Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

COVID-19 vaccine strain updates

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Purpose

This guidance describes how the Therapeutic Goods Administration (TGA) intends to review applications for registration of mRNA vaccines which are variations on existing mRNA vaccines designed to confer protection from newly identified variants of concern (VOC). This guidance will assist in enabling safe and efficacious vaccines to be rapidly available for COVID-19, where these new vaccines have been developed from existing registered messenger RNA (mRNA) COVID-19 vaccines.

Scope

- This guidance only applies to vaccines against variants of concern where a closely related form of the same mRNA-based COVID-19 vaccine has full registration on the Australian Register of Therapeutic Goods (ARTG)
- Variants of concern will be confirmed by the TGA based on advice from the World Health Organization (WHO) and a public health risk assessment of new variants.
- COVID-19 vaccines that are provisionally registered, or for indications with provisional registration, are out of scope for this guidance.
- Vaccines produced from other technologies are out of scope at this time, but may be considered for inclusion under this guidance in the future. Advice from the Advisory Committee on Vaccines (ACV) will be sought in adjusting this scope.

Approach

Applications for vaccines against new variants, are proposed in most instances to be considered under the minor variation (“Category 3”) pathway for applications under section 23 of the *Therapeutic Goods Act 1989*, and to be processed under a streamlined submission pathway. Under this approach new COVID-19 vaccines that are targeted at VOCs would, if accepted for registration, be entered in the Australian Register of Therapeutic Goods (the Register) in their own right and receive their own ARTG number. This would mean that any related earlier COVID-19 vaccines would also remain in the Register.

The Advisory Committee on Vaccines (ACV) has provided advice to the TGA that the risk-benefit assessment of such vaccines can vary significantly by age group and potentially by variant type, and therefore alternative evaluation approaches may be required in some instances.

Evidence requirements

- The TGA intends to undertake evaluation for all applications containing variant-specific changes (including minor variations). The TGA will consider the strain selections, formulation, pre-clinical and animal data, information from other regulators, and available clinical trial and real-world post-market safety and effectiveness data from ancestral and earlier variant vaccines with the same manufacturing process. Independent advice from ACV will also usually be sought to inform the registration decision.
- Clinical data from an earlier related vaccine, including related ones with provisional registration may provide supportive evidence for an application for a new COVID-19 vaccine that is designed to address a new VOC and that is based on an earlier COVID-19 vaccine.

- In some cases the TGA may require additional data and/or evidence be provided to evaluate safety and efficacy as part of Product Information (PI) evaluation.
- The TGA accepts a combination of clinical trial and real-world evidence. It is anticipated that a combination of types of evidence will be provided by sponsors for the purpose of registration.
- Where a sponsor provides real world evidence, such evidence is expected to comply with the principles of either the EMA or FDA guidelines (insert link here to TGA RWE hub page).

Dossier requirements

- The TGA expects that all dossiers comply with the Australian specification of eCTD.

Pharmacovigilance requirements

Additional conditions of registration may be applied where early evidence is accepted, including minor variations.

Transparency of submissions and changes made

The TGA will publish either an AusPAR or an addendum to existing AusPARs for new variant vaccines approved as a minor variation.

Pathway selection for evaluation and decision making

The TGA has other application categories in addition to minor variations, in relation to the review of the safety and efficacy of vaccines, including COVID-19 vaccines. This section provides overall guidance to sponsors by providing the following examples:

Case: Adjustment of variant-specific component only of mRNA vaccine, with similar vaccine components (including lipid nanoparticles).

Advice: This may be considered a minor variation submission if initial vaccine has full registration and will need individual consideration by the TGA. Sponsors should apply for a new INN for each variant to facilitate registration. Please contact streamlinedsubmission@health.gov.au for further advice.

Case: New formulation including a broader combination of mRNAs of very different sequences or lengths, introducing new antigens, or different types of lipid nanoparticles etc.

Advice: Likely requires a submission for the registration of a new entity (e.g. Category 1, type A) (www.tga.gov.au/resources/publication/publications/australian-regulatory-guidelines-prescription-medicines-argpm).

Case: New formulation including changes to the excipients or to the total quantity of mRNA included within the ingredients.

Advice: Likely requires a submission for the registration of a major variation (www.tga.gov.au/resources/publication/publications/australian-regulatory-guidelines-prescription-medicines-argpm).

Case: New dosage, strength, dose form, route, patient group or route of administration.

Advice: Likely requires a submission for the registration of a major variation (www.tga.gov.au/resources/publication/publications/australian-regulatory-guidelines-prescription-medicines-argpm).

Case: Requests to import, supply or export a vaccine that does not comply with standards.

Advice: Likely follows the normal approach for a submission under s14 of the *Therapeutic Goods Act 1989* (www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-prescription-medicine/application-types/consent-import-supply-or-export-therapeutic-goods-do-not-comply-standards-information-industry).

Version history

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