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 medicines set out in the Schedule hereto:
Schedule

Product:	**Comirnaty (10mcg/0.2mL 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-Sint-Amands, Belgium

Provisional consent is granted for two years from 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 any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
6. 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.
7. Provide the final Clinical Study Reports for Study C4591007 within five working days of these being produced.
8. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
9. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
10. 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 (30mcg/0.3mL dose)**
Active Ingredient:	Tozinameran 0.1mg/mL
Dosage Form:	Suspension for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgium Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany Patheon Italia S.p.A, Milan, Italy BioNTech Manufacturing Marburg GmbH, Marburg, Germany Mibe GmbH Arzneimittel, Brehna, Germany Allergopharma GmbH & Co. KG, Germany

Provisional consent is granted for two years from 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 any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.
6. 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.
7. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.
8. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
9. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
10. 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 (3mcg/0.2mL 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-Sint-Amands, Belgium

Provisional consent is granted for two years from 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 intended for the New Zealand market, prior to distribution.
3. To 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. Provide the final clinical study reports from Study C4591007 within five working days of these being produced.
5. Provide any reports on efficacy and safety including duration and the requirement for booster doses 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 any safety reports and safety reviews conducted or they 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.

Product:	**Comirnaty**
Active Ingredient:	Tozinameran 0.5mg/mL
Dosage Form:	Concentrate for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	Novartis Pharma Stein AG, Stein, Switzerland Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgium Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany Baxter Oncology GmbH, Halle-Kunsebeck Westfalen, Germany Patheon Italia S.p.A, 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

Provisional consent is granted for two years from 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 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.

Product:	**Comirnaty Original/Omicron BA.1**
Active Ingredients:	Riltozinameran 0.05mg/mL Tozinameran 0.05mg/mL
Dosage Form:	Suspension for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgium Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany BioNTech Manufacturing Marburg GmbH, Marburg, Germany Mibe GmbH Arzneimittel, Brehna, Germany Allergopharma GmbH & Co. KG, Reinbek, Germany

Provisional consent is granted for two years from 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 this product.
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 intended for the New Zealand market, prior to distribution.
4. To 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. To reassess the acceptance criteria for RNA ratio in the finished product specifications. Due date: 30 June 2023.
6. Provide the final clinical study report that includes for immunogenicity and safety data after the second booster (fourth) dose in subjects 55 years of age and older from Study C4591031 Phase III Substudy E within five working days of the report being produced.
7. Provide the final clinical study report that includes for immunogenicity and safety data after the second booster (fourth) dose in subjects 18 to 54 years of age from Study C4591031 Phase III Substudy D within five working days of the report being produced.
8. Provide interim and final clinical study reports that include immunogenicity and safety data after the first booster (third) dose of in subjects 12 to 17 years of age from Study C4591031 Phase III Substudy C within five working days of the reports being produced.
9. Provide the final clinical study report that includes safety data after the first booster (third) dose in subjects 12 to 17 years of age from Study C4591031 Phase III Substudy B within five working days of the report being produced.
10. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
11. Provide any safety reports and safety reviews conducted or they 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 Original/Omicron BA.4-5**
Active Ingredients:	Famtozinameran 0.05mg/mL Tozinameran 0.05mg/mL
Dosage Form:	Suspension for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgium Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany Baxter Oncology GmbH, Westfalen, Germany Patheon Italia S.p.A, Milan, Italy BioNTech Manufacturing Marburg GmbH, Marburg, Germany Mibe GmbH Arzneimittel, Brehna, Germany Allergopharma GmbH & Co. KG, Reinbek, Germany

Provisional consent is granted for two years from 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 intended for the New Zealand market, 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 the acceptance criteria for RNA ratio in the finished product specifications. Due date: 30 June 2023.
5. Provide the final clinical study report that includes for immunogenicity and safety data after the second booster (fourth) dose in subjects 55 years of age and older from Study C4591031 Phase III Substudy E within five working days of the report being produced.
6. Provide the final clinical study report that includes for immunogenicity and safety data after the second booster (fourth) dose in subjects 18 to 54 years of age from Study C4591031 Phase III Substudy D within five working days of the report being produced.
7. Provide interim and final clinical study reports that include immunogenicity and safety data after the first booster (third) dose of in subjects 12 to 17 years of age from Study C4591031 Phase III Substudy C within five working days of the reports being produced.
8. Provide the final clinical study report that includes safety data after the first booster (third) dose in subjects 12 to 17 years of age from Study C4591031 Phase III Substudy B within five working days of the report being produced.
9. Provide the final clinical study report that includes safety and immunogenicity data for Cohorts 2 and 3 through 6 months after a booster dose in subjects 12 years of age and older from Study C4591044 Phase II within five working days of the report being produced.
10. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
11. Provide any safety reports and safety reviews conducted or they 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.

Dated this 1st day of November 2023.

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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