MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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30 January 2024

Erika Whittome

By email: fyi-request-25124-c3ff613b@requests.fyi.org.nz
Ref: H2023033891

Tēnā koe Erika

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 | Manatū Hauora (the Ministry) on 11 December 2023.

On 29 January 2024, parts 1, 6, and 7 of your request were transferred to Health New Zealand - Te Whatu Ora; however, upon further review, the Ministry is reconsidering the information requested under questions 6 and 7. You will be advised in due course should a re-transfer be required for these parts. We apologise for any inconvenience. Please find a response to each remaining part of your request below:

> *The provisional approval in the Gazette for the Comirnaty medicine had 8 conditions here https://www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf*
> *Would you kindly share the evidence of these 8 conditions being approved?*
>
> *2. Provide independent batch certification, such as UK National Institute for Biological Standards and Control (NIBSC) certification, EU Official Control Authority Batch Release (OCABR) certification, Australian TGA batch release assessment, or any other certification agreed with Medsafe, on request for all batches distributed in New Zealand.*

Certificates for last three deliveries are attached to this letter as Document 1. This is released to you with some information withheld under section 9(2)(ba)(ii) of the Act, to protect information that is subject to an obligation of confidence and making it available would likely damage the public interest. 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.

> *3. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.*

Data sheets were updated to include the need for booster vaccines. Please find the data sheet for the Pfizer COVID-19 Comirnaty vaccine here:
www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf

> *4. Provide any reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post-marketing studies, within five working days of these being produced.*

The information you have requested is publicly available in the Pfizer COVID-19 Comirnaty vaccine data sheets here: www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf.

> *5. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.*

Due to the changes in disease landscape, evolving variants and introduction of booster doses, the initially planned follow up period is no longer considered clinically relevant for C4591001 (Phase I/II/III in adults and children 12 years and older), C4591007 (Phase I/II/III paediatric), and BNT162-01 (Phase I/II in adults). This requirement was removed by Medsafe.

> *8. Perform the required pharmacovigilance activities and interventions detailed in the agreed RMP and any agreed updates to the RMP. An RMP should be submitted at the request of Medsafe or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important milestone being reached.*

The published risk management plan (RMP) summary has been updated on Medsafe's website here: www.medsafe.govt.nz/searchResults.asp?q=RMP+summary.

I trust this information fulfils your request. 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

Derek Fitzgerald
Acting Group Manager
Medsafe

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach 63207 Langen

Our reference: N2.02.01.0072/0008#0020

Annelien Everaert
PGS Puurs
Rijksweg 12

2870 Puurs, Belgium

EC/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE TESTING CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directive 2001/83/EC (Immunological Medicinal Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	COMIRNATY
INN / Ph. Eur. name / common name:	COVID-19 mRNA Vaccine
Batch number and other identification numbers associated with this batch:	EP9605
Type of container:	vial
Total number of containers in this batch:	s 9(2)(ba)(ii)
Nominal dose per container:	6
Date of start of period of validity:	13.01.2021
Date of expiry:	30.06.2021
Marketing authorisation number:	EU/1/20/1528
Name and address of manufacturer:	Pfizer Manufacturing Belgium NV / 2870 Puurs, Belgium
Name and address of MAH	BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on either:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation application.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed on behalf: s 9(2)(ba)(ii)
Section 2/1 Viral Vaccines

Date of issue: 10.02.2021

Certificate number: 21177/21

This document was issued electronically and is therefore valid without signature.

PAUL-EHRLICH-INSTITUT LANGEN 20

COO.2220.100.5.2891636

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach 63207 Langen

Our reference: N2.02.01.0072/0008#0017

Annelien Everaert
PGS Puurs
Rijksweg 12

2870 Puurs, Belgium

EC/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE TESTING CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directive 2001/83/EC (Immunological Medicinal Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	COMIRNATY
INN / Ph. Eur. name / common name:	COVID-19 mRNA Vaccine
Batch number and other identification numbers associated with this batch:	EP2163
Type of container:	vial
Total number of containers in this batch:	s 9(2)(ba)(ii)
Nominal dose per container:	6
Date of start of period of validity:	23.12.2020
Date of expiry:	31.05.2021
Marketing authorisation number:	EU/1/20/1528
Name and address of manufacturer:	Pfizer Manufacturing Belgium NV / 2870 Puurs, Belgium
Name and address of MAH	BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on either:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation application.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed on behalf: s 9(2)(ba)(ii)
Section 2/1 Viral Vaccines

Date of issue: 05.02.2021

Certificate number: 21033/21

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PAUL-EHRLICH-INSTITUT LANGEN 20

COO.2220.100.8.2884881

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach 63207 Langen

Our reference: N2.02.01.0072/0008#0029

Annelien Everaert
Pfizer Manufacturing Belgium NV
PGS Puurs
Rijksweg 12

2870 Puurs, Belgium

EC/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE TESTING CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directive 2001/83/EC (Immunological Medicinal Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	COMIRNATY
INN / Ph. Eur. name / common name:	COVID-19 mRNA Vaccine
Batch number and other identification numbers associated with this batch:	ER7449
Type of container:	vial
Total number of containers in this batch:	s 9(2)(ba)(ii)
Nominal dose per container:	6
Date of start of period of validity:	27.01.2021
Date of expiry:	30.06.2021
Marketing authorisation number:	EU/1/20/1528
Name and address of manufacturer:	Pfizer Manufacturing Belgium NV / 2870 Puurs, Belgium
Name and address of MAH	BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on either:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation application.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed on behalf: s 9(2)(ba)(ii)
Section 2/1 Viral Vaccines

Date of issue: 26.02.2021

Certificate number: 21708/21

This document was issued electronically and is therefore valid without signature.

PAUL-EHRLICH-INSTITUT LANGEN 20

COO.2220.100.8.2915390