

15 December 2020

[REDACTED]

By email: [REDACTED]
Ref: H202008781

Dear [REDACTED]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 4 December 2020 for:

*"It was reported in October 2020 that Johnson and Johnson's ENSEMBLE trial of its Covid-19 vaccine was paused due to an "unexplained illness".
What information has the NZ Ministry of Health sought or been supplied about the pause in this trial and the illness that reportedly triggered it?"*

The Ministry of Health (via Medsafe) was informed by Johnson and Johnson on 16 October 2020 that they had paused the study. They contacted us again on 26 October 2020 to say that they had resumed the study. The Ministry has no further information regarding the trial.

Please see the below link for publicly available information:

<https://www.jnj.com/our-company/johnson-johnson-prepares-to-resume-phase-3-ensemble-trial-of-its-janssen-covid-19-vaccine-candidate-in-the-us>.

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.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely



Dr Kelvin Watson
**Group Manager, Immunisation, Testing and Supply
COVID-19 Health System Response**