MEDSAFE
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1 February 2024

R. Kingi

By email: fyi-request-25158-2e25b18c@requests.fyi.org.nz
Ref: H2023034032

Tēnā koe R

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 13 December 2023 for information regarding the SV40 promoter in the Pfizer injectables.

Please find a response to each part of your request below.

> *Can you please confirm if Pfizer provided the full DNA sequence of the plasmid used in the manufacture bnt162b2 and others, and if the SV40 promoter was specifically identified or annotated in the plasmid map or elsewhere?*

Your request for this information is withheld under section 9(2)(ba)(i) of the Act as it was provided under an obligation of confidence. The release of this information would likely prejudice the provision of similar information in the future. I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

> *Additionally, can you release any internal discussion regarding the risks of having batch testing being done by pfizer, particularly your confidence in the use qPCR to accurately detect levels of dsDNA.*

This part of your request is refused under section 18(e) of the Act as this information does not exist.

Medsafe is aware of claims that sequences of the SV40 present in Comirnaty starting material can lead to health issues such as cancer.

The starting material for the manufacture of mRNA is a DNA template. The mRNA is treated with DNAse to digest residual DNA. There are careful, internationally agreed upon specifications in place for the amount of residual DNA present in all biological products, including the mRNA vaccines. The specification for the mRNA vaccines for residual DNA following DNAse treatment results in DNA at less than one-three thousandth of the RNA dose by weight. This has been determined (and continues to be determined during production of lots) using a validated quantitative PCR assay. Non-infectious fractions of a SV40 sequence are present in the starting material; no SV40 proteins are encoded or present in the vaccine.

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