MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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11 October 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022012687

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 the Environmental Protection Authority (EPA) on 1 September 2022. Your request was transferred to Manatū Hauora (Ministry of Health) on 14 September 2022 pursuant to section 14(b)(ii) of the Act. Each part of your request is responded to below:

> *"1. If there is possibility that the treatment can pass through to fetal or breast milk is there not a possibility that it could transfer through sexual fluids? How has this been addressed?"*

EPA have provided the below information for your query in their formal transfer of your request (ENQ-44610-V2Z7C8 refers):

> *"We would like to note that while we discussed the potential transmissibility of CARVYKTI on Page 16 of the Staff Assessment Report, which advised the decision maker on APP204391 (see: APP204391-EPA-staff-assessment-report.pdf), we merely noted that any possibility that the potential for the transmission of CARVYKTI T cells to a foetus is unknown, but any such transmission is highly improbable because the approval holder does not recommend the use of CARVYKTI in women who are pregnant, or are of childbearing age and not using contraception.*
>
> *The EPA holds no further information that addresses your question 1. Medsafe, as the agency that is responsible for regulating its usage in clinical settings and addressing any potential health risks, may have additional information that addresses this and your other questions.*
>
> *For further information about this approval, please see here: www.epa.govt.nz/news-and-alerts/latest-news/gmo-blood-cancer-therapy-gains-epa-approval/."*

Medsafe holds no further information addressing the potential transmissibility of CARVYKTI. As such, your request is refused under section 18(g) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

"2. In the case of an accident we would like you to consider requiring the patient to wear a bracelet detailing the therapy so the ambulance people to know. This is to avoid any interaction with other treatments given that could seriously affect the patient.
3. Is this approved APP204391 part of a clinical phase II/ III trial approved as GRAS or has it undergone full clinical trials? If so please can you point us to the earlier trial documentation outcomes?"

A New Medicine Application has been made for Caryrti, which is currently under evaluation by Medsafe. However, the release of this application is withheld in full under section 9(2)(ba)(ii) of the Act, to protect information that is subject to an obligation of confidence and making it available would likely damage the public interest.

Information on the Medsafe evaluation process can be found at: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

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

Matthew Spencer
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Medsafe