

Thank you for the opportunity to comment on the agenda for the 63rd Meeting of the Medicines Classification Committee.

Regulating for safer use of alkyl nitrites

This is a joint submission by the New Zealand Drug Foundation¹ and the New Zealand AIDS Foundation (NZAF)² to the Medicines Classification Committee for the October 2019 meeting agenda item around the classification of alkyl nitrites. This submission describes alkyl nitrite use among MSM (Men who have Sex with Men) in New Zealand and provides recommendations for classification based upon the decision by the Australian Therapeutic Goods Administration (TGA).

The final classification of alkyl nitrites by the TGA³ was positive

The initial proposal emerged from a spike in harm of retinal maculopathy⁴ but did not consider the risk of harm from individual alkyl nitrites and suggested an unrealistic blanket scheduling. This approach would have further increased the risk of harm with potential substitution for more toxic and dangerous products and would have pushed this product further into an unregulated black market. Through public consultation⁵ and advocacy by the LGBTQI community a more balanced position was reached which was led by evidence and therapeutic considerations. While, the June 2019 TGA decision was an improvement from the currently unregulated market, it does not provide access to fully meet the needs of the community. The decision to have alkyl nitrates as prescription-only medicine creates barriers for people who do not feel comfortable speaking with their doctor, or with doctors who are not unfamiliar with alkyl nitrates. While down-scheduling amyl nitrate to be a pharmacy medicine addresses some of these issues, some people may still struggle to discuss their sexual activity in the open context of a pharmacy.

Alkyl nitrites reduce the risk of harm during receptive anal sex

Also known as poppers, the chemicals have a legitimate beneficial use to enable enjoyable anal sex for MSM (and others). When inhaled, alkyl nitrites cause a non-specific smooth muscle relaxation, including in the sphincter of the anus. This effect facilitates anal penetration and may prevent rectal injury.

International studies show that many MSM experience high levels of distress associated with painful receptive anal intercourse, often referred to as

¹ <https://www.drugfoundation.org.nz/>

² <https://www.nzaf.org.nz/>

³ <https://www.tga.gov.au/scheduling-decision-final/final-decisions-matters-referred-march-2019-joint-acms-accs-meeting>

⁴ Rewbury, R., Hughes, E., Purbrick, R., Prior, S., & Baron, M. (2017) Poppers: legal high with questionable contents? A case series of poppers maculopathy. Br J Ophthalmol, 101: 1530-1534.

⁵ <https://www.tga.gov.au/alkyl-nitrites-consultation>

anodyspareunia. In a US survey, 14% of gay and bisexual respondents reported frequent and severe pain when engaging in receptive anal sex. That study reported that poppers non-use was strongly associated with greater severity of painful receptive intercourse.⁶

A Portuguese study found that moderately or severely distressing anodyspareunia was reported by 17.8% of the participants, presenting as the most frequent sexual problem for gay men.⁷

No therapeutic agents are registered with the indication to enable anal sex for individuals who suffer from painful anal intercourse. Anecdotal evidence suggests some MSM use local numbing creams for anaesthetic effects – their use is not recommended due to loss of sensation of pain without muscle relaxation, that may increase the risk of injury.

Use of alkyl nitrites is common among MSM in New Zealand

Alkyl nitrites currently exist in a grey market. These chemicals are technically classified as medicines but are not available from a doctor or in a pharmaceutical formulation yet, and can be purchased under a guise of not fit for human consumption.

Local research has found that use of poppers is socially acceptable, non-habit forming and used within a sexual setting. A local cohort study this year 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). Most of this recent use was infrequent with 48% having only used poppers once or twice in the six month period. Only 0.5% of those who had recently used poppers were using them daily.⁸

Previous research found higher rates of recent use with the NZAF 2017 Ending HIV survey finding 37.3% of respondents who were sexually active had used poppers in the past 6 months.⁹ Use has been consistent across time with the GOSS 2008 online survey finding 40.1% of respondents having used amyl during sex in the past six months. The face to face part of this research found similar rates of recent amyl use during sex at 41.8%.¹⁰

Use of these products as a harm minimisation technique was also found. One respondent wrote "I only use poppers with the boyfriend in low doses when I'm a bit tight". There was also evidence that this use was alongside other safe sex

⁶ 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.

⁷ Peixoto, M. M., & Nobre, P. (2015). Prevalence of sexual problems and associated distress among lesbian and heterosexual women. *J Sex Marital Ther*, 41(4), 427-439. doi:10.1080/0092623x.2014.918066

⁸ Flux NZ 2019 baseline preliminary findings (unpublished)

⁹ NZAF Ending HIV 2017 Test Often study (unpublished)

¹⁰ https://www.fmhs.auckland.ac.nz/assets/fmhs/soph/sch/gmsh/docs/BFReport_34LoRes.pdf (p. 70)

practices with the comment "I use poppers during receptive sex (always protected with condoms) and usually only once at the start for the muscle relaxing effect rather than a 'High'."¹¹

Increased access to some alkyl nitrites will meet public health goals

Most of the risk from these products comes from the lack of control in the market with no approved product or requirements for accurate labelling. Historically this was not an issue but as more and more alkyl nitrites are banned more harmful substances replace them. This is a common result of prohibition. Further restrictions will not remove harm but lead to more elaborate mechanisms of disguising the product (for example, currently these products can be found in shops masquerading as 'CD cleaner'). A lack of accessibility is a missed opportunity for regulation of a therapeutic product.

Benefit of use needs to be balanced with risk of harm

The introduction of more harmful forms of alkyl nitrites has disrupted the balance of this grey market. This impacts most directly upon the rainbow community with the specific therapeutic role that these products can have as a harm minimisation technique. Balance can be found with a split model of classification as decided in Australia, however wider access beyond pharmacies is needed. Any moves to increase enforcement or reduce availability of currently sold alkyl nitrite products before ensuring a legal viable alternative would be detrimental to the community. This would be a missed opportunity for health promotion and could result in a full shift to the increasingly unpredictable black market.

Reclassify amyl nitrite to increase access

The New Zealand Drug Foundation and NZAF are advocating for:

- Allowing for the regulated sale of amyl nitrite at sex stores, sex on site venues, pharmacies and other health organisations
- Allowing amyl nitrite products approved in Australia to be sold in New Zealand
- Ensuring strict regulations around packaging with child-proof bottles, ingredient lists and guidance on safer use

¹¹ Flux NZ (2019) responses to question "Would you like to tell us in your own words how you try to keep yourself safe when using or injecting drugs?" (unpublished)

Amyl nitrite is widely researched and has been used in medical formulations in New Zealand previously,¹² and already have exemptions for wider sale.¹³ By regulating the least harmful product, as was done in Australia, it ensures a legally viable option and can go a long way to countering risk of harm from the current grey market which is unpredictable and increasingly harmful.

We believe that this can best be achieved with a *general sale* classification of amyl nitrites specifically with location for sale restricted to pharmacies, sex stores, sex on site venues and health organisations. This is preferable to a *pharmacy only* classification, as was agreed upon in Australia, as it matches current access points and is the only model that will reach consumers who are already purchasing unknown products online. If a more restrictive model of *pharmacy only* is required, then allowing exemptions for sales beyond pharmacies is crucial. Sex on site venues and sex stores are both age restricted locations and are well placed to have conversations around safe therapeutic use of poppers, addressing the barrier of having to have conversations on sexual practices in the open context of the pharmacy

The more restrictive *pharmacist only* will greatly reduce access and is likely to have low uptake as it requires disclosure of sexual practice which for some can be difficult, especially those less experienced who would be at greater risk of experiencing harm.

If the cost to enter the market is prohibitive or the cost of a regulated product too high and difficult to obtain then the classification will be futile.

Maintain the *prescription only* classification of other alkyl nitrites

Isobutyl nitrite, butyl nitrite, octyl nitrite and isoamyl nitrite are currently prescription only medications under the Medicines Regulations Act 1984 and following with the Australian decision these should remain.

Further restrict access to most harmful alkyl nitrites

Isopropyl nitrite and n-propyl nitrite are the two chemicals linked to increases in acute harm. They appear to not currently be regulated or restricted in New Zealand. Reducing ability to import or sell these products is necessary to reduce harm, especially if restrictions are provided around the existing sale of prescription only alkyl nitrites. This decision to restrict access was decided in Australia and earlier in France.

¹² <https://www.medsafe.govt.nz/regulatory/DbSearch.asp>

¹³ 'Amyl nitrite; except when sold to a person who is appropriately authorised under the [Health and Safety at Work Act 2015](#)' Schedule one, Part one Medicines Regulations Act 1984

In addition to the points above, we would like to encourage the Committee to review the feedback submitted by the Nitrates Action Group to the TGA consultation, as it gives a detail and nuanced look at the factors involved in reclassification:

<https://www.tga.gov.au/sites/default/files/consultation-submission-regulatory-options-alkyl-nitrites-nag.pdf>

Thank you for your consideration. Should you require clarification or further discussion on any of the points made, please don't hesitate to contact Samuel Andrews, Harm Reduction Projects Advisor at the New Zealand Drug Foundation at samuel.andrews@drugfoundation.org.nz, or Brooke Hollingshead, Policy Officer at the New Zealand AIDS Foundation at brooke.hollingshead@nzaf.org.nz or on (09) 306 3424.

