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Athina Andonatou

By email: fyi-request-14982-bcadc163@requests.fyi.org.nz
Ref: H202108633

Tēnā koe Athina

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 18 July 2021 as a follow up of your previous request (reference H202103354).

Please find a response to each part of your request below.

> *"The link you provided me only covered Sittings of 7 November 2017 to 2 September 2020, so I was not able to see the Statements of Indemnity informing the public of those decisions that were provided to the House of Representatives on 11 February 2021. Please send me the correct link."*

The Ministry has been in contact with the Ministry of Business, Innovation and Employment (MBIE) regarding this part of your request as it is a follow up from MBIE's part of a previous OIA transfer. MBIE has provided the following links for each individual indemnity statement:

Pfizer:
- www.parliament.nz/resource/enNZ/PAP_108020/594cae3df86bd50cd51884cb299ca93a650df927.

Novavax:
- www.parliament.nz/resource/enNZ/PAP_108022/078f83d8d627e2d967f1521c2d27d6cae4a42832.

AstraZeneca:
- www.parliament.nz/resource/enNZ/PAP_108023/60064690a748132f1b98525abfd8a0224a7a91ce.

Janssen:
- www.parliament.nz/resource/enNZ/PAP_108024/26cec0146f2f3a8a72d9380cd0a3a7ccdcb01db5.

"1) The due diligence process used to assess the performance and delivery of Pfizer's vaccine"

On 29 July 2021, you clarified that you were seeking information regarding how the effectiveness of the vaccine is measured and what definition of 'effective' is being used. The measures of efficacy and effectiveness of the vaccine are publicly available. You can find information at the following links:

- www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-effectiveness-and-protection#How-effective.
- www.medsafe.govt.nz/profs/PUArticles/June2021/Spotlight-on-Comirnaty-vaccine.html.
- https://pubmed.ncbi.nlm.nih.gov/33301246/
- www.nejm.org/covid-vaccine.

"2) What information you used to inform your decision that Pfizer has not been reckless in the development of its vaccine?"

On 29 July, you clarified that you were seeking evidence used to determine that Pfizer's COVID-19 vaccine (Comirnaty) was fit for purpose. Medsafe has interpreted this as a request for information regarding the efficacy, safety and quality of Comirnaty. The documents to support the assessment are commercially sensitive. As such, this part of your request is withheld under section 9(2)(b)(ii) of the Act where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

However, the standards for efficacy, safety and quality of vaccines are publicly available from the clinical trials and trial protocols, which can be found at the links above and also here: https://covid19.trackvaccines.org/vaccines/.

"3) You quote that "This assessment has been reinforced through Medsafe's extensive review of the safety and effectiveness of the vaccine, with Medsafe granting provisional approval for its use on 3 February 2021". However, not all of the conditions of Medsafe's provisional approval have been addressed so how can you truly say their has been an extensive review of the safety and effectiveness of the vaccine?"

We note that this is an opinion of Medsafe's assessment process. Medsafe has thoroughly reviewed the information provided and granted provisional approval by assessing all the information that is available. While the Act enables people to request official information from the Ministry of Health (the Ministry), it only applies to information the Ministry holds. There is no obligation to create information in order to respond to requests, nor is the Ministry obliged to provide an opinion. The Act does not support requests in which a requester quotes information or asserts an opinion and then seeks some form of comment on it, couched as a request for official information. This part of your request is refused under section 18(g)(i) of the Act on the grounds that the information requested does not exist.

"4) You quote that "It is not unexpected for pharmaceutical companies to seek indemnities from governments in circumstances where clinical trials are restricted, or where a purchase agreement is concluded before full trials are completed". Which of these categories does the indemnity granted for the Pfizer vaccination fall under?"

The Ministry has been in contact with MBIE regarding this part of your request. MBIE has advised that it was of the view that both categories applied when considering COVID-19 vaccine indemnities.

"5) Please provide the criteria ACC uses to diagnose a "treatment injury" and what evidence one would have to supply to be provided treatment and support for injuries caused by a vaccination.
6) Finally, please provide me with details of how many people have successfully been awarded treatment and support for any vaccine related injury."

On 28 July 2021, parts 5 and 6 of your request were transferred to Accident Compensation Corporation (ACC). You can expect a response to that part of your request from ACC in due course.

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 Ministry of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

Clare Perry
Deputy Director-General
Health System Improvement and Innovation