MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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30 October 2024

Jodie Bruning

By email: fyi-request-28602-c1010dad@requests.fyi.org.nz
Ref: H2024052860

Tēnā koe Jodie

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 30 September 2024. Each section of your request is answered below:

> *What year did the Hardys DEN formulation first become recognised by Medsafe.*

Hardys DEN has been marketed as a dietary supplement. There is no pre-market assessment or approval process for dietary supplements, as such Medsafe has not 'recognised' the product and is unaware of when this product was first marketed in New Zealand.

> *Number of adverse events reported to Medsafe annually over the time period identified in question, and what each adverse event comprised (1).*

This section of your request is refused under section 18(d) of the Act, as the information requested is publicly available. You can find relevant reports by searching for any of the ingredients contained in the product on Medsafe's website here: .

> *Minutes from any Medsafe and/or Ministry of Health consultations seeking advice for*
>
> *(a) removing DEN's status as a dietary supplement, and/or*
> *(b) recategorizing the original DEN a prescription medicine.*

Neither Medsafe nor the Ministry of Health has consulted or sought advice to remove DEN's status as a dietary supplement, or to recategorize it as a prescription medicine. As such, your request for this information is therefore refused under section 18(e) of the Act as the information requested does not exist.

DEN does not meet the definition of a dietary supplement as it contains ingredients that exceed the maximum daily doses specified in the Dietary Supplements Regulations 1985 and some ingredients are scheduled medicines. It is a medicine because it is marketed for an intended therapeutic purpose (please refer to section 4 of the Medicines Act 1981). Additionally, it is a prescription medicine because one of the ingredients it contains is included in Part 1 of Schedule 1 of the Medicines Regulations 1984 as a prescription medicine.

Terms of reference used throughout this consultation and decision-making process, including all the relevant legislation and/or regulatory protocols and/or guidelines which guide officials in the Ministry of Health and Medsafe concerning this matter.

As above, there was no consultation and therefore the Ministry does not hold the information requested for this section of your request. As such, this section of your request for information is refused under section 18(e) of the Act.

Ministry of Health and Medsafe information concerning actions by foreign medicines regulators to reclassify the DEN product as a prescription medicine, particularly in Canada, Australia, the UK, South Africa and the United States.

Medsafe was informed by the New Zealand supplier of DEN, of action taken by Health Canada in March 2003 to stop shipments of DEN crossing the border from the United States of America as it did not have the required approval to be supplied as a medicine.

The classification of a medicine applies once a determination that a product is a medicine has been made and the product has been granted consent / approval for distribution as a medicine. Medicines in New Zealand may be classified as prescription medicine, restricted medicine, pharmacy only medicine or general sales medicine. Australia, like New Zealand classifies substances and medicines are classified based on the classification of their ingredients. In the UK medicines are classified.

Medsafe is unaware of any actions taken by overseas medicines regulators to change the classification of a substance or a medicine specifically to make DEN a prescription medicine. As such, this section of your request for information is refused under section 18(e) of the Act as the information does not exist.

All information which considered by officials pertaining to the risk profile of this dietary supplement, including:
(a) The dose/dosage; and/or
(b) The risk profile of specific ingredients; and/or
(c) The concentrations (levels) of each ingredient; and/or
(d) References used by Medsafe which inform and guide officials on the safety profile of each of the ingredients of concern, and the concentrations/dose of each ingredient.

As above, Medsafe does not hold information about the risk profile of DEN. The following legislative references were the basis for the decision made by Medsafe to advise the company marketing the DEN product that it was a medicine that had not been granted consent, and that it did not meet the requirements to be marketed as a dietary supplement. As such, this section of your request for information is refused under section 18(e) of the Act.

- Regulation 2A of the Dietary Supplements Regulations 1985 (www.legislation.govt.nz/regulation/public/1985/0208/latest/DLM2856310.html)
- Regulation 3 of the Dietary Supplements Regulations 1985
- Regulation 11 of the Dietary Supplements Regulations 1985
- Section 4 of the Medicines Act 1981 (www.legislation.govt.nz/act/public/1981/0118/latest/DLM55001.html)
- Section 3 of the Medicines Act 1981
- Section 20 of the Medicines Act 1981
- Schedule 1 Part 1 of the Medicines Regulations 1985 (https://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM96863.html)

All published literature held by Medsafe on the safety and efficacy profile of DEN or equivalent formulations.

Medsafe does not hold any published literature on the safety and efficacy profile of DEN or equivalent formulations. As such, this section of your request for information is refused under section 18(e) of the Act as the information does not exist.

Any information received by Medsafe officials concerning the expected rise in cost of the DEN product as a consequence of Hardys Nutritionals complying with the Medsafe directive and moving to process the product (which cannot be patented) as a pharmaceutical."

Medsafe does not hold any information relating to the cost or any proposed increase in cost of the DEN product. As such, this section of your request for information is refused under section 18(e) of the Act as the information 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 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