

INDEPENDENT REGULATORY COMPLIANCE ANALYSIS

Documentation Regulatory Gap Analysis

Audit of TGA COVID-19 Vaccine Safety Monitoring Plan

Executive Summary

Audit Scope & Methodology

Comprehensive evidence-based assessment of TGA's February 2021 COVID-19 Vaccine Safety Monitoring Plan implementation across 20 specific measurable outputs. Analysis based on TGA's own systematic searches conducted September 2024 under OAIC direction (FOI Act s55V(2)), Senate testimony, FOI responses, and public documentation spanning four years (2021-2025).

3

Fully Implemented (15%)

11

Partial/Undocumented (55%)

6

Not Documented (30%)

Key Finding: While monitoring activities occurred (evidenced through 150+ weekly safety reports), systematic documentation of HOW enhanced COVID-19 vaccine safety monitoring was conducted is absent. Zero coordination protocols found linking AusVaxSafety's 6.8M surveys to TGA's 148 signal investigations. This creates an accountability gap: activity \neq systematic implementation.

Implementation Breakdown by Objective:

- Objective 1 (AEFI Collection): 40% implemented
- Objective 2 (Signal Detection): 0% publicly documented as enhanced - most problematic
- Objective 3 (Communication): 100% implemented - best performance
- Objective 4 (Data Integration): 0% implemented
- Objective 5 (Research): 0% implemented
- Governance: 0% implemented - critical gap

Audit Methodology Framework

Evidence-Based Approach

- Gap analysis comparing Feb 2021 Plan commitments against documented implementation
- Assessment against 20 specific measurable outputs
- Evidence hierarchy: TGA's own searches against 12 document categories > Senate testimony > FOI responses > public documents and official statements
- Objective evaluation: What can be demonstrated vs what cannot through temporal analysis over four years
- Falsifiable and replicable research framework

Primary Evidence Sources

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

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

Implementation Status Classification Criteria

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

Evidence Hierarchy & Quality Assessment

TIER 1: TGA's Own Systematic Searches

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

TIER 2: Senate Testimony Under Privilege

October 2025 Senate Community Affairs Legislation Committee Official statements by TGA senior officials under parliamentary privilege. Dr Dascombe's characterisation of monitoring as 'day-to-day processes' and 'some difficulty' producing documents confirms record-keeping failure.

TIER 3: FOI Responses (Formal Records)

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

TIER 4: Public Documentation

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

Key Assumptions & Limitations

Key Assumptions

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

Limitations

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

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

TGA's Own Regulatory Guidance - Provisional Approval

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

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

TGA Provisional Approval Requirements

Enhanced Post-Market Safety Monitoring Obligation

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

Risk Management Plans

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

Additional Studies Required

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

Performance Conditions

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

Regular Reporting

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

TGA Oversight Obligation

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

TGA's Accountability Gap

No Enhanced COVID-19 Vaccine Safety Monitoring Evidence

TGA published COVID-19 Vaccine Safety Monitoring Plan (Feb 2021) promising 'enhanced' protocols. While TGA investigated 148 safety signals and took 57 regulatory actions (Senate testimony, October 2025), officials characterised this work as 'day-to-day processes' rather than enhanced monitoring. No documentation demonstrates activities were 'enhanced' beyond standard pharmacovigilance, and no audit trails link specific signals to specific actions as required by international standards (ICH E2E, CIOMS).

No Performance Verification

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

Contradictory Characterisation

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

No Oversight Documentation

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

Systemic Framework Failure

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

Provisional Approval Lifecycle - Verification Failure

Provisional Approval Lifecycle Framework Legislative Requirements (TGA Act 1989)

s22C: Determination Phase

TGA assesses whether medicine qualifies for provisional approval based on preliminary data and development stage.

s23AA & s28(2A)(aa): Provisional Registration

TGA imposes conditions including enhanced post-market monitoring requirements to compensate for incomplete safety data, as set out in its provisional registration guidance.

s29: Time-Limited Approval

Provisional registration operates for defined periods (typically 2 years) with mandatory review at each extension.

s29(3)-(6): Verification Requirement

Extension and transition to full registration require TGA to verify that provisional conditions are satisfied, with sponsors providing data demonstrating fulfilment; guidance describes this as verification that those conditions have been met.

TGA Guidance Requirements

Risk Management Plans (RMPs)

Sponsors must submit detailed RMP outlining safety specification, pharmacovigilance activities, risk-minimisation measures, timelines and milestones for provisional period.

Transition to Full Registration

Requires documented evidence that provisional conditions met, including completion of planned studies, delivery of updated safety and efficacy data, and confirmation that required enhanced monitoring has been implemented.

Scale and Significance

68 million doses (94% of rollout) administered under provisional approval between February 2021 and July 2023—Australia's largest deployment of provisionally approved medicines.

Evidence Gap: Zero Verification Documentation

MR22/00538 Searches (September 2024)

531+ TRIM containers searched using eight Plan-aligned terms under OAIC direction. Zero documents found demonstrating:

- Verification that enhanced monitoring conditions satisfied before transitions
- TGA's documented assessment of whether provisional conditions met
- Decision-making criteria or rationale for granting full approval
- Verification checklist or evaluation of implementation against February 2021 Safety Monitoring Plan

FOI 25-0166 (June 2025)

399 Plan-aligned documents identified across 12 document categories. TGA refused to process any documents under s24(1)(b), citing practical refusal provisions.

AusPAR Analysis: No Verification Evidence

Comirnaty AusPAR (July 2023): Documents conversion to full registration (TGA decision 13 July 2023, ARTG entry 14 July 2023) but contains no evaluation of Safety Monitoring Plan implementation. No verification checklist showing provisional conditions met. No plan-level governance documentation.

Spikevax transition (April 2023): TGA media release contains no reference to Plan verification.

Pattern: AusPARs summarise clinical data, RMP and conditions but do not identify any verification checklist or evaluation of enhanced monitoring implementation.

Critical Accountability Gap: Compliance with provisional-approval verification requirements is not documented in the public and FOI record. No documented process shows how enhanced monitoring commitments and other provisional conditions were checked before full registration, so the evidentiary basis for transitioning 68 million provisionally approved doses to full approval cannot be independently verified.

International Comparison - Regulatory Transparency Standards

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

FDA Practice (US)

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

EMA Practice (EU)

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

TGA Practice (Australia)

Published Documentation:

- Australian Public Assessment Reports (AusPARs) – published summaries of TGA's evaluation of sponsor submissions, including clinical data, key benefit–risk considerations
- Media releases announcing transitions and related decisions

Notably Absent (in public and FOI record):

- X TGA's own post-market monitoring results and analysis
- X Systematic evaluation of compliance with provisional-approval conditions, including in TGA annual performance reports
- X Safety Monitoring Plan implementation assessment
- X Independent expert committee review of transition decisions
- X Documentation of how enhanced monitoring conditions were verified

Implementation Status by Safety Plan Objective and Output

Objective	Total outputs	Implemented	Partial	Not Documented
1: Timely collection and management of AEFI	5	2 (40%)	3 (60%)	0 (0%)
2: Proactive signal identification and assessment	8	0 (0%)	4 (50%)	4 (50%)
3: Clear communication to consumers and providers	1	1 (100%)	0 (0%)	0 (0%)
4: Integration of data from multiple sources	1	0 (0%)	1 (100%)	0 (0%)
5: Contribution to evidence base through research	1	0 (0%)	1 (100%)	0 (0%)
Cross-cutting 1: Collaborations	2	0 (0%)	2 (100%)	0 (0%)
Cross-cutting 2: Governance and performance measurement	2	0 (0%)	0 (0%)	2 (100%)

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

AusVaxSafety: Active Surveillance Without Documented Integration

COVID-19 vaccine safety data – at a glance

As at 14 April 2025

6,887,520

COVID-19 vaccine safety surveys completed*

106,929

COVID-19 vaccine safety surveys completed by Aboriginal and Torres Strait Islander people*

43.5%

reported at least one adverse event†

0.9%

reported visiting a GP or emergency department

* Surveys sent on day 3 post vaccination.

† Adverse events are self-reported, have not been clinically verified, and do not necessarily have a causal relationship with the vaccine.



 **AusVaxSafety**
An NCIRS led collaboration

Critical Documentation Gap:

- Zero coordination protocols found linking AusVaxSafety data to TGA's 148 signal investigations
- No documented integration between active surveillance (6.8M surveys) and passive surveillance (DAEN database)
- No audit trails showing how population-level adverse event data informed TGA's 57 regulatory actions
- Cannot verify disposition of 91 signals resulting in "no further action"

Why This Matters:

- Active surveillance promised as core pillar of TGA-led pharmacovigilance in Australian COVID-19 Vaccination Policy
- Strategy 2.4 commitment: "Collaborate with AusVaxSafety to receive active surveillance information and coordinate safety signal detection and investigation activities"
- Without documented integration frameworks: Cannot verify whether 62,000 medical attention reports and 3 million adverse event reports systematically informed signal prioritization and regulatory decisions
- Enhanced monitoring standard: International pharmacovigilance standards (ICH E2E, CIOMS) require documented coordination protocols with audit trails—not parallel operation of surveillance

Key finding: Operational capability ≠ enhanced COVID-19 vaccine safety monitoring framework – infrastructure functioned, but systematic integration is undocumented and remains unverified.

Accountability Implications of Documentation Gaps

Absence of verifiable documentation creates profound accountability deficits across multiple dimensions

Legal Basis Questioned

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

Public Trust Implications

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

Ministerial Accountability Deficit

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

Provisional Approval Framework Integrity

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

Accountability Implications of Documentation Gaps

Absence of verifiable documentation creates profound accountability deficits across multiple dimensions

Parliamentary Oversight Impossible

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

International Standing

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

Legislative Breaches* - Commonwealth Framework

Statute	Provision	Requirement	TGA Breach Pattern
PGPA Act 2013	S 37(1)	Records must properly record and explain entity's performance in achieving objectives	Cannot 'explain performance' - monitoring never tracked by objectives. Severity: ★★☆☆☆☆
Commonwealth Risk Mgmt Policy	Mandatory under PGPA s16	Risk management framework required. Performance monitoring mandatory component	No documented risk framework for Plan implementation. No performance monitoring documented. Severity: ★★☆☆
Archives Act 1983	s 24(1)	Commonwealth records must not be destroyed except in accordance with normal admin practice	If implementation docs existed then destroyed - Archives Act breach. If never created - records management failure. Severity: ★★☆☆
Therapeutic Goods Act 1989	Ss 22C, 23AA	Provisional approval includes conditions requiring enhanced post-market safety monitoring.	TGA's Vaccine Safety Monitoring Plan and related framework cannot be demonstrated to have been operationalised. No documented evidence of "enhanced" monitoring vs standard pharmacovigilance; full approval granted without verification. Severity: ★★☆☆☆☆
FOI Act 1982	s24AA	Must take reasonable steps to identify documents within scope	Sept 2024: organised docs by objectives (3 hrs). June 2025: claimed 'too subjective'. Capability then impossibility. Severity: ★★☆☆
FOI Act 1982	s24AA(1)(a) vs (1)(b)	Practical refusal must cite correct statutory ground	June 2025: cited (1)(b) but 3 hrs identification vs 177 hrs decision-making proves (1)(a). Wrong test applied. Severity: ★★☆☆☆☆

*Assessment of apparent non-compliance patterns, subject to formal investigation and legal determination

International Pharmacovigilance Standards - Context

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

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

Systemic Issues Identified - Pattern Analysis

1

Documentation vs Activity Gap

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

2

Enhanced vs Standard Monitoring

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

3

Governance Vacuum

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

4

Records Management Failure

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

5

Temporal Contradictions in FOI

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

6

Provisional Approval Integrity

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

*Cannot demonstrate on public record

Key Findings - Critical Oversight Failures Uncovered

TGA published 150+ weekly safety reports but cannot produce documented evidence distinguishing enhanced monitoring from routine surveillance. Officials admitted processes were 'day-to-day' without systematic tracking. Absence of coordination protocols, investigation frameworks, and governance mechanisms undermines provisional approval framework integrity and public trust.

1. No Evidence of Systematic Enhanced COVID-19 vaccine safety Monitoring

TGA promised enhanced surveillance beyond routine processes as provisional approval condition. No documented evidence found despite reviewing 1,674 documents (Sept 2024) and identifying 399 Plan-aligned documents (FOI 25-0166) refused for processing. Officials admitted 'day-to-day processes' without systematic tracking. Zero coordination protocols linking AusVaxSafety's 6.8M surveys to TGA's 148 signal investigations. Legal compliance unproven. (Outputs 1.2, 2.1, 2.4; Senate Oct 2025; FOI 25-0166)

2. Complete Absence of Governance and Accountability Frameworks

No documented oversight, performance measurement, or governance mechanisms exist. Searches found zero governance documents. Over 3 years since Feb 2022 review promise with no formal reviews, evaluations, or audit trails. TGA 2023-24 Annual Report contains zero Plan references despite 68 million doses, creating profound accountability gap. (Outputs GOV.1, GOV.2; TGA Annual Report 2023-24)

3. No Documented Risk-Based Signal Detection Systems

TGA investigated 148 safety signals and took 57 regulatory actions (Senate Oct 2025), yet cannot produce frameworks, protocols, or methodological standards for risk prioritisation, signal investigation, or causality assessment. No documentation links signals to actions or provides audit trails required by international standards (ICH E2E, CIOMS). Zero coordination protocols between AusVaxSafety's surveys and signal investigations. Searches found 0 documents for outputs 2.2, 2.3, 2.4. (Outputs 2.2, 2.3, 2.4)

4. Transparency Failures Undermine Public and Parliamentary Oversight

Despite identifying 399 Plan-aligned documents (FOI 25-0166) and reviewing 1,674+ documents (Sept 2024), TGA consistently refused release citing 'subjectivity' and resource constraints. TGA used identical document classifications systematically for OAIC (Sept 2024) then claimed same classifications 'too subjective' for citizen requests (June 2025). Contradictory statements erode trust and impede parliamentary scrutiny. FOI delays exceeded 1,400 days.

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

Required Reforms - Restoring Framework Integrity

While public communication outputs (Objective 3) performed relatively well with 100% implementation, detailed analysis reveals comprehensive regulatory reform required across documentation standards, governance frameworks, and transparency mechanisms to restore provisional approval pathway integrity.

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

1. Governance & Accountability

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

2. Documentation & Records Management

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

3. Systems for Risk Assessment & Verification

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

4. Transparency & Public Engagement

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

5. Emergency Preparedness

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