Gmail

Paul <paulrekaris@gmail.com>

RE: Contact Us message from the ANAO website [SEC=OFFICIAL]

1 message

ag1 <ag1@anao.gov.au> 19 January 2026 at 11:52
To: "paulrekaris@gmail.com" <paulrekaris@gmail.com>
Cc: ag1 <ag1@anao.gov.au>

OFFICIAL

Dear Paul Rekaris,

Thank you for your correspondence. The Australian National Audit Office (ANAO) publishes an annual audit work program (AAWP) in July each year. The program reflects the ANAO's audit strategy and informs the Parliament, government entities and the public of the planned audit coverage for the Australian Government sector, covering financial statements audits, performance audits, performance statements audits and other assurance reviews. The annual audit work program is also designed to anticipate and respond to current and emerging risks and challenges impacting on public administration, and complements the ANAO's primary planning document, the corporate plan.

Your request for audit has been passed on to the annual audit work program team. While your contribution will be considered, and handled with care, you will not automatically receive feedback about your contribution. For updates, please refer to the ANAO website at: Annual Audit Work Program.

Kind regards,

Australian National Audit Office

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www.anao.gov.au

From: anao2.noreply@govcms.gov.au <anao2.noreply@govcms.gov.au>
Sent: Saturday, 29 November 2025 11:05 AM
To: ag1 <ag1@anao.gov.au>
Subject: Contact Us message from the ANAO website

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Name: Paul Rekaris
Email address: paulrekaris@gmail.com
Enquiry type: the functions of the ANAO

Message:

Dear ANAO

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

I have submitted a request for ANAO to conduct a performance audit of the Therapeutic Goods Administration's implementation of its COVID-19 Vaccine Safety Monitoring Plan (February 2021) and compliance with provisional approval conditions.

Between February 2021 and November 2023, approximately 63.8 million COVID-19 vaccine doses were administered under provisional approval requiring enhanced monitoring - Australia's largest medical intervention in history. Despite multiple ANAO audits of TGA since the 1990s, there has been no performance audit of TGA's COVID-19 vaccine pharmacovigilance system or compliance with provisional approval monitoring requirements.

My independent audit assessment employs ISO 19011:2018 audit principles and ANAO better practice guidance, mapping TGA's 24 plan outputs against TGA's own regulatory guidelines (ARGPM), Commonwealth records management requirements (PGPA Act 2013, Archives Act 1983), and international pharmacovigilance standards Australia has adopted (ICH E2E, EMA GVP Module I). The methodology benchmarks provisional approval processes against FDA and EMA frameworks.

Key findings: 21% fully documented, 54% partial/undocumented, 25% no evidence. The assessment identifies potential breaches of the Therapeutic Goods Act 1989 provisional approval conditions and international pharmacovigilance standards. Findings strongly point to regulatory failure requiring investigation.

An ANAO performance audit is required to ensure compliance with legislative requirements, restore public trust in Australia's therapeutic goods regulation, and identify improvements to provisional approval monitoring systems.

The complete assessment is publicly available with permanent academic archiving:

Repository: github.com/paulrekaris/TGA-COVID19-Vaccine-Safety-Monitoring-Audit
DOI: <https://doi.org/10.5281/zenodo.17731055>

All findings are falsifiable and independently verifiable from publicly available sources.

Detailed submission and supporting documentation sent separately via email.

Paul Rekaris
paulrekaris@gmail.com
Delivered to:
ag1@anao.gov.au

Classification: OFFICIAL

Classified on: 19/01/2026 11:51:36 AM

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