

11 July 2024

Chris McCashin
fyi-request-27374-908e4fcd@requests.fyi.org.nz

Tēnā koe Chris,

Your request for official information, reference: HNZ00054125

Thank you for your email on 25 June 2024, asking Health New Zealand | Te Whatu Ora for the following under the Official Information Act 1982 (the Act):

"Any additional safety studies or reports that Te Whatu Ora considers to be part of the gold standard for vaccine safety assessment for the childhood immunisation schedule vaccines."

Health NZ does not collate studies for assessing safety of vaccines on the childhood immunisation schedule. We are therefore refusing this part of your request under section 18(g), as we do not hold this information and there are no reasonable grounds to believe it is held by, or more closely connected with the functions of, another Minister or agency.

"The gold standard safety reports associated with each vaccine currently included in the New Zealand childhood immunisation schedule. This should include, but not be limited to:

Results from randomized controlled trials (RCTs) conducted during the pre-licensure phase, including Phase 1, 2, and 3 studies.

Data from post-authorization surveillance, including both passive and active surveillance systems.

Results from any real-world evidence (RWE) studies conducted on these vaccines in New Zealand or internationally.

Information on any international collaborative studies that have been used to assess the safety of these vaccines.

Reports from regulatory bodies (such as Medsafe or international equivalents) that were used in the approval process for these vaccines."

Your request asks for information which is more closely aligned with the functions of the Ministry of Health. For this reason, Health New Zealand has decided to transfer the below part of your request to the Ministry under section 14(b)(ii) of the Act. You can expect a response from them in due course.

How to get in touch

If you have any questions, you can contact us at hnzOIA@tewhatauora.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Health NZ may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release.

Nāku iti noa, nā

A handwritten signature in black ink that reads "Danielle Coe". The signature is fluid and cursive, with a large initial 'D'.

Danielle Coe

**Manager (OIA) Government Services
Health New Zealand | Te Whatu Ora**