MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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20 November 2024

s 9(2)(a)

Ref: H2024054495

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 – Manatū Hauora (the Ministry) on 23 October 2024 regarding Pfizer's Comirnaty COVID-19 vaccine. You asked:

> *"1. Please confirm the regulatory limit used by Pfizer for testing residual DNA in the mRNA Covid-19 vaccines is 10ng per dose. If not, please provide the correct regulatory limit.*
>
> *2. I understand the WHO guidance for residual DNA in biologic products stipulates that fragments should not be greater than 200bp. Please confirm whether this is correct.*
>
> *3. Has there been any size analysis undertaken by Pfizer and/or Medsafe on the residual DNA fragments in the Comirnaty original mRNA Covid-19 vaccine and for subsequent Pfizer mRNA covid-19 vaccines approved by Medsafe? Was this information provided on the Certificate of Compliance and Analysis for the New Zealand vaccine batches?*
>
> *4. Has there been any analysis performed by Pfizer for the residual intact circular DNA template in the linearized DNA template starting material? Was this information provided on the Certificate of Compliance and Analysis for the New Zealand vaccine batches?*
>
> *5. Please advise whether the testing of DNA by qPCR carried out by Pfizer relates only to the quality rather than the fragment size?"*

Regarding Pfizer's Comirnaty vaccine, release testing according to registered specifications is conducted on every batch of Comirnaty prior to release. The amount of residual DNA is controlled with an appropriately chosen and qualified specification limit for DNA, tested via quantitative PCR (qPCR) and only batches that meet this specification are released.

The specific measurements you are seeking are commercially sensitive and are therefore withheld 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. I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

Medsafe is aware of claims that mRNA vaccines contain 'excessive levels of DNA' encapsulated in lipid nanoparticles, and the claim that this presents a safety risk. The Therapeutic Goods Administration (TGA) has published education information in relation to these claims.

Medsafe agrees with the TGA material. The TGA information can be seen here: www.tga.gov.au/news/media-releases/addressing-misinformation-about-excessive-dna-mrna-vaccines.

The Ministry has also published a previous response regarding Comirnaty evaluation and approval that may be of interest to you. This can be viewed at: www.health.govt.nz/system/files/2021-10/h202106950_-_response.pdf.

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
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Medsafe