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

Product:	**Comirnaty**
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, 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**
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, Belgium Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany Baxter Oncology GmbH, Halle-Kunsebeck 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

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 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:	**NUVAXOVID**
Active Ingredient:	SARS-CoV-2 rs 10mcg/mL
Dosage Form:	Suspension for injection
New Zealand Sponsor:	Biocelect New Zealand Limited
Manufacturer:	Serum Institute of India Pvt Limited, Pune, India

Provisional consent is granted until 4 November 2022.

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 (the reference numbers have been retained from the original provisional consent conditions as per *New Zealand Gazette*, 4 February 2022, Notice No. 2022-go330):

2. Only batches that have been released for supply by an approved finished product manufacturing or testing site may be supplied in New Zealand.
3. 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.

5. 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.

31. Provide updated specifications for non-compendial raw materials used in the manufacture of drug substance at SIIPL that include an identity test method. Due date: 30 June 2022.

34. Characterise the glycosylation profile for the next 10 drug substances batches manufactured at SIIPL and provide an evaluation of the need for any further monitoring or control of the glycosylation profile. Due date: 30 June 2022.
35. Develop a host cell protein (HCP) ELISA assay to better control HCP impurities in the drug substance. Once a suitable assay is qualified, it should be implemented to demonstrate in-process HCP clearance. Due date: 30 June 2022.
36. Screen the most abundant host cell protein/host virus proteins present at > 0.5% of total protein for an overlap in epitopes with human proteins and provide the results. Due date: 30 June 2022.
37. Update the procedure for screening for infectious baculovirus to confirm the titre of the positive control and to include a positive control generated by spiking into a test sample. Due date: 30 June 2022.
38. Provide a re-evaluation of the drug substance and finished product total protein specification limits after the statistical analysis of 30 commercial scale lots and implement a shelf-life specification for purity of active substance using SDS-PAGE. Due date: 30 June 2022.
39. Develop an HPSEC-MALS method intended to provide a qualitative assessment of the various structures present in the drug substance. Due date: 30 June 2022.
40. Develop a purity test for finished product using SDS-PAGE and establish a release and shelf-life purity specification. Due date: 30 June 2022.
41. Revise the Matrix-A and Matrix-C specifications and implement the same acceptance limits at release and shelf-life, unless otherwise justified. Due date: 30 June 2022.
42. Provide a justification for the absence of testing PS80 content in the finished product with regards to quality, safety and efficacy across its shelf life, including any possible effects on particulate formation. Due date: 31 July 2022.
43. Provide saponin integrity characterization data for finished product lots collected at release and during stability assessment until there is data for a sufficient number of batches (i.e. n= 30) at commercial scale, covering all sites of antigen and Matrix production. Due date: 31 July 2022.
44. Provide characterisation data for adjuvant ingredients (Matrix-A and Matrix-C) manufactured at full-scale. Due date: 31 July 2022.
45. Provide data to bridge the reference standards used during product development and review the finished product potency limits. Due date: 31 July 2022.
46. Inform Medsafe of any results arising during the ongoing product container leachables study that indicate unsuitability and provide the final study report. Due date: 30 September 2022.
47. Include mean particle size and polydispersity index by dynamic light scattering in the drug substance and finished product release and stability specifications. Due date: 30 September 2022.
48. Develop a CE-SDS method and provide identification of the peaks in the final electropherogram, including a discussion of the data and final confirmation of the molecular weights. Upon completion of successful method development and validation, implement justified acceptance criteria for drug substance and finished product release and stability testing. Due date: 31 December 2022.
49. Provide the final report for non-clinical study NVX 702-115. Due date: 30 September 2022.
50. Provide final report for non-clinical study NVX 702-087 within five working days of them being produced.

52. Provide further efficacy and safety data from the pivotal clinical studies, including the crossover parts of the studies, within five working days of reports being produced.
53. Provide any reports on the requirement for and timing of booster doses within five working days of these being produced

56. Investigate the ability of the vaccine to neutralise existing and emerging SARS-CoV-2 variants and provide associated reports within five working days of these being produced.
57. 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.
58. Provide the final reports for clinical studies 2019nCoV-301 and 2019nCoV-302. Final reports to be provided within five working days of being produced.
59. Provide the final report for the ICMR/SII Covovax clinical study within five working days of being produced.
60. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
61. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.
62. 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.

Note: This consent relates to the application received 28 February 2022 for administration of a homologous booster dose and the application received 11 March 2022 for administration of a heterologous booster dose.

Dated this 17th day of June 2022.

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

2022-go2431 17-06-2022 12:00