Renewal of Provisional Consent to the Distribution of a Medicine

Pursuant to section 23(4A) of the Medicines Act 1981, the Minister of Health hereby renews the provisional consent to the sale, supply or use in New Zealand of the medicine set out in the Schedule hereto:

Schedule

Product:	**Comirnaty (COVID-19 mRNA vaccine)**
Active Ingredient:	BNT162b2 [mRNA] 0.5mg/mL
Dosage Form:	Concentrate for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	Pfizer Manufacturing Belgium NV, Puurs, Belgium Polymun Scientific Immunobiologische Forschung GmbH, Klosterneuburg, Austria Mibe GmbH Arzneimittel, Brehna, Germany BioNTech Manufacturing Marburg GmbH, Marburg, Germany Baxter Oncology GmbH, Westfalen, Germany Allergopharma GmbH & Co. KG, Reinbek, Germany Novartis Pharma Stein AG, Stein, Switzerland Delpharm Saint Remy, Saint Remy Sur Avre, France

Provisional consent is granted for two years from 3 November 2021.

This consent is given subject to the following conditions:

The New Zealand Sponsor must fulfil the following obligations within the timelines specified, which may be altered by mutual agreement with Medsafe:

1. The New Zealand site of batch release will only release batches for distribution in New Zealand once the sponsor has verified that the shipping temperature profile meets specifications.
2. Provide independent batch certification, such as UK National Institute for Biological Standards and Control (NIBSC) certification, EU Official Control Authority Batch Release (OCABR) certification, Australian TGA batch release assessment, or any other certification agreed with Medsafe, on request for all batches distributed in New Zealand.
3. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
4. Provide any reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post-marketing studies, within five working days of these being produced.
5. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.
6. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
7. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
8. Perform the required pharmacovigilance activities and interventions detailed in the agreed RMP and any agreed updates to the RMP. An RMP should be submitted at the request of Medsafe or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important milestone being reached.

Dated this 28th day of October 2021.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

2021-go4666 28-10-2021 12:30