MEDSAFE
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29 November 2023

J Bruning

By email: fyi-request-24621-91912a8d@requests.fyi.org.nz
Ref: H2023032704

Tēnā koe J

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 1 November 2023 for information regarding the equity of access for low side-effect formulations for therapeutic treatment of anxiety, depression, and ADHD. Please find a response to each part of your request below.

> *The processes required for a company (who has market authorisation) seeking approval of broad-spectrum multinutrient formulations to secure approval as a medicines. This is so that this product may be approved on the Pharmac schedule.*

This part of your request is refused under section 18(d) of the Act, as the information requested that relates to Medsafe's approval of medicines is publicly available here: www.medsafe.govt.nz/medicines/regulatory-approval-process.asp.

> *If Pharmac does not require a broad-spectrum multinutrient formulation to be approved as a medicine in order to go on the Pharmac register, please confirm.*

Irrespective of regulation or approval, a funding application would be required to be considered for funding. If a product is considered as a medicine, an application is usually required to be made to Medsafe and the product approved in New Zealand, prior to the funding process. Pharmac is still able to work through the funding application process if the product is considered a supplement and therefore not required to be registered for use within NZ.

> *Please advise the fee structure at all stages to securing approval for a broad-spectrum multinutrient formulation. Please confirm that that fee structure is never altered during the application process.*

This part of your request is refused under section 18(d) of the Act, as the information requested is publicly available through the following links:

- www.medsafe.govt.nz/regulatory/fees.asp.
- www.medsafe.govt.nz/consumers/safety-of-medicines/medsafe-evaluation-process.asp.

Please advise the processes by which a safety is judged when a risk profile is known and is very low.

This part of your request is refused under section 18(d) of the Act, as the information requested is publicly available here: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

Please advise how improved access to socially disadvantaged populations and Māori and so addressing inequities for nutrient-deficient populations are judged.

A funding application goes through Pharmac's regular process that involves getting clinical advice on the population for who the treatment is intended. This advice is taken into consideration when deciding on whether a product will be open listed (eg. no restrictions on access) or whether restrictions such as Special Authority criteria are put in place.

Please advise how exposures to young people are considered if a young person has a choice of psychiatric medication or a broad-spectrum multinutrient formulation. Is the impact of side-effects to young people and the potential for young people to stop medication (non-compliance) of a psychiatric medicine judged against a broad-spectrum multinutrient formulation?

The applicant is responsible for providing relevant post-market data.

Are cohort studies as well as clinical trials included for consideration when the safety profile is considered for low-risk nutrients which have a known lower risk-threshold?

It is up to the applicant to provide evidence to support the safety profile, noting that cohort studies do not prove causal association, or a lack of side effects and that benefit can only be shown in a clinical trial.

How the new Act takes account of financial uncertainties for multinutrient formulations which are not patented and as such can be reverse engineered by other companies. I.e. drug companies with a newly patented product will understand that there will be a limited range of market entrants with similar claims - however this assurance does not apply to multinutrient retailers.

The principles of the Therapeutic Products Act 2023 (the TPA) include that regulation of therapeutic products should support an open and well-functioning market for those products. The TPA does not contain any provisions related to patents.

I trust this information fulfils your request. 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

Derek Fitzgerald
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Medsafe