Environmental Protection Authority
Te Mana Rauhī Taiao

Official Information Act Request

Requester's details
Date: 17 January 2025
Name: Jon Muller
Organisation: GE Free NZ
Email: secretary@gefree.org.nz
Reference number: ENQ-48851-D1R4J5

Tēnā koe e Jon

I refer to the second request in your letter received on 8 December 2024 for information relating to APP203530:

> **"Re: APP203530 genetically modified live-attenuated vaccinia virus (Pexa-Vec)**
>
> We note that in 2018 you approved the release of the Pexa-Vec (pexastimogene devacirepvec; JX594) for the Phase 1b clinical trial for patients with renal cell carcinoma (APP203530).
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> We note that the earlier trial you approved in 2016 with the same genetically modified vaccinia virus, Pexa Vec, for liver cancer (APP202601) was withdrawn early due to not meeting its end points. We were told that of the 49 NZ patients, 26 patients (53%) dropped out of the trial, which included those who withdrew, or died from the disease.
>
> In this trial (APP202601) we note that pustules were treated but any adverse effects from them were not reported as the EPA only required reporting of adverse events if there was transmission to others. We ask -
>
> 1. Why did the EPA not require adverse event reporting regardless of transmission?
> 2. Has the Phase 1b clinical trial ended?
> 3. Why was this trial approved when the outcome of the earlier trial APP202601 had such a concerning outcome?
> 4. Have the pustules for monkey pox been tested to confirm they are not really transmission of the Pexa Vec trials?
> 5. Please may we have the annual reports to the EPA as required under control 7 of the APP203530 application?"

We are responding to your questions individually.

1. Why did the EPA not require adverse event reporting regardless of transmission?

Pexa-Vec was assessed by the Environmental Protection Authority (EPA) under section 38I of the Hazardous Substances and New Organisms Act (the HSNO Act). Under section 38I(4)(a) of the HSNO Act, the EPA cannot take into account or assess any effect of a qualifying organism on the patient(s) to whom it is given. However, under section 38I(3), the EPA must assess the risk of any potential adverse effects on the public. This means adverse

event reporting was limited only to cases of transmission to any member of the public who was not a trial participant.

2. Has the Phase 1b clinical trial ended?

The Phase 1b clinical trial for APP203530 was not initiated, and the approval for this trial has now expired.

3. Why was this trial approved when the outcome of the earlier trial APP202601 had such a concerning outcome?

As noted above in our response to Question 1, the EPA does not and cannot make assessments based on effects on individual recipients. APP203530 was approved on 20 April 2018, while the Pexa-Vec trial covered by approval APP202601 was still ongoing. That trial concluded in July 2020. No adverse effects to participants were reported at 142 sites around the world at the conclusion of the clinical trial covered by APP202601.

4. Have the pustules for monkey pox been tested to confirm they are not really transmission of the Pexa Vec trials?

The EPA holds no information related to this question. Therefore, this part of your request is refused under section 18(e) of the Official Information 1982 (OIA), because the information requested does not exist. We note that the monkeypox virus is a different species to the vaccinia virus.

5. Please may we have the annual reports to the EPA as required under control 7 of the APP203530 application?

As the trial did not take place, annual reports were neither required, nor submitted. Therefore, this part of your request is refused under section 18(e) of the OIA, because the documents requested do not exist.

I hope this information is helpful. You have the right to seek an investigation and review by the Ombudsman of this decision under section 28(3) of the OIA. 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 We may publish your request and our response on our website, www.epa.govt.nz. We make OIA responses available so others can read more about the work we do and the questions we are asked. Any information that might identify you will be removed to protect your privacy.

Nāku noa nā

Dr Christopher Hill
General Manager, Hazardous Substances and New Organisms