

26 August 2024

Erika Whittome

By email: fyi-request-25124-c3ff613b@requests.fyi.org.nz
Ref: H2024048146

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 2 August 2024 for:

You have provided documents but none of them are Periodic Safety Update Reports which were a condition for the conditional approval:

Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.

The periodic safety update reports are withheld in full under section 9(2)(ba)(i) of the Act, to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source. 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.

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