

29 August 2024

Catherine Jamieson
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Tēnā koe Catherine,

Your request for official information, reference: HN200058865

Thank you for your email of 31 July 2024, asking Health New Zealand | Te Whatu Ora for the following under the Official Information Act 1982 (the Act):

1. Please explain, or provide material that does explain, the apparent variation in expiry length of the paediatric Pfizer Covid vaccines that entered New Zealand.

FN4074 first entered NZ 13/1/22 and had expiry date of 30/4/23.

An extension to expiry dates for paediatric vaccines was applied 13/4/22 which increased the expiry date from 9 months to one year from manufacture.

A further extension to 18 months expiry date was applied to multiple dose vials with orange caps and labels with an orange border in late in 2022.

2. Please confirm the date this extension to 18 months expiry was applied.

For FN4074 to have an expiry date of 30/4/23 the expiry date prior to the extension to 18 months would have been 31/10/22. Taking into account the extension to one year expiry applied in April 2022, this infers a manufacturing date for FN4074 of November 2021. Original expiry would have been 9 months at 30/7/22 then the extension to one year revised expiry date to 31/10/22.

FN4074 would only have been captured by the extension to 18 months if this was applied prior to 31/10/22.

3. If FN4074 was given an extension, why would this not have applied to FR4268 with an expiry of 30/11/22?

Response

Following approval by Medsafe, Data Sheets for any COVID-19 vaccine are published on Medsafe's website on behalf of pharmaceutical companies. It contains information for health care professionals about the safe and effective use of the vaccine. The data sheet also includes details on special warnings and precautions for use, any known side effects such as adverse events, and information about the vaccine's pharmacological properties such as any update on shelf-life.

On publication of the Data Sheets, Health NZ applies the expiry extensions to the batches which have stock remaining in -90°C to -60°C storage at the New Zealand warehouse and distribution centres. To clarify, the extension approved in December 2022 to 18-months was applied in January 2023.

Please see **Appendix One**, which contains New Zealand Data Sheets for COMIRNATY® (orange cap, must dilute) 5 to 11 years of age (10 micrograms/0.2 mL dose) and reflect the following shelf-life extensions for -90°C to -60°C storage.

- December 2021 approved shelf life extended from 6 months to 9 months
- April 2022 approved shelf life extended from 9 month to 12 months
- December 2022 approved shelf life extended from 12 months to 18 months
- July 2023 approved shelf life extended from 18 months to 24 months

This means that batch FN4074, with initial expiry date of 30/04/2022, was extended to 31/07/2022, 31/10/2022 and then 30/04/2023.

However, while stock of batch FR4268 was extended to a 12-month expiry date in April 2022, it was depleted in New Zealand in October 2022 and the extension to 18-month expiry was not required.

How to get in touch

If you have any questions, you can contact us at h.nzOIA@tewhatuora.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



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Te Kāwanatanga o Aotearoa
New Zealand Government