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19/02/2021

Virginia Crawford

By email: fyi-request-14492-f5b3ebf2@requests.fyi.org.nz
Ref: H2021001196

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 12 February 2021 for follow up information relating to your previous request for regarding COVID vaccines.

You asked the following:

> *'I note that this vaccine has been provisionally approved with 58 conditions.*
>
> *If any or some of these conditions are not fulfilled to your satisfaction by the scheduled reporting date, what will be the effect?'*
>
> *In particular, the following condition:*
>
> *"Any homology between translated proteins (other than the intended spike protein) and human proteins that may, due to molecular mimicry, potentially cause an autoimmune process should be evaluated. Due date: July 2021. Interim report: March 2021".*

Medicines with provisional approval may be used in New Zealand. One vaccine (Comirnaty) has been provisionally approved for nine months. At the end of this period the options are to:

- Give full approval if the obligations are fulfilled and the data provided show that quality, safety and efficacy are acceptable.
- Renew the provisional approval if some but not all obligations are fulfilled.
- Not renew the provisional approval so that the vaccine becomes unapproved if the obligations are not met or the data shows the vaccine does not have acceptable quality, safety and efficacy.

I trust this information fulfils your request. 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.

Yours sincerely

Chris James
Group Manager
Medsafe