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12 June 2023

Sunil Williams

By email: fyi-request-22818-c5f7416a@requests.fyi.org.nz
Ref: H203025372

Tēnā koe Sunil

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 15 May 2023. You requested:

The Ministry received this advice from Medsafe's manager of compliance Derek Fitzgerald.

"If the ministry advocated that certain medicines be used off-label, this could come in for criticism as a potential breach of the [Medicines Act 1981]...

... You may wish to obtain a legal opinion on the information the ministry publishes/wishes to publish on this."

Until recently, the Ministry published advice to the public on its website in regard to the safety and reversibility of chemical puberty blockade for treating childhood gender distress.

This is an off-label use of certain medicines.

I am asking if the Ministry did seek legal advice in regard to its advocacy for this off-label use.

I am also asking for any documents pertaining to this advice. Including documentation of requests made to, and responses from legal advisory.

Medicines currently used as puberty blockers in New Zealand may fall under the "unapproved use of approved medicines" category. While they may not have Medsafe 'approval' for this use, they can still be prescribed by authorised prescribers, if their patients are deemed to require the treatment. You can read more about use of unapproved medicines or the use of approved medicines for unapproved purposes here: www.medsafe.govt.nz/profs/RIss/unapp.asp.

No legal advice has been identified in relation to advocacy for off-label use of puberty blockers. Therefore, your request is refused under section 18(e) of the Act as the requested document does not exist.

Please note, Manatū Hauora adjusted the website content regarding puberty blockers while an evidence brief to support this area was being completed. The relevant evidence brief is currently being prepared for release and is scheduled to be published in July 2023.

The September 2022 update to the website recognised that overseas jurisdictions were reviewing the use of puberty blockers in their health systems particularly in younger people.

Any medical intervention carries a balance of benefit and risk that needs to be considered in context by the person in partnership with their health professional.

It is important that health services meet the needs of all New Zealanders, with inclusiveness and dignity for all. Manatū Hauora is committed to providing better access, support and safe treatment for rainbow communities through our health system and ensuring the system is responsive to the needs of transgender, intersex, and gender-diverse people.

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

A handwritten signature in blue ink, appearing to read 'Phil Knipe', with a stylized flourish extending to the right.

Phil Knipe
Chief Legal Advisor
Government and Executive Services | Te Pou Whakatere Kāwanatanga