Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine safety monitoring plan

Version 1.0, February 2021

TGA Health Safety Regulation

Contents

Background

Before a vaccine is approved for use in Australia, it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA evaluates information provided by the vaccine's sponsor (usually a pharmaceutical company) that includes data on clinical studies, non-clinical/toxicology studies, chemistry, manufacturing and risk management. The decision to approve a new vaccine is always made on the basis that the benefits outweigh the risks for the group of people in which it is intended to be used.

Clinical studies that are conducted before vaccines and medicines are approved provide extensive information about the safety of these products. However, they may not detect very rare adverse events that can only be identified when a product is used in very large numbers of patients. Similarly, clinical trials may not fully characterise the safety profile of a product in certain population groups, such as the very elderly, pregnant women, or people with other medical conditions, because these people may not have been included in the trials.

The TGA, like other regulatory agencies around the world, continues to monitor the safety of vaccines and medicines after they are approved to contribute to a better understanding of their safety profile when they are used outside the controlled conditions of clinical trials. The TGA is the Government body responsible for ensuring that medicines and vaccines supplied in Australia continue to meet the required standards of safety, effectiveness and quality for their intended use. The TGA also has oversight of sponsors of vaccines and medicines who are legally responsible for monitoring the safety, quality and effectiveness of their products.

The rapid development of COVID-19 vaccines due to the urgent global need to effectively combat this pandemic has meant that the typical regulatory approval and production processes are being expedited. It is expected that, in most cases, sponsors of COVID-19 vaccines will apply for registration using the TGA's provisional approval pathway, which allows for temporary registration of promising new medicines and vaccines where the need for early access outweighs the risks. Information from ongoing clinical trials and safety studies will continue to be collected and analysed after provisional approval. The TGA, other international regulators, and vaccine sponsors will also continuously review safety and effectiveness information collected from use in mass vaccination programs worldwide.

This plan builds on the Department of Health's already well-established vaccine safety monitoring activities (known as 'pharmacovigilance') to closely monitor the safety of COVID-19 vaccines. The plan includes details of the TGA's involvement in Australia's broader national vaccine safety surveillance system and how we work closely with states and territories, other government agencies, overseas regulators and expert bodies to ensure a coordinated approach.

Aims and objectives

The aim of the COVID-19 Vaccine Safety Monitoring Plan is to strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects (also known as adverse events) following COVID-19 immunisation. This will enable the TGA to manage any emerging safety issues and help maintain public confidence in the immunisation program.

The key objectives of the COVID-19 Vaccine Safety Monitoring Plan are:

1. timely collection and management of reports of COVID-19 vaccine adverse events following immunisation
2. timely detection and investigation of COVID-19 vaccine safety signals
3. timely action to address any COVID-19 vaccine safety concerns
4. timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public confidence in vaccines
5. close collaboration and coordination of effort with other vaccine safety stakeholder groups.

Strategies

Five key strategies based on international guidelines and expert advice frame the Department's approach to strengthening the vaccine safety monitoring system in Australia.

1. Enhanced reporting of Adverse Events Following Immunisation

The TGA, like other regulatory agencies around the world, monitors adverse event reports relating to vaccines. Every Adverse Event Following Immunisation (AEFI) report is valuable and contributes to the TGA's safety monitoring of vaccines. We receive AEFI reports directly from consumers, health professionals, as well as through state and territory health departments, other Australian vaccine safety organisations and vaccine sponsors. These reports are added to the TGA's adverse event database.

Strategy	Objectives	Outputs
1.1 Enhanced reporting of AEFI	Encourage consumers and health professionals to report COVID-19 vaccine AEFI in an appropriate and timely manner. Reminding health professionals that in most Australian states and territories they are obligated to report AEFI.	Information about how consumers and health professionals can report AEFI for COVID-19 vaccines published on the TGA website. Requirement for general practices submitting expressions of interest in participating in the COVID-19 vaccine roll-out to have ability to report adverse events. Consumer and health professional communication activities, including contributing to other government COVID-19 communication products (advertising, articles and similar materials), to raise awareness of AEFI reporting and educate audiences on how to report.
1.2 Enhanced AEFI reporting forms	Ensure AEFI reporting forms are fit for COVID-19 vaccine purposes.	Updated TGA AEFI reporting forms that capture information specific to COVID-19 vaccines and outline the need for follow-up information on COVID-19 Adverse Events of Special Interest (AESI).
1.3 Enhanced AEFI report sharing	Ensure COVID-19 AEFI reports are able to be shared between the TGA and state and territory jurisdictions in an appropriate and timely manner.	Criteria, processes and timelines for the sharing of COVID-19 vaccine AEFI reports to and from state and territory jurisdictions. Improved automated flow of AEFI reports from jurisdictions into the TGA's adverse event report database.

Strategy	Objectives	Outputs
1.4 Enhanced AEFI data collection and management capabilities	Ensure the TGA's data processing and management capabilities are able to meet COVID-19 vaccine AEFI data requirements.	The TGA's adverse event report database and team prepared to meet the anticipated increase in data entry and management requirements relating to COVID-19 vaccine AEFI.
1.5 Enhanced AEFI report escalation processes	Ensure that criteria for COVID-19 vaccine report escalation and clinical review are appropriate and effective.	Criteria for COVID-19 vaccine report escalation and clinical review incorporated into the TGA's standard procedures.

2. Enhanced safety signal detection and investigation

Signal detection involves identifying patterns of adverse events associated with a particular medicine or vaccine that warrant further investigation. A safety signal may arise from:

- a previously unrecognised safety issue
- a change in the frequency or severity of a known safety issue
- identification of a new 'at risk' group.

When a safety signal is identified, the TGA will conduct a thorough investigation to determine what, if any, action is required.

An adverse event might occur soon after immunisation, but that does not mean it was caused by the vaccine. Our investigations aim to determine whether vaccination could be the cause of the adverse event and includes assessment of the 'background rate' of the adverse event in the population to see if the reported rate is higher than expected.

Strategy	Objectives	Outputs
2.1 Understanding COVID-19 vaccine safety profiles	Understand baseline safety profiles, background adverse event rates and AESI for each COVID-19 vaccine.	Expected AEFI rates for approved COVID-19 vaccines, informed by premarket evaluations of safety data and understanding of the risks associated with the new types of vaccines, established. Background rates of certain health events (for example heart problems) in the general population calculated for comparison with COVID-19 vaccine AEFI rates. A list of COVID-19 vaccine AESI established, informed by premarket product evaluations and World Health Organization (WHO) and Brighton Collaboration guidelines.
2.2 Enhanced capacity and capability for investigating individual COVID-19 AEFI reports	Ensure that the TGA has the capacity to undertake appropriate and timely investigation of COVID-19 AEFI reports.	Specific protocols for investigating COVID-19 AEFI reports. The TGA is prepared to meet the anticipated increase in investigation requirements relating to COVID-19 vaccine AEFI reports.
2.3 Enhanced cumulative data reviews for each COVID-19 vaccine	Enable rapid analysis of AEFI rates to detect, confirm or disprove emerging COVID-19 safety signals.	Access to Australian Immunisation Register and vaccine distribution data for calculating COVID-19 immunisation rates. Refined processes and statistical methods for analysing observed COVID-19 AEFI rates for detecting safety signals. Enhanced processes to determine if the frequency of particular AEFI are higher than expected. Processes for conducting subpopulation analyses to identify and investigate potential safety signals in at-risk populations.

Strategy	Objectives	Outputs
2.4 Active surveillance	Establish real-time collaboration with COVID-19 active surveillance activities for safety signal detection and analysis.	Collaborate with AusVaxSafety to receive active surveillance information and coordinate safety signal detection and investigation activities. AusVaxSafety will be using SMS messaging to survey some people who receive a COVID-19 vaccine as part of their planned active surveillance activities.
2.5 Clinical studies and reports	Strengthen processes for receiving new safety information from COVID-19 vaccine clinical studies and monthly Safety Summary Reports	Conditions of registration include additional safety monitoring requirements for COVID-19 vaccines including timely submission of post market safety studies and monthly safety summaries. Establish new processes and prioritise staff resources to analyse COVID-19 safety study reports and monthly Safety Summary Reports.
2.6 Environmental scanning	Strengthen environmental scanning activities (such as reviewing medical literature and overseas data) for detecting COVID-19 vaccine safety issues.	Confirm processes for monitoring COVID-19 vaccine safety alerts from overseas regulators, significant safety issue notifications from vaccine sponsors, AEFI surveillance reports from international agencies, the WHO adverse event database and other sources of safety information.
2.7 International safety signals	Improve mechanisms for sharing information on COVID-19 safety signals between international regulators.	The TGA co-Chairs a group that facilitates the sharing of COVID-19 vaccine specific safety information through the International Coalition of Medicines Regulatory Authorities (ICMRA).
2.8 Expert advice	Strengthen expert advisory committee capabilities for COVID-19 vaccine safety issues.	Establish a standing COVID-19 expert advisory committee ready to provide advice on COVID-19 vaccine safety issues, drawing on Advisory Committee on Vaccines (ACV) and Australian Technical Advisory Group on Immunisation (ATAGI) members.

3. Actions in response to safety concerns

In the event that the TGA confirms that there is a safety concern in relation to a COVID-19 vaccine, there is a range of actions that can be taken to address or reduce the risk.

Strategy	Objectives	Outputs
3.1. Regulatory and programmatic action	Use legislative provisions available to achieve effective and timely regulatory action in response to any emerging COVID-19 vaccine safety concerns, as well as any non-regulatory action that may help to address or reduce the risk of a safety concern.	Processes to enable rapid action in response to any emerging COVID-19 vaccine safety concerns, including broadening the reach of risk communication activities.

4. Communications

The TGA has a number of mechanisms in place to provide information on the safety of COVID-19 vaccines to consumers, health professionals and sponsors. Clear, timely and reliable communication is critical in managing any emerging safety issues and to help maintain public confidence in vaccines.

Strategy	Objectives	Outputs
4.1 Communications and media	Timely communication messages provided to consumers and health professionals regarding COVID-19 vaccine safety monitoring activities, adverse event reporting, safety issues and reassurances.	Key messages for consumers and health professionals including an explanation of COVID-19 safety monitoring activities, reminders to report adverse events, information on emerging safety issues and safety reassurances where appropriate. Regular reports of significant safety information, including AEFI data, to be published on the TGA website.
	Timely media engagement regarding COVID-19 vaccine safety concerns.	Enhanced media scanning activities for identifying COVID-19 vaccine safety concerns and media readiness.

5. Collaborations

The Department works closely with states and territories, other government agencies, overseas regulators and expert bodies to ensure a coordinated approach to COVID-19 vaccine safety.

Strategy	Objectives	Outputs
5.1 National vaccine safety stakeholder collaborations	Consolidate timely information sharing, communication and collaboration with national stakeholders on COVID-19 vaccine safety activities and issues.	Utilise Jurisdictional Immunisation Coordinator meetings to coordinate COVID-19 vaccine safety activities and issues with state and territory health departments. Participate in ATAGI COVID-19 Working Groups to inform and receive technical advice on COVID-19 vaccine safety activities and issues. Seek expert advice from the ACV on COVID-19 and vaccine safety activities and issues. Seek expert advice from and strengthen partnerships with academic institutions including the National Centre for Immunisation Research and Surveillance (NCIRS) and regional surveillance centres, such as the Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC), on COVID-19 vaccine safety signal detection and investigation activities. Strengthen collaboration with the Adverse Events Following Immunisation – Clinical Assessment Network (AEFI-CAN) regarding COVID-19 vaccine adverse events.
5.2 International collaborations	Timely international information sharing on COVID-19 vaccine safety preparedness activities and safety signals.	Co-lead an ICMRA working group to share knowledge, experience and communications on safety monitoring activities and the emerging benefit-risk profiles of vaccines. Lead an ICMRA working group in developing statements for the general public and healthcare professionals on COVID-19 vaccine confidence highlighting the importance, safety and effectiveness of COVID-19 vaccines. Strengthen collaborations with other overseas regulators on COVID-19 vaccine safety issues. Obtain expert advice from the WHO Global Advisory Committee on Vaccines Working Group on COVID-19 safety monitoring preparedness.

Version history

Version	Description of change	Author	Effective date
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Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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