Corrigendum—Provisional Consent to the Distribution of New Medicines

This corrigendum amends the notice with the above heading, published in the *New Zealand Gazette*, 16 December 2021, Notice No. 2021-go5403, by replacing the notice with the following:

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 set out in the Schedule hereto:

Schedule

Product:	**Comirnaty (30mcg/0.3mL dose)**
Active Ingredient:	Tozinameran 0.1mg/mL
Dosage Form:	Concentrate for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturer:	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. Prepare a “Dear Healthcare Professional” letter or comparable instructive material and provide this to Medsafe for review and approval prior to distribution of these products. Due date: 10 January 2022.
2. 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.
3. 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.
4. 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.
5. Reassess and revise the finished product specifications acceptance limits for RNA and lipid content as further data becomes available. Due date: 31 December 2022.
6. Provide updated stability data for the primary stability and process performance qualification supportive stability batches. Due date: 28 February 2022.
7. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
8. 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.
9. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.
10. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
11. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
12. 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.

Product:	**Comirnaty (10mcg/0.2mL dose)**
Active Ingredient:	Tozinameran 0.1mg/mL
Dosage Form:	Suspension for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturer:	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, the dates of which may be altered by mutual agreement with Medsafe:

1. Prepare a “Dear Healthcare Professional” letter or comparable instructive material and provide this to Medsafe for review and approval prior to distribution of these products. Due date: 10 January 2022.
2. 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.
3. 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.
4. 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.
5. Reassess and revise the finished product specifications acceptance limits for RNA and lipid content as further data becomes available. Due date: 31 December 2022.
6. Provide updated stability data for the primary stability and process performance qualification supportive stability batches. Due date: 28 February 2022.
7. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
8. Provide the six months analysis data from Study C4591007. Due date: 28 February 2022.
9. 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.
10. Provide the final Clinical Study Reports for Study C4591007 within five working days of these being produced.
11. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
12. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
13. 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 17th day of December 2021.

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

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