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24 May 2023

Mal Robertson

By email: fyi-request-22777-5c06a3de@requests.fyi.org.nz
Ref: H2023025613

Tēnā koe Mal,

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Haoura (the Ministry of Health) on 19 May 2023 for information regarding tasimelteon. Please find a response to each part of your request below:

> *1) "Could you please provide information regarding tasimelteon as a treatment for N24 disorder in New Zealand? Specifically, the accessibility, legality, cost, and any other relevant information relating to New Zealanders using tasimelteon."*

There are no products containing tasimelteon that are approved for use in New Zealand. Products containing tasimelteon would therefore be 'unapproved medicines'. This part of your request is therefore refused under section 18(e) of the Act, as the documents alleged to contain the information requested do not exist.

Information about access to unapproved medicines can be found on the Medsafe website: https://www.medsafe.govt.nz/profs/riss/unapp.asp.

You can search for approved medicines using the Medsafe product database: https://www.medsafe.govt.nz/regulatory/dbsearch.asp.

> *2) "If tasimelteon is not available in this country at this stage, please provide any information regarding the decision to not make it available, if this information exists. If there has not been a decision, and this medication is not available to New Zealanders, please advise why this is."*

Companies that wish to sell a new medicine in New Zealand must first make an application to Medsafe. No applications have been made to Medsafe for approval of a product containing tasimelteon. Therefore, this part of your request is refused under section 18(g)(i) of the Act, as the information requested is not held by Manatū Hauora and there are no grounds for believing is it held by another agency subject to the Act.

Information on Medsafe's approval process is publicly available here: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

Questions relating to decisions to funding should be directed to Pharmac, who are responsible for funding medicines in New Zealand. You may wish to contact Pharmac at: enquiry@pharmac.govt.nz.

> *3) "If tasimelteon is available, please advise approximate numbers of those regularly receiving this medication in 2023, if you hold this data."*

Medsafe does not hold records of tasimelteon being supplied as an unapproved medicine in New Zealand. Therefore, this part of your request is refused under section 18(g)(i) of the Act, as the information requested is not held by Manatū Hauora and there are no grounds for believing it is held by another agency subject to the Act.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe