MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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9 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022016818

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 Manatū Haoura (the Ministry of Health) on 14 November 2022 for information relating to Export Certificates for Dietary Supplements. You requested:

> *Can you send me some information about the number of Export Certificates for Dietary Supplements that Medsafe have dealt with over the last two years? I'm interested to know:*
> 1. *How many were applied for*
> 2. *How many were approved*
> 3. *How many were rejected*
> 4. *For the rejections the reasons for the rejection*

On 14 November 2022, you noted that in relation to:

- Questions 1 to 3: data for the 2021 calendar year and 2022 calendar year (to the end of October) would suffice; and
- Question 4: *"We want to know if it is a therapeutic claim on the label, or somewhere else or how and by what criteria you have determined it is a therapeutic purpose. For "# rejected as does not meet the definition of a dietary supplement' - on what basis does the product not meet the definition of a dietary supplement? For example is this because it is a topically applied product or what is the reason?"*

On 5 December 2022, you were contacted in accordance with section 18B of the Act and agreed to refine the timeframe of your request for question 1 to 3 to the 2022 calendar year (to the end of October).

Export Certificates for Dietary Supplements that Medsafe have dealt with for the 2022 calendar year end of October details are provided in the table below:

Table 1.

Applications made	87
Issued	64
In progress (awaiting payment, processing, or release)	7
Declined	16

1. *For the rejections the reasons for the rejection*

The reasons for rejections of Export Certificates for Dietary Supplements that Medsafe have dealt with for the 2022 calendar year end of October details are provided in the table below:

Table 2.

Reason for Rejection	Therapeutic Purpose Noted by Medsafe
Product labelling and content on New Zealand website indicated that the product was for a therapeutic purpose.	Erectile disfunction Removal of mucus build-up and congestion
Product labelling indicated that the product was for a therapeutic purpose.	Treat enlarged prostate, increase testosterone levels Menopause support, inflammation management Manage menopause and acne Lower cholesterol Control chronic inflammation Treat disk degeneration Prevention of viral infection Treatment of anorexia Prevention and treatment of constipation Treatment of injured muscles Treatment of heart disease and chronic fatigue syndrome Enhancement of cognition and memory (nootropic mode of action) Treat liver damage and protect against alcohol Treatment of joint injury and degeneration Treatment of mineral deficiencies Skin whitening
Product in breach of dietary supplement regulation 18.	N/A
Incorrect labels were provided in the application to Medsafe. Labels did not match those the product was to be labelled and marketed with.	N/A

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.

Yours sincerely

Chris James
Group Manager
Medsafe