical attention (approximately 62,000 individuals).
- Regular public reporting maintained throughout the roll-out period.

This demonstrates high-volume, systematic collection of population-level safety data from a large, nationally representative sample.

Documentation gap:[61]

Despite 6.8 million active surveillance surveys documenting 62,000 medical attention reports, TGA produced zero coordination protocols, integration frameworks, or audit trails showing how this data informed its 148 signal investigations or 57 regulatory actions. This represents systematic failure to implement Strategy 2.4's explicit coordination commitment.

Specific documented gaps include:

- No documented protocols for integrating AusVaxSafety data with TGA signal detection processes.
- No documented coordination frameworks between active (AusVaxSafety) and passive (DAEN) surveillance systems.
- No documented decision criteria for when AusVaxSafety findings would trigger TGA signal investigations.
- TGA's September 2024 OAIC-directed search acknowledged AusVaxSafety within scope but omitted it as a search term and could not locate publicly available AusVaxSafety reports (OAIC MR22/00538, Tables 3-4, pp.18-21).
- No traceable linkages between AusVaxSafety's approximately 3 million adverse-event reports and TGA's investigation of 148 safety signals over the corresponding period.
- No documentation explaining how AusVaxSafety's medical-attention rate informed TGA regulatory actions.

Implications

The absence of documented coordination between AusVaxSafety (6.8+ million surveys) and TGA signal investigation processes means the assessment cannot verify whether enhanced monitoring commitments were implemented. Senate officials characterised COVID-19 vaccine safety monitoring as "day-to-day processes" of pharmacovigilance

[61] Therapeutic Goods Administration. (2024, September). *Submission to Office of the Australian Information Commissioner - Internal Review MR22/00538*. Tables 3-4 (pp.18-21).

(October 2025), yet no documentation exists to show that these processes met the enhanced monitoring framework set out in the Plan.

International pharmacovigilance standards (for example, ICH E2E and CIOMS guidance on signal detection) expect documented, auditable processes for integrating multiple data sources, including active and passive surveillance streams. In this context, the lack of documented multi-source integration prevents confirmation that TGA's approach met accepted standards for enhanced monitoring.

For provisionally approved COVID-19 vaccines, where enhanced post-market monitoring formed part of the provisional registration framework under the Therapeutic Goods Act 1989 and associated provisional-approval regulations and related guidance, and where approximately 94% of doses (around 68 million of 72.3 million) were administered while primary vaccines remained under provisional approval, the inability to demonstrate systematic coordination between surveillance systems represents a significant compliance-verification gap.

The absence of documented coordination protocols is not a matter of administrative preference or 'gold-plating.' Under international pharmacovigilance standards adopted by TGA (ICH E2E) and provisional approval frameworks requiring enhanced monitoring, systematic integration of active and passive surveillance data is a regulatory expectation, not optional best practice. Without documented protocols, TGA cannot demonstrate that enhanced monitoring—a condition of provisional approval—was systematically delivered rather than claimed.

4.6 Institutional Response Pattern: Direct TGA Communications

Between 31 January and 27 February 2022, three escalating requests were made to TGA seeking formal implementation reporting on the Plan's objectives and outputs. TGA's responses establish the baseline institutional position regarding Plan documentation.

TGA's consistent response:

- Pre-FOI emails (31 January and February 2022): Provided the same four generic pharmacovigilance links (YouTube explainer, weekly safety reports, DAEN causality guidance, monitoring overview) with no Plan-specific references.
- FOI 3643 decision (27 February 2022): Explicitly stated that "no implementation report exists" (para 7) while claiming that "ample documentation" existed (para 8), repeating the same four links for Objectives 1-4 and offering five unsubstantiated collaboration examples for Objective 5.

Key implications:

- Statutory confirmation: The FOI decision provides legal confirmation of a governance gap (Output GOV.2: 0% performance measurement documented).
- Substitution pattern: Routine pharmacovigilance outputs consistently substituted for Plan-specific enhanced monitoring evidence.
- Internal contradiction: TGA asserted capability while refusing access under FOI Act s 24A on the basis that requested implementation documents do not exist.

This primary evidence establishes TGA's institutional baseline in early 2022, later corroborated by OAIC-directed searches (September 2024), annual reporting omissions (Appendix A, Section A.5.1), and Senate testimony in October 2025. Full correspondence analysis is provided in Appendix B.

In addition, the 24 April FOI 25-0166 Request Consolation Correspondence identified 399 relevant documents but invoked ‘substantial and unreasonable diversion of resources’ to refuse processing, mis-citing FOI Guidelines paragraph 3.117 and reinforcing a pattern of using workload arguments rather than facilitating access to Plan-related records.

5. Root Cause Analysis

The absence of documented implementation frameworks for signal-detection coordination, data-integration protocols, research tracking and governance oversight indicates systematic control failures rather than isolated incidents. TGA's direct communications documented in Appendix B—including three escalating requests and statutory FOI responses—establish that this documentation gap was evident from February 2022 and has persisted through comprehensive OAIC-directed searches in September 2024. Four potential root causes have been identified.

Scenario 1: Records never created

Implication: Records-management control failure and potential non-compliance with PGPA Act 2013 obligations to establish and maintain effective systems of risk management and internal control, and associated PGPA Rule requirements[62]

Scenario 2: Records created but not retrievable

Implication: Information-management system deficiency. Operational ineffectiveness of document-management controls, evidenced by failure to retrieve implementation

[62] Public Governance, Performance and Accountability Act 2013 (Cth), including duties of accountable authorities and performance-reporting requirements (for example, s 37), and Archives Act 1983 (Cth) s 24 recordkeeping obligations.
https://classic.austlii.edu.au/au/legis/cth/consol_act/pgpaaa2013432/s37.html

records through OAIC-directed comprehensive searches using eight distinct search terms across more than 531 TRIM containers, despite AusVaxSafety being identified as within scope of the Safety Monitoring Plan but not used as a search term.

Scenario 3: Records created and subsequently destroyed

Implication: Potential non-compliance with Archives Act 1983 requirements governing disposal and destruction of Commonwealth records (including s 24) if relevant records were destroyed without proper authority.

Scenario 4: Enhanced monitoring never implemented

Implication: Provisional-approval and pharmacovigilance conditions not satisfied in practice; gap between published Safety Plan commitments and “day-to-day” operational processes.

Scenario 5: Records exist and are retrievable, but access is administratively denied.

Implication: FOI 25-0166 demonstrates that TGA can locate Plan-aligned implementation documents using standard search methodology, identifying 399 relevant records across defined document types. The subsequent decision to invoke practical refusal provisions and decline to process any of these records indicates a transparency and governance failure rather than a records-management or implementation failure, with institutional processes limiting external scrutiny of documented Plan delivery.

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

Assessment

Available evidence most strongly supports Scenario 1 (records never created) or Scenario 4 (enhanced monitoring never implemented) as consistent with the documented pattern: formal advice that no implementation report exists (FOI 3643, February 2022), OAIC-directed searches across multiple systems and search terms that identified no Plan-specific implementation, governance or AusVaxSafety-integration documents (MR22/00538, September 2024), subsequent refusal to process 399 already-identified Plan-aligned records on practical-refusal grounds (FOI 25-0166, April-June 2025), complete absence of Plan implementation in institutional performance reporting, and characterisation of COVID-19 vaccine safety monitoring as “day-to-day processes” in Senate testimony.

The OAIC-directed MR22/00538 searches, conducted by senior officers using eight distinct search terms and examining more than 531 TRIM containers classified for

SOPs, protocols, workflows and implementation guidelines yet locating zero Safety-Plan implementation documents, support Scenario 1 or 4 rather than a simple search-limitation explanation.

While routine AEFI and signal-processing SOPs and workflows exist within AEMS and related systems, OAIC-directed searches and public documentation reveal no Plan-specific procedures that explain how AusVaxSafety's active-surveillance data were used to trigger, prioritise or validate the 148 safety signals and 57 regulatory actions reported during the COVID-19 program.[63] [64] [65]

For provisionally approved vaccines where approximately 68 million of 72.3 million recorded doses (about 94 per cent) were administered under conditions requiring enhanced monitoring, the inability to demonstrate systematic implementation through documented evidence creates an accountability gap that prevents Parliament and oversight bodies from verifying compliance with provisional-approval conditions, a transparency failure between public assurances and verifiable records, and a governance deficiency with implications for future provisional-approval frameworks.

Whether this represents documentation failure or implementation failure, the accountability gap is the same: TGA cannot verify compliance with provisional approval conditions.

6. Priority Reform Areas

This assessment has documented systematic gaps in implementation documentation, governance frameworks, and transparency mechanisms for TGA's COVID-19 Vaccine Safety Monitoring Plan. The following recommendations address the specific deficiencies identified through FOI requests, OAIC oversight, parliamentary testimony, and comprehensive documentary review.

These recommendations are directed to TGA, the Department of Health, Parliament, and relevant oversight bodies including the Australian National Audit Office, Office of the Australian Information Commissioner, and National Archives of Australia.

6.1 Plan-Level Implementation and Governance Documentation

Documented Gap: No implementation frameworks found for Signal Detection coordination, Data Integration protocols, Research tracking, or Governance oversight

[63] https://ncirs.org.au/sites/default/files/2025-09/2022%20AEMS%20COVID-19%20vaccines%20annual%20report.pdf
[64] https://www.tga.gov.au/resources/guidance/pharmacovigilance-responsibilities-medicine-sponsors
[65] https://www.tga.gov.au/news/covid-19-vaccine-safety-reports

despite OAIC-directed comprehensive searches across eight search terms and 531+ containers.

Recommendation

TGA must produce and publish a consolidated implementation and governance statement for the COVID-19 Vaccine Safety Monitoring Plan (or its successor), explicitly mapping Plan objectives and strategies to operational processes, data sources, decision pathways, and responsible roles.

Future safety monitoring plans for provisionally approved medicines must include minimum documentation standards: implementation matrix, governance map, integration protocols, and performance indicators.

6.2 Documented Integration of AusVaxSafety and Other Data Sources

Documented Gap: No documented protocols for integrating AusVaxSafety active surveillance data (6.8+ million surveys with approximately 3 million respondents reporting at least one adverse event) with TGA's signal detection processes. No traceable linkages between surveillance systems and the 148 safety signal investigations reported.

Recommendation

TGA must develop and publish protocols describing how AusVaxSafety, DAEN, sponsor, and international data streams are combined for signal detection, prioritisation, and regulatory action, consistent with ICH E2E and CIOMS guidance.

Establish routine, auditable reconciliation processes between AusVaxSafety outputs and TGA's signal lists and COVID-19 safety report narratives, with documented audit trails for all 148 signal investigations including the 91 signals where no regulatory action was taken.

6.3 Strengthened FOI and Records Management Practice

Documented Gap: FOI 25-0166 identified 399 relevant documents but refused processing under s24A practical refusal provisions. OAIC-directed searches failed to locate Plan-specific implementation, audit, or governance documents despite comprehensive searches across multiple record management systems.

Recommendation

TGA must review its FOI practices for high public interest safety matters to reduce reliance on s24A practical refusal decisions where finite corpora of relevant records exist.

Align records management for pharmacovigilance with Archives Act 1983 and ISO 15489 principles to ensure implementation and governance records for major safety monitoring plans are identifiable, retrievable, and properly retained.

Process the 399 documents identified in FOI 25-0166 or provide detailed justification for practical refusal that addresses OAIC concerns about TGA's pattern of non-disclosure.

6.4 Governance and Performance Measurement

Documented Gap: No governance frameworks or performance measurement mechanisms identified. TGA 2023-24 Annual Report contains zero Plan references, zero output tracking, zero performance metrics for COVID-19 vaccine safety monitoring located despite 68 million doses administered under provisional approval.

Recommendation

TGA must implement documented governance structures and performance measurement frameworks for all provisional approval monitoring commitments, consistent with PGPA Act 2013 requirements for effective systems of risk management and internal control.

Annual Reports must include specific performance reporting against provisional approval monitoring plan commitments, with measurable indicators demonstrating whether enhanced monitoring occurred as specified.

6.5 Independent Performance Audit of COVID-19 Vaccine Pharmacovigilance

Documented Gap: Australia's largest provisional approval experience (68 million doses, 94% of rollout) has produced no publicly available implementation assessment, documented lessons learned, or systematic evaluation against Plan objectives.

Recommendation

The Australian National Audit Office should commission a performance audit focused specifically on TGA's COVID-19 vaccine pharmacovigilance system, including:

- Implementation of the February 2021 Safety Monitoring Plan
- Integration with AusVaxSafety and other partner surveillance systems
- Compliance with PGPA Act and Therapeutic Goods Act obligations
- Records management effectiveness and FOI compliance

This audit should benchmark Australian practice against EMA, FDA, and WHO guidance on enhanced post-marketing surveillance for provisionally approved medicines.

6.6 Transparency and Public Accountability

Documented Gap: Of 148 signals investigated, 91 (61%) have no public documentation of investigation outcomes or regulatory decisions. Public communications stated "rigorous and enhanced safety monitoring" but systematic enhancement beyond routine pharmacovigilance cannot be verified.

Recommendation

TGA must publish comprehensive signal investigation summaries for all COVID-19 vaccine safety signals, including those where no regulatory action was taken, with documented rationale for closure decisions.

Future provisional approval monitoring plans must specify explicit transparency commitments with defined public reporting schedules, investigation disclosure thresholds, and performance metrics enabling independent verification.

7. Evidence Assessment and Anticipated Objections

Three tiers of evidence support these findings, with predictable institutional objections addressed below:

1. **Documented absence of implementation records**
   The record shows that: public material contains no Plan-specific implementation, governance or integration documents searches across more than 531 TRIM containers, using Plan-aligned terms, likewise found none. FOI 3643 and OAIC decision AICmr54 formally accept that no Plan “implementation report” exists and FOI 25-0166 confirms a corpus of 399 relevant documents exists but TGA refuses to process them, leaving the evidentiary gap unresolved. Together, these strands provide a powerful, triangulated basis for concluding that there is no verifiable implementation trail for the Plan.
2. **Signal-detection and AusVaxSafety integration gap.**
   The analysis combines AusVaxSafety outputs (more than 6.8 million surveys and about 62,000 medical-attention reports), TGA’s 148 safety signals and 57 regulatory actions, the absence of any protocols linking the two in MR22/00538 searches or FOI releases, and ICH E2E/CIOMS expectations for traceable signal-management audit trails. This makes the finding of a critical control deficiency in signal detection and governance difficult to rebut without producing actual Plan-specific integration and audit-trail documentation.
3. **Pattern over time, not a one-off glitch.**
   The FOI/OAIC timeline shows a consistent trajectory from early 2022 to late 2025: generic assurances in pre-FOI emails, a s 24A “no documents” decision for FOI 3643 and its confirmation in AICmr54, OAIC-directed MR22/00538 searches that still found zero Plan records, and a 2025 practical-refusal decision on FOI 25-0166

despite 399 in-scope documents being identified. This pattern supports the conclusion that the gap is systemic, not an isolated administrative oversight.

7.1 Potential counter-arguments and responses

“Generic pharmacovigilance SOPs implicitly cover the Plan.

Response: MR22/00538 demonstrates that while TGA holds extensive AEFI and signal-management SOPs, no documents map those procedures to the Plan’s objectives, outputs or enhanced multi-source integration requirements, particularly Strategy 2.4 on AusVaxSafety coordination. Without such mapping or governance records, there is no evidence that generic SOPs were systematically adapted to deliver the Plan’s additional requirements beyond “business as usual”.

“AusVaxSafety existed and functioned, so enhanced monitoring requirements were met.”

Response: AusVaxSafety’s active-surveillance system clearly operated and published aggregate reports (6.8M+ surveys and ~62,000 medical-attention reports), but MR22/00538 and FOI releases identify no protocols, decision rules or audit trails showing how AusVaxSafety data were integrated with TGA’s AEFI workflows, 148 signals, 57 actions or 91 “no further action” signals, as envisaged by Strategy 2.4. The existence of a system is not, by itself, evidence that Plan-mandated integration and governance were implemented, however without documented decision criteria and risk assessments, it's impossible to verify whether these 91 closures represented appropriate safety judgments or system failures to detect problems.

“Enhanced monitoring occurred even if documentation is incomplete.”

Response: For provisionally approved vaccines, enhanced monitoring is a regulatory condition, and standards such as ICH E2E and CIOMS require documented, traceable signal-management processes with clear audit trails. The absence of protocols, decision criteria, cross-system reconciliation rules and case-level audit trails four years after Plan publication means enhanced monitoring cannot be independently verified and does not meet the expected control standard.

“Relevant records may exist but were not captured by searches.”

Response: MR22/00538 used eight Plan-aligned search terms across TRIM and Promapp, covering more than 531 containers and over 2,200 sampled pages, with searches structured by objective. OAIC’s AICmr54 decision accepted those searches as “all reasonable steps” and upheld the s 24A “no documents” finding for an implementation report, which significantly weakens claims that substantial Plan-specific implementation records exist but were missed.

“Workload justified refusing FOI 25-0166.”

Response: FOI 25-0166 was already tightly scoped, and TGA successfully identified a finite corpus of 399 in-scope documents aligned with Plan objectives and standard document types. TGA chose not to process even a prioritised sample, instead relying on generic public web links. In light of earlier “no documents” findings and MR22/00538 searches, this use of s 24(1)(b) operates as a barrier to scrutiny of Plan implementation rather than a proportionate administrative safeguard.

“Expert committees substitute for documented implementation.”

Response: Committees such as ATAGI, ACV and SITAG provided clinical and technical advice on vaccines, risk–benefit assessment and rollout strategy, but advisory structures do not replace the need for records showing how that advice was operationalised into Plan-level processes, integrated surveillance and performance measurement. No Plan-specific terms of reference, standing agendas or decision records were identified that demonstrate how ATAGI, ACV and AEFI-CAN systematically fed COVID-19 vaccine safety advice into TGA’s signal-management workflows and regulatory actions; available documentation shows that committees existed and met, but not how their deliberations were linked to Plan-level implementation. The absence of such records remains an accountability gap even if expert advice was sound.

“FOI 3643 and AICmr54 have already resolved the issue.”

Response: MR22/00538 searches used eight distinct terms including operational vocabulary (signal detection, pharmacovigilance, implementation, audit) across Plan-aligned objectives, not merely the Plan title. TGA's September 2024 searches successfully located extensive routine pharmacovigilance documentation (>2,218 sampled pages of AEFI workflows, signal procedures, regulatory actions), demonstrating that operational documents *are* retrievable through TGA's systems when they exist.

The absence extends beyond operational documents to governance frameworks, performance measurement systems, and coordination protocols—categories that would have been created specifically for the Plan rather than predating it. The counter-argument would require TGA to explain why routine procedures are well-documented while Plan-specific enhancements are not, and why FOI 25-0166 identified 399 relevant documents that TGA then refused to process. OAIC's AICmr54 decision accepted TGA's search methodology as meeting "all reasonable steps" requirements, further weakening claims that substantial Plan-specific implementation records exist but were missed.

“FOI 25-0166 proves implementation records exist, so ‘Not documented’ ratings are invalid”

Response: FOI 25-0166 does confirm that Plan-aligned implementation records exist within TGA’s systems and can be located using standard search parameters; this is fully consistent with, and strengthens, the assessment’s findings. The classification “Not documented” in this report refers to the absence of publicly verifiable, Plan-specific implementation documentation available through published sources, FOI 3643, OAIC MR22/00538 and related processes; FOI 25-0166 shows that when 399 relevant records were identified, TGA chose not to process them, invoking practical refusal provisions, which shifts the problem from potential non-existence of records to an institutional decision to restrict access to

7.2 Overall assessment

On the central test—whether the regulator can demonstrate, on the record, that the Plan’s enhanced monitoring objectives and multi-source integration requirements were implemented and governed—the case presented here is very strong. To dislodge it, critics would need to do more than question the interpretation; they would have to produce Plan-specific implementation, governance or integration documents that multiple FOI processes, OAIC-directed searches and this independent review have not been able to identify.

8. Conclusion

This assessment documents a systematic gap between TGA's February 2021 COVID-19 Vaccine Safety Monitoring Plan and verifiable implementation. Key process controls—signal detection coordination, data integration, governance frameworks, and performance measurement—were not evidenced. TGA cannot provide documentation demonstrating systematic enhanced monitoring beyond routine operational pharmacovigilance.

The AusVaxSafety case study exemplifies this gap: 6.8 million surveys documenting 3 million adverse events and 62,000 medical attention visits, yet zero documented coordination protocols linking this population-level data to TGA's 148 signal investigations. Infrastructure existed and functioned. Systematic integration cannot be verified.

Across FOI processes, OAIC-directed TRIM searches and product-level AusPARs, no verifiable documentation was identified showing implementation, governance or performance-measurement of the February 2021 COVID-19 Vaccine Safety Monitoring Plan, including for key products later transitioned from provisional to full registration.

For provisionally approved products, enhanced monitoring is not optional—it is a regulatory condition imposed because standard surveillance is insufficient for products with incomplete safety data. TGA characterised COVID-19 vaccine safety work as "day-to-day processes." If enhanced monitoring was operationally indistinguishable from routine pharmacovigilance, the fundamental rationale for provisional approval—accepting uncertainty in exchange for enhanced oversight—collapses.

TGA's own performance reports for 2022-23 and 2023-24 do not report against the COVID-19 Vaccine Safety Monitoring Plan or the enhanced monitoring obligations attached to provisional approvals, leaving these core commitments outside the agency's formal performance framework.

After four years of investigation—statutory FOI processes, OAIC-directed searches across 531+ containers, institutional performance reporting review, Senate testimony under oath—the probability that systematic implementation documentation exists but remains undisclosed is negligible. The evidence indicates enhanced monitoring frameworks were not systematically implemented with the documented governance, coordination protocols, and performance tracking required to demonstrate compliance with provisional approval conditions.

Australia's COVID-19 vaccine rollout represents the nation's largest deployment of provisionally approved medicines: 68 million doses, 94% of the total rollout, administered under conditions requiring enhanced monitoring that cannot be verified through documented evidence.

TGA can resolve this by producing the missing documentation. If documentation cannot be produced, this matter requires investigation by the Australian National Audit Office, Commonwealth Ombudsman, or relevant parliamentary oversight committees. After identifying 399 relevant documents but refusing to process them (FOI 25-0166), after comprehensive OAIC-directed searches finding zero Plan implementation records (MR22/00538), and after four years of consistent institutional inability to demonstrate enhanced monitoring beyond routine processes, two possibilities remain: either the enhanced monitoring framework was never systematically implemented, or it was implemented but TGA failed to document it. Both scenarios represent regulatory failure and potential non-compliance with Commonwealth accountability frameworks. Neither is acceptable for 68 million doses administered under provisional approval.

9. Detailed Methodological Framework and Standards

9.1 Assessment Framework

Section 9 expands on the scope and methodology overview in Section 1.2.

This assessment employs ISO 19011:2018 audit principles, ISO 15489 (records management), Australian National Audit Office better practice standards and international pharmacovigilance standards (including ARGPM, ICH E2E and EMA GVP) to systematically evaluate implementation of TGA's COVID-19 Vaccine Safety Monitoring Plan. The framework evaluates not only operational activities but also governance processes, performance-measurement arrangements and the adequacy of documented information, and is benchmarked against international pharmacovigilance guidance that TGA has adopted for use in Australia, including ICH E2E Pharmacovigilance Planning (in place internationally since 2005), EMA Good Pharmacovigilance Practice modules and CIOMS risk-minimisation guidance.[66]

9.2 Independence and Scope

This is an independent assessment conducted without TGA funding, authorisation, or oversight. The assessor has no financial, professional, or personal conflicts of interest relating to TGA, COVID-19 vaccine manufacturers, or related commercial entities:

- Assessment period: February 2021 (Plan publication) to December 2025 (assessment finalisation).
- Evidence collection period: January 2022 (initial FOI request) to October 2025 (Senate testimony).
- Key source document: TGA COVID-19 Vaccine Safety Monitoring Plan (February 2021 version).

9.3 Assessment Limitations

This assessment is limited to publicly available documentation and information provided through FOI/OAIC statutory processes. It cannot:

- Access TGA's internal systems, databases, or non-public records
- Interview TGA staff or review internal communications, emails, or meeting records
- Verify whether coordination processes occurred informally without documentation
- Determine specific root causes without internal investigation and staff interviews

[66] See TGA, International scientific guidelines adopted in Australia (ICH E2E Pharmacovigilance Planning); ICH E2E guideline; EMA Good Pharmacovigilance Practices and CIOMS IX risk-minimisation guidance.

- Assess clinical or scientific quality of safety monitoring (scope limited to documentation and governance)

Implications: Findings reflect what can be verified through documented evidence accessible to Parliament, oversight bodies, and the public. The assessment documents absence of verifiable implementation evidence, not definitive conclusions about what did or did not occur within TGA's internal processes. If systematic implementation occurred without adequate documentation, this would indicate a records-management control failure and potential non-compliance with Archives Act 1983 requirements for the proper creation, retention and authorised disposal of Commonwealth records, and with PGPA Act 2013 duties to establish effective systems of risk management and internal control.[67] [68] If systematic implementation did not occur as planned, this would represent an implementation failure inconsistent with the enhanced monitoring commitments attached to provisional approval conditions

9.4 Evidence Hierarchy

All findings derive from TGA's own documents and official statements. Evidence is categorised by reliability, verifiability, and legal weight:

Tier 1: Primary Statutory Evidence

- FOI decision FOI 3643 (27 February 2022) - statutory admission of document non-existence
- OAIC submissions MR22/00538 (September 2024) and MR25/01153 - formal positions under statutory oversight
- Direct TGA communications to the applicant (31 January - 27 February 2022) - establishing institutional baseline

Tier 2: Primary Documentary Evidence

- Senate Community Affairs Legislation Committee testimony under oath (9-10 October 2025)
- TGA Annual Reports 2022-23 and 2023-24 - statutory performance reporting
- TGA published COVID-19 vaccine safety reports, including November 2023 Safety Signals Report
- TGA COVID-19 Vaccine Safety Monitoring Plan (February 2021)

[67] Archives Act 1983 (Cth) s 24 (unlawful destruction or disposal of Commonwealth records).
[68] National Archives of Australia, Disposal of Commonwealth records in the absence of an agency-specific records authority.

Tier 3: Secondary Documentary Evidence

- Partner organisation reports (NCIRS AEMS COVID-19 vaccines annual report; AusVaxSafety surveillance data)
- Department of Health Australian Immunisation Register data (vaccination statistics)
- Publicly accessible surveillance data and performance metrics

Tier 4: Tertiary Contextual Evidence

- International regulatory guidance (EMA, MHRA, FDA enhanced monitoring frameworks)
- Pharmacovigilance standards (ICH E2E signal detection; CIOMS multi-source integration)
- Comparative regulatory frameworks

Higher-tier evidence takes precedence in case of conflict. All findings are anchored in Tier 1 or Tier 2 evidence. Full search methodology and source verification are documented in Appendix A. Direct TGA communications establishing the institutional baseline are documented in Appendix B.

9.5 Audit Criteria Hierarchy

The assessment applies multi-layered criteria to ensure findings are grounded in TGA's own commitments while applying recognised professional standards:

- **Primary criteria:** TGA Plan commitments (Strategies 1.1-5.2) - the entity's specified outputs and deliverables
- **Secondary criteria:** ISO 19011 governance requirements (management review, performance measurement, documentation adequacy)
- **Tertiary criteria:** Commonwealth legislative obligations (PGPA Act 2013 s37 performance measurement and reporting; Archives Act 1983 s24 recordkeeping and disposal requirements)[69]
- **Quaternary criteria:** International pharmacovigilance standards (ICH E2E documented signal detection processes; CIOMS multi-source surveillance integration)

Primary criteria form the assessment baseline; secondary through quaternary criteria provide benchmarks for evaluating whether implementation met recognised standards for enhanced monitoring of provisionally approved medicines.

[69] See Public Governance, Performance and Accountability Act 2013 (Cth) s 37 on keeping records that properly record and explain an entity's performance, and Archives Act 1983 (Cth) s 24 on unlawful destruction or disposal of Commonwealth records.
https://classic.austlii.edu.au/au/legis/cth/consol_act/pgpaaa2013432/s37.html

9.6 Assessment Scope

The Plan specifies 17 numbered strategies (1.1-1.5, 2.1-2.8, 3.1, 4.1, 5.1-5.2). To ensure comprehensive evaluation consistent with ISO 19011 and provisional approval accountability frameworks, the assessment evaluates 20 outputs:

- **Operational strategies (17 outputs):** Plan-specified activities across five objectives
- **Governance framework (2 outputs):** Management review and performance measurement (ISO 19011 Clause 5.2.3; PGPA Act 2013 s37)
- **Documentation systems (1 output):** Records management adequacy (ISO 15489; Archives Act 1983)

This approach evaluates whether enhanced monitoring was designed, implemented, operated, and documented as specified, with particular attention to coordination mechanisms between surveillance systems (Strategy 2.4 AusVaxSafety integration).

Each output was classified as:

- **Implemented:** Documented operational delivery with independently verifiable evidence
- **Partially documented:** Operational activity occurred but systematic documentation incomplete or not independently verifiable
- **Not documented:** No evidence of systematic implementation found through comprehensive search processes

Classification decisions required minimum evidentiary thresholds: 'Implemented' status required documented protocols, verifiable outputs, and audit trails enabling independent verification. 'Not Documented' status was assigned only after comprehensive search across multiple systems and evidence tiers failed to locate systematic implementation frameworks.

9.7 Methodological Principles

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

Falsifiability: Every finding can be disproved through production of contradicting documentation. If TGA provides:

- Documented protocols for coordinating AusVaxSafety data with signal investigations
- Documented signal investigation procedures specific to COVID-19 vaccines
- Documented Plan implementation governance and performance measurement systems

- Documented decision-making criteria linking investigated signals to regulatory actions

...then corresponding findings would be revised or withdrawn accordingly.

Temporal Analysis: Tracking institutional statements across four years (FOI 3643 February 2022 → OAIC MR22/00538 September 2024 → TGA Annual Report October 2024 → Senate testimony October 2025) reveals systematic patterns rather than isolated incidents or retrieval failures.

Replicability: Independent researchers using identical sources, assessment framework, and audit criteria would reach consistent findings. All evidence derives from publicly available sources or FOI-released documents, ensuring transparency and independent verification.

Search Comprehensiveness: Evidence collection encompassed statutory FOI processes, OAIC-directed searches across TGA's TRIM and Promap records management systems using eight distinct search terms reviewing 531+ containers, systematic review of TGA annual reports and safety publications, parliamentary testimony, and partner organisation reporting. Detailed search methodology documented in Appendix A.

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69. Therapeutic Goods Administration (2024). *OAIC Submission MR22/00538 - FOI Internal Review Decision* (24 September 2024). Tables 3-4 (pp.18-21) document search methodology acknowledging AusVaxSafety collaboration within scope but omitting "AusVaxSafety" as search term. Tables demonstrate systematic failure to link implementation outputs to Plan objectives in records management systems.

11. Glossary of Key Terms

Active surveillance: Proactive systematic collection of safety data through direct contact with vaccine recipients, typically using structured surveys or follow-up protocols (e.g., AusVaxSafety SMS surveys). Contrasts with passive surveillance which relies on voluntary reporting.

ACV (Advisory Committee on Vaccines): A statutory expert advisory committee, established under the Therapeutic Goods Regulations, that provides independent medical and scientific advice to the Minister for Health and the TGA on the safety, quality and efficacy of vaccines supplied in Australia, including advice on pre-market evaluation, post-market safety monitoring and vaccine use in national immunisation program.

Adverse Event Following Immunisation (AEFI): Any untoward or unexpected medical occurrence that follows immunisation, which may or may not be causally related to the vaccine, and which must be monitored, managed and reported through vaccine safety surveillance systems.

AEMS (Adverse Event Management System): TGA's electronic system and portal for receiving, storing, and managing adverse event reports for medicines and vaccines, including draft and submitted reports and follow-up information.

ANAO (Australian National Audit Office): Independent Commonwealth auditor providing assurance to Parliament on public sector performance, accountability, and use of public resources. Better Practice Guides establish professional standards for performance measurement and reporting.

Australian Public Assessment Report (AusPAR): A public regulatory document prepared by the TGA that summarises the evaluation of a prescription medicine submission, explains the scientific reasoning for the approval (or non-approval) decision, and records key outcomes at a specific point in time.

ATAGI (Australian Technical Advisory Group on Immunisation): Expert committee that provides technical advice on immunisation to the Minister and Department of Health, including recommendations on vaccine use, schedules and risk–benefit assessments.

Audit: Systematic, independent examination of processes, systems, and documentation to determine whether activities conform to planned arrangements and whether arrangements are implemented effectively. Conducted according to ISO 19011:2018 principles.

Audit trail: Documented sequence from signal detection through assessment to regulatory decision, enabling independent verification of pharmacovigilance system performance. Required under ICH E2E and CIOMS standards.

AusVaxSafety: Active surveillance system operated by NCIRS using SMS surveys to collect safety data from vaccine recipients. Documented 6.8+ million surveys for COVID-19 vaccines capturing 3 million adverse events and 62,000 medical attention visits.

Business as Usual (BAU): Routine operational activities carried out under standard policies, processes, and controls, as opposed to special, time-limited, or “enhanced” arrangements put in place to meet provisional approval conditions or emergency response requirements.

Capability without integration: Pattern where monitoring infrastructure is established and operational but systematic coordination, documented protocols, or integration frameworks cannot be verified.

Critical control: Essential process, procedure, or system required to ensure regulatory compliance, protect public safety, or enable verification of system performance. Failure of critical controls represents material governance deficiency.

DAEN (Database of Adverse Event Notifications): TGA's passive surveillance system for voluntary reporting of adverse events by health professionals and consumers.

Documentation gap: Absence of verifiable records demonstrating systematic implementation of planned activities, protocols, or frameworks. Distinguished from implementation failure (activity did not occur) versus records management failure (activity occurred but was not documented).

Enhanced monitoring: Pharmacovigilance activities that exceed routine post-market surveillance through documented protocols, systematic processes, dedicated resources, and governance structures. Required as condition of provisional approval under Therapeutic Goods Act 1989.

Evidence base: Complete collection of documented information used to support findings, including primary statutory evidence (FOI decisions, OAIC submissions), primary documentary evidence (Senate testimony, TGA reports), secondary documentary evidence (partner reports), and tertiary contextual evidence (international standards).

Expert advice: Independent specialist assessment provided to inform regulatory decisions on complex safety signals. Should be documented including terms of reference, expert qualifications, advice provided, and how advice informed decisions.

Follow-up: Systematic process of obtaining additional information on reported adverse events or safety signals through targeted investigation, data collection, or clinical assessment. Requires documented protocols and decision criteria.

FOI (Freedom of Information): Australian statutory regime under the Freedom of Information Act 1982 (Cth) that provides a legally enforceable right of public access to documents held by Commonwealth agencies, subject to exemptions, with decisions reviewable internally and externally by the Office of the Australian Information Commissioner (OAIC).

Fully implemented: Classification indicating documented operational delivery with independently verifiable evidence of systematic implementation including protocols, outputs, and audit trails.

Governance: Framework of accountability, oversight, decision-making authority, and performance measurement ensuring activities are conducted systematically and comply with regulatory obligations. Includes management review, documentation systems, and quality assurance.

ICMRA (International Coalition of Medicines Regulatory Authorities): High-level coalition of medicines regulators from multiple jurisdictions that coordinates regulatory responses and information-sharing on issues such as COVID-19 vaccine safety.

Information asymmetry: Situation where regulatory authority possesses complete information about its activities and documentation while external parties (Parliament, oversight bodies, public) can only verify what is documented and disclosed. Creates accountability risk if documentation systems are inadequate.

ISO 15489: International standard for records management establishing requirements for creating, capturing, and maintaining records as evidence of business activities. Adopted by Australian Government for Commonwealth recordkeeping obligations.

ISO 19011: International standard for auditing management systems. Clause 5.2.3 requires evaluation of operational activities, governance processes, performance measurement, and documentation adequacy.

Multi-source integration: Pharmacovigilance practice of systematically combining data from multiple surveillance systems (active surveillance, passive reporting, clinical studies, international reports) to enable comprehensive signal detection. Requires documented coordination protocols and integration frameworks.

NCIRS (National Centre for Immunisation Research and Surveillance): Australia’s leading independent research organisation on vaccine-preventable diseases and immunisation, which operates AusVaxSafety and provides immunisation surveillance and vaccine-safety research, as well as technical advice to bodies such as ATAGI and

the Australian Immunisation Handbook; NCIRS is a partner organisation acknowledged in TGA's COVID-19 Vaccine Safety Monitoring Plan.

Not documented: Classification indicating no evidence of systematic implementation found through comprehensive search processes across multiple evidence tiers and records management systems.

OAIC (Office of the Australian Information Commissioner): Independent Commonwealth statutory agency that reviews FOI decisions and ensures government compliance with information access obligations under FOI Act 1982.

Partially documented: Classification indicating operational activity occurred but systematic documentation incomplete or not independently verifiable through audit trails, protocols, or performance records.

Passive surveillance: Voluntary reporting of adverse events by health professionals and consumers without proactive follow-up (e.g., DAEN database). Contrasts with active surveillance which systematically contacts vaccine recipients.

PGPA Act (Public Governance, Performance and Accountability Act 2013): PGPA Act (Public Governance, Performance and Accountability Act 2013): Commonwealth legislation establishing governance, performance and accountability obligations for Commonwealth entities. Section 37 requires entities to keep records that properly record and explain their performance; broader duties of accountable authorities cover governance, risk management and internal control, while detailed recordkeeping obligations are primarily set out in the Archives Act 1983.[71]

Pharmacovigilance: Science and activities relating to detection, assessment, understanding, and prevention of adverse effects or other medicine-related problems. Systematic pharmacovigilance requires documented processes, performance measurement, and audit trails.

Promapp: A cloud-based business process management tool used to document and maintain workflow process maps (e.g. case-handling steps, escalation flows) in a central repository for operational procedures.

Provisional approval: Time-limited registration pathway under the Therapeutic Goods Act 1989 that allows earlier market access for medicines treating serious conditions where preliminary clinical data indicate likely benefit. Under TGA's provisional-registration guidance, sponsors are subject to additional post-market

[71] https://classic.austlii.edu.au/au/legis/cth/consol_act/pgpaaa2013432/s37.html

obligations, including enhanced safety monitoring and further data submission, to offset reduced pre-market evidence requirements.[72]

Regulatory failure: A situation where the responsible regulator cannot demonstrate, through adequate records, governance frameworks, and performance evidence, that it has complied with the legal, policy, and provisional approval conditions governing COVID-19 vaccine safety monitoring, despite having the operational capability and statutory obligation to do so.

Root cause analysis: Systematic investigation methodology identifying underlying causes of observed problems rather than addressing symptoms. Applied in this assessment to determine whether documentation gaps indicate records management failure, implementation failure, or both.

Safety signal: Information suggesting potential causal association between medicine and adverse event requiring evaluation. Distinct from "signal" (preliminary information) and "confirmed safety issue" (causality established).

Signal: Information arising from one or multiple sources suggesting a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events.

Signal detection: Systematic process of identifying, evaluating, and prioritising potential safety signals from multiple surveillance sources. Requires documented protocols, assessment criteria, and decision frameworks under ICH E2E and CIOMS VIII standards.

Signal identification and assessment: Two-stage pharmacovigilance process: (1) identification—systematic screening of data sources to detect potential signals; (2) assessment—evaluation of signal validity, clinical significance, and need for regulatory action. Both stages require documented procedures and decision criteria.

Signal investigation: Detailed examination of validated safety signal including literature review, analysis of additional data sources, statistical evaluation, expert consultation, and risk-benefit assessment. Should be documented with clear outcomes informing regulatory decisions.

Sponsor: The individual or company legally responsible for a therapeutic good in Australia, including applying for inclusion on the Australian Register of Therapeutic

[72] See TGA, Guidance: Applying for provisional registration of a prescription medicine; TGA, Guidance: Provisional registration extension and transition to full registration; and TGA, COVID-19 Vaccine Safety Monitoring Plan (February 2021).

Goods (ARTG), maintaining regulatory compliance, and meeting post-market reporting and monitoring obligations.

Standard Operating Procedure (SOP): A formally approved, written document that sets out step-by-step instructions for performing a specific routine task or process, so that staff carry it out the same way each time, ensuring consistency, quality, safety, and compliance with applicable laws, policies and standards.

Surveillance: Ongoing systematic collection, analysis, and interpretation of safety data to detect, assess, and understand adverse events associated with medicines. Includes both active and passive surveillance methodologies.

TGA (Therapeutic Goods Administration): Australia's medicines and therapeutic devices regulator operating within the Department of Health and Aged Care. Responsible for evaluating, approving, and monitoring medicines including implementation of enhanced monitoring for provisionally approved products.

The Therapeutic Goods Act 1989: establishes the high-level framework for registration, listing and provisional registration of medicines, but most detailed requirements for enhanced post-market monitoring, risk-management and conditions of provisional registration are set out in associated regulations, legislative instruments and TGA guidance (including the 2017 Provisional Approval reforms, provisional registration guidance, and pharmacovigilance guidelines).

The Plan: TGA’s COVID-19 Vaccine Safety Monitoring Plan (February 2021), which sets out an enhanced safety monitoring framework for COVID-19 vaccines under provisional approval, with 17 implementation strategies across five objectives (plus cross-cutting collaboration and governance outputs).

TRIM (Content Manager): The Department’s electronic document and records management system (EDRMS), used to store, classify, and retrieve official digital and physical records in compliance with Commonwealth recordkeeping obligations.

Appendix A: Documentary Sources Review and Methodology

A.1 Scope and Objectives

This appendix documents the systematic review of publicly available TGA documents, parliamentary submissions, and regulatory correspondence conducted to verify evidence supporting the implementation ratings assigned to the 20 outputs in the February 2021 *COVID-19 Vaccine Safety Monitoring Plan*. The review was undertaken to address the audit question: **Can the TGA demonstrate, through publicly available documentation, implementation of the enhanced pharmacovigilance enhancements committed to in the published Plan?**

A.2 Search Methodology

A.2.1 Search Strategy

In December 2025, a systematic, stratified search was conducted across TGA's publicly available output channels using forensic audit principles consistent with Australian National Audit Office (ANAO) Better Practice Guides on evidence integrity and document authentication. [ANAO 2023]

A.2.2 Online Document Search Methodology

The online review used a structured, keyword-based documentary search (not automated data scraping) to test whether TGA’s public outputs demonstrated implementation of the February 2021 Safety Monitoring Plan’s five objectives and 20 revised outputs. Searches were conducted using Google (domain-restricted to official Australian Government sites) and TGA’s own site search/navigation, targeting COVID-19 safety reports, corporate/performance reports, guidance pages and relevant partner publications. Plan-aligned terms (for example “safety monitoring plan”, “signal detection”, “AusVaxSafety”, “ICMRA”, “implementation tracking”) were applied, and retrieved documents were manually reviewed and mapped to the objectives and outputs, then classified as providing direct, indirect or no documented evidence of implementation, governance or performance tracking.

The following primary search terms and keywords were used, reflecting Plan language and pharmacovigilance standards:

Search Term	Rationale	Search Dates
"COVID-19 Vaccine Safety Monitoring Plan"	Direct Plan reference; identifies Plan-specific outputs	December 2025
"implementation" + "COVID-19 vaccine safety"	Identifies documentation of Plan implementation	December 2025
"signal detection" + "COVID-19 vaccine"	Outputs 2.1–2.7; identifies enhanced signal processes	December 2025
"enhanced monitoring" + "pharmacovigilance"	Objective 2; identifies enhanced process documentation	December 2025
"data integration" + "TGA" + "vaccine safety"	Objective 4; identifies cross-system data linkage evidence	December 2025
"governance" + "vaccine safety" + "TGA"	Cross-cutting governance; identifies oversight mechanisms	December 2025
"AusVaxSafety" + "TGA" + "coordination"	Output 2.4; identifies coordination documentation	December 2025
"ICMRA" + "COVID-19 vaccine safety" + "TGA"	Output 2.7; identifies international signal sharing	December 2025
"audit" + "COVID-19 vaccine safety monitoring"	Identifies internal/external audit/evaluation evidence	December 2025

A.2.3 Secondary Search Terms (Supplementary)

Secondary terms were applied to identify contextual or implicit references to Plan implementation:

- "provisional approval" + "conditions" + "COVID-19 vaccine"
- "enhanced pharmacovigilance" + "Australia"
- "AEFI" + "escalation" + "COVID-19"
- "performance metrics" + "vaccine safety"
- "risk management plan" + "COVID-19 vaccine"

A.3 Search Repositories

A.3.1 Primary TGA Sources

The following TGA-maintained repositories were searched:

Repository	Search Conducted	Results
TGA COVID-19 Vaccine Safety Reports	Yes; December 2025	150+ weekly/fortnightly reports (2021–2023). No Plan implementation tracking; reports limited to AEFI statistics, AESI monitoring, regulatory actions. Last report: 02-11-2023.
TGA Annual Performance Reports	Yes; December 2025	2022-23 and 2023-24 Performance Report (40,000+ characters). General pharmacovigilance metrics, vaping reforms. **Zero references to "Safety Monitoring Plan" or 20 outputs.**
TGA News & Updates	Yes; December 2025	General regulatory updates. No Plan-specific announcements post-2021 publication.
TGA COVID-19 Vaccine Information	Yes; December 2025	Regulatory status, approval timelines. No Plan implementation detail.
TGA FOI Decisions	Yes; December 2025	Reviewed FOI schedules and decisions, including OAIC submission MR22/00538 (September 2024). Documented absence of "implementation report" or Plan-tracking records.

Direct TGA correspondence establishing institutional baseline documented in Appendix B, including FOI 3643 decision (February 2022) confirming absence of implementation report.

A.3.2 Parliamentary and Government Sources

Source	Search Conducted	Results
Senate Community Affairs Legislation Committee Estimates (9-10 October 2025)	Yes; December 2025	Testimony by Dr Michelle Dascombe (TGA, Pharmacovigilance Branch) and Prof Tony Lawler. Key admissions: 148 signals investigated, 57 regulatory actions, monitoring characterised as "day-to-day processes" with **no systematic Plan tracking**.
Australian Parliament Questions on Notice	Yes; December 2025	Searched for government responses to questions on COVID-19 vaccine safety monitoring. Found responses referencing AusVaxSafety and AEMS but **no reference to TGA's published Plan implementation**.

Source	Search Conducted	Results
Department of Health Annual Reports	Yes; December 2025	Reviewed Department's reporting on vaccine safety oversight. General references to TGA's pharmacovigilance role; **no Plan-specific implementation metrics**.

A.3.3 Partner and External Sources

Source	Search Conducted	Results
AusVaxSafety Annual Reports	Yes; December 2025	2023 annual report. Documents active surveillance infrastructure (500,000+ survey responses). **No documentation of coordination with TGA signal detection or Plan integration.**
COVID-19 vaccine safety data – at a glance As at 14 April 20252025	Yes; December 2025	Publicly accessible dashboard documenting 6.8M+ surveys. No evidence of systematic coordination with TGA signal detection processes.
NCIRS/AEMS COVID-19 Vaccine Reports	Yes; December 2025	2022 AEMS COVID-19 Annual Report. Surveillance findings; **no reference to TGA's published Safety Monitoring Plan.**
ANAO Performance Audit: Australia's COVID-19 Vaccine Rollout	Yes; December 2024	2022 ANAO audit examined rollout efficiency and TGA role. **No systematic audit of Plan implementation against 20 outputs.** Examined operational outcomes, not governance/documentation gaps.

A.4 Quality Assurance and Verification

A.4.1 Link Verification

All hyperlinks and URLs cited in this appendix were verified for accuracy and active status as of 1–7 February 2025. Verification was conducted using URL resolution tools and direct access to published repositories.

Link	Verified Date	Status
TGA COVID-19 Vaccine Safety Reports	8 Dec 2025	**VERIFIED Active; content accurate**
TGA Performance Report 2022-23	8 Dec 2025	**VERIFIED Active PDF; content verified**
TGA Performance Report 2023-24	8 Dec 2025	**VERIFIED Active PDF; content verified**

Link	Verified Date	Status
Senate Estimates Hansard (9-10 Oct 2025)	8 Dec 2025	**VERIFIED Active; testimony transcript verified**
AusVaxSafety 2023 Report	8 Dec 2025	**VERIFIED Active; content verified**

A.4.2 Source Attribution

All quoted material and findings are traced to original published documents with page/section references. Where documents were truncated during retrieval, notation "[TRUNCATED]" is used and complete original sources were re-verified.

A.4.3 Temporal Scope

Searches focused on publicly available documentation created or published between **February 2021** (Plan publication) and **February 2025** (review date). This 4-year window aligns with the audit's assessment period through November 2024.

A.5 Key Findings: Forensic Analysis

A.5.1 Absence of Plan-Specific Documentation in Official Reports

Finding: TGA's most comprehensive public output — the 2023–24 Performance Report (40,000+ characters)—contains **zero references** to the "COVID-19 Vaccine Safety Monitoring Plan", zero output tracking, and zero governance or performance metrics mapped to the Plan's 20 outputs.

Significance: An organisation implementing a detailed, published safety monitoring plan as a regulatory commitment would reasonably be expected to reference it, and report against its objectives, in annual performance statements prepared under the PGPA Act 2013 performance-reporting framework.[73] The complete absence of any reference in performance reporting suggests either:

1. Plan implementation was not tracked at the institutional level, or
2. Implementation was not considered material enough for public accountability reporting.

ANAO Principle Applied: Audit trail integrity and institutional accountability require contemporaneous documentation linking strategic commitments to performance measurement and reporting (ANAO Better Practice Guide: Reporting Meaningful Performance Information).

[73] See PGPA Act 2013 s 39 annual performance-statements requirements and associated Finance/ANAO guidance on reporting meaningful performance information. https://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/num_act/pgpaaa2013432/s39.html

A.5.2 Senate Estimates Testimony: "Day-to-Day Processes" Admission

Finding: TGA officials testified to Senate (October 2025) that vaccine safety monitoring was conducted through "day-to-day processes" rather than systematic tracking against the Plan's five key objectives.

Evidentiary Status: Testimony under oath constitutes primary evidence of institutional position. The characterisation contradicts the Plan's stated objective of "enhanced", "coordinated" and "systematic" monitoring.

Significance: Supports the audit's core finding that operational activity (investigating 148 signals) is distinct from documented implementation of an enhanced monitoring framework requiring governance, oversight and audit trails per ICH E2E standards.

A.5.3 AusVaxSafety Coordination: No Documented Integration Protocol

Search result: Across OAIC-directed TRIM searches using eight terms and 531+ containers, TGA identified no AusVaxSafety–TGA coordination protocols, no multi-source integration procedures, and no Plan-specific implementation guidelines.

Finding: Despite Output 2.4 requiring TGA to "collaborate with AusVaxSafety and coordinate safety signal detection", review of publicly available coordination agreements, joint protocols, or integrated signal management documentation reveals **zero evidence** of formal documented coordination.

Significance: AusVaxSafety operates an active surveillance system; TGA investigates signals. Absence of public documentation of their integration with TGA's signal-detection and regulatory-action processes suggests parallel operation rather than the "coordinated" system promised in the Plan.

Cross-Reference: TGA's OAIC submission (MR22/00538) confirms that when specifically asked to search for "close collaboration and coordination of effort with other vaccine safety stakeholder groups" (Objective 5), TGA advised the scope was "unable to be meaningfully interpreted into a searchable item" and did not perform a meaningful search. This corroborates the finding.

A.5.4 FOI/OAIC Evidence: No "Implementation Report" Located

Finding: Yes, it is worth updating that finding so Appendix A aligns with your later analysis.

A.5.4 FOI/OAIC Evidence: No “Implementation Report” Located

Finding: TGA’s September 2024 OAIC submission (MR22/00538) documents comprehensive TRIM searches using terms including “Implementation of COVID-19

Vaccine Safety Monitoring Plan", "implementation vaccine safety" and "audit report COVID-19 vaccine safety monitoring". No implementation reports or audit documents were located within scope. In March 2025, AICmr54 upheld TGA's position that no discrete "implementation report" exists, confirming that the absence of such a document is not due to inadequate searching.

Result: No implementation reports or audit documents located within scope.

Significance: The OAIC-directed searches and subsequent AICmr54 decision provide independent confirmation that TGA undertook a detailed, FOI-compliant search for an implementation report under the Freedom of Information Act 1982. The documented absence of any implementation report or systematic Plan-tracking documentation is therefore strong primary evidence supporting this audit's conclusion that there is a governance and records-management failure, rather than a search-limitation issue.

A.6 Online Document Search Methodology

The online review used a structured, keyword-based documentary search (not automated data scraping) to test whether TGA's public outputs demonstrated implementation of the February 2021 Safety Monitoring Plan's five objectives and 20 revised outputs. Searches were conducted using Google (domain-restricted to official Australian Government sites) and TGA's own site search/navigation, targeting COVID-19 safety reports, corporate/performance reports, guidance pages and relevant partner publications. Plan-aligned terms (for example "safety monitoring plan", "signal detection", "AusVaxSafety", "ICMRA", "implementation tracking") were applied, and retrieved documents were manually reviewed and mapped to the objectives and outputs, then classified as providing direct, indirect or no documented evidence of implementation, governance or performance tracking.

The online documentary review applied an open-source intelligence–style search methodology: the scope was defined in advance; key repositories were identified (TGA, NCIRS, ANAO, OAIC, parliamentary records, legislation databases); structured queries and advanced search operators were used; and searches were iteratively refined as new leads and terminology emerged. Publicly available documents were cross-checked across independent sources before being relied on, and information was only treated as evidentiary where multiple sources were consistent or could be verified against primary records.[74]

[74] For a general description of structured open-source investigation methods, see Elshafie A (2025), OSINT for beginners: A practical guide to OSINT basics, Authentic8

A.7 Limitations and Caveats

This documentary review is limited to publicly accessible sources available as of February 2025. The review cannot assess:

- Internal TGA documents not released through FOI or OAIC processes
- Unpublished communications between TGA and partner organisations
- Internal governance processes that may exist but are not publicly documented
- Informal coordination or decision-making that occurred outside documented frameworks

The absence of public documentation does not conclusively prove that activities did not occur—it proves only that such activities cannot be independently verified through available evidence. However, for regulatory frameworks tied to provisional approval conditions, the ability to demonstrate implementation through systematic documentation is a fundamental accountability requirement.

Specific Limitations

Public Documentation Scope: TGA's internal records (not released via FOI or OAIC) may contain additional Plan-tracking documentation. However, absence of such documentation in public reporting and under statutory search raises questions about compliance with recordkeeping obligations (Archives Act 1983) and transparency standards (PGPA Act 2013 s37).

Temporal Snapshot: This review captures information as of February 2025. Updates to TGA websites, new publications, or additional FOI releases post-February 2025 may supplement available evidence.

Search Term Limitations: While comprehensive, keyword searching cannot capture all relevant documentation. However, the absence of Plan references even in TGA's own performance reporting (2022-23 and 2023-24 Performance Report: zero Plan mentions) suggests broader searches would likely yield similar results.

A.8 Audit Conclusion

Proposition: TGA's February 2021 COVID-19 Vaccine Safety Monitoring Plan committed to systematic, enhanced monitoring across five key objectives and 20 specific outputs.

Evidence Review Result: Publicly available TGA documentation, parliamentary testimony and government reports contain **zero systematic evidence** of implementation tracking against these 20 outputs, zero performance metrics, zero governance frameworks and zero documented coordination mechanisms for outputs

that explicitly required inter-agency coordination (particularly Output 2.4: AusVaxSafety collaboration).

TGA has not produced any documentation showing how AusVaxSafety data fed into its 148 signal investigations or 57 actions, or any audit trail explaining triage decisions for the 91 signals where no further regulatory action was taken.

Across OAIC-directed TRIM searches, TGA identified no AusVaxSafety–TGA coordination protocols, no multi-source integration procedures, and no Plan-specific implementation guidelines.

Audit Assessment: This documentary gap is consistent with the audit's core finding that operational pharmacovigilance activity occurred (148 signals investigated, 150+ safety reports published) but was not governed, tracked or documented as a systematic implementation of the published Plan. Absence of implementation documentation represents a material control deficiency requiring investigation and reform.

Overall Assessment: The convergence of evidence—formal advice that no implementation report exists (FOI 3643), OAIC-directed comprehensive search failure (MR22/00538), an OAIC decision upholding that position (AICmr54), Senate testimony characterising COVID-19 vaccine safety monitoring as “day-to-day processes”, and a four-year inability to produce Plan-level documents despite strong institutional incentives—makes it highly unlikely that systematic implementation documentation exists but remains undisclosed. The documented pattern is most consistent with implementation documentation never having been created.

A.8: References

1. Australian National Audit Office (2023). *Better Practice Guide: Reporting Meaningful Performance Information*. Commonwealth of Australia. Available at: https://www.anao.gov.au/work/insights/reporting-meaningful-performance-information and https://www.anao.gov.au/pubs/better-practice-guides
2. Australian National Audit Office (ANAO) (2025). ANAO Audit Manual — Shared Content. ANAO, Canberra. Available at: https://www.anao.gov.au/work/audit-manual/shared-content
3. Elshafie A (2025). OSINT for beginners: A practical guide to OSINT basics. Authentic8. Available at: https://www.authentic8.com/blog/osint-for-beginners-guide
4. Therapeutic Goods Administration (2021). *COVID-19 Vaccine Safety Monitoring Plan*. Australian Government Department of Health and Aged Care. https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf
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8. Therapeutic Goods Administration (2024). *OAIC Submission MR22/00538* (20 September 2024). Office of the Australian Information Commissioner.

Appendix B: Primary Evidence - Direct TGA Responses to Applicant

B.1 Summary of TGA Communications and FOI Decision on Implementation of COVID-19 Vaccine Safety Monitoring Plan

Between January and February 2022, inquiries were made to the Therapeutic Goods Administration (TGA) via email requesting a report on implementation of their COVID-19 Vaccine Safety Monitoring Plan, specifically focusing on the Plan's five key objectives:

1. Timely collection and management of COVID-19 vaccine adverse events following immunisation (AEFI)
2. Timely detection and investigation of COVID-19 vaccine safety signals
3. Timely actions addressing COVID-19 vaccine safety concerns
4. Timely communications to the public regarding emerging safety information
5. Close collaboration and coordination with other vaccine safety stakeholders

Evidence Collection Methodology

- Detailed email inquiries sent 31 January 2022 and February 2022 requesting specific implementation details related to the Plan's key objectives, outputs, outcomes, methodologies, and communications.
- Formal Freedom of Information (FOI) request (FOI 3643) filed 18 February 2022 seeking access to an implementation report documenting progress against the Plan's five key objectives and specified outputs.

TGA Response Summary

- **Pre-FOI Responses (31 January and February 2022):** General assurances of robust, intensified vaccine safety monitoring system; encouragement to report adverse events; links to publicly available resources including weekly vaccine safety reports and explanatory materials on vaccine safety assessment processes.
- **FOI Decision (27 February 2022):** Official refusal of access under section 24A (document does not exist) to a specific implementation report, with explicit statement that no such document exists despite ongoing monitoring activity. The decision included general reference material previously provided and outlined instances of TGA's collaborations with other agencies but failed to present documentation evidencing implementation progress or governance against specific Plan outputs.

This correspondence forms the evidentiary basis for findings in Section 4 (Detailed Observations), Section 5 (Root Cause Analysis), and is cited throughout the assessment as primary statutory evidence (Evidence Hierarchy Tier 1, see Section 8.4).

Table B1: TGA Correspondence Detail Table

Date	Document type	Key content provided	Reference to Safety Monitoring Plan	Response to request	Document reference
31 Jan 2022	Pre-FOI email response 1	"Robust monitoring" assurance; four links (YouTube explainer, weekly COVID-19 vaccine safety reports, DAEN causality/monitoring overview); encouragement to report adverse events.	None	No outputs or progress; only partial AEFI reports via links; no remedies, long-term monitoring, trials or methodology.	Email: Request for update on implementation of the COVID-19 Vaccine Safety Monitoring Plan (Jan 2022)
Feb 2022	Pre-FOI email response 2	Identical four links plus general assurance; no new content.	None	Identical to January response; no new information.	Email: Follow-up request for update on implementation of the Plan (Feb 2022)
27 Feb 2022	FOI 3643 decision	Refuses access under FOI on grounds that no implementation report exists. Admission: "No implementation report exists" (para 7). States there is "ample documentation" but no evaluation report (para 8). Repeats same four links (paras 9–13). Cites five Objective 5 examples (ICMRA, states, ATAGI, NCIRS, ACV) instead of implementation records (paras 14–15).	Mentions objectives but provides no implementation evidence.	No progress report; only partial AEFI/remedies via links; no long-term monitoring, trials or methodology.	FOI 3643 – Notice of decision
24 Apr 2025	FOI 25-0166 – request consultation	Advises that processing 399 identified documents would be a "substantial and unreasonable diversion of the TGA's resources" and that "the balance of interests does not favour the expenditure of considerable resources". Directs applicant instead to public COVID-19 vaccine safety reports and Advisory Committee on Vaccines (ACV) pages.	None. No documents are identified as implementing or evidencing the Plan.	Practical-refusal position maintained: TGA refuses to process 399 in-scope documents on resource-diversion grounds and relies on generic web links rather than providing Plan-related implementation records.	FOI 25-0166 – consultation letter (24 April 2025)

FOI 25-0166 Request Consultation

2025 FOI decision FOI 25-0166 identified 399 relevant documents but invoked “substantial and unreasonable diversion of resources” to refuse processing and reinforcing a pattern of using workload arguments rather than facilitating access to Plan-related records.

In response to the TGA’s s 24AB consultation, the applicant refined the request to an objectively defined sample: up to six of the most recent documents per Plan objective (February 2021–February 2025) across standard document categories such as SOPs, case-processing guidelines, workflows, protocols, regulatory-action procedures, public-communication procedures and collaboration mechanisms. This revision specified document types, date range and selection method, addressing s 15(2)(b) FOI Act requirements for objectively identifiable documents. Despite this refinement, FOI 25-0166 maintained a practical-refusal position and did not release any Plan-implementation documents.

This outcome should be read alongside the OAIC-directed MR22/00538 searches summarised in Section B.4, which showed that the volume of potentially relevant documents and pages had increased significantly since the initial September 2024 sampling, yet no Plan-specific implementation records could be produced.

B.3 Institutional Response Pattern Analysis: Evidentiary Significance for Audit Findings

The correspondence documented above reveals a systematic institutional response pattern that directly corroborates the audit's core findings. The pattern is characterised by:

1. **Identical substitution:** All email responses provide the same four generic pharmacovigilance links despite escalating formality.
2. **Explicit non-existence:** The FOI decision (paragraph 7) provides statutory confirmation that no implementation report exists.
3. **Internal contradiction:** The FOI decision claims that "ample documentation" exists (paragraph 8) but refuses access under section 24A.
4. **Routine versus enhanced:** Routine business-as-usual outputs are substituted for the Plan-specific enhanced monitoring evidence that was requested.
5. **Pattern of institutional non-disclosure:** The consistent response of providing generic pharmacovigilance resources, without any specific documentation or governance evidence regarding implementation of the Plan, strongly supports the audit finding that TGA does not document Plan implementation systematically.
6. **Self-admitted lack of documentation:** The FOI decision explicitly states that no single evaluation or implementation report exists, confirming the governance and

performance measurement ratings of 0% documented implementation for monitoring and oversight outputs.

7. **Routine pharmacovigilance versus Plan commitment:** The substitution of routine DAEN reporting and ongoing monitoring material for a formal Plan implementation report highlights a significant gap between TGA's operational activity and its enhanced monitoring obligations under the Plan.
8. **Collaboration claims lack documentation:** While collaborations are listed, there are no documented frameworks, audit trails or performance evidence verifying how these collaborations are integrated into delivery of the Plan.

Audit ratings supported

Taken together, these responses reinforce the audit ratings that most outputs are either partially documented or not documented at all, particularly in relation to governance, systematic implementation tracking and oversight. See Section 5 (Root Cause Analysis) for detailed examination of whether these documentation gaps represent records management failure, implementation failure, or both.

B.4 OAIC-Directed Search Results (September 2024): Statistical Analysis and Summary

Following the February 2022 FOI 3643 decision confirming no implementation report existed, TGA conducted a second comprehensive search 2.5 years later in response to OAIC internal review directions (MR22/00538, September 2024). This submission documented systematic TRIM searches using Plan-specific terminology, providing statutory evidence of TGA's record-keeping systems and search capabilities.

The MR22/00538 submission is a 33 page document that seeks to defend a "no documents" FOI refusal by presenting sampling based counts of potentially relevant documents in TRIM and Promapp, and by emphasising the volume and complexity of material associated with the COVID-19 Vaccine Safety Monitoring Plan.

Attachment A estimates at least 2,218 pages of relevant documents across Objectives 1–4 based on limited samples, while explicitly declining to sample Objective 5.

Attachment B documents 8 search terms run by two staff members, across which 653+ hits and 531 containers produce zero documents that TGA is willing to class as "implementation" or "audit" reports for the Plan. Attachment C shows that searches were largely confined to TRIM and Promapp, with emails, diaries, devices and external holdings mostly excluded or only given cursory "sample" attention.

B.4.1 Search Methodology

TGA's OAIC submission (Tables 3-4, pp.18-21) documented searches conducted by two separate staff members—a Senior Medical Officer and an Assistant Director in the Vaccines Surveillance Section—using the following search terms:

Plan Implementation Terms:

- "Implementation of COVID-19 Vaccine Safety Monitoring Plan"
- "Implementation vaccine monitoring plan"
- "Implementation vaccine safety"
- "COVID-19 Vaccine Safety Monitoring Plan"

Audit and Evaluation Terms:

- "Audit report COVID-19 vaccine safety monitoring"
- "Audit COVID-19 vaccine"
- "Audit report COVID-19 vaccine pharmacovigilance plan"

Pharmacovigilance-Specific Terms:

- "Implementation COVID-19 vaccine pharmacovigilance plan"

All searches were conducted across TGA's TRIM records management system—the agency's primary document repository required under Archives Act 1983 for Commonwealth recordkeeping.

B.4.2 Search Results

Zero implementation reports, evaluation documents, or systematic Plan-tracking documentation were located within scope. Specifically:

"Implementation of COVID-19 Vaccine Safety Monitoring Plan": 12 documents found—4 were TGA email responses to applicant's implementation inquiries, 8 were internal documents about the FOI request itself. Zero implementation documentation found.

"Implementation vaccine monitoring plan": 13 documents found—12 were emails to applicant, 1 was an unrelated 2008 paper file. Zero Plan implementation documents located.

"Audit report COVID-19 vaccine safety monitoring": Zero documents found.

"Audit COVID-19 vaccine": 531+ containers found—all related to manufacturing audits, vaccine taskforce activities, and COVID-19 vaccine program administration. Zero documents related to Safety Monitoring Plan implementation found.

"COVID-19 Vaccine Safety Monitoring Plan": 20 documents found—7 about the Plan itself, 13 were email responses to applicant. Zero implementation tracking documents located.

"Implementation vaccine safety": 86 records/containers found—all related to pre-COVID-19 TGA activities (2001-2008), non-TGA health promotion areas, or HPV vaccine implementation. Zero COVID-19 Plan implementation documents found.

"Implementation COVID-19 vaccine pharmacovigilance plan": 1 document found—draft Pharmacovigilance Branch input for Australian COVID-19 Vaccination Policy (publicly available). Not an implementation report; contained no timelines or progress tracking.

"Audit report COVID-19 vaccine pharmacovigilance plan": Zero documents found.

B.4.3 Critical Gaps Identified – AusVaxSafety Search Omission

TGA's September 2024 OAIC-directed search acknowledged that Output 2.4 of the COVID-19 Vaccine Safety Monitoring Plan committed TGA to "collaborate with AusVaxSafety to receive active surveillance information and coordinate safety signal detection and investigation activities". However:

- TGA did not use "AusVaxSafety" as a search term in the OAIC-directed TRIM searches, despite acknowledging the collaboration was within the Plan's scope, and reported an inability to locate AusVaxSafety partner-organisation reports in TRIM.
- AusVaxSafety's aggregate reports remained publicly accessible throughout the search period, documenting more than 6.8 million completed COVID-19 vaccine safety surveys and approximately 62,000 self-reported medical-attention events.
- OAIC-directed MR22/00538 TRIM searches and FOI releases confirm that while TGA holds generic AEFI and signal-management SOPs, there is no documented bridge between those procedures and AusVaxSafety's active-surveillance outputs. No documents show how AusVaxSafety data fed into signal prioritisation or investigation, when AusVaxSafety findings should trigger a signal, or how discrepancies between surveillance systems were reconciled; nor do any records explain how the 148 signals and 57 regulatory actions were triaged, closed or dropped, or how the 91 "no further action" signals were risk-assessed relative to AusVaxSafety's medical-attention reports.

Taken together, these gaps indicate that there is no Plan-specific implementation or integration documentation showing how active and passive surveillance systems were systematically coordinated as Strategy 2.4 requires.

Objective 5 Collaboration Search Impossibility

When directed to search for documents implementing Objective 5 ("close collaboration and coordination of effort with other vaccine safety stakeholder groups"), TGA advised OAIC that this commitment was "unable to be meaningfully interpreted into a searchable item" (Table 1, Item 5, p.10).

TGA stated searches would require accessing documents from "all communications with the ACV, ACM, Department of Health, ATAGI, AusVaxSafety, NCIRS, every state and territory government, each COVID-19 vaccine pharmaceutical company, each international regulatory body including all ICMRA and ACCESS meetings, all state and territory Coroner's [offices]."

This response indicates either:

- Collaboration activities were not systematically documented in searchable records, or
- TGA could not identify appropriate search terms because systematic collaboration frameworks did not exist

One sample ICMRA sub-group meeting alone generated >274 documents involving 30 third parties across multiple international regulatory authorities and WHO. TGA did not conduct meaningful searches of this material.

B.4.4 Evidentiary Significance

This OAIC-directed search, conducted under statutory oversight 2.5 years after initial FOI 3643 request, confirms the pattern established in 2022: Plan implementation documentation does not exist in TGA's searchable records systems. See Section 5 (Root Cause Analysis) and Section 6.1 (Documentation and Records Management) for how this evidence informs governance findings.

Document Classification Search Evidence

TGA's document classification capabilities are further evidenced by the search methodology it employed. TGA's capability to search for specific document types is evidenced by its September 2024 OAIC submission (MR22/00538), which used the following classifications to structure TRIM searches:

- Standard Operating Procedures (SOPs)
- Case processing instructions and guidelines

- Protocol documents for investigating safety signals
- Workflow process documents
- Implementation guidelines
- Operational protocols

TGA's successful use of these categories demonstrates that records systems can identify and retrieve documents by type, supporting the assessment's finding that absence of implementation documentation represents actual non-existence rather than search limitations.

Relevance to Plan Implementation Assessment: The search methodology confirms that if SOPs, protocols, or implementation guidelines for the COVID-19 Vaccine Safety Monitoring Plan existed in TGA's records systems, they would have been locatable through the comprehensive searches documented in this appendix.

B.4.5 Key Findings

Exhaustive search, zero results: Eight distinct search terms across two independent searchers, multiple database queries, systematic review of 531+ containers—yet zero documents tracking Plan implementation progress, outputs, outcomes, or timelines as specified in applicant's request were produced.

Email correspondence = only "evidence": The only documents TGA located mentioning Plan implementation were emails to the applicant stating no implementation report exists—creating a circular evidentiary pattern where absence of documentation is documented through correspondence about absence of documentation.

"Unable to meaningfully interpret" Objective 5: TGA's admission that stakeholder collaboration commitments could not be "meaningfully interpreted into a searchable item" suggests collaboration occurred without systematic documentation frameworks, contradicting Plan commitments to coordinated, documented stakeholder engagement.

For Commonwealth agencies subject to Archives Act 1983 recordkeeping requirements and PGPA Act 2013 performance measurement obligations (s37), the inability to locate Plan implementation documentation through systematic TRIM searches after OAIC direction provides *prima facie* evidence of governance and records management control deficiency.

The comprehensive nature of these searches—multiple terms, direct Plan references, OAIC statutory oversight, two independent searchers—provides strong evidence that the documentation gap identified represents actual absence rather than search limitations. If Plan implementation had been systematically tracked as required under Commonwealth accountability frameworks, searches using direct Plan terminology

("Implementation of COVID-19 Vaccine Safety Monitoring Plan") would have located relevant documents.

Document classification capability confirmed: TGA's September 2024 OAIC submission demonstrates institutional capability to search for documents by type (SOPs, protocols, guidelines, workflows). TGA's organisational capability to systematically document processes is further evidenced by >36 Promap workflow processes maintained for routine AEFI operational procedures, yet searches for Plan implementation workflows returned zero results. This search methodology provides assurance that absence of Plan implementation documentation represents actual non-existence rather than retrieval limitations. If systematic implementation frameworks had been documented, they would have been located through searches using these document classifications.

TRIM technical limitations disclosed: TGA disclosed TRIM "Date Created" function limitations for historical documents, noting COVID-19 "pace of administrative change" as complicating factor (Attachment D, pp.24-25). However, this technical limitation affects temporal scope precision for operational documents, not substantive existence of implementation tracking documentation. Date limitations explain when specific AEFI forms were created but do not explain why zero audit reports were found across all timeframes, why Objective 5 was "unable to meaningfully interpret," or why AusVaxSafety coordination protocols are absent from any searchable period. The gap exists regardless of temporal precision capabilities.

The OAIC submission reveals three reinforcing patterns supporting this conclusion:

First, operational activity without implementation tracking: Sample searches located >2,218 pages documenting routine pharmacovigilance operations (AEFI case processing: >303 pages, general signal detection procedures: >679 pages, regulatory actions: >406 pages), contrasted with zero pages produced documenting systematic Plan implementation including audit reports, evaluation reports, governance meeting minutes, AusVaxSafety coordination protocols specific to Output 2.4, or progress tracking against Plan objectives (Tables 3-4, pp.18-21). This demonstrates operational activity occurred but was not tracked as Plan-specific enhanced monitoring implementation.

Second, TGA internal admission: TGA's search notes acknowledged documents fragmented across >5 teams without unified frameworks, with "no guarantee all relevant documents identified," and available documentation "is not likely to answer the applicant's question" regarding implementation progress, outputs, outcomes, and timelines (Attachment D, pp.24-25).

Third, forced choice framework: Evidence indicates two possibilities: either enhanced monitoring was implemented but not adequately documented, raising potential

non-compliance risks with Commonwealth recordkeeping obligations under the Archives Act 1983 s 24, or systematic implementation did not occur as envisaged, meaning the enhanced monitoring commitments attached to provisional approval may not have been demonstrably satisfied under the Therapeutic Goods Act 1989 provisional-registration framework. Either scenario points to a material governance deficiency when assessed against the Commonwealth public-sector accountability and performance framework established by the PGPA Act and related policies.

These findings, documented under OAIC statutory oversight with potential AAT challenge implications and conducted by two senior TGA officers (Senior Medical Officer and Assistant Director, Vaccines Surveillance Section), provide the strongest available statutory evidence that Plan implementation documentation does not exist in TGA's searchable records systems.

It is notable that the FOI “reasonable search” process required two senior TGA officers (a Senior Medical Officer and an Assistant Director in the Vaccines Surveillance Section) to undertake manual searches for such a critical implementation document, which itself suggests the absence of routine governance or records-management systems that would ordinarily track and surface Plan-level implementation documentation.

At a minimum, it implies three theoretical weaknesses in the TGA’s document control environment:

1. No central register of critical implementation documents
   If senior specialists must manually trawl systems to look for an implementation report, it suggests there is no routine mechanism (register, dashboard, or governance log) that tracks the existence and status of key Plan-level documents.
2. Reliance on individual knowledge rather than systematised recordkeeping
   The need for senior officers to conduct the search implies that locating core governance records depends on who remembers where things might be, rather than on structured records-management controls and metadata.
3. Weak integration between safety governance and FOI/assurance processes
   For a flagship safety commitment, you would normally expect the implementation artefacts to be easily retrievable for internal assurance, external audit, and FOI. The fact they are not suggests a gap between operational safety work and the entity’s broader accountability and documentation frameworks.

Cross-Reference: Full OAIC submission: MR22/00538 (September 2024), Tables 3-4 (pp.18-21) documenting comprehensive TRIM search methodology and results.

B.5 Conclusion

Statistically, the submission demonstrates that a large body of potentially relevant COVID-19 vaccine safety documentation exists in TRIM, Promapp and related systems, but it does not quantify coverage, does not search key Plan concepts such as AusVaxSafety, and does not identify a single implementation or audit document for the Plan despite using multiple search strings and reviewing more than 531 containers. The heavy reliance on “non-exhaustive sampling”, the omission of critical search terms, and the absence of any Plan-output-by-document matrix mean the submission cannot, on its own numbers, establish that “all reasonable steps” have been taken or that Plan implementation documentation does not exist. Instead, it quantifies a large, poorly mapped search space and confirms that, as at September 2024, TGA has not produced or cannot locate any formal implementation, governance or performance documentation for the COVID-19 Vaccine Safety Monitoring Plan.

The three TGA responses documented in this appendix—two pre-FOI emails and one formal FOI decision—establish TGA’s baseline institutional position regarding Plan implementation documentation as at February 2022. The consistent pattern of substituting generic pharmacovigilance links for Plan-specific evidence, culminating in statutory confirmation that no implementation report exists, provides primary evidence supporting the audit’s governance and performance-measurement findings.

The OAIC-directed searches (September 2024) confirmed this pattern under external statutory oversight, with findings detailed in B.4 demonstrating systematic absence of implementation documentation across comprehensive searches of more than 531 containers. Combined with annual reporting omissions (Appendix A) and Senate testimony (October 2025), the evidence demonstrates a four-year pattern of institutional inability to produce Plan implementation documentation when explicitly requested through multiple channels.

This pattern is characterised by: identical responses across escalating formality levels (email → FOI decision → OAIC review); explicit statutory admission that no implementation report exists; substitution of routine pharmacovigilance outputs for Plan-specific enhanced-monitoring evidence; and inability to locate or meaningfully search for collaboration-framework documentation. See Section 5 (Root Cause Analysis) for examination of whether this pattern represents records-management failure, implementation failure, or both; the Evidence Hierarchy (Section 8.4) classifies this correspondence as Tier 1 primary statutory evidence.

B.6 References

1. Therapeutic Goods Administration (2022). Email response to request for update on implementation of COVID-19 Vaccine Safety Monitoring Plan (31 January 2022). Reference: CCEMS_00780000319. [Email correspondence held by applicant]
2. Therapeutic Goods Administration (2022). Follow-up email response to request for update on implementation of COVID-19 Vaccine Safety Monitoring Plan (18 February 2022). Reference: CCEMS_09930001535. [Email correspondence held by applicant]
3. Therapeutic Goods Administration (2022). *Freedom of Information Request FOI 3643: Notice of Decision* (27 February 2022). Decision maker: Elspeth Kay, Assistant Secretary, Pharmacovigilance Branch. TRIM Reference: D22-5201218. [FOI decision letter held by applicant]
4. Therapeutic Goods Administration (2024). *OAIC Submission MR22/00538 - FOI Internal Review Decision* (20 September 2024). Tables 3-4 (pp.18-21) document comprehensive TRIM search methodology using eight distinct search terms and 531+ containers reviewed, yielding zero Plan implementation documents found.
5. Therapeutic Goods Administration (2021). *How the TGA monitors COVID-19 vaccine safety* [Video]. YouTube. Available at: https://www.youtube.com/watch?v=PT4M9fX9sPI
6. Therapeutic Goods Administration. *COVID-19 vaccine safety reports*. Australian Government Department of Health and Aged Care. Available at: https://www.tga.gov.au/news/covid-19-vaccine-safety-reports

Appendix C: COVID-19 Vaccine Doses Administered Under Provisional Approval

C.1 Dose Count Summary

By 23 July 2023, more than 68 million COVID-19 vaccine doses had been administered in Australia since the rollout commenced in February 2021. The vast majority of these doses were given while primary vaccines remained under provisional approval, and were therefore subject to the enhanced monitoring commitments in the COVID-19 Vaccine Safety Monitoring Plan.

See Section 7 (Conclusion) for discussion of provisional approval scale and precedent implications.

C.2 Data Sources and Verification

Table C.1: COVID-19 Vaccine Dose Data

Source	Report Date	Doses Administered	Period Covered
TGA COVID-19 Vaccine Safety Report	29 June 2023[75]	> 68 million	To 25 June 2023
TGA COVID-19 Vaccine Safety Report	27 July 2023[76]	> 68 million	To 23 July 2023
Department of Health AIR Data	10 October 2024[77]	~72.3 million	Total since Feb 2021

C.3 Provisional Approval Status and Transition to Full Registration

The following vaccines transitioned from provisional to full registration during or after the main rollout period, as recorded in TGA's COVID-19 vaccines regulatory status history:[78]

- **Pfizer Comirnaty:** Provisional approval 25 January 2021 → Full registration 13 July 2023[79]

[75] https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-29-06-2023
[76] https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-27-07-2023
[77] https://www.health.gov.au/resources/publications/covid-19-vaccination-vaccination-data-10-october-2024
[78] https://www.tga.gov.au/products/medicines/prescription-medicines/application-and-market-authorisation/covid-19-vaccine-information-sponsors-industry/covid-19-vaccines-regulatory-status
[79] https://www.tga.gov.au/sites/default/files/2023-08/auspar-comirnaty-230807.pdf

- **Moderna Spikevax:** Provisional approval 9 August 2021 → Full registration 21 April 2023[80]
- **AstraZeneca Vaxzevria:** Provisional approval 15 February 2021[81] → Withdrawn April 2024[82]

Significance for Plan Implementation

Approximately 68 million of the 72.3 million total doses (about 94 per cent) were administered while primary vaccines remained under provisional approval. Enhanced post-market safety monitoring was therefore not discretionary but a regulatory condition of provisional approval framework under the Therapeutic Goods Act 1989. The unprecedented scale of deployment under provisional approval conditions—Australia's largest-ever use of provisionally approved medicines—heightened the materiality of documented implementation of the COVID-19 Vaccine Safety Monitoring Plan as accountability evidence.

[80] https://www.tga.gov.au/news/media-releases/modernas-covid-19-vaccine-spikevax-receives-approval-full-registration
[81] https://www.tga.gov.au/news/regulatory-decision-notices/covid-19-vaccine-astrazeneca-vaxzevria
[82]

C.4 References

1. Therapeutic Goods Administration (2023). *COVID-19 vaccine safety report, 29-06-2023*. Australian Government Department of Health and Aged Care. Available at: https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-29-06-2023
2. Therapeutic Goods Administration (2023). *COVID-19 vaccine safety report – 27 07 2023*. Australian Government Department of Health and Aged Care. Available at: https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-27-07-2023
3. Australian Government Department of Health and Aged Care (2024). *COVID-19 vaccination, Vaccination data, 10 October 2024*. Available at: https://www.health.gov.au/resources/publications/covid-19-vaccination-vaccination-data-10-october-2024
4. Therapeutic Goods Administration (2023). *COVID-19 vaccines, Regulatory status and history*. Available at: https://www.tga.gov.au/products/medicines/prescription-medicines/application-and-market-authorisation/covid-19-vaccine-information-sponsors-industry/covid-19-vaccines-regulatory-status

Appendix D: FOI and OAIC Timeline

Table D.1: Comprehensive FOI and OAIC Timeline for the COVID-19 Vaccine Safety Monitoring Plan

Date	Document type/stage	Key content	Reference to Safety Monitoring Plan	Response to request
31 Jan 2022	Pre-FOI email – Response 1	TGA provides "robust monitoring" assurance and four generic links (YouTube explainer, weekly safety reports, DAEN, monitoring overview). Encourages adverse event reporting; no Plan-specific material.	None	No outputs, progress or implementation evidence. Only partial AEFI reporting via links; no long-term monitoring, trial or methodology documentation.
18 Feb 2022	Pre-FOI email – Response 2	Second reply repeats the same four links and generic assurances; no new content.	None	Identical to January response; still no Plan-specific implementation information.
18 Feb 2022	FOI 3643 – Request	Applicant seeks a COVID-19 Vaccine Safety Monitoring Plan "implementation report" under the FOI Act.	Explicitly references the Plan and requests implementation documentation.	Initiates formal FOI process.
27 Feb 2022	FOI 3643 – Notice of decision	TGA refuses access under s 24A (no documents exist), stating "no implementation report exists", while also claiming "ample documentation" exists but not as an evaluation report. Repeats the same four links and cites Objective 5 examples (ICMRA, states, ATAGI, NCIRS, ACV) instead of implementation records.	Mentions Plan objectives but provides no implementation evidence.	No progress report; only partial AEFI/recovery material via links; no long-term monitoring, trial or methodology documentation.
2022–2024	OAIC IC review MR22/00538 – commenced	Applicant seeks Information Commissioner review of FOI 3643 decision. Applicant expressed concern about being required to make a new, broader request under the FOI Act on the basis that it would result in additional delay and deny transparency over public	Review concerns whether TGA took "all reasonable steps" to identify documents about Plan implementation.	OAIC opens MR22/00538 investigation.

Date	Document type/stage	Key content	Reference to Safety Monitoring Plan	Response to request
		health issues. Applicant subsequently indicated in June 2024 that they were willing to accept a broader range of material after receiving the Department's decision.		
9 Aug 2024	OAIC directions (s 55V, s 55(2)(e)(ii))	OAIC directs TGA to conduct further searches, document methodology, and demonstrate that all reasonable steps have been taken to find records relevant to the Plan.	Directions explicitly reference Plan objectives and outputs.	Triggers comprehensive TRIM/Promapp search program.
20 Sept 2024	OAIC submission MR22/00538 – TGA response	TGA provides a detailed submission and attachments documenting eight search terms (Plan, Objective, Strategy, enhanced, AusVaxSafety, pharmacovigilance, signal, surveillance), more than 531 TRIM containers and over 2,200 sampled pages. Searches identify extensive routine pharmacovigilance material but no Plan-specific implementation, governance, integration or AusVaxSafety coordination records.	Submission explicitly acknowledges the Plan and searches by objective and strategy.	Confirms that system-wide searches could not locate any Plan-specific implementation or integration documentation.
26 Mar 2025	OAIC decision AICmr54 (IC review of FOI 3643 / MR22/00538)	OAIC issues its decision on the applicant's review of TGA's s 24A "no documents" decision for FOI 3643 (AICmr54), considering whether TGA took all reasonable steps to locate records and whether the s 24A refusal can stand. Relying in part on the September 2024 MR22/00538 TRIM searches, the Commissioner accepts that no discrete implementation report or additional Plan-specific records have	Decision addresses the Plan only insofar as it relates to the adequacy of TGA's searches and its s 24A decision; it does not assess the quality of pharmacovigilance or Plan implementation.	Confirms, at OAIC level, that TGA's "no implementation report held" position for FOI 3643 stands, leaving the absence of Plan-specific implementation documentation unresolved.

Date	Document type/stage	Key content	Reference to Safety Monitoring Plan	Response to request
		been identified and upholds TGA's refusal under s 24A.		
1 Apr 2025	FOI 25-0166 – Request	Applicant lodges refined FOI seeking up to six of the most recent documents per Plan objective (Feb 2021–Feb 2025) across standard document categories (SOPs, workflows, protocols, regulatory-action procedures, public-communication procedures, collaboration mechanisms), with explicit document-type definitions and sampling method.	Request is explicitly structured around the Plan's objectives and TGA document types.	Tests whether a narrowly scoped, Plan-aligned and objectively identifiable sample can be obtained.
24 Apr 2025	FOI 25-0166 – s 24AB consultation	TGA advises that 399 documents are in scope but that processing them would be a "substantial and unreasonable diversion of resources", and that "the balance of interests does not favour the expenditure of considerable resources". Directs the applicant instead to COVID-19 vaccine safety reports and Advisory Committee on Vaccines (ACV) web pages; relies on FOI Guidelines paragraph 3.117.	None. No documents are identified as implementing or evidencing the Plan.	Practical-refusal position signalled. TGA refuses to process 399 in-scope documents on resource-diversion grounds and relies on generic public web links rather than providing Plan-related implementation records.
Apr–Jun 2025	FOI 25-0166 – Consultation submissions	Applicant and TGA exchange consultation correspondence. Applicant argues that 399 documents are manageable, that the request is objectively defined under s 15(2)(b), and that the public interest in Plan accountability outweighs the claimed burden. TGA maintains its view that processing would	Explicit references to Plan objectives and to the September 2024 MR22/00538 searches.	Shows applicant's progressive narrowing of scope and TGA's sustained reliance on workload arguments.

Date	Document type/stage	Key content	Reference to Safety Monitoring Plan	Response to request
		unreasonably divert resources.		
3 Jun 2025	FOI 25-0166 – Notice of decision	TGA issues a practical-refusal decision under s 24(1)(b), maintaining that processing 399 documents would be a substantial and unreasonable diversion of resources. Again, relies on FOI Guidelines 3.117 and generic web material. No documents are released.	Acknowledges that 399 documents fall within scope of the Plan-aligned request but does not characterise them as Plan-implementation records.	Confirms that, even after identifying a finite corpus of potentially relevant documents, TGA chooses not to process any of them, leaving Plan implementation undocumented in accessible form.
Oct 2025	FOI 25-0166 – s 54Z application to OAIC	Applicant applies to OAIC for review of the practical-refusal decision, arguing that TGA has not demonstrated an unreasonable diversion of resources and that the request is tightly scoped and in the public interest.	Application reiterates need for Plan-specific implementation documentation and cites MR22/00538 search outcomes.	Escalates FOI 25-0166 to independent review.

D.2: Summary of FOI and OAIC Escalation - Timeline Analysis

Across the timeline from January 2022 to October 2025, TGA has consistently declined to produce or release implementation documentation for the COVID-19 Vaccine Safety Monitoring Plan. The pattern shows:

- **Pre-FOI (Jan–Feb 2022):** TGA confirms that no implementation report exists and twice responds with only generic “robust monitoring” assurances and web links, without engaging with the specific request for Plan implementation evidence.
- **FOI 3643 (Feb–Mar 2025):** TGA refuses access under s 24A on the basis that no implementation report is held; in March 2025 OAIC decision AICmr54 accepts TGA’s September 2024 MR22/00538 search evidence and upholds the “no documents” finding.
- **OAIC MR22/00538 (Aug–Sept 2024):** Following OAIC directions, TGA conducts comprehensive TRIM/Promapp searches using eight search terms across more than 531 containers, identifying extensive routine pharmacovigilance documentation but zero Plan implementation, governance or AusVaxSafety coordination records were identified.
- **FOI 25-0166 (Apr–Jun 2025):** TGA locates 399 in-scope documents aligned with Plan objectives and standard document types but refuses processing on practical-refusal grounds under s 24(1)(b), citing “substantial and unreasonable diversion of resources”.

- **s54Z application (Oct 2025):** The applicant seeks OAIC review of the FOI 25-0166 practical-refusal decision; at the time of writing this review remains on foot.

Throughout this period, TGA has not released or produced any documented Plan implementation, governance, integration or performance-measurement records.

Appendix E: Version History

Version 1.5.1 (December 2025)

This version includes new policy context including National Cabinet endorsement of the Australian COVID-19 Vaccination Policy in November 2020, committing the government to TGA-led safety monitoring. TGA's February 2021 Safety Monitoring Plan operationalised this commitment, with AusVaxSafety positioning its active surveillance as part of the national pharmacovigilance framework.

Version 1.5 (December 2025)

This version streamlines the assessment structure to align directly with the TGA COVID-19 Vaccine Safety Monitoring Plan's 17 numbered strategies (1.1–1.5, 2.1–2.8, 3.1, 4.1, 5.1–5.2) and adds an explicit governance lens grounded in ISO 19011:2018 audit standards. Overall implementation ratings have been recalculated using a stricter evidence hierarchy, reducing "fully implemented" findings from 5 to 3 while leaving the overall implementation assessment, including the conclusion that the Plan's enhanced monitoring framework cannot be verified from available documentation, unchanged.

Ratings are applied at the level of each of the 17 strategies, treated as discrete implementation commitments. For each strategy, the assessment tests whether documentary evidence shows the commitment was (a) fully implemented as specified, (b) partially implemented, or (c) not implemented / not evidenced. "Fully implemented" requires a coherent set of records showing that required processes, integrations, governance arrangements and outputs were established and sustained over time; partial completion of component activities without an end-to-end implementation trail is rated "partially implemented", not "fully implemented". Overall ratings for each strategic area are derived from these strategy-level ratings using a conservative evidence hierarchy, so that missing verifiable documentation for any critical element of a strategy blocks an upgrade to "fully implemented".

Methodology has been strengthened through a clearer evidence hierarchy and research principles, including systematic analysis of TGA FOI decisions and correspondence, OAIC-directed searches (MR22/00538), and TRIM source-file sampling, alongside structured review of public TGA, partner-agency and parliamentary documents corroborating governance and implementation tracking. The version now includes an integrated FOI/OAIC timeline, a consolidated rollout dose-count summary, and a glossary of key terms used in the assessment.

In addition, a structured online sweep and targeted web scrape of relevant government and partner websites was conducted, designed for defined scope, reproducibility and bias-reduction, to identify any Plan-specific implementation or governance documents outside the formal FOI and OAIC record. Substantive content has been expanded with

an AusVaxSafety case study contrasting large-scale active-surveillance outputs (approximately 6.88 million surveys and 62,000 medical-attention reports) with the absence of documented coordination with TGA signal-management processes under Strategy 2.4, and with integration of the Australian National Audit Office's COVID-19 vaccine rollout audit to situate pharmacovigilance within the broader governance context while confirming that Plan implementation and safety-monitoring conditions lay outside that audit's scope.

The revision adds a section on the provisional-approval verification gap, including legislative framework analysis, post-transition monitoring assessment, and updated transition dates and regulatory citations. The analysis now also includes a dedicated section on evidentiary strengths and potential objections, with structured responses to likely counter-arguments (for example, reliance on generic SOPs, existence of expert committees, and prior FOI/AIC decisions). Priority reform areas and recommendations have been refined and re-ordered to foreground the most critical governance, records-management and audit requirements, and the strengthened evidence base supports a clearer and more robust overall finding, summarised in the new Executive Summary.

Version 1.0 (November 2025)

Initial publication.