Australian Government

Department of Health
Therapeutic Goods Administration

TGA Health Safety Regulation

Extract from minutes of ACV meeting 16, held 30 September 2020

Item 3.2 COVID Vaccine Pharmacovigilance Plan

Disclosure of interests

Disclosure of interests, if any, are recorded under Item 1 of the minutes of this meeting, as required by Regulation 42 of the Therapeutic Goods Regulations 1990.

Vaccine details

The vaccines of interest are those that immunise against Severe Acute Respiratory Syndrome coronavirus-2 (SARS-CoV-2)

There are no products currently on the Australian Register of Therapeutic Goods (ARTG), however there is potential for multiple products to be registered, using a number of different platform technologies, in the coming months to years.

Delegate's Overview

The Department of Health is developing a COVID Vaccine Pharmacovigilance Plan ('Plan') to prepare the existing national pharmacovigilance system for the registration of vaccines against SARS-CoV-2 infection in Australia and potential supply through the National Immunisation Program (NIP).

The plan builds on Australia's already robust passive and active surveillance methodologies, including existing highly effective pharmacovigilance systems at the Department of Health (including the TGA), the National Centre for Immunisation Research and Surveillance (NCIRS), and regional pharmacovigilance centres such as State and Territory Health Departments. The plan falls under the Australian Government COVID-19 Vaccine and Treatment Strategy.

The Plan focuses on the early detection and investigation of Adverse Events Following Immunisation (AEFI), and timely responses to potential safety signals to minimise negative impacts on both the health of individuals and public confidence in vaccination. It addresses potential safety signals in the context of limited baseline safety data relating to novel vaccines and vaccine technologies, expedited vaccine development, and rapid production and delivery.

ACV discussion

The ACV noted that the Plan is a work-in-progress, and that further iterations will be presented to the ACV for advice. The version presented to the meeting was dated 22 September 2020.

There will be intense public interest and concern regarding AEFI that are attributable to the vaccine.

ACV advice to the Delegate

The ACV advised the following points in response to the Delegate's specific requests for advice:

1. ***Adequacy of the draft COVID Vaccine Pharmacovigilance Plan with regard to its key strategies, objectives and activities:***

   a. enhanced reporting of Adverse Events Following Immunisation (AEFI)

   - This is critical to the Plan.
   - Two way exchange of information needed between states and territories and the TGA.
   - Ease of reporting contributes to timeliness of reporting.
   - Inter-operability of reporting systems will contribute to this.

   b. enhanced safety signal detection and investigation

   - It is critical to have current Australian background rates for AEFI of particular significance.
   - Important to have accurate denominators in statistical analysis of clusters
   - AEFI rates to provide context in communications
   - Relevant baseline data may be available from the Brighton Collaboration, SPEAC[1] and GACVS[2].
   - AEFI of particular significance might include multiple sclerosis, Guillain-Barre syndrome, transverse myelitis.
   - AEFI of particular significance may vary with the safety profile of each vaccine, including class effects from its method of manufacture.
   - Importance of using common terminology, from SNOMED and MedDRA.
   - Doses of COVID-19 vaccine administered to be reported to the Australian Immunisation Register (AIR).
   - Data from a range of sources, including:
     - Emergency Department triage (NSW)
     - Data matching of hospital admissions to AIR
     - NPS MedicineWise MedicineInsight program
   - Data from AIR to be accessible by states and territories.

   c. regulatory and programmatic actions

   - Pooled data with other countries with comparable pharmacovigilance systems.

   d. communications

   - Importance of pre-emptive communications on how reviews of safety and efficacy will be conducted, to build trust and counter 'fake news' if information on process only appears with adverse information.

[1] The Safety Platform for Emergency vACcines (SPEAC) is funded by CEPI through the Brighton Collaboration with the objective of harmonizing safety assessments from clinical trials (monitoring, investigation and analysis) with standard case definitions, tools and information aids.
[2] WHO Global Advisory Committee for Vaccine Safety

- Social media needs to be covered.

e. collaborations

- Close collaboration and coordination of effort with government agencies and stakeholder organisations with an interest in vaccine safety.
- Regional engagement with Pacific neighbours.

2. Appropriateness of the use of the Vaccine Special Interest Group (VSIG) and its Work Instruction with regard to investigating individual reports or clusters of COVID vaccine AEFI of particular significance, and/or safety signals of concern.

- Supportive of a standing committee.
- Supportive of preliminary meeting prior to vaccine distribution e.g. to reach agreement on definitions.
- As an unpredictable and potentially large volume of work, the work process needs to be as streamlined and pre-planned as possible:
  - how issues will be categorised and presented
  - which reports would be referred
  - pre-identify data sets with best probability of addressing questions for a range of populations, e.g. aged persons, health care workers
  - separately, form an incident management team with the reporting jurisdiction(s) so that information can be actively and rapidly compiled from clinicians
  - consider scheduled meetings rather than multiple ad hoc meetings.
- Membership should reflect:
  - Causality assessment is a complex undertaking. Members should be selected to be able to assess complex medical problems.
  - If initially the vaccinated population is adult (e.g. healthcare workers) then expertise in adult neurology etc. is needed.
  - Expertise in Workplace Health and Safety, for reports from vaccinated healthcare workers.
- Work processes that are as streamlined and pre-planned as possible will contribute to timeliness and reduce administrative burden overall.

3. How the ACV and the Australian Technical Advisory Groupon Immunisation (ATAGI) should work together to provide advice on COVID vaccine safety issues, and to provide advice on how the TGA might best work with the two groups when requesting expert advice on future COVID vaccine pharmacovigilance activities.

- The legislation describes the role of ACV in vaccine safety and pharmacovigilance. ACV members participate in VSIG. (Note: VSIG has not been established as an ACV subcommittee).
- The activities of ATAGI are separate, and the ATAGI could provide expertise as needed.

Ratified October 2020.