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19 June 2025

s 9(2)(a)

Ref: H2025067388

Tēnā koe 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 Ministry of Health – Manatū Hauora (the Ministry) on 21 May 2025 for information regarding the importation of melatonin. Please find a response to each part of your request below.

> *"Medsafe has recently taken action to block the personal importation of the low-dosage sleep supplement melatonin. This has not previously been the case. Melatonin is available without prescription or restriction to over 380 million citizens of Canada and the United States.*
>
> *I would very much like to have some further information about this policy. In particular:*
>
> *1. Was this policy instigated at the request of the Minister of Health or by Medsafe?*

There has been no new policy instigated in relation to the importation of unapproved products containing melatonin. Therefore, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

For your information, a recent change was made to the classification of melatonin as signalled in the Gazette Notice available at: https://gazette.govt.nz/notice/id/2025-go3258

Further information about this change will be published on the Medsafe website soon.

For context, I can advise that on 24 April 1996, at the 16th meeting of the Medicines Classification Committee (MCC), a statutory committee constituted under the Medicines Act 1981, the classification of melatonin was considered and a recommendation made that it should be a prescription medicine. This was in line with availability in other developed regulatory regimes such as Australia, UK, Europe. Recommendations from the MCC that are accepted by the Minister of Health, or their delegate, are signed and published in the New Zealand Gazette.

Broadening access to melatonin containing medicines has been considered by the MCC on five subsequent occasions.

In 2019 a recommendation from the MCC was accepted that permitted sale of melatonin as a pharmacist only medicine for the treatment of primary insomnia in patients aged 55 years or older, when supplied in packs that met the requirements specified. Although this provision is

available, and packs that meet the requirements have been approved for sale in Australia, no company, to date has applied to have such a pack approved for sale in New Zealand.

In 2023 a recommendation from the MCC was accepted, adding the treatment of jet lag in adults aged 18 years and over to the indications permitted for a pharmacist only pack. Again, although this provision is available, and packs that meet the requirements have been approved for sale in Australia, no company, to date has applied to have such a pack approved for sale in New Zealand.

> *2. What decision making process led to this policy of seizure at the border in cooperation with NZ Customs?*

There is no new policy relating to seizure at the border. This part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

Section 43 of the Medicines Act 1981 specifies that a person accessing a prescription medicine can only do so on the authority of an authorised prescriber. There is information published on the Medsafe website that explains the requirements around importation of medicines, please see the following link: www.medsafe.govt.nz/Consumers/MIET/ImportMedicines.asp.

Medsafe is referred parcels, thought to contain medicines, by New Zealand Customs at the border, for review. If the parcel is a personal import and contains medicines that are unscheduled (general sale), pharmacy only or pharmacist only, the parcel is released to the recipient. If the parcel is a personal import and contains prescription medicines, the recipient is contacted and asked to get authorisation from a prescriber for the release of the parcel. It is possible that some medicine containing parcels are not identified by Customs and so are not referred to Medsafe but are released to the recipient.

> *3. What is the cost of implementing this policy?*

This is not a new policy that has been implemented. This part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

> *4. Can you specify the number and nature of the reported adverse events in NZ that have arisen due to personal importation of low dosage melatonin sleep supplements?*

Information on suspected adverse reactions reported to the Centre for Adverse Reactions Monitoring (CARM) is publicly available here: www.medsafe.govt.nz/SMARS/Disclaimer. Since the source of a medicine is not required to be reported, the Ministry is unable to provide the information you have requested. Please note that as reporting is voluntary, the information provided in reports to CARM cannot be used to estimate the rate of problems associated with any medicine.

> *5. How many hospital admissions have been due to imported melatonin?*

The Ministry does not hold information within scope of this part of your request. The Ministry consulted with Health New Zealand – Te Whatu Ora, which also advised that it does not hold this information. Therefore, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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.

Nāku noa, nā

Chris James
Group Manager
Medsafe