

## Provisional Consent to the Distribution of New Medicines

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicines which were referred to the Minister of Health under the provisions of section 24(5) of the Act and set out in the Schedule hereto:

### Schedule

<b>Product:</b>	<b>Comirnaty</b>
<i>Active Ingredient:</i>	Tozinameran 0.1mg/mL
<i>Dosage Form:</i>	Suspension for injection
<i>New Zealand Sponsor:</i>	Pfizer New Zealand Limited
<i>Manufacturer:</i>	Pfizer Manufacturing Belgium NV, Puurs, Belgium

Provisional consent is granted until 3 November 2023.

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 Certificates of Analysis to Medsafe for the first three batches of vaccine of each presentation intended to be distributed in New Zealand, prior to distribution.
3. 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.
4. Reassess and revise the finished product specifications acceptance limits for RNA and lipid content as further data becomes available. Due date: 31 December 2022.
5. Provide updated stability data for the process performance qualification supportive stability batches. Due date: 30 April 2022.
6. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
7. 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.
8. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.
9. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
10. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
11. 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.

<b>Product:</b>	<b>Comirnaty</b>
<i>Active Ingredient:</i>	Tozinameran 0.5mg/mL
<i>Dosage Form:</i>	Concentrate for injection
<i>New Zealand Sponsor:</i>	Pfizer New Zealand Limited

## NEW ZEALAND GAZETTE

*Manufacturers:* Novartis Pharma Stein AG, Stein, Switzerland  
Pfizer Manufacturing Belgium NV, Puurs, Belgium  
Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany  
Baxter Oncology GmbH, Westfalen, Germany  
Patheon Italia SpA, Milan, Italy  
Polymun Scientific Immunobiologische Forschung GmbH, Klosterneuburg, Austria  
Siegfried Hameln GmbH, Hameln, Germany  
Delpharm Saint Remy, Saint Remy Sur Avre, France  
Catalent Anagni SRL, Anagni, Italy  
BioNTech Manufacturing Marburg GmbH, Marburg, Germany  
Mibe GmbH Arzneimittel, Brehna, Germany  
Allergopharma GmbH & Co. KG, Reinbek, Germany

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Dated this 5th day of April 2022.

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