

Medicines Classification Committee

Comments on Submissions Cover Sheet

Meeting	64th Meeting of the Medicines Classification Committee	
Agenda item	5.3 Update on outstanding agenda items from the 63rd meeting - Alkyl Nitrites	
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1. I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
2. I would like my name to be removed from all documents prior to publication and for my name not to be included within the list of submissions on the Medsafe website.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
3. If answered yes to point 2, to have my name removed from all documents prior to publication. I have provided a copy of my submission with my name removed along with my original submission.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> N/A



The Medicines Classification Committee
Medsafe
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19 March 2020

Decision to add a group entry for Alkyl Nitrites to the New Zealand Medicines Schedule

We would like to comment on alkyl nitrites noted in the Agenda Item 5.3 for the 64th Meeting of the Medicines Classification Committee.

The New Zealand AIDS Foundation (NZAF) is a registered charity and non-governmental organisation funded through contracts with the Ministry of Health and independent fundraising to provide a range of HIV and AIDS related services, including: HIV prevention and health promotion, HIV testing, counselling and support, research, policy, and information services.

We are extremely disappointed that the recommendation made at the 63rd meeting of the Medicines Classification Committee, to add a group entry for alkyl nitrites to the New Zealand Schedule as a prescription medicine, has been approved. The recommendation has been made without community consultation and a thorough understanding of poppers use and the poppers market in New Zealand. Our previous submission raised concerns around introducing changes to the classification, but these were not addressed at the MCC meeting.

We strongly recommend that the New Zealand classification for alkyl nitrites is reversed and enforcement delayed until a legal and viable alternative is made available. We also recommend community consultation is sought to understand poppers use and the market in New Zealand and develop a New Zealand specific approach. The decision to partially follow Australia's recent classification of alkyl nitrates has removed the opportunity to learn from the Australian experience over time and address the specific needs of affected LGBTQI communities in New Zealand. There are also key differences in the alkyl nitrites markets in Australia and New Zealand that will not be addressed through harmonisation and require further investigation.

This decision to add a group classification for alkyl nitrites (known informally as poppers) has effectively criminalised their use, disproportionately impacting LGBTQI communities and increasing the likelihood of harm. It is an extreme response to a drug which has had low levels of harm in New Zealand. Adding a group entry which restricts the sale of alkyl nitrites as a prescription medicine means there is no legal viable alternative to alkyl nitrites available in New Zealand that can help reduce discomfort during receptive anal sex.

We are also concerned at the lack of consultation and the difficulties we have experienced engaging in the classification process. As a community organisation with limited experience providing feedback to the Medicines Classification Committee, it has been difficult to understand the nature of the decisions being made by the Committee, the timeframes and stages within a decision making process,

and how to meaningfully engage in consultation. It remains unclear from the minutes and agenda exactly what information is being discussed and provided at the 64th meeting of the Medicines Classification Committee. This makes it difficult for us to provide relevant feedback. In this instance, the inclusion of alkyl nitrites in the 64th MCC meeting agenda, implied to us that this issue will be further discussed before any enforceable decisions are made.

Alkyl nitrites

Alkyl nitrites are used to improve the comfort levels during penetrative anal sex. When inhaled, they cause a non-specific smooth muscle relaxation, including in the sphincter of the anus. This effect facilitates anal penetration and may prevent rectal injury.

Research in New Zealand has shown poppers are most often used within a sexual setting, are socially acceptable and non-habit forming. A 2019 local cohort study found 53% of the 836 men surveyed had used poppers once or more in their lifetime and 33% had used them recently within the past 6 months.¹ This corresponds with the NZAF 2017 Ending HIV survey results for gay and bisexual men which found that 37.3% of respondents who were sexually active had used poppers in the past 6 months.² The group classification of alkyl nitrites criminalises a large proportion of the community who use poppers.

International studies show that many men who have sex with men (MSM) experience high levels of discomfort associated with painful receptive anal intercourse, often referred to as anodyspareunia. In a US survey, 14% of gay and bisexual respondents reported frequent and severe pain when engaging in receptive anal sex.³ That study reported that poppers non-use was strongly associated with greater severity of painful receptive intercourse.

Harmonisation will fail to minimise harm and impact on health promotion efforts

This is a missed opportunity for health promotion and harm minimisation. We are concerned that harmonising the classification of alkyl nitrites with Australia will negatively impact and further marginalise affected communities in New Zealand. There is currently no legally obtainable or viable alternative to alkyl nitrites available in New Zealand or Australia. Restricting the availability of alkyl nitrites products before ensuring a legal viable alternative encourages criminal behaviour and a shift to the increasingly unpredictable black market.

There is also a concern that people will shift to misusing much more dangerous volatile substances or using other illicit drugs. This is of significant concern with reports of ethyl chloride (chloroethane) being substituted for alkyl nitrates in New Zealand and overseas. Ethyl chloride is found in over the counter sprays for sport injuries and provides a head rush when inhaled without the muscle relaxation effect of poppers. This increases the risk of harm in sexual encounters as well as harm from 'huffing', including the risk of sudden sniffing death. Other substances that may substitute for poppers include

¹ Flux NZ 2019 baseline preliminary findings (unpublished)

² New Zealand AIDS Foundation (2017) Ending HIV survey (unpublished)

³ Damon, W., & Rosser, B. R. (2005). Anodyspareunia in men who have sex with men: prevalence, predictors, consequences and the development of DSM diagnostic criteria. *J Sex Marital Ther*, 31(2), 129-141.

gamma-hydroxybutyric acid (GHB) and related compounds that act as depressants and are associated with a significant risk of fatal overdose.

The decision to have amyl nitrates as prescription-only medicine also creates barriers for people to access the compound. Research shows that half of gay and bisexual men in New Zealand are not open with their GP about their sexual orientation or behaviour.⁴ These barriers were greater among non-European ethnicities, due to issues in accessing and navigating healthcare. While down-scheduling amyl nitrate to be a pharmacist-only medicine, conditional on the availability of the product, addresses some of these issues, many people may still struggle to discuss their sexual activity in the open context of a pharmacy. There is also no available product that meets these requirements and has been approved for use, which effectively means changing classification becomes a ban of any use.

A public health approach focussed on harm minimisation is a more effective approach for LGBTQI communities who are already disproportionately affected by poorer health and justice outcomes. Criminalising drug use can instead lead to greater harm. We support education and behaviour change initiatives alongside manufacturing regulations to minimise harm amongst LGBTQI communities.

The poppers market in New Zealand is not aligned with Australia.

There are key differences between the New Zealand and Australian markets. In Australia the active ingredient in poppers was isobutyl nitrate. However, in New Zealand it is isopropyl nitrate, more closely resembling the poppers market in the United Kingdom. Our current understanding from suppliers in New Zealand is that products sold in New Zealand are made for the European market. Due to this they meet UK packaging requirements and must have a childproof cap and warning labels, which was not the case in Australia.

It is also not clear at this stage whether a pharmaceutical-grade product yet to be developed for the Australian market, based on amyl nitrate, would be available in New Zealand. As far as we are aware, to date, there have been no products in development to meet the legislative thresholds for registration as medicine. This further negates the intent of the classification, that amyl nitrate products are available on prescription, and establishes an effective ban on poppers in New Zealand.

We acknowledge there have been concerns raised internationally about the effects of isopropyl nitrate. However, the UK Advisory Council on the Misuse of Drugs (2016) advised not to restrict or classify access to 'poppers' (isopropyl nitrate) as the harm is rare.⁵ Data available from the New Zealand Poisons Centre show that in the last ten years there were 25 calls made concerning alkyl

⁴ Ludlam A, Saxton P, Dickson N, Hughes A. General practitioner awareness of sexual orientation among a community and internet sample of gay and bisexual men in New Zealand. *Journal of Primary Health Care*. 2015;7(3):204-12

⁵ Advisory Council on the Misuse of Drugs (2016) ACMD review of alkyl nitrites ("poppers"). Accessed from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/508179/Poppersadvice.pdf

nitrites.⁶ While most of these calls were referred for medical advice, further data is not collected and it is not clear what the outcomes may have been.

The decision to apply a group entry for alkyl nitrites effectively criminalises poppers use and is a disproportionate response to the known low-level harms seen from poppers in New Zealand. It directly affects LGBTQI communities who already face greater discrimination and poorer health outcomes. We believe a targeted public health approach focussing on education and behaviour change would be more effective at minimising harm within these communities.

Thank you again for the opportunity to feed back. Please don't hesitate to contact our Senior Policy Officer, Kate Macpherson at kate.macpherson@nzaf.org.nz should you require clarification on any of the points made.

Warm regards,

A handwritten signature in blue ink, appearing to read 'J. Myers', is positioned above the printed name.

Jason Myers
Chief Executive

⁶ Data received from New Zealand Poisons Centre for calls made during the period 1 January 2010 to 31 December 2019 regarding amyl nitrite, butyl nitrite, isoamyl nitrite, isobutyl nitrite, octyl nitrite, n-propyl nitrite, isopentyl nitrite, propyl nitrite, cyclohexane nitrite, amyl nitrite, alkyl nitrite, OR popper(s).