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2 September 2020

Claire Bleakley
President
GE Free NZ in Food and Environment

By email: president@gefree.org.nz
Ref: H202005963

Dear Claire Bleakley

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) relating to the SillaJen Biotherapeutics Inc trial (APP202601). The following questions were partially transferred by the Environmental Protection Authority to the Ministry of Health (the Ministry) on 7 August 2020:

> *"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?*
> *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"?"*

My responses to your questions are as follows:

2. "Of the 25 patients how many died whilst undergoing the trial?"

Medsafe issues guidance for the sponsors of clinical trials of new medicines (www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf). Sponsors are required to report all fatal adverse reactions but not all fatalities.

As of June 2019, 49 patients were recruited into this trial across two sites in New Zealand. Of the 49 patients, 26 patients dropped out of the trial, which includes those who withdrew or were deceased due to disease progression. The Ministry does not hold information on the numbers of patients who died while in the trial and whether that was considered related to treatment. There are also no grounds to believe this information is held by another agency subject to the Act. As such, I am unable to provide the number who died during the trial under section 18(g) of the Act.

3. "How many patients are still alive in June 2020?"

Information of this nature is not required to be provided to the Ministry as part of the trial. As such, I am unable to provide this information to you under section 18(g) of the Act as it is not held by the Ministry and is not held by another agency subject to the Act.

4. "What kind of adverse events occurred in the trial?"
6. "How many of the patients suffered from adverse events?"

Only fatal or life-threatening suspected unexpected serious adverse reactions (SUSARs) occurring in New Zealand trial participants, where the treatment is known, are required to be reported. I can advise that one adverse event requiring hospitalisation was reported during the trial.

5. "How many patients had pustules?"

The Ministry does not hold this information as the sponsor is not required to report information of this nature and there are no grounds to believe that this information is held by another agency subject to the Act. As such, this part of your request is refused under section 18(g) of the Act.

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?"

Medsafe did not request the reports of treatment related serious adverse events (SAE) listing.

Line listings may be available from the sponsor – PPD Global. The contact details for its Auckland office are available at: https://www.ppd.com/who-we-are/location/auckland-new-zealand/.

11. "Why did the EPA not require the serious adverse events to be reported unless there was "transmission"?"

Medsafe does not require SUSARs that are not fatal or life-threatening to be routinely notified. Instead, SUSARs must be held in an accessible form and made available to Medsafe on request.

I trust that 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.

Please note that this response, with your personal details removed, may be published on the Medsafe website.

Yours sincerely

Chris James
Group Manager
Medsafe