MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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28 November 2023

s 9(2)(a)

Ref: H2023032720

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 2 November 2023. You requested:

1. *Please provide copies of all advice and decisions relevant to the decisions referred to in gazette notice 2023-go5029 published last Friday. https://gazette.govt.nz/notice/id/2023-go5029*

2. *Please also provide information to show why 3 November was chosen as the expiry date and any communications with outgoing and/ or prospective incoming Ministers / government.*

3. *Please also provide any information to show intentions for each current and/ or proposed version of the PfizerVax and other COVID vaccines after 3 November 2023.*

One document has been identified within scope of this part of your request and is appended to this letter. This decision memo was provided to me as the Minister's delegate.
Some information has been withheld under the following sections of the Act:

- 9(2)(a) to protect the privacy of natural persons;
- 9(2)(ba)(i) to protect information which is subject to an obligation of confidence where the making available of the information would be likely otherwise to damage the public interest; and
- 9(2)(g)(ii) maintain the effective conduct of public affairs through the protection of employees from improper pressure or harassment.

Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

In response to part 3 of your request, please refer to the Medsafe's recommendation subheading on pages 5-6.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Memo

Date:	31 October 2023
To:	Chris James, Group Manager, Medsafe
From:	s 9(2)(g)(ii) Manager, Product Regulation, Medsafe
Subject:	Pfizer New Zealand Limited's application for renewal of provisional consent for **Comirnaty vaccines** – decision required under section 23(4A) of the Medicines Act 1981.
For your:	Action and Decision

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Purpose

This memo seeks your decision under section 23(4A) of the Medicines Act 1981 (the Act) on whether to renew provisional consent to the sale or supply or use of the medicines listed below and if so, on what conditions (if any) and for what period of time. The Minister of Health's (Minister) decision-making under section 23 of the Act has previously been delegated to you.[1]

- Comirnaty (purple cap) concentrate for injection 30 µg/30 mL (TT50-10853) (**Comirnaty purple cap**)
- Comirnaty (grey cap) suspension for injection 30 µg/30 mL (TT50-10853/1) (**Comirnaty grey cap**)
- Comirnaty (orange cap) concentrate for injection 10 µg/20 mL (TT50-10853/1a) (**Comirnaty orange cap**)
- Comirnaty (maroon cap) concentrate for injection 3 µg/20 mL (TT50-10853/1b) (**Comirnaty maroon cap**)
- Comirnaty Original/Omicron BA.1 suspension for injection 15/15 µg/30 mL (TT50-11081) (**Comirnaty BA.1**)
- Comirnaty Original/Omicron BA.4-5 suspension for injection 15/15 µg/30 mL (TT50-11095) (**Comirnaty BA.4-5**)

Statutory framework

Under section 23(4A) of the Act, you may, in your capacity as the Minister's delegate, renew any provisional consent previously given under section 23(1) of the Act.

The Act does not specify a process for a decision to renew under section 23(4A). The Act also does not expressly state criteria that you must take into account when considering a decision to renew under section 23(4A). However, when considering whether or not to renew a provisional consent under section 23(4A) it is appropriate to apply similar criteria that must be taken into account before provisional consent can be given under section 23(1). Therefore, you should:

(a) consider any further particulars and information relating to the medicine submitted by the sponsor since the provisional consent was given, as well as any other matters that appear to you to be relevant;

[1] Delegation made by the Minister of Health 11 September 2013 under section 28 of the State Sector Act 1988; and sub-delegated by Director-General of Health on 20 September 2013 under section 41 of the State Sector Act 1988.

(b) weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person; and

(c) consider whether it remains desirable that the medicine be sold, supplied or used.

Desirable

Section 23 provides no explicit guidance on the circumstances when it would be desirable for a medicine to be provisionally consented (or renewed). However, the legislative history of section 23 indicates that it is desirable to give provisional consent to a medicine:[2]

(a) where limits on the available information mean that a full consent process under section 20 of the Act is not feasible;

(b) there is an identified public health need for the medicine; and

(c) you are satisfied that the assessment of therapeutic benefits and risks supports New Zealanders having timely access to the medicine.

Conditions

On giving (or renewing) provisional consent, you may impose conditions as you see fit.[3] These can be:

(a) conditions relating to the persons to whom the medicine may be sold or supplied;

(b) conditions relating to the area in which the medicine may be distributed; or

(c) any other conditions (provided such other conditions are not inconsistent with the purpose of section 23 of the Act).[4]

Time limited

A provisional consent may be renewed for a period not exceeding two years on any one occasion.[5] You have discretion to renew a provisional consent for a period shorter than two years. Provisional consents may be renewed more than once.

If a full consent under section 20 is granted during the currency of a provisional consent, the provisional consent is deemed to be revoked.[6] In other words, if you decided to grant or renew a provisional consent for two years, that would not preclude a full consent being given under section 20 before the expiry of the two years.

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2 See in particular the Medicines Amendment Bill, 41-1, explanatory note.

3 Medicines Act 1981, section 23(3) and section 23(4B).

4 There is no explicit purpose statement in section 23. However, the legislative history of section 23 indicates that the purpose of section 23 is to ensure that New Zealanders have timely access to safe and effective medicines where there is a public health need (see the explanatory note in the Medicines Amendment Bill, 41-1).

5 Medicines Act 1981, section 23(4).

6 Medicines Act 1981, section 23(5).

Background

Provisional consent – Comirnaty purple cap

On 3 February 2021, you gave provisional consent to Comirnaty purple cap under section 23 of the Act for a period of nine months with a number of conditions. That provisional consent was for the following indication:

> *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 16 years of age and older.*
>
> *The use of this vaccine should be in accordance with official recommendations.*

On 28 October 2021, you renewed the provisional consent for Comirnaty purple cap under section 23(4A) of the Act for a period of two years with a number of conditions. The renewed provisional consent was for the following indication:

> *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older.*
>
> *The use of this vaccine should be in accordance with official recommendations.*

The provisional consent for Comirnaty purple cap expires on 3 November 2023.

Provisional consent – Comirnaty grey cap and orange cap

On 16 December 2021, you gave provisional consent to Comirnaty grey cap and Comirnaty orange cap under section 23 of the Act for a period expiring on 3 November 2023 with a number of conditions. The provisional consent for Comirnaty grey cap was for the following indication:

> *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older.*
>
> *The use of this vaccine should be in accordance with official recommendations.*

The provisional consent for Comirnaty orange cap was for the following indication:

> *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in children aged 5 to 11 years.*
>
> *The use of this vaccine should be in accordance with official recommendations.*

Provisional consent – Comirnaty maroon cap

On 1 December 2022, you gave provisional consent to Comirnaty maroon cap under section 23 of the Act for a period expiring on 3 November 2023 with a number of conditions. That provisional consent was for the following indication:

> *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in infants and children aged 6 months to 4 years.*

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The use of this vaccine should be in accordance with official recommendations.

Provisional consent – Comirnaty BA.1 and BA.4-5

On 21 December 2022, you gave provisional consent to Comirnaty BA.1 and Comirnaty BA.4-5 under section 23 of the Act for a period expiring on 3 November 2023 with a number of conditions. Those provisional consents were for the following indication:

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Changed medicine notifications

Pfizer New Zealand Limited (Pfizer) has subsequently submitted a number of changed medicine notifications (CMNs) under section 24 of the Act for all of these Comirnaty products. These have largely involved changes to quality aspects of the medicine, such as the introduction of new active ingredient and finished product manufacturing, testing and packing sites, changes to the active ingredient and finished product manufacturing process, changes to the active ingredient and finished product quality control specifications and test methods, changes to the suppliers, manufacture and control of excipients, and changes to the shelf life and storage condition of the vaccine. Most of the CMNs received to date have been assessed by Medsafe, while some remain under evaluation (further detail regarding the CMNs is included in the evaluation reports). Some of the CMNs were referred to you (as the Minister's delegate) under section 24(5). All remaining CMNs were consented by the Director-General's delegate under section 24(3).

If you would like any further information regarding the CMNs that have been assessed to date, the evaluation reports for the CMNs can be provided upon request.

Conditions

To date Pfizer has complied with all conditions imposed by the provisional consents for all Comirnaty products that have fallen due. Please note that it is proposed that the current conditions are retained for renewal given that separate applications for conversion of the provisional consents for these Comirnaty products are currently under evaluation. The status of the conditions is addressed as part of those applications.

Pfizer's application for renewal

On 1 May 2023, Pfizer applied to renew the provisional consents under section 23(4A) of the Act.

Pfizer's application to renew the provisional consents under section 23(4A) has been processed for the indications for each of the Comirnaty products stated above.

Pfizer has also applied to renew the labelling exemptions given under regulation 12(5) of the Medicines Regulations 1984 for each of the Comirnaty products. The application has been approved by the Manager, Product Regulation in accordance with Medsafe's standard processes.

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Decisions required

Provisional consent

You are being asked to decide whether to renew the provisional consents for the Comirnaty products under section 23(4A) of the Act.

If you decide to renew, you will also need to decide:

(a) what conditions (if any) to impose on the provisional consent under section 23(3) of the Act; and

(b) the period of the renewed provisional consent.

If you agree to renew the provisional consent for the sale or supply or use of the Comirnaty products, you will need to sign a consent notice that will be published in the *New Zealand Gazette*. That consent notice, once published, will give effect to your decision to renew provisional consent. A draft *Gazette* notice has been prepared and is attached in Appendix Two for your consideration.

Medsafe's recommendation

Comirnaty COVID-19 vaccines were developed in response to the global pandemic of the SARS-CoV-2 virus that causes COVID-19. Given the rapid development of Comirnaty COVID-19 vaccine and continued up-scaling of the manufacturing process in order to meet this public health need, there was some data not yet available when the original and renewed provisional consent were previously given.

Since provisional consent was granted, Pfizer has provided further data to Medsafe, much of which has been given in accordance with a condition of the applicable provisional consent. This information has helped to further characterise and validate the manufacturing process and quality of the medicine, particularly as manufacturing continues to be scaled up to meet global demand. Of particular note, additional information has included further follow up data from the phase three clinical trials.

Pfizer has also made an application to convert the original (tozinameran) versions of Comirnaty (TT50-10853, /1, /1a, /1b) from provisional to full consent. Medsafe's evaluation of the conversion application includes a full review of the status of all conditions for these vaccines. s 9(2)(ba)(i) [redacted]

Decision memos regarding these applications will be provided to you in the coming weeks.

While the abovementioned applications are underway, it is proposed that the existing provisional consents for Comirnaty products that expire on 3 November 2023 are renewed to allow for them applications to be properly assessed. It is noted that since the granting of provisional consent or renewed provisional consent for these products, there have been no changes to the safety signals observed through post-market pharmacovigilance monitoring and as such it is considered that the benefit-risk profile remains the same.

Medsafe recommends that provisional consent for Comirnaty products be renewed for the following reasons:

a) COVID-19 is an infectious disease caused by the SARS-CoV-2 virus that can cause severe acute respiratory syndrome and death. The COVID-19

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pandemic has and continues to be associated with substantial disease burden globally and in New Zealand.

b) The availability of COVID-19 vaccines is important to protect the health of New Zealanders in light of the risk of serious health consequences requiring hospitalisation, sometimes resulting in death, posed by COVID-19.

c) No new significant safety signals have been observed through post-market monitoring that have adversely changed the benefit-risk profile of any of the Comirnaty products.

d) Notwithstanding the reported side effects, in light of the ongoing risk posed by COVID-19 and the evidence Comirnaty vaccines are effective at preventing COVID-19 it is desirable to renew the provisional consent for Comirnaty COVID-19 vaccine while applications for conversion to full consent under section 20 of the Act for these products are under evaluation.

If the provisional consent is renewed:

(a) We recommend that this consent be for a period of two years. This is maximum allowable time period for a provisional consent, and it is considered that there is no reason not to impose a shorter duration. This will give ample time to properly assess and provide recommendations regarding the ongoing applications for conversion to full consent under section 20 of the Act.

(b) We recommend imposing the conditions set out in the attached *Gazette* notice. These are the same conditions current imposed on the existing provisional consents. No changes are proposed at this time given that the status of the conditions will be fully reviewed as part of the assessment of the applications for conversion to full consent under section 20 of the Act.

In summary, Medsafe recommends you renew the provisional consents for the Comirnaty purple cap, grey cap, orange cap, maroon cap, BA.1 and BA.4-5 under section 23(4A) of the Act for two years with conditions imposed on those consents (the conditions are set out in the draft *Gazette* Notice attached as Appendix Two).

Recommendations
It is recommended that you:

1.	Agree	the likely therapeutic value of Comirnaty purple cap outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 12 years or older.	Yes/~~No~~
2.	Agree	it is desirable for Comirnaty purple cap to continue to be sold, supplied or used in New Zealand.	Yes/~~No~~
3.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty (purple cap) concentrate for injection 30 µg/30 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes/~~No~~

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4.	Agree	the likely therapeutic value of Comirnaty grey cap outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 12 years or older.	Yes~~/No~~
5.	Agree	it is desirable for Comirnaty grey cap to continue to be sold, supplied or used in New Zealand.	Yes~~/No~~
6.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty (grey cap) concentrate for injection 30 µg/30 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes~~/No~~
7.	Agree	the likely therapeutic value of Comirnaty orange cap outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 5 to 11 years.	Yes~~/No~~
8.	Agree	it is desirable for Comirnaty orange cap to continue to be sold, supplied or used in New Zealand.	Yes~~/No~~
9.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty (orange cap) concentrate for injection 10 µg/20 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes~~/No~~
10.	Agree	the likely therapeutic value of Comirnaty maroon cap outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 6 months 4 years.	Yes~~/No~~
11.	Agree	it is desirable for Comirnaty maroon cap to continue to be sold, supplied or used in New Zealand.	Yes~~/No~~
12.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty (maroon cap) concentrate for injection 3 µg/20 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes~~/No~~
13.	Agree	the likely therapeutic value of Comirnaty BA.1 outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 12 years or older.	Yes~~/No~~
14.	Agree	it is desirable for Comirnaty BA.1 to continue to be sold, supplied or used in New Zealand.	Yes~~/No~~

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15.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty Original/Omicron BA.1 suspension for injection 15/15 µg/30 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes~~/No~~
13.	Agree	the likely therapeutic value of Comirnaty BA.4-5 outweighs any potential risk of the vaccine injuriously affecting the health of any person aged 12 years or older.	Yes~~/No~~
14.	Agree	it is desirable for Comirnaty BA.4-5 to continue to be sold, supplied or used in New Zealand.	Yes~~/No~~
15.	Agree	to renew provisional consent for the sale or supply or use of Comirnaty Original/Omicron BA.4-5 suspension for injection 15/15 µg/30 mL under section 23(4A) of the Act, with such consent to have effect for two years from the date of publication of the relevant *Gazette* notice subject to the conditions set out in the draft *Gazette* notice (attached at Appendix One).	Yes~~/No~~
16.	Sign	the draft *Gazette* notice, which, when published will give effect to your decision to renew provisional consents to the sale or supply or use of Comirnaty vaccines (attached as Appendix One).	Yes/~~No~~
17.	Sign	the attached letter to the sponsor informing them of your decision to renew the provisional consents for Comirnaty vaccines for a period of two years (attached as Appendix Two).	Yes/~~No~~

Signature s 9(2)(a) Date: 31 Oct 2023

s 9(2)(g)(ii)

Manager, Product Regulation Branch, Medsafe

I am satisfied, for the reasons set out in this memo, that it is desirable that Comirnaty vaccines continue to be able to be sold, supplied and used in New Zealand.

Signature _____ Date: 01 Nov 2023

Chris James
Group Manager
Medsafe

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