Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Minutes

Meeting 17, held 2 December 2020

COMMITTEE IN CONFIDENCE

TRIM Reference no. D20–3788127

TGA Health Safety Regulation

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7.5 COVID Vaccine Pharmacovigilance Plan

The ACV noted the changes to the COVID Vaccine Pharmacovigilance Plan since ACV 16.

The committee emphasised the following points in analysis of adverse events following immunisation (AEFI).

- Common AEFI vs serious vs deaths
- Impact of various types of AEFI on rollout. Including real and perceived AEFI
- Various systems contribute different intelligence, which needs integration and analysis for signal detection purposes and recognition of the different lag times in different systems:
  - Passive spontaneous reporting to TGA and sponsors
  - Passive reporting via existing clinical networks (AEFI-CAN/SAEFVIC), which are long-standing and mature systems that continue to have a role for a novel vaccine
  - Active surveillance post vaccination e.g. AusVaxSafety
  - International experience, which may be from populations where there is a high prevalence of Covid seropositive persons prior to vaccination, and relate to vaccines not in use in Australia
  - Social media (real vs noise)
- Possibility of mixed schedules (different brand for first and second injection), which will not have been tested in clinical trials. Cytokine storms and systemic inflammatory conditions could suggest mixed schedules.

- Increased reactogenicity in the real world population (e.g. vaccination of persons who are seropositive after undiagnosed asymptomatic infection).
- Governance
  - Need for timely clinical assessment, especially for 2-dose protocols. AEFI following the first injection will need to be investigated and determined prior to the date for the second injection.
  - Program implications, communication to providers/public, and countering misinformation.
  - While VSIG has a role in reviewing individual cases, a separate mechanism / standing committee may be required for the analysis of clusters and signal detection expertise, for example, a group with social science and statistics expertise.

The TGA would welcome any further comments from members.