Gmail **Paul <paulrekaris@gmail.com>**

# Request for Performance Audit: TGA COVID-19 Vaccine Safety Monitoring Plan Implementation

**Paul** <paulrekaris@gmail.com> 10 December 2025 at 14:35
To: External.Relations@anao.gov.au
Cc: community.affairs.sen@aph.gov.au, "Antic, Alex (Senator)" <senator.antic@aph.gov.au>
[redacted]

Dear ANAO,

Further to my submission of 27 November 2024 regarding the TGA COVID-19 Vaccine Safety Monitoring Plan implementation audit, I am writing to provide updated reference details and to clarify the specific performance-audit gap this work addresses.

The audit materials are now published as Version 1.5 with a permanent Digital Object Identifier (DOI) and should be treated as the authoritative source for any ANAO review:

- GitHub repository (documentation and version history):
https://github.com/paulrekaris/TGA-COVID19-Vaccine-Safety-Monitoring-Audit

- Zenodo record (stable, citable release – v1.5, December 2025):
10.5281/zenodo.17731054

The key reports (main documentation-gap analysis, summary slide deck and FOI/OAIC timeline) are attached to this email for ease of reference, and are identical to the Version 1.5 files available via the links above. This published version supersedes the email attachments from my original submission.

To my knowledge, ANAO has examined TGA several times since the mid-1990s, including the COVID-19 vaccine rollout performance audit (Report No. 3 2021-22) and, more recently, *Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods. These audits have focused on rollout efficiency, procurement and logistics, regulatory processes, enforcement and cost-recovery. They have **not** examined whether TGA's specific pharmacovigilance commitments in the February 2021 COVID-19 Vaccine Safety Monitoring Plan were implemented as designed, whether "enhanced" monitoring distinct from routine surveillance actually operated under provisional approval, or whether those conditions were verified and documented before vaccines transitioned to full registration.

The attached citizen-led audit is explicitly designed to fill this oversight gap. It applies ISO 19011:2018 auditing principles and ANAO better-practice guidance to publicly available and FOI/OAIC-released evidence, and documents four critical weaknesses: the absence of signal-by-signal audit trails linking 148 investigated signals to 57 regulatory actions; no documented verification of enhanced-monitoring conditions before approximately 68 million provisionally approved doses transitioned to full registration; a lack of documented integration between AusVaxSafety active-surveillance data and TGA decision-making; and missing governance and performance-reporting arrangements for the Safety Monitoring Plan.

On the current record, these are not gaps in public explanation but gaps in demonstrable regulatory governance. The work is fully transparent, replicable and falsifiable; any finding can be overturned if TGA produces contradicting documentation.

An ANAO performance audit focused specifically on COVID-19 vaccine pharmacovigilance and provisional-approval monitoring would provide the independent assurance that has so far been missing, test compliance with legislative and accountability frameworks, and help identify reforms needed to restore public trust in Australia's therapeutic-goods regulation.

Please feel free to contact me if further information would be useful.

Thank you for your consideration.

Yours sincerely,
Paul Rekaris
paulrekaris@gmail.com
[Quoted text hidden]

**3 attachments**

**Documentation Gap Analysis_Independent Audit of TGA COVID-19 Vaccine Safety Monitoring Plan_V1.5 .pdf**
1040K

**TGA_COVID-19 Safety Plan Implementation_Audit_Dec 25 V1.5.pdf**
727K

**TGA FOI Analysis Dec 2025_V1.5.pdf**
1084K