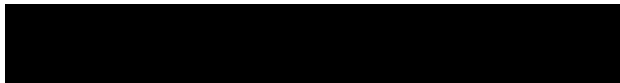




14 December 2023



Kia ora



Your Official Information Act request, reference: GOV-029164

Thank you for your email of 22 November 2023, asking for the following information under the Official Information Act 1982 (the Act):

- 1. Does ACC review the reports from the product's manufacturer on the product's adverse events/effects?*
- 2. In the case of a provisionally approved medicine (eg Fluvax, Comirnaty), does ACC review the Periodic Safety Update reports from the manufacture? For example, this is a periodic safety report from Pfizer on Comirnaty.*
- 3. Does ACC review the post marketing report published by Pfizer in the case of Comirnaty for claims of adverse events for this provisionally approved medicine? Is this document.*

Our response

ACC would most likely review such reports to assist in making a decision on providing cover for a treatment injury claim relating to one of the specific medicines. As advised in our response of 16 November 2023 (*our ref: GOV-028541*), cover decisions for treatment injury claims are made on an individual basis, and will take into consideration any information and evidence relevant to the claim. This may include the reports and other resources you have noted if they are relevant. Please refer to the policies provided in GOV-028541 for information about the treatment injury cover decision process and what information is used to make those decisions. Noting this, ACC will review reports, such as those mentioned in your request, if they are relevant to an individual treatment injury claim.

As this information may be of interest to other members of the public

ACC has decided to proactively release a copy of this response on ACC's website. All requester data, including your name and contact details, will be removed prior to release. The released response will be made available www.acc.co.nz/resources/#/category/12.

If you have any questions about this response, please get in touch

You can email me at GovernmentServices@acc.co.nz. If you are not happy with this response, you can also contact the Ombudsman via info@ombudsman.parliament.nz or by phoning 0800 802 602. Information about how to make a complaint is available at www.ombudsman.parliament.nz.

Ngā mihi

Sara Freitag
Acting Manager Official Information Act Services
Government Engagement