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23 September 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022011176

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 26 August 2022 for information relating to verve therapeutics approval. You stated:

> *We have been notified that Medsafe has given approval to Verve Therapeutics for a genome edited phase 1 trial for lowering cholesterol.*

Medsafe will respond to each part of your request in turn.

> *Please can Medsafe provide all the documentation for VERVE-101. Namely, the application number and the approval conditions and ethical discussion that took place?*

The application number for VERVE-101 is TT55-0298 (2890), 2022 SCOTT 12078. All documents for VERVE-101 requested are publicly available. For the approval for VERVE-101 companies need to meet the conditions specified in section 30 of the Medicines Act 1981 available here: www.legislation.govt.nz/act/public/1981/0118/latest/DLM55429.html?search=ts_act%40bill%40regulation%40deemedreg_medicines+act_resel_25_a&p=1. Companies also need to meet the Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand Part 11, available on the Medsafe website at: www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf.

The Health and Disability Ethics Committee meeting minutes from the project titled 'A Study of VERVE-101 in Patients with Heterozygous Familial Hypercholesterolemia, Atherosclerotic Cardiovascular Disease, and Uncontrolled Hypercholesterolemia' is publicly available here: https://ethics.health.govt.nz/about/meeting-dates-venues-and-minutes/southern-minutes/ under 2022 Minutes; 8 March 2022.

> *Have any of the participants suffered any adverse effects?*
>
> *Do you require regular reports on the adverse effects?*
>
> *We are concerned over the approval as we did ask that we would be consulted on all GE medical trials."*

No reports have been received for participants of VERVE-101 suffering any adverse effects. The sponsor is required to report all fatal or life-threatening suspected unexpected serious adverse reactions (SUSARs) occurring in New Zealand trial participants where the treatment is known, as detailed in Medsafe's Guideline.

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

Chris James
Group Manager
Medsafe