Environmental Protection Authority
Te Mana Rauhī Taiao

ENQ-39107-W8M5N9

8 July 2020

Private Bag 632
Wellington 6140, New Zealand

Level 10, Grant Thornton House
215 Lambton Quay
Wellington 6011, New Zealand

epa.govt.nz
+64 4 916 2426

[redacted]
[redacted]
GE Free NZ in Food and Environment

Via: [redacted]@gefree.org.nz

Official Information Act Request

Dear [redacted]

I refer to your request received on 27 June 2020, for the following information:

1. *Where is the 2018-19 report?*
2. *Of the 25 patients how many died whilst undergoing the trial?*
3. *How many patients are still alive in June 2020?*
4. *What kind of adverse events occurred in the trial?*
5. *How many patients had pustules?*
6. *How many of the patients suffered from adverse events?*
7. *Please may I have a copy of the contingency Plans v1.0 2016 that were developed?*
8. *Did the EPA request the reports of treatment related Serious adverse events (SAE) listing?*
9. *If so please can we see a copy?*
10. *If not is there a way to obtain them and send them to me?*
11. *Why did the EPA not require the serious adverse events to be reported unless there was "transmission"?*
12. *How was it known that transmission did not occur if the patients were living and mingling in the community?*

Your request has been treated as a request for information under the Official Information Act 1982 (OIA).

The 2018-19 report (Question 1) that was inadvertently omitted from the previous OIA response to [redacted] on 26 June was sent to you on 29 June.

With regards to your other questions, the EPA does not assess, monitor or hold any records of effects, including adverse effects, on patients (s38I of the Hazardous Substances and New Organisms Act 1996). The information you are seeking is believed to be more closely connected with the functions of MedSafe, which is the government agency with responsibility for oversight of clinical trails. In these circumstances, we are required by section 14 of the Official Information Act to transfer your request.

We have transferred Questions 2 to 6, and 8 to 11 to MedSafe. You will hear further from MedSafe in response to these questions. You can contact MedSafe at askmedsafe@health.govt.nz.

With regard to Question 7, the EPA does not hold the document “contingency plans v1.0 2016”. Therefore I am refusing your request under s18 (g) of the OIA.

With regard to Question 11, which has been transferred to MedSafe to answer,“transmission” applies to anyone who is not the patient, who is within the scope of our consideration and ability to impose controls. Under section 38I(4)(a), we cannot take into account any effect of the medicine on the person to whom the medicine is administered.

With regard to Question 12, the EPA imposed controls regarding pustule management and bandage disposal, as well as requiring the sponsor to ensure the recipients were informed of those requirements, and for the reporting of any evidence of transmission. The decision document, on the EPA website, lists the controls imposed: https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP202601/49e237a0ad/APP202601-APP202601-Decision.pdf

You have the right to seek an investigation and review of this decision by the Ombudsman. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz.

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz.

Yours sincerely

Dr Clark Ehlers
Acting General Manager
Hazardous Substance and New Organisms