133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

03 August 2021

Andy Hooley

By email: fyi-request-15555-c25afc8b@requests.fyi.org.nz
Ref: H202106403

Dear Andy Hooley

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 25 May 2021 for:

> *"Can you please provide all communications from this government that have been directed to and received from any representative from the company called Pfizer in relation to the Comirnaty vaccine or with any connection to the covid19 virus in the period 01/01/18 to present day 25/05/21."*

On 2 June 2021 you refined your request, by narrowing the timeframe to:

> *"1 October 2020 to 7 April 2021."*

As this scope is still too large, we will release the information in two tranches. The first tranche is for all communications with Pfizer for October, November, and December 2020.

Twenty documents have been identified within scope of your request. These are itemised in Appendix 1 to this letter, and copies of the documents are enclosed. The table in Appendix 1 also outlines the grounds under which I have decided to withhold information. Where information is withheld, this is noted in the document itself. Information deemed out of scope of your request has also been excluded.

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 Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Derek Fitzgerald
Acting Group Manager
Medsafe

Appendix 1: List of documents.

#	Date	Title	Decision on release
1	15 October 2020 - 23 December 2020	Email correspondence between Ministry of Health and Pfizer #1	Released with some information withheld under the following sections of the Act: • 9(2)(a) to protect the privacy of natural persons; and • 9(2)(g)(ii) to protect Ministers, members of organisations, officers, and employees from improper pressure or harassment.
2	10 December 2020	Email correspondence between Ministry of Health and Pfizer #2	Withheld in full under section 9(2)(b)(ii) of the Act, where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.
3	18 December 2020 – 21 December 2020	Email correspondence between Ministry of Health and Pfizer #3	Released with some information withheld under the following sections of the Act: • 9(2)(a) • 9(2)(b)(ii) • 9(2)(g)(ii); and • 9(2)(k) to prevent the disclosure or use of official information for improper gain or advantage.
4	16 December 2020	Email correspondence between Ministry of Health and Pfizer #4	Withheld in full under section 9(2)(b)(ii), of the Act.
5	Unknown	Email correspondence between Ministry of Health and Pfizer #5	
6	01 December 2020	US EUA application	
7	03 December 2020	Label #1	Released with some information withheld under section 9(2)(k), of the act.
8	03 December 2020	Label #2	
9	03 December 2020	Label #3	
10	03 December 2020	Label #4	
11	03 December 2020	Label #5	
12	03 December 2020	Pfizer presentation #1	
13	10 November 2020	Medsafe-Pfizer meeting notes #1	Released with some information withheld under section 9(2)(g)(ii), of the Act.

#	Date	Title	Decision on release
14	10 December 2020	TGA non-clinical questions	Withheld in full under section 9(2)(b)(ii) of the Act.
15	11 November 2020	Pfizer presentation #2	
16	11 December 2020	Medsafe-TGA-Pfizer meeting notes	Withheld in full under section 6(b)(i) as its release would prejudice information entrusted to the Government of New Zealand from another Government or agency.
17	15 October 2020	Medsafe-Pfizer meeting notes #2	Released in full.
18	15 October 2020	Module 1.7.2	Released in full.
19	15 October 2020	Pfizer presentation #3	Released in full.
20	18 November 2020	Letter to Pfizer	Released with some information withheld under the following sections of the Act: • 9(2)(a); and • 9(2)(g)(ii).

Sent by: s 9(2)(a)
15/10/2020 11:23 am

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer COVID-19 Vaccine Pre-submission Meeting Briefing Document

Dear s 9(2)(g)(ii)

Thank you for providing Medsafe's responses to the questions raised by Pfizer during our pre-submission meeting in relation to the proposed COVID-19 vaccine. Please find attached;

1. A record of the discussion at the pre-submission meeting between Medsafe and Pfizer
2. An 'Additional Data' document that outlines what supporting documentation will be provided after the initial COVID-19 vaccine filing
3. A slide that outlines details of shipping, storage, preparation and administration of the proposed vaccine.

Please advise if you have any questions regarding any of the content.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

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From: s 9(2)(g)(ii) [redacted]
Sent: Wednesday, 14 October 2020 2:27 PM
To: s 9(2)(a) [redacted]
Cc: s 9(2)(a) [redacted]
Subject: [EXTERNAL] RE: Pfizer COVID-19 Vaccine Pre-submission Meeting Briefing Document

Dear s 9(2)(a) [redacted],

Medsafe's answer attached as Module 1.7.2, Medsafe-Pfizer meeting notes #2, and Pfizer presentation #3.

Please find attached Medsafe's answers to the questions raised in your COVID-19 vaccine pre-submission briefing.

I hope this information is helpful and please let me know if you have any further questions. We looking forward to hearing more about Pfizer's submission plans.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Out of scope
Out of scope

Sent by: s 9(2)(g)(ii)

29/10/2020 12:26 pm

To: s 9(2)(a)
cc: s 9(2)(a), s 9(2)(g)(ii)
bcc:

Subject: Application Received: COVID-19 Vaccine, NMA (Provisional Consent Section 23) submission

From: s 9(2)(g)(ii)
Sent: Wednesday, October 28, 2020 11:26:25 PM
To: s 9(2)(a)
Cc: s 9(2)(a), s 9(2)(g)(ii)
Subject: Application Received: COVID-19 Vaccine, NMA (Provisional Consent Section 23) submission

Dear s 9(2)(a)

This email acknowledges receipt of your NMA submission letter dated 21 October 2020 that was received via Medsafe's EFT system for:

- COVID-19 Vaccine, Injection, concentrate 30µg/0.3mL Pfizer (Not yet classified).

Your submission has been assigned to the screening queue. The acknowledgement letter and invoice for this application can be expected within 10 business days if all the information has been provided.
The evaluator will contact you if they require more information during screening.

Kind regards
s 9(2)(g)(ii)

s 9(2)(g)(ii) | He/Him | Assistant Advisor | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

IMPORTANT NOTICE:
Please visit the Medsafe website for regular updates and more information on how to register with our Electronic File Transfer system (EFT):
https://www.medsafe.govt.nz/Medicines/policy-statements/SubmittingApplicationsElectronically.asp.

image001.png

Sent by: s 9(2)(g)(ii)
09/11/2020 03:14 pm

To: s 9(2)(a)
cc:
bcc:

Subject: COVID-19 Vaccine (Pfizer) NMA screening

From: s 9(2)(g)(ii)
Sent: Monday, November 9, 2020 2:14:13 AM
To: s 9(2)(a)
Subject: COVID-19 Vaccine (Pfizer) NMA screening

Dear s 9(2)(a)

Screening of the NMA for Pfizer's COVID-19 vaccine has been completed. However, before it can be accepted one administrative change is required.

This NMA has been submitted for consideration for provisional consent under section 23 of the Medicines Act 1981. I understand that this is in response to our previous guidance that any initial approvals granted to these vaccines are likely to be provisional in accordance with section 23. While this remains true, Medsafe has since decided that all NMAs for COVID-19 vaccines are to be submitted via the standard application pathway and it will be determined during the evaluation process whether it is most appropriate to grant consent under section 20 or section 23. This affords Medsafe greater flexibility, which is required to properly assess these applications given their rolling nature, the ongoing status of the clinical development programme and the constant evolution of the supply situation.

To this end, please revise the cover letter and NMA form accordingly, amending the application category and calculated fee specifically, and resubmit. Please note that the rest of the submission is considered acceptable and does not require revision or resubmission.

Please let me know if you have any questions, and we are happy to discuss further during our meeting tomorrow.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Sent by: s 9(2)(a)

10/11/2020 07:46 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(g)(ii)

Meeting notes attached as Medsafe-Pfizer meeting notes #1.

Pfizer wishes to thank the Medsafe team for their time and collaboration at today's meeting. The very fruitful discussions have been summarised in the attached meeting notes. Please let me know if you believe that anything has not been captured appropriately or accurately.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

Pfizer | Breakthroughs that change patients' lives

 - COVID-19 Vaccine_10Nov2020_Meeting Notes_Pfizer-Medsafe.pdf  - put-in-cabinet-data.json

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Sent by: s 9(2)(a)

10/11/2020 12:42 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Medsafe-Pfizer meeting

Dear s 9(2)(g)(ii),

I am pleased to hear that you found this morning's meeting beneficial. We are grateful for your availability to discuss Pfizer's proposals around the provision of the Module 3 components.

As was mentioned at our meeting, the first roll of Module 3 data is planned to be submitted on 13 Nov 2020 and the final roll of Mod 3 data is expected to be available in Q1 (Jan/Feb) 2020. This is the same proposal that has been agreed to with the Australian TGA.

We will be sending a written summary of today's meeting for your information and records, as soon as it has been finalised. Do not hesitate to send through any additional questions you might have.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

From: s 9(2)(g)(ii) [redacted]
Sent: Tuesday, 10 November 2020 10:04 AM
To: s 9(2)(a) [redacted]
Subject: [EXTERNAL] Medsafe-Pfizer meeting

Dear s 9(2)(a) [redacted]

Thanks again for the meeting this morning, it was a very useful update. I've just got two requests to follow up with:

- Can you please provide something in writing to confirm the new proposal for submission dates? This is to update others in the Ministry/government on the regulatory process.
- Can you please confirm whether the same submission plan for CMC data is intended for Australia?

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

- put-in-cabinet-data.json

Sent by: s 9(2)(a)
11/11/2020 03:59 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(g)(ii)

Pfizer slide deck attached as Pfizer presentation #2.

Further to my e-mail yesterday, please find attached the Pfizer slide deck that was requested during the meeting.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

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or any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you are not an addressee, please inform the sender immediately. Pfizer Australia has its registered office at Level 15-18, 151 Clarence Street, Sydney, NSW, 2000

From: s 9(2)(a)
Sent: Tuesday, 10 November 2020 5:46 PM
To: s 9(2)(g)(ii)
Cc: s 9(2)(a)
Subject: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(g)(ii)

Pfizer wishes to thank the Medsafe team for their time and collaboration at today's meeting. The very fruitful discussions have been summarised in the attached meeting notes. Please let me know if you believe that anything has not been captured appropriately or accurately.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

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 - COVID-19_Vaccine_Medsafe_Meeting_CMC_Rolls_Strategy_Nov2020_Final.pptx  - put-in-cabinet-data.json

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Sent by: s 9(2)(a)

To: s 9(2)(a)
cc: s 9(2)(a)
bcc:

18/11/2020 02:35 pm

Subject: COVID-19 Vaccine (Pfizer), TT50-10853, NMA 13 Nov 2020, App ID 109400

From: s 9(2)(g)(ii)
Sent: Wednesday, November 18, 2020 1:35:23 AM
To: s 9(2)(a)
Cc: s 9(2)(a)
Subject: COVID-19 Vaccine (Pfizer), TT50-10853, NMA 13 Nov 2020, App ID 109400

Dear Sir/Madam,

Acknowledgment letter attached as Letter to Pfizer.

Please find attached the acknowledgement letter and invoice for the above mentioned application.

As the applicant it is your responsibility to ensure that payment for this invoice is made. Please ensure you monitor the status of your application through the Product/Application Search on the Medsafe website and follow up with your finance department if payment is not made by the required date.

Please visit the Medsafe website indicative evaluation timeframes: https://medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp
Please ensure you are using the latest application forms when submitting applications, all of which are available on the Medsafe website: https://www.medsafe.govt.nz/regulatory/forms.asp

Kind regards

s 9(2)(g)(ii)

s 9(2)(g)(ii) | He/Him | Assistant Advisor | Product Regulation | Medsafe | Ministry of Health |
s 9(2)(g)(ii)

IMPORTANT NOTICES:

- Medsafe Office Closure Christmas/New Year 2020/2021 (https://www.medsafe.govt.nz/other/christmas.asp)
- Please visit the Medsafe website for regular updates and more information on how to register with our Electronic File Transfer system (EFT):

https://www.medsafe.govt.nz/Medicines/policy-statements/SubmittingApplicationsElectronically.asp.

739135.pdf

Sent by: s 9(2)(a)

26/11/2020 05:57 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(g)(ii)

At this stage, there have been no assessment reports issued by EMA, MHRA or Swissmedic. We would be happy to provide such reports as they become available. We look forward to speaking with you at our next meeting (time and date to be confirmed)

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level s 9(2)(a)

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unauthorised. If you are not an addressee, any disclosure or copying of the contents of this e-mail or any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you are not an addressee, please inform the sender immediately. Pfizer Australia has its registered office at Level 15-18, 151 Clarence Street, Sydney, NSW, 2000

From: s 9(2)(g)(ii)
Sent: Friday, 13 November 2020 8:23 AM
To: s 9(2)(a)
Subject: [EXTERNAL] RE: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(a)

Thanks very much, this looks accurate to us.

I had one further question. Given that it seems the same dossier submitted in Europe will be provided to Medsafe, would it be possible to provide Medsafe with any assessment reports from the EMA/MHRA/Swissmedic as they become available? At this early, stage we would be particularly interested in any non-clinical assessment report that may have been produced.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

From: s 9(2)(a) [redacted]
Sent: Tuesday, 10 November 2020 7:46 pm
To: s 9(2)(g)(ii) [redacted]
Cc: s 9(2)(a) [redacted]
Subject: Pfizer_COVID-19 Vaccine_Meeting Notes

Dear s 9(2)(g)(ii) [redacted]

Pfizer wishes to thank the Medsafe team for their time and collaboration at today's meeting. The very fruitful discussions have been summarised in the attached meeting notes. Please let me know if you believe that anything has not been captured appropriately or accurately.

Kind regards,

s 9(2)(a) [redacted] Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a) [redacted]

 - put-in-cabinet-data.json

Sent by: s 9(2)(a)

01/12/2020 12:35 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a), s 9(2)(g)(ii)
bcc:
Subject: PLACEHOLDER - Pfizer - COVID-19 Vaccine Logistics Issues [SEC=OFFICIAL]

Thank you very much, s 9(2)(g)(ii), for organising these joint agency meetings between Pfizer, the TGA and Medsafe. We look forward to productive discussions.

Dear s 9(2)(g)(ii)

Ahead of our meeting to discuss our planned upcoming data rolls this Friday, we wish to share with you the application for emergency use authorization (EUA) containing the final efficacy analysis (164 cases) of Phase 2/3 Study, C4591001 which was submitted to the FDA recently.

Please do not hesitate to contact myself or s 9(2)(a) should you have any questions, otherwise, we will speak with you later this week.

Kind regards,

s 9(2)(a)

s 9(2)(a) **| Senior Regulatory Affairs Associate | Global Regulatory Affairs - International**

Pfizer Australia, Level 15-18, 151 Clarence Street, Sydney NSW 2000 | s 9(2)(a)

Sent by: s 9(2)(a)
03/12/2020 10:47 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a), s 9(2)(g)(ii)
bcc:

Subject: Pfizer COVID-19 Vaccine Supply, Storage, Preparation and Administration

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Dear s 9(2)(g)(ii)

Slide deck attached as Label #1, Label #2, Label #3, Label #4, Label #5 and Pfizer presentation #1.

Please find attached a slide deck that should provide a useful summary of how Pfizer's COVID-19 Vaccine is proposed to be supplied, stored, prepared and administered. These and other related issues will be covered during our meeting, together with TGA representatives, on 9 December.

If you have any questions about the attached slides, please let me know.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

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- Pfizer COVID Stepwise Vaccination Process Nov 2020 FINAL APPROVED Aust.pptx - put-in-cabinet-data.json

Sent by: s 9(2)(a)

03/12/2020 07:08 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a), s 9(2)(g)(ii)
bcc:

Subject: Pfizer_COVID-19 Vaccine: Latest EU Artwork

Dear s 9(2)(g)(ii)

Please find attached, the latest EU labels for Pfizer's COVID-19 vaccine, as requested. Sorry I could not get them to you any earlier.

Please note that:

- The labels are provided in versions with and without varnish overlays.
- The proposed tradename has been added to the labels, however, we cannot advise at this stage, whether initial ANZ stock will include these labels or will have the "Emergency Use Stock" labels.

s 9(2)(g)(ii), could you kindly share these with the proposed Medsafe attendees, prior to our meeting on Friday 1 pm (NZ time).

Please let me know if you haver any questions about these. We look forward to our discussions with you.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Sent by: s 9(2)(a)

10/12/2020 07:59 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer COVID-19 vaccine - next CMC roll

Dear s 9(2)(g)(ii),

Indeed, our recent discussion have been very beneficial and we are grateful for your flexibility and availability to join these.

By now, you should have the next roll of COVID-19 data which includes updates to M 2, 3, 4 & 5 (including the final efficacy analysis of the pivotal study). This was sent by EFT today. The EUA filed in the USA was sent to you on 1 Dec 2020. Please let me know if you do not have this.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

From: s 9(2)(g)(ii) [redacted]
Sent: Wednesday, 9 December 2020 11:51 AM
To: s 9(2)(a) [redacted]
Subject: [EXTERNAL] Pfizer COVID-19 vaccine - next CMC roll

Dear s 9(2)(a) [redacted]

Thanks very much for the joint meetings over the last week, they've been very helpful.

Following up on the discussion at the meeting on Friday, I just wanted to confirm that Medsafe would like to receive the second CMC data roll (i.e. the consolidated EU MAA) as soon as it is possible to submit. If it is also possible to provide the EUA application package, this would also be useful, but would not be considered part of the formal application.

If you can confirm that this is still an option, and if so, what the timelines will be, that would be much appreciated.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

- put-in-cabinet-data.json

Sent by: s 9(2)(a)
11/12/2020 10:39 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: COVID-19 Vaccine Meeting_Pfizer_TGA_Medsafe_4Dec2020

Dear s 9(2)(g)(ii),

I would like to express our gratitude and appreciation for the opportunity to speak to the TGA and Medsafe together, regarding the latest data developments with Pfizer's COVID-19 vaccine. We found this meeting most beneficial and insightful, and are available for more such meetings, if required.

Pfizer notes withheld in full under section 6(b)(i) of the Act.

Please find attached, Pfizer's notes from the joint agency meeting to share with your colleagues. Please advise if any of the points appear incorrect or in any way inaccurate.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

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- COVID-19 Meeting_TGA&Medsafe-4Dec.pdf - put-in-cabinet-data.json

Sent by: s 9(2)(g)(ii)
16/12/2020 03:45 pm

To: s 9(2)(a)
cc:
bcc:
Subject: COVID-19 Vaccine Meeting_Pfizer_TGA_Medsafe_4Dec2020

Dear s 9(2)(a)

Thank you very much for providing this summary, it appears to be an accurate description of what was discussed.

Following receipt of the most recent data submission, can you please confirm for me the following:

- That there is not further clinical data to be submitted before a 6 month safety analysis in March 2021.
- When an RMP will be available to submit to Medsafe? If it is available now, are you able to provide this?

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

Sent by: s 9(2)(a)

18/12/2020 10:41 am

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: COVID-19 Vaccine_Pfizer

Dear s 9(2)(g)(ii),

In relation to our COVID-19 vaccine, Pfizer did not have any clinical data planned for submission other than the scheduled safety analysis at 6 months post-final dose.

Your comment about the RMP prompted a check of the submission components in the filing made on 10 Dec. It appears that most Mod 1 files did not download correctly and so the cover letter, DS, CMI, labels, 1.4 Expert and RMP were all missing from the Mod 1 submitted.

A new Mod 1 folder with the 'missing files' has just been submitted this morning, via EFT. Please accept our apologies for this technical error, which we are currently investigating. If there are any other concerns or questions, do not hesitate to contact me.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

Sent by: s 9(2)(a)

18/12/2020 04:40 pm

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Request for Information on Pfizer's COVID-19 Vaccine

Dear s 9(2)(g)(ii),

Thank you for letting us know about the OIA request for Pfizer's clinical data and for giving us an opportunity to comment before you respond.

We agree with your assessment that the request should be declined on the basis that disclosure of clinical data provided to Medsafe by Pfizer for the COVID-19 vaccine would be likely to unreasonably prejudice Pfizer's commercial position (section 9(2)(b)(ii) of the Act).

The clinical data supplied is commercially sensitive and confidential. It comprises Pfizer's valuable intellectual property generated during the development, manufacture and supply of the vaccine. That information is not currently in the public domain. There is a material risk of prejudice to Pfizer's commercial position were that information to be released.

We understand there is considerable public interest in the vaccine. However, we do not think that any of the clinical data supplied to Medsafe should be disclosed at this time. We note that reliable clinical information necessary to keep the public informed will become publicly available once the vaccine is approved and distributed in New Zealand — including by way of data sheets and consumer medicine information.

We would be grateful if you could let us know if the request goes any further. We are more than happy to provide additional information to support Medsafe's decision if that would be helpful.

Kind regards

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s 9(2)(a)

To: s 9(2)(a)
From: s 9(2)(g)(ii)
Date: Wed, 16 Dec 2020 00:04:24 +0000
Subject: [EXTERNAL] Request for COVID-19 vaccine data

Dear s 9(2)(a)

Medsafe has received a request made under the Official Information Act 1982 for all clinical data provided by Pfizer for the COVID-19 vaccine. We are proposing not to release this data due to its commercially sensitive nature (i.e. section 9(2)(b)(ii) of the Act). Please confirm whether

Pfizer agrees with this approach and provide statement as to why it would be considered commercially sensitive. If Pfizer believes that some or all of the data should be released, please confirm what data and why.

If you could please provide a response by COB Friday 18 December that would be much appreciated.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

[IMAGE]

- image001.png - put-in-cabinet-data.json

Sent by: s 9(2)(a)

23/12/2020 10:56 am

To: s 9(2)(g)(ii)
cc: s 9(2)(a)
bcc:

Subject: Pfizer COVID-19 Vaccine - permission to receive EMA assessment reports

---

Good morning s 9(2)(g)(ii),

I have been advised by my global regulatory colleagues that the request for the EMA assessment report has been passed on to BioNTech, but we have not yet received anything from them and will chase it up again tomorrow. In any case, Pfizer has no objection to the EMA releasing their assessment reports directly to Medsafe.

With respect to your query yesterday about real world data, we are seeking comment from our clinical colleagues, but any such data would not be available until well into 2021 and would need to be derived from a country/region that used the Pfizer vaccine, exclusively.

The EU SmPC and conditional marketing authorisation obligations you requested can be found in Annex I and II, published on the EU Commission website at:

https://ec.europa.eu/health/documents/community-register/2020/20201221150522/anx_150522_en.pdf

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISAT FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a o 726/2004, the MAH shall complete, within the stated timeframe, the following

Description
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.
In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data.
In order to confirm the purity profile and ensure comprehensive quality contro and batch-to-batch consistency throughout the lifecycle of the finished produc the MAH should provide additional information about the synthetic process a control strategy for the excipient ALC-0315.
In order to confirm the purity profile and ensure comprehensive quality contro and batch-to-batch consistency throughout the lifecycle of the finished produc the MAH should provide additional information about the synthetic process a control strategy for the excipient ALC-0159.

Description
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled observer-blind study C4591001.

I trust this is of use to you. Please let me know if you have any other requests in relation to the evaluation of this vaccine.

Kind regards,

s 9(2)(a) Senior Regulatory Affairs Associate, Global Regulatory Affairs - International

Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / Ph: s 9(2)(a)

From: s 9(2)(g)(ii)
Sent: Wednesday, 23 December 2020 8:12 AM
To: s 9(2)(a)
Subject: [EXTERNAL] Pfizer COVID-19 Vaccine - permission to receive EMA assessment reports

Dear s 9(2)(a),

Following from my emails yesterday, we have requested assessment reports directly from the EMA. However, in order for them to provide these to Medsafe, they require Pfizer's permission to do so.

Therefore, can I please ask that Pfizer allow the EMA to release unredacted assessment reports directly to Medsafe?

Alternatively, if you have access to these reports and are able to provide them to us then you can ignore this request.

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii) | Team Leader | Product Regulation | Medsafe | Ministry of Health | s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

 - put-in-cabinet-data.json

From: s 9(2)(g)(ii)
Sent: Friday, 18 December 2020 3:56 pm
To: s 9(2)(a)
Cc: s 9(2)(g)(ii)
Subject: Pre-xmas discussion - Pfizer vaccine timelines

Hi s 9(2)(a) ,

Liz has passed on your details noting Pfizer is keen to have a discussion with MoH regarding timelines around regulatory approval and delivery of the first doses of vaccine.

I have set up a placeholder for a meeting at 10am on Monday. Can you please let me know if this does or doesn't suit and if not I can try to make other arrangements. We will have some people from our immunisation programme team present. The teams link is below:

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting
Or call in (audio only)
9(2)(k) New Zealand, Wellington
Phone Conference ID: 9(2)(k)
Find a local number | Reset PIN

Learn More | Meeting options

Have a great weekend!

Kind regards,

s 9(2)(g)(ii)

s 9(2)(g)(ii)
Principal Policy Analyst, Therapeutics | System Strategy & Policy | Ministry of Health | New Zealand
C: s 9(2)(g)(ii) **| E:** s 9(2)(g)(ii)

From: s 9(2)(g)(ii)
Sent: Monday, 21 December 2020 10:07 am
To: s 9(2)(g)(ii) ; s 9(2)(a)
Subject: PLACEHOLDER: Pfizer timelines meeting
When: Monday, 21 December 2020 10:00 am-11:00 am (UTC+12:00) Auckland, Wellington.
Where: Microsoft Teams Meeting; ROOM WLG GN.2-VC-Display-Semi Public (10)

Pfizer have signalled the following and are seeking a pre-xmas meeting to discuss:

- s 9(2)(b)(ii)
- The TGA is looking like it might provide provisional consent depending on supplementary data being provided
- Pfizer are keen to have an open dialogue on timelines to assist with planning for delivery.

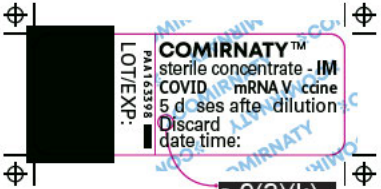
Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting
Or call in (audio only)
9(2)(k) New Zealand, Wellington
Phone Conference ID: 9(2)(k)
Find a local number | Reset PIN

Learn More | Meeting options

date:25-Nov-20 16:44:11

s 9(2)(k)

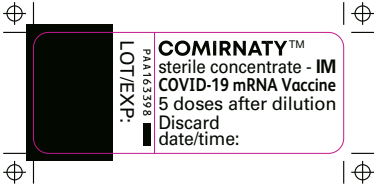


s 9(2)(k)

s 9(2)(k)

date:26-Nov-20 16:24:39

s 9(2)(k)



s 9(2)(k)

COMIRNATY™

Concentrate for solution for injection

COVID-19 mRNA Vaccine

Intramuscular use after dilution

195 multidose vials

(After dilution, each vial contains 5 doses of 0.3 mL.)

torage: Prior t dilution, stor at -90°C to -60°C in the origin l package in order to protec from light. After dilution, store the vaccine at 2°C to 30°C and use within 6 hour . Discard any unused vaccine.

D lute before se: Dilute each v al with 1.8 mL sodium chloride 9 mg/mL (0 9%) solution for injection.

Read e package leaflet before use

Excipients: ALC-0315, ALC-0159, 1,2-distearoyl-sn-glycero-3-phosphocholine, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose, water for injections

BIONTECH | Pfizer

BioNTech Manufacturing GmbH
An der Goldg ube 12
55131 M inz, Germany

Scan QR code for more inf rmation

COMIRNATY™

Co centrate for sol t on for injection

COVID-19 mRNA Vaccine

Intramuscular use af r dilution

195 multidose vials

Prior to dilution, store at -90°C to 60°C.

PAA163397

PC: 04260703260002
Lot/EXP/SN

OVERPRINT AREA

INLINE DM AREA

COMIRNATY™

Concentrate for solution for injection

COVID-19 mRNA Vaccine

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BIONTECH | Pfizer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Scan QR code for more information

COMIRNATY™
Concentrate for solution for injection
COVID-19 mRNA Vaccine
Intramuscular use after dilution
195 multidose vials
Prior to dilution, store at -90°C to -60°C.

PAA163397

PC: 04260703260002
Lot/EXP/SN

OVERPRINT AREA

INLINE DM AREA

30 November 2020

Explanation to EMA about updated labelling for

COMIRNATY

concentrate for solution for injection

(COVID-19 mRNA Vaccine)

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

1 Introduction

The applicant BioNTech would like to inform the EMA about the final updates of the COMIRNATY labelling (box and vial label) in comparison to the last provided versions, dated 4 November 2020.

2 Updates of the box label

- An amendment of the listed excipient names was required to achieve consistency within documents, such as with the SmPC and package leaflet. This applied to the:
  - deletion of “N-ditetradecylacetamide” as this was forgotten to delete from the full wording which is already covered by the abbreviation of the lipid ALC-0159
  - replacement of the lipid name “distearoylphosphatidylcholine” with “1,2-Distearoyl-sn-glycero-3-phosphocholine”
- The original storage wording “Prior to dilution, store at -90°C to 60°C.” was extended to “Prior to dilution, store at -90°C to -60°C in the original package in order to protect from light.” to reflect necessary amendments to other documents, such as the SmPC and package leaflet.
- The following information was inserted at the top of the overprint area: PC: 04260703260002 and Lot/EXP.

  The GTIN has been implemented, which is used as the product code valid in all countries of the European Economic Area. Furthermore, the abbreviations Lot/EXP/SN have been inserted as this area is intended for printing the required information of the batch number and expiry date. Two hyphens will be inserted in lieu of the serialisation number for the initial months of production with the submitted labels. These will be replaced by the serialisation number of each pack as soon as serialisation can be started July 2021.
- s 9(2)(k) [redacted]
- s 9(2)(k) [redacted]
- The logo of the MAH and of the local representative have be changed from coloured to black/white versions, which makes both less prominent.

3 Updates of the vial label

- s 9(2)(k) [redacted]
- [redacted]

COVID-19 Vaccine
Stepwise Vaccination Summary

09.15.2020

Important Disclaimer:

Please Note: The information in this document constitutes confidential information and business secrets of BioNTech and Pfizer. The Australian Government have executed a Confidential Disclosure Agreement 3rd August 2020 to maintain the confidentiality of this information. In addition, the information in this document, including scientific approaches, assumptions regarding potential safety and efficacy, clinical trial and manufacturing plans and timing estimates, are subject to change based on emerging data, regulatory guidance, and technical developments, among other risks.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements (current as of 17th November, 2020).

There may be country specific regulations and considerations in your market.

Product Packaging Overview

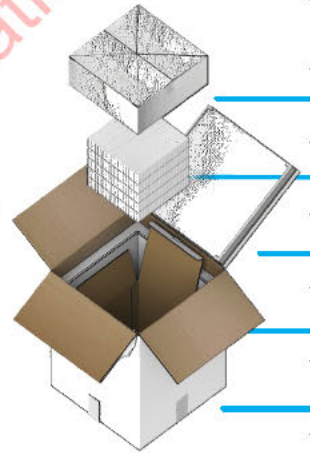
1 Primary Packaging

- 2ml type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45ml frozen liquid drug product
- 5 dose per vial

2 Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 975 doses per tray

3 Tertiary Container: Thermal Shipper



Item	Description
1	Dry Ice Pod
2	Payload (Vial Trays)
3	Inner Lid
4	Payload Sleeve
5	Outer Carton

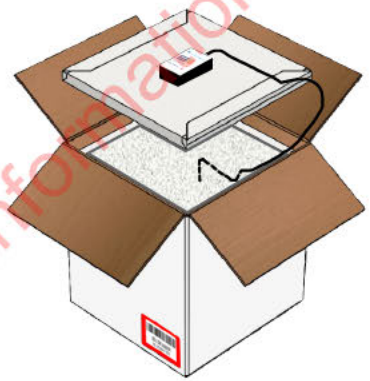
- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15ºC) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

Overview of Direct Shipments to Points of Vaccination

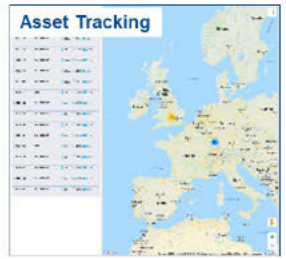
Direct Shipments* to Vaccination Center by Transport Courier

- Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation



Reusable
RTM Logger



- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments.
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Vaccine Storage Options* At the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage up to 6 months.
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

ILLUSTRATIVE ONLY

2 Thermal Shipper Designed for Temporary Storage

- Upon receipt and after opening the thermal shipper, it should be replenished/inspected with dry ice within 24 hours (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Multiple dry ice replenishments possible; up to 3 re-icings.
- Loca dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)

3 2 to 8°C Refrigerator

- Product to be stored at 2 to 8°C refrigerator up to 5 days

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current [illegible]ntly. Current as of September 8, 2020.

Vaccine Preparation and Administration of BNT162b2

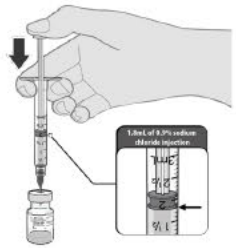
Removing the Vials to Thaw

From storage, **remove 1 vial for every 5 patients** according to planned number of vaccinations per day.

Allow to thaw for approximately 30 minutes at room temperature.

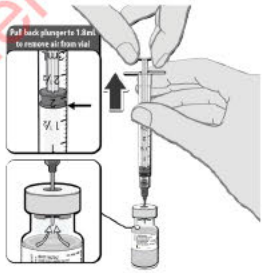
Dilute the Vaccine

Obtain 0.9% Sodium Chloride Injection (normal saline), for use as a diluent Do not use any alternate diluents. Regardless of the volume of the locally sourced diluent vial (2ml, 3ml, 5ml or 10ml), it must be used for ONE TIME dilution.



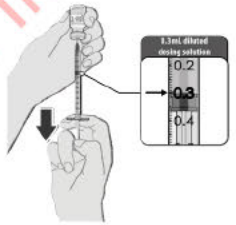
Using aseptic technique, cleanse the vial stopper with a single- use antiseptic swab, then dilute the thawed vial of BNT162b2 by adding **1.8 mL of 0 9% Sodium Chloride Injection (normal saline),** into the vial. Needles 21 gauge or narrower are recommended.

You may feel some pressure in the vial as you add the diluent. Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

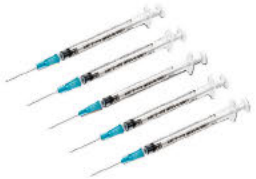


Preparing the Syringes

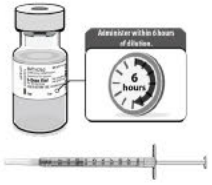
Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab, and **draw up 0.3 mL of the diluted dosing solution** into a new sterile dosing syringe with a needle appropriate for intramuscular injection. Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of dosing solution.



For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.



Vaccine Administration



BNT162b2
30 mcg/0.3 mL

Diluted vials must be used within **6 hours from the time of dilution** and stored between 2°C to 30°C (35°F to 86°F).

A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

21 DAYS

COVID-19 Vaccine Pre-submission Meeting between Pfizer and Medsafe
10 November 2020
Discussion Summary

Issue Raised by	Details
Pfizer	Outlined the proposal to submit the first Mod 3 roll in Mid-Nov (13th) 2020 and the final roll of Mod 3 data in Q1 2021, likely (Jan/Feb). Pfizer welcomed Mod 3 evaluation questions after the first Mod 3 roll, but asked for flexibility on the timing of the responses, in order to enable Pfizer's CMC team to remain focused on preparing and finalising the outstanding Mod 3 components. Pfizer proposed to address evaluation questions after the final Mod 3 roll was filed. Questions that do not require substantial or extensive responses may be answered earlier.
Medsafe	The timing of the Mod 3 documentation and Pfizer's proposed approach to responding to evaluation questions was considered acceptable. Clarity was sought regarding which manufacturing sites would be relevant to New Zealand.
Pfizer	Explained that in order to cope with the amount of testing required to keep up with vaccine demand, multiple testing sites are proposed to be registered. Not all of these will be relevant to New Zealand, but we are currently unable to identify the 'extra' or redundant sites.
Medsafe	At the pre-submission meeting, Pfizer stated that stability studies at 'higher temperatures' would be conducted. Comment was sought on this matter.
Pfizer	Pfizer confirmed that these studies are being undertaken and that these data are included with the first Mod 3 roll.
Medsafe	Asked whether data has been generated to confirm that Pfizer would be able to supply vaccine into NZ, within the proposed storage conditions.
Pfizer	The final roll should have the complete data. Partial information may be available before that. Pfizer re-affirmed that supply to NZ would be via a 'drop-shipping' arrangement to government-nominated sites.
Pfizer	Explained that we proposed to submit the first roll of the Mod 3 data in the same submission as the amended cover letter and amended application form that was requested by s 9(2)(g)(ii) on 9 Nov 2020.
Medsafe	The Pfizer proposal was considered acceptable by Medsafe.

COVID-19 Vaccine Pre-submission Meeting between Pfizer and Medsafe
24 September 2020
Discussion Summary

Issue Raised by	Details
Medsafe	What will be the timelines for post-approval CMC changes referenced in the Briefing Document?
Pfizer	During the 2020-21 time period. These will include changes such as additional manufacturing lines to increase capacity and meet demand, and transfer of testing sites. There is a lyophilised powder product under development, which would be expected to have more favourable storage conditions.
Pfizer	There is no current timeframe for any change to storage conditions of the current vaccine.
Medsafe	Medsafe would be keen to see data to support lack of bacterial growth once thawed, given the multi-dose presentation and preservative-free formulation.
Pfizer	Pfizer is already undertaking studies to demonstrate this; microbial/chemical data will be provided to support the in-use period.
Medsafe	Rolling submissions are not normally accepted but given the COVID circumstances, Medsafe would accept this approach for the proposed vaccine. What timeframes would be expected for availability of clinical and quality data?
Pfizer	Update as of today: Non-clinical data (entire Module 4 and associated Module 2 summaries) are currently anticipated on 5 Oct 2020. The first interim analysis of clinical data is expected in 3rd week of Oct and final analysis around the end of November. The Emergency Use Authorisation (EUA) application is also expected to be filed in the US in November.
Pfizer	CMC data are expected to follow a rolling process from the beginning of November through end December.
Medsafe	Asked about the trial size and investigational study in children.
Pfizer	The recent amendment to include participants 16 years and above has now been approved and a new proposal to include children aged 12 and above has been put forward to the FDA. 16-17 yrs: recruiting has already commenced 12-15 yrs: is proposed to be recruited to generate safety and immune response data in children. A few thousand children aged 12-17 will be enrolled.
Medsafe	It is more appropriate to apply for provisional consent (section 23 as opposed to section 20) for the COVID vaccine. This would allow for conditions to be applied to the consent allowing for subsequent data to be filed without imposing a number of post-approval commitments. What are the filing plans for EU and Australia?
Pfizer	The EU is likely to follow very similar rolls to the US (as mentioned earlier).
Pfizer	A pre-submission meeting has already taken place with the TGA in Australia.
Medsafe	Will the Aus and NZ filings be made in parallel with the EU and the US?

Pfizer	Yes. Pfizer is not planning to wait for approval in another jurisdiction in order to use the NZ abbreviated pathway. What is the level of evidence required to reach a decision?
Medsafe	Provisional consent would stipulate the need for additional clinical data, which could then alter the conditions of use, as appropriate.
Pfizer	Sought comment on the acceptability of providing CMC data as it becomes available.
Medsafe	This approach is not entirely unprecedented. It is similar to that which is used when evaluating the seasonal flu vaccines. The first filing of CMC data should be provided together with an estimated timeframe for subsequent data provision. Outline what is not included, what is coming up next and what will be submitted thereafter. This enables Medsafe to plan more effectively, e.g. aligning with RFIs. EFT should be used to provide the updates as they become available.
Pfizer	Pfizer should be able to tell Medsafe what will be ready on Nov, and then in December.
Pfizer	Advised Medsafe of our intent to ship direct to Government-nominated sites, as opposed to traditional sponsor warehouse.
Medsafe	Sponsor needs to ensure the product meets quality/transportation requirements as per section 42 of the legislation. Medsafe is responsible for the approval of the product; distribution chain is usually government-managed for vaccines.
Pfizer	Explained the planned shipping arrangements with regards to the shippers, pizza box cartons containing 195 vials, the inclusion of dry ice, temp monitoring and GPS devices. Pfizer plans to “drop-ship” product at sites selected by the government.
Medsafe	Other parts of the Ministry of Health will need to comment on Pfizer’s distribution plans. Flexibility on the plan would be required and would have to be agreed on.
Pfizer	Should Pfizer be speaking with other departments about our distribution plans?
Medsafe	The immunisation program organisers would need to consider the details of the proposed distribution plan and its challenges, costs etc.
Medsafe	Information on logistics, supply chain should be detailed in CMC section of the dossier
Pfizer	Are there any issues with the proposal to: - require saline to be sourced locally? - supply as a multi dose vial?
Medsafe	The immunisation program organisers would need to comment on the requirement for saline. This is not expected to affect the CMC part of the assessment.
Medsafe	The suitability of the saline as a diluent would need to be justified, concern is mainly around sufficient sterility
Pfizer	Sought comment on the issue of non-compliance with local requirements.
Medsafe	Approval under S23 does not allow for approval of non-compliant medicines unless an exemption has been sought in relation to the non-compliance. We may need to consider requiring “Dear HCP” letters to address various aspects of the vaccine such as safety information.
Medsafe	Medsafe is not able to provide a commitment on the time for review of the vaccine submission due to the uncertainty around the availability of data. Medsafe would have

	to advise government in this respect in order to manage expectations with respect to the likelihood of meeting an end of January 2021 decision timeline.
Pfizer	No product name would be submitted at the time of initial filing. Also, we would not have a NZ terminology listing in relation to the active ingredient.
Medsafe	No issue with filing prior to a product name being finalized however would be required by the time of consent by Medsafe.
Pfizer	Initial supplies of the vaccine won't have the final trade name, but rather a generic product name. These labels are currently being printed. Later supplies will have the agreed tradename on the packaging.
Medsafe	Would like to see an RMP for the vaccine.
Pfizer	The EU RMP will be included in the application.

1.7.2 DETAILS OF ANY ADDITIONAL DATA TO BE SUBMITTED

As agreed in the pre-submission meeting (see Module 1.7.1 Details of Compliance with Pre-Submission Meeting Outcomes) between the Sponsor and the TGA held 18 September 2020, given the nature of the current global pandemic, data to support Pfizer's application to provisionally register a COVID-19 Vaccine will be provided on a rolling basis as more data become available.

As at the time of submission of this application, the following indicative dates for provision of data are tentatively proposed. Please note that dates and components are subject to change.

Proposed Dossier Components	Indicative Submission Date
Initial Roll (Sequence [0000])	
MODULE 2: COMMON TECHNICAL DOCUMENT SUMMARIES 2.4 Nonclinical Overview 2.6 Nonclinical Written and Tabulated Summaries 2.7.1 Summary of Biopharmaceutic Studies & Associated Analytical Methods MODULE 4: NON-CLINICAL STUDY REPORTS 4.2.1 Pharmacology 4.2.2 Pharmacokinetics 4.2.3 Toxicology 4.3 Literature References MODULE 5: CLINICAL STUDY REPORTS 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies (SARS-CoV-2 Assays) 5.3.5.1 C4591001 Interim Phase 1 Clinical Study Report & Appendices 5.3.5.1 BNT162-01 Interim Clinical Study Report & Appendices	October 2020
C4591001 First Successful Interim Analysis (based on successful IA at 32, 62, 92 or 120 cases)	
MODULE 5: CLINICAL STUDY REPORTS 5.3.5.1 C4591001 Phase 1/2/3 Clinical Study Report	November/December 2020
C4591001 Final Analysis (based on 164 cases)	
MODULE 2: COMMON TECHNICAL DOCUMENT SUMMARIES 2.5 Clinical Overview 2.7 Clinical Summaries MODULE 5: CLINICAL STUDY REPORTS 5.2 Tabular Listing of Clinical Studies 5.3.5.1 C4591001 Updated Clinical Study Report, Narratives, Appendices 5.3.5.1 BNT162-01 Updated Clinical Study Report, Appendices	January 2021
Chemistry Manufacturing and Controls	
MODULE 2: COMMON TECHNICAL DOCUMENT SUMMARIES 2.3 Quality Overall Summary MODULE 3: QUALITY Components will include: • Description of complete manufacturing process	January/February 2021

Proposed Dossier Components	Indicative Submission Date
• Process qualification • Manufacturing process initial control strategy and development history • Initial specifications and justifications of specifications • Description of analytical procedures and initial validation of analytical procedures • Comparability assessments	
MODULE 3: QUALITY Components will include: • Process performance qualification data • Additional process characteristaion data • Continuous evaluation of specifications with additional data • Test method validations ongoing • Analytical comparability across clinical material through initial drug product batches	March 2021

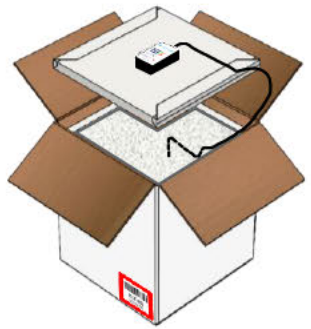
COVID-19 Vaccine Logistics Overview

One slide leave behind for countries EU Countries with or without CDA

09.15.2020

Stepwise Vaccination Summary with BNT162b2

Direct Shipment to Point of Vaccination



- Minimum 1 tray (195 Multi Dose Vial) or up to 5 trays (975 MDV) delivered to vaccination center in a thermal shipper that keeps ultra low temperature (ULT) up to 10 days.
- Each thermal shipper arrives with a reusable GPS enabled temperature monitoring device to ensure end-to-end distribution within required temperature.

Vaccine Storage

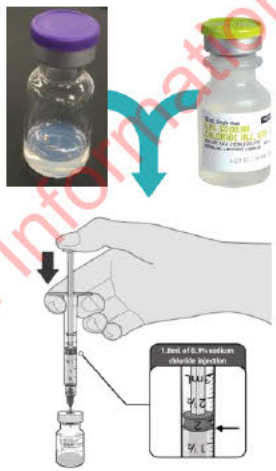
After receipt of the shipper; three storage options

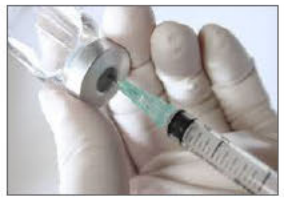
1. **ULT Freezer**
   - Store at label claim up to expiry. (at -75°C±15°C for storage up to 6 months)

2. **Thermal shipper designed for temporary storage**
   - Multiple dry ice replenishments possible. Up to 15 days

3. **2-8°C refrigerator**
   - 5 days at 2-8°C storage

Vaccine Preparation





- From storage, remove 1 vial for every 5 patients according to planned number of vaccinations per day.
- Dilute with 1.8mL of 0.9% sodium chloride for injection, single use at room temperature in no more than 2 hours.
- Withdraw dose 30 mcg/0.3 mL of final diluted product for each vaccination.

Vaccine Administration

- Diluted product must be used within 6 hours at room temperature.
- Administer intramuscularly as a series of two doses.
- A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

This slide contains information about an investigational vaccine that remains subject to regulatory authorization or approval. It is possible that final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping (current as of September 8, 2020).

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000

18 November 2020

s 9(2)(a)
Senior Regulatory Affairs Associate
Pfizer Australia Pty Limited
Level 15-18
151 Clarence Street
Sydney NSW 2000
AUSTRALIA

Application: 109400
File Ref: TT50-10853

Dear s 9(2)(a)

ACKNOWLEDGEMENT OF A NEW MEDICINE APPLICATION MADE UNDER SECTION 20 OF THE MEDICINES ACT 1981

COVID-19 Vaccine Concentrate for injection
30 mcg/0.3mL Pfizer

This letter acknowledges receipt of the above application that was received by Medsafe on 13 November 2020.

Your request for priority assessment on the grounds of significant clinical advantage has been granted.

The applicable fee for the application (based on the information provided on the form) is detailed on the attached invoice.

Payment of the invoice is requested within 7 days **and is required to validate your application and enable evaluation to commence.** Please ensure you quote the invoice number when payment is made.

If payment is not received by the 20th of next month, this invoice will be cancelled and there will be no consideration of the invalid application.

An initial evaluation will commence once payment has been received . You may be asked for further information during this process. You will be advised of the outcome of the evaluation once it has been completed.

Yours sincerely
s 9(2)(g)(ii)

s 9(2)(g)(ii)
Assistant Advisor, Product Regulation
s 9(2)(g)(ii)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000

s 9(2)(g)(ii) [redacted]

MEDSAFE - TAX INVOICE

GST NO. 14-290-389

File Ref: TT50-10853

Debit to:

Pfizer New Zealand Limited
P O Box 3998
AUCKLAND 1140

Invoice number: 739135
Customer reference:
Pfz_Covid_NMA_2020
Invoice date: 18/11/2020

For:

New Higher-risk Medicine Application received 13 November 2020

Application Type	Number	Amount
New higher-risk medicine containing one or more new active substances	1	$88,878.26

Fee Amount	88,878.26
GST	$13,331.74
Total Fee	$102,210.00

Due by 25/11/2020

Please return lower section with your remittance, or email details to receivables@health.govt.nz

Remittance Advice

Ministry of Health
P O Box 5013
WELLINGTON
Attn: Accounts Receivable
E-mail:
receivables@health.govt.nz

Customer name: Pfizer New Zealand Limited
Customer number: 13257
Invoice number: 739135
Invoice date: 18/11/2020
Invoice total: $102,210.00
Total paid:

Payment can be made by direct credit to the Ministry of Health bank account at Westpac Trust, NZ Government Branch, Wellington, New Zealand 6145, account number 03-0049-0001805-008. Swift code for overseas payments is WPACNZ2W. Please use your invoice number as a reference.
Credit card payment accepted online at www.medsafe.govt.nz. A 2% transaction fee applies.