

19 August 2024

## FOI request 5275

*3. A document containing generalised information in relation to the decision makers and/or committees who were involved in the decision making of the AusPar for Comirnaty BNT162b2 dated January 2021, such as; title/classification level, and the experience and/or training credentials required by the staff who are authorised to make these decisions. In addition to this, general information on the authors of relevant supporting documents that informed the AusPAR, such as the Delegate's Overview.*

### Background

Applications for the registration of prescription medicines in the Australian Register of Therapeutic Goods (ARTG) are evaluated by a large team of medical and scientific experts at the TGA prior to a senior medical officer, Medical Officer Class 4 and above ('the Delegate'), making a regulatory decision under the *Therapeutic Goods Act 1989*. Independent expert advice may also be sought from the Advisory Committee on Medicines or the Advisory Committee on Vaccines to inform the decision made by the Delegate.

Medical officers employed by the TGA hold a range of qualifications, including General Practice and non-General Practice specialty fellowships, as well as other relevant qualifications in fields such as epidemiology and public health.

An AusPAR (Australian Public Assessment Report) is a document published by the TGA that provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. AusPARs are compiled by a team of TGA staff based on internal reports written by scientific evaluators, clinical evaluators, and Delegates during the course of an application evaluation and decision. These reports include, but are not limited to, the Delegate's Overview, clinical evaluation reports, and non-clinical evaluation reports.

An AusPAR was compiled for Comirnaty BNT162b2 as it was an application for a new biological entity (a medicine that was new to the Australian market).

More information about registration of new chemical entities is also available on our website:

[Prescription medicines: registration of new chemical entities in Australia.](#)

More information about AusPARs is available on our website: [Australian Public Assessment Reports for prescription medicines \(AusPARs\).](#)