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16 July 2024

Chris McCashin

By email: fyi-request-27374-908e4fcd@requests.fyi.org.nz
Ref: H2024046260

Tēnā koe Chris

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) about the Childhood Immunisation Schedule, which was transferred from Health New Zealand – Te Whatu Ora to the Ministry of Health – Manatū Hauora (the Ministry) on 11 July 2024. Please find a response to each part of your request below.

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

These parts of your request are refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

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

The collection of spontaneous adverse reactions is often referred to as being passive. Please refer to the Suspected Medicine Adverse Reaction Search (SMARS), which is publicly available here: www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp.

The Active Monitoring Post Vaccine Symptom Check is publicly available here: www.tewhatuora.govt.nz/health-services-and-programmes/vaccine-information/vaccine-service-delivery/vaccine-safety-monitoring/active-monitoring-post-vaccine-symptom-check/.

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

Studies about vaccines are publicly available on the National Library of Medicine website here: https://pubmed.ncbi.nlm.nih.gov/.

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

Reports that Medsafe has received from international medicine regulators are withheld in full under section 6(b)(ii) of the Act, as the making available of the information would be likely to prejudice the entrusting of information to the Government of New Zealand on a basis of confidence by any international organisation.

Please note that Medsafe does not use its own data or reports when approving vaccines.

Dates these vaccines were approved.

The information you have requested can be found using the Medicine Product and Application search on the Medsafe website here: www.medsafe.govt.nz/regulatory/dbsearch.asp.

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
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Medsafe