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S Mills

By email: fyi-request-12608-db54e312@requests.fyi.org.nz

Ref: H202002284

Dear S Mills

Response to your request for official information

Thank you for your request on 12 April 2020 under the Official Information Act 1982 (the Act) for information on the recommendation made by the Medicines Classification Committee (the Committee) in regard to the reclassifications of Alkyl Nitrites including Amyl Nitrites.

A copy of your full request and information in response to your queries is outlined below.

"- A synthesis of material presented and/or made available to the committee providing evidence to support these schedule changes." —

The document 'Feedback from consultation (joint feedback from NZAF and the NZ Drug Foundation)' was identified within the scope of your request and can also be found available publicly on the Medsafe website:

https://www.medsafe.govt.nz/profs/class/CommentsOnSubmissionAgen63.html

"- If for some reason this does not exist, instead any communication, correspondence, documentation, or further discussion given for or against the following resolution made in the discussion section of 8.2.1: The Committee recommended harmonising the group entry for alkyl nitrites a prescription medicine.". -

Documents identified in scope of this part of your request are outlined in Appendix 1 and copies are enclosed. For your reference, the below documents may be of further interest to you and these can also be found publicly available on the Medsafe website.

- Agenda for the 63rd meeting: https://www.medsafe.govt.nz/profs/class/Agendas/Agen63/agen63.htm
- Minutes from the 63rd meeting: https://www.medsafe.govt.nz/profs/class/Minutes/2016-2020/mccMin10Oct2019.html

Please also note that the Committee considers recent classification changes in Australia routinely at each meeting in the interests of harmonisation. This means the Committee will consider whether the classification of these substances should be the same in New Zealand as they have become in Australia.

At the 63rd meeting, the Committee was asked to consider harmonisation of the classification of amyl nitrite, isoamyl nitrite, butyl nitrite, isobutyl nitrite, octyl nitrite, isopropyl nitrite and n-propyl nitrite and a group entry for alkyl nitrites, with Australia.

The Committee recommended harmonising the group entry for alkyl nitrites only. The Committee asked that Medsafe provide further information about the other specific nitrites, in particular amyl nitrite, for consideration at a future meeting. It should be noted that New Zealand already classifies amyl nitrite, isobutyl nitrite, butyl nitrite, octyl nitrite, and isoamyl nitrite as prescription medicines and has done so for many years. Isopropyl nitrite and n-propyl nitrite (which are associated with higher levels of harm) were unclassified and are now prescription medicines as they are captured by the new class entry.

There will be further consideration by the Committee at their 64th meeting to see if lowering the classification is appropriate for any alkyl nitrites. It is expected that this further information will be provided in an information paper that will be available for consultation before it is presented to the Committee again.

Once this paper is available, it will be published for consultation.

"- Any follow up communication or correspondence pertaining to the following point in the discussion section of 8.2.1: The Committee discussed how the indicated population are Men who have Sex with Men (MSM) and it was not clear to the Committee what the risks were around these substances."—

There has been no information identified within the scope of this request and as such your request is refused under section 18(e) of the Act as the information does not exist.

For your information however a paper is being developed to provide the Committee with this information.

"- Any follow up communication, correspondence, or planning for future engagement pertaining the following point in the discussion section of 8.2.1: The Committee was also not sure if the LGBTQI community was aware that these substances were being considered by reclassification and suggested that feedback from them should be sought.

This final point is of specific importance as it seems that feedback from the LGBTQI community was not sought prior to the schedule changes coming into effect in February 2020." –

As mentioned above, a paper on the reclassification of other specific alkyl nitrites (in particular amyl nitrite) is being prepared for the next Committee meeting and will be available for consultation. It is proposed to bring this paper to the attention of the LGBTQI community so they can provide feedback to the Committee.

There has been no additional information identified within the scope of this request and as such your request is refused under section 18(e) of the Act as the information does not exist.

I trust this fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review any decisions made on this request.

Please note that this response, with your personal details removed, may be published on the Medsafe website.

Yours sincerely

Chris James

Group Manager Medsafe

Appendix One:

#	Date	Title	Decision on release
1	15 July 2019	MCC 63: Harmonisation of the New	Information deemed out of
		Zealand and Australian schedules	scope of the request has
			been excluded
2	26 April 2019	Notice of final decisions to amend (or	Released in full
		not amend) the current Poisons	
		Standard	
3	6 June 2019	Notice of a final decision to amend (or	Released in full
		not amend) the current Poisons	
		Standard	
4	6 September	Products containing ingredient: Amyl	Some information has been
	2019	Nitrite	withheld under section
			9(2)(b)(ii) of the Act as it
			commercially sensitive.