19 April 2021

A Mark
Via email: fyi-request-14970-91b7a6e9@requests.fyi.org.nz

Dear A Mark

REQUEST FOR INFORMATION: INFORMATION REGARDING FUNDING FOR TRIKAFTA

Thank you for your request dated 21 March 2021 to the Ministry of Health under the Official Information Act 1982 (OIA) for information relating to the funding of Trikafta. Your request was transferred from the Ministry to PHARMAC on 22 March 2021 as your request falls within our portfolio responsibilities.

We note that "Trikafta" is a brand name used in some overseas countries for the pharmaceutical "elexacaftor/tezacaftor/ivacaftor and ivacaftor". This product is not currently registered in New Zealand.

You requested:

1. *Copies of all briefings, advice, aides memoire, meeting notes or any other information regarding decisions made or to be made relating to the funding of Trikafta in New Zealand*
2. *Has [Vertex] approached Pharmac to begin the process of approving Trikafta for New Zealanders with cystic fibrosis, and, if not, whether the Minister of Health has considered approaching Vertex to ask them to do so.*

New Zealand's medicines funding process
PHARMAC is the New Zealand government agency that decides which medicines and related products are funded in New Zealand. Refer to the PHARMAC website to read about the medicines funding process: https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/

A funding application must be submitted to PHARMAC for a medicine to be considered for public funding. Anyone can submit a funding application (eg suppliers, clinicians, consumers) however most applications are submitted by suppliers as they generally hold all the information required for assessing a funding application.

In general, PHARMAC requires medicines to be approved by Medsafe before assessing an application for funding.

Medsafe is the authority responsible for evaluating the safety and efficacy of therapeutic products (eg medicines) in New Zealand. Suppliers must apply to Medsafe for approval of their products before they can be distributed in New Zealand. Refer to the Medsafe website

to read about Medsafe's evaluation and approval process: https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp

Copies of documents relating to the funding of Trikafta
PHARMAC has not yet considered or discussed funding Trikafta as we do not hold the information necessary to assess funding this medicine.

We have not provided any documents for your request for "copies of all briefings, advice, aides memoire, meeting notes or any other information regarding decisions made or to be made relating to the funding of Trikafta" as these documents do not currently exist (section 18(e) of the OIA).

Discussions with Vertex about the funding of Trikafta
PHARMAC operates independently of the Minister of Health, and the Ministry of Health. This independence allows the public to have confidence in the impartiality of funding decisions. Therefore, the Minister is unable to intervene in PHARMAC's decision-making process.

At this time, PHARMAC has not received any funding applications for Trikafta however, PHARMAC has engaged with Vertex about the possibility of their putting forward an application for Trikafta.

PHARMAC also recently attended a meeting with representatives from Vertex, Medsafe, and two consumer advocacy groups, Trikafta for Kiwis and Cystic Fibrosis NZ. We have been advised by Vertex that it is actively working on applications to both Medsafe and PHARMAC for Trikafta. We have invited Vertex to concurrently apply to Medsafe for approval and to PHARMAC for funding of Trikafta. Medsafe and PHARMAC would consider the applications in parallel.

Release of information under the OIA
Please note that PHARMAC approaches its assessment of requests for information under the OIA on the basis that, once released, the information becomes publicly available - in other words once we release the information to you it becomes available to any other party in that exact form (whether by you distributing it to others or by virtue of us receiving the same request from a different third party).

Please note you have the right, by way of complaint under section 28(3) of the OIA to an Ombudsman, to seek an investigation and review of our decision.

We trust that this information answers your queries. We are making our information more freely available, so we will now publish selected OIA responses (excluding personal details) on our website. Please get in touch with us if you have any questions about this.

Yours sincerely

Rachel Read
Manager, Policy and Government Services