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

19 April 2022

s 9(2)(a)

By email s 9(2)(a)
Ref H202204257

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 the Ministry of Health (the Ministry) on 22 March 2022 for information regarding COVID-19 vaccines. I will respond to each part of your request in turn.

1. *Certificates of Analysis for the first three batches of vaccine distributed in New Zealand.*

Please find copies of these documents enclosed with some information withheld under the following sections of the Act:

- 9(2)(a) to protect the privacy of natural persons; and
- 9(2)(b)(ii) as its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and
- 9(2)(ba)(ii) to protect information that is subject to an obligation of confidence in which making it available would likely damage the public interest.

Where information is withheld, this is noted in the document itself. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

2. *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 for all batches distributed in New Zealand.*

These documents are withheld in full under section 6(b)(ii) of the Act, as its release would prejudice information entrusted to the Government of New Zealand on a basis of confidence by any international organisation.

3. *Data to further characterise the truncated and modified mRNA species present in the finished product which addresses results from ion pairing RP-HPLC addressing 5'cap levels and presence of the poly(A) tail and addresses the potential for translation into truncated S1S2 proteins/peptides or other proteins/peptides.*
4. *Relevant protein/peptide characterisation data for predominant species.*

5. *Evaluation of any homology between translated proteins (other than the intended spike protein) and human proteins that may, due to molecular mimicry, potentially cause an autoimmune process.*

6. *Analysis of the main peak of the RNA integrity test representing the full-length RNA that addresses 5'cap levels and presence of the poly(A) tail.*
7. *Reassessment of the active substance specification for the DNA template purity and impurities.*
8. *Active substance process validation data regarding the finalised indirect filter qualification assessment and the shipping validation between sites.*
9. *The capability of the next generation sequencing technology platform to detect lower amounts of RNA species of alternative sequence in the presence of the correct, more abundant RNA for the active substance.*
10. *The results and the assay suitability for the cell-based flow cytometry and the western blot method used for biological characterisation of protein expression for the active substance.*
11. *A summary of the validation/verification status of the immunoblot analytical procedure used to detect double stranded RNA (dsRNA) in the active substance.*
12. *Data comprising batch analyses of a suitable number of commercial batches as well as analyses of batches that have been used in the (ongoing) clinical trials.*
13. *Specifications and results of introducing an active substance to control poly(A) tail length and how it was controlled on each batch.*
14. *Data to support the suitability of the method used for %poly(A) tail in Q14* [Q13] *above.*
15. *Revised specifications of the mRNA integrity and polydispersity finished product.*
16. *Data to support the suitability of the method used for potency determination.*
17. *The finished product acceptance criteria for potency.*
18. *Control strategy assessment results for Lipid-related impurities.*
19. *The risk assessment with respect to the potential presence of elemental impurities in the active product based on the general principles outlined in Section 5.1 of ICH Q3D and Ph. Eur. monograph Pharmaceutical Preparations (2619).*
20. *Process development for ALC-0315 with emphasis on the identification and purge of impurities.*
21. *Specified impurities for ALC-0315 and appropriate specification limits for individual impurities.*
22. *Acceptance criteria for specified and un-specified impurities for ALC-0315.*
23. *Details about how the solvent residues that are used in the manufacture of the ALC-0315 excipient are controlled.*
24. *The ALC-0315 assay and impurities limits.*
25. *Method validation reports for assay, impurities, and residual solvents for ALC-0315.*
26. *ALC-0315 impurity standard information for any identified impurities reported.*
27. *The impact of the molecular weight and polydispersity of carboxy-MPEG on ALC-0159, including acceptance criteria, for these parameters in the starting material.*
28. *Reports on the duration of efficacy and the requirement for booster doses.*

This information is 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. Please note, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Information on the duration of efficacy of the Pfizer Comirnaty vaccine is available in the data sheet published at: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.

The Ministry is continuing to monitor international research and developments surrounding COVID-19 variants and COVID-19 vaccines. The most recent variants update includes a summary of vaccine effectiveness against the Omicron variant and can be found at: www.health.govt.nz/system/files/documents/pages/variants_update_-_omicron_-_25_march_2022.pdf.

The Ministry also regularly updates the Science News page for up to date information regarding COVID-19 and the vaccine: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news.

More information about booster doses is available at www.covid19.govt.nz/covid-19-vaccines/how-to-get-a-covid-19-vaccination/getting-your-booster-dose/.

29. *Reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, and efficacy in population subgroups.*

Clinical study reports provided to Medsafe by Pfizer are withheld in full under section 9(2)(b)(ii) of the Act.

30. *The final Clinical Study Reports for Study C4591001 and Study BNT162-01.*

This information is refused under section 18(g)(i) as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

31. *The latest Safety Update Report.*

Safety reports for the COVID-19 vaccine are published on the Medsafe website at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp. The publication date for the next report is also available at this link. Therefore, this part of your request is refused under section 18(d) as the information requested is publicly available.

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.

Nāku noa, nā

Jan Torres
Acting Manager, OIA Services
Office of the Director-General

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	20 December 2021	Certificate of Analysis for the Comirnaty (Pfizer) COVID-19 Vaccine.	Released with some information withheld under the following sections of the Act: • section 9(2)(a) to protect the privacy of natural persons; • 9(2)(b)(ii) as its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and • section 9(2)(ba)(ii) to protect information that is subject to an obligation of confidence in which making it available would likely damage the public interest.
2	19 January 2022		

Document 1

Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
RIJKSWEG 12
B-2870 PUURS (BELGIUM)
TEL: +32 (0)3 890.92.11
FAX: +32 (0)3 889.65.32

Batch Number: FP8234 **Date Generated:** 20/12/2021

Product Name: COMIRNATY™ (COMIRNATY 0.5mg/ml 195x0.45ml GVL PFE EU)

Material Number: F000055442

Date of Manufacture: 21/11/2021

Expiration Date: 31/07/2022

Importing Country: All countries that accepted Marketing Authorisation Application or WHO Emergency Use Listing

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual) Appearance	S9(2)(ba)(ii)	MEETS TEST
Appearance (Particles) Visible Particulates		MEETS TEST
Subvisible Particulate Matter Subvisible particles		23 Particles/container 3 Particles/container
Potentiometry pH		7.3
Osmometry Osmolality		573 mOsmol/kg
Dynamic Light Scattering (DLS) LNP Size LNP Polydispersity		77 nm 0.2
Fluorescence assay RNA Encapsulation RNA Content		97 % 0.48 mg/mL
HPLC-CAD ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		6.47 mg/mL 0.81 mg/mL 1.40 mg/mL 2.78 mg/mL
Container content Vial content (volume)		>=0.406 mL
IDENTITY		
HPLC-CAD Lipid identities		MEETS TEST
RT-PCR Identity of encoded RNA sequence		MEETS TEST
POTENCY		

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
Cell-based Flow Cytometry In Vitro Expression	s 9(2)(b)(ii) [redacted]	77 %
PURITY		
Capillary Gel Electrophoresis RNA Integrity		68 %
ADVENTITIOUS AGENTS		
Endotoxin (LAL) Bacterial endotoxins		<5.00 EU/mL
Sterility Sterility		MEETS TEST

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.

QUALITY ASSURANCE REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS WERE FOUND ACCEPTABLE. ALL DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED. THE RESULTS OF ALL IN-PROCESS TESTING MEET THE REQUIREMENTS. THE BATCH HAS ALSO BEEN TESTED AND CONFORMS TO ALL MAA SPECIFICATIONS AND INTERNAL CONTROL TARGETS. ALL BATCH DOCUMENTATION IS RETAINED AT PFIZER MANUFACTURING BELGIUM NV AND AVAILABLE FOR REVIEW.

MANUFACTURING/PACKAGING REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS OF THE MANUFACTURING AND PACKAGING WERE JUDGED ACCEPTABLE AND CONSISTENT WITH THE REQUIREMENTS OUTLINED IN THE MAA AND MASTER MANUFACTURING DOCUMENTS. ALL MANUFACTURING DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Prepared by:

s 9(2)(a) [redacted]

Document 2

Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
RIJKSWEG 12
B-2870 PUURS (BELGIUM)
TEL: +32 (0)3 890.92.11
FAX: +32 (0)3 889.65.32

Batch Number: FR8392 **Date Generated:** 19-Jan-2022

Product Name: COMIRNATY™ Tris/Sucrose, 10 mcg/0.2 mL Concentrate for Dispersion for Injection (COMIRNATY 0.1mg/ml 10x1.3ml GVL EU)

Material Number: F000054850

Date of Manufacture: 24.11.2021

Expiration Date: 30.04.2022

Importing Country: All countries that accepted Marketing Authorisation Application

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual) Appearance	S9(2)(ba)(ii)	Meets test
Appearance (Particles) Visible Particulates		Meets test
Subvisible Particulate Matter Subvisible particles		18 Particles >= 10 µm per container 1 Particles >= 25 µm per container
Potentiometry pH		7.4
Osmometry Osmolality		361 mOsmol/kg
Dynamic Light Scattering (DLS) LNP Size LNP Polydispersity		68 nm 0.1
Fluorescence assay RNA Encapsulation RNA Content		97 % 0.097 mg/mL
HPLC-CAD ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		1.30 mg/mL 0.16 mg/mL 0.28 mg/mL 0.56 mg/mL
Container content Vial content (volume)		>=1.222 mL
IDENTITY		
HPLC-CAD Lipid identities		Meets test
RT-PCR Identity of encoded RNA sequence		Identity confirmed

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
POTENCY		
Cell-based Flow Cytometry In Vitro Expression	s 9(2)(b)(ii)	91 %
PURITY		
Capillary Gel Electrophoresis RNA Integrity		73 %
ADVENTITIOUS AGENTS		
Endotoxin (LAL) Bacterial endotoxin		<5.00 EU/mL
Sterility Sterility		No growth detected

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.

QUALITY ASSURANCE REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS WERE FOUND ACCEPTABLE. ALL DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED. THE RESULTS OF ALL IN-PROCESS TESTING MEET THE REQUIREMENTS. THE BATCH HAS ALSO BEEN TESTED AND CONFORMS TO ALL MAA SPECIFICATIONS AND INTERNAL CONTROL TARGETS. ALL BATCH DOCUMENTATION IS RETAINED AT PFIZER MANUFACTURING BELGIUM NV AND AVAILABLE FOR REVIEW.

MANUFACTURING/PACKAGING REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS OF THE MANUFACTURING AND PACKAGING WERE JUDGED ACCEPTABLE AND CONSISTENT WITH THE REQUIREMENTS OUTLINED IN THE MAA AND MASTER MANUFACTURING DOCUMENTS. ALL MANUFACTURING DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Prepared by:

s 9(2)(a)