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Director, Scheduling Project Management
Regulatory Engagement and Planning Branch
Regulatory Practice and Support Division
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

MADE BY EMAIL ONLY

Dear Director

Submission in response to the Therapeutic Goods Administration's interim decision to amend the listing of alkyl nitrites within the Poisons Standard

We welcome the opportunity to make a submission to this important inquiry.

About the LGBTIQ Legal Service and the St Kilda Legal Service

St Kilda Legal Service (**SKLS**) provides free and accessible legal services to members of the community within the Cities of Port Phillip, Bayside, Stonnington and parts of Glen Eira. The Legal Service is committed to redressing inequalities within the legal system through casework, legal education, community development and law reform activities.

In pursuit of this aim, in May 2017, the LGBTIQ Legal Service commenced in partnership with Thorne Harbour Health. The LGBTIQ Outreach Lawyer provides advice and representation to the LGBTIQ community on a wide-range of legal issues including discrimination. As part of the program, our lawyer provides assistance (both case work and legal education) to members of the LGBTIQ community in relation to criminal matters as well as discrimination.

Summary

Alkyl nitrites (the active ingredients in "**poppers**" or "**amyl**") are used as an effective means of enabling safe and enjoyable anal sex for gay men, bisexual men and men who have sex with men ("**men who have sex with men**").

Accordingly, this decision will have a substantial impact on the lives of men who have sex with men.

Until September 2018, alkyl nitrites were available without prescription from sex shops and online stores; this is because they have been classified under Schedule 4 (medicines) of the *Therapeutic Goods Act 1989* (Cth). In accordance with 'Schedule 4', substances may be sold without prescription as long as they are not sold for human consumption. As a result, alkyl nitrites are often sold as 'aroma', 'leather cleaner', or 'video head cleaner'.

In September 2018, the Therapeutic Goods Administration (**TGA**) made an interim decision that proposes moving all forms of alkyl nitrites to Schedule 9 'prohibited substances'. Schedule 9 currently includes prohibited drugs like heroin, methamphetamine and cocaine. As a Schedule 9 substance, there would be serious penalties for the importation, possession, use or supply of alkyl nitrites.

We have reviewed the submission of the Nitrites Action Group (**NAG**) to this inquiry, and endorse its recommendations. In particular, the LGBTIQ Legal Service supports the recommendations that the TGA address NAG's concerns about adverse effects associated with poppers by doing the following:

1. Amending the *Therapeutic Goods Act 1989* (Cth) (the **Act**) to reschedule isopropyl nitrite (only) to Schedule 9. All other alkyl nitrites should remain in Schedule 4.
2. Mandating for better packaging, including child-proof caps and labelling that clearly states the product should not be swallowed. This could be done in collaboration with state governments, or by amending the Act to include alkyl nitrates under Schedule 5 ('Caution') or 6 ('Poison') instead of Schedule 9.
3. Consulting with LGBTIQ health organisations to develop appropriate health promotion materials to support safe use and minimise harms associated with overuse.
4. Rescheduling some poppers products in a way that would allow them to be sold in pharmacies or restricted premises (e.g. adult shops) with more appropriate packaging, labelling and with guidance about correct use.

Considerations for the TGA

Under s52D(2) of the Act provides that the Secretary may:

- a) Amend the current Poisons Standard; or

- b) Prepare a document (including schedules containing the names or descriptions of substances or classes of substances), in substitution for the current Poisons Standard.

In carrying out their power under s52D of the Act, S52E requires that the Secretary must take the following matters into account (where relevant):

- a) the risks and benefits of use of the substance;
- b) the purposes for which the substance is used, and the extent of use;
- c) the toxicity of the substance;
- d) the dosage, formulation, labelling, packaging and presentation of the substance;
- e) the potential for abuse of the substance; and
- f) any other matters that necessary to protect public health.

In addition, the TGA's criteria for listing a substance in Schedule 9 requires that the substance have 'no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use'.¹

The LGBTIQ Legal Service submits that the interim decision does not fully address the matters that the Secretary is required to take into account under s 52D and s 52E(1), and therefore does not comply with the TGA's criteria for schedule 9 substances.

Benefits and therapeutic uses

Alkyl nitrites have an important therapeutic use in enabling sexual intimacy for people who experience difficulties with receptive anal intercourse. They work by relaxing smooth muscle in the body, which includes the inner anal sphincter, which is a ring of muscle that is highly sensitive to anxiety and not able to be voluntarily controlled.

The LGBTIQ Legal Service shares the concern of the NAG that the interim decision has, in essence, listed the benefits of alkyl nitrites use as the risks of use (for example analgesic and muscle relaxant effects).

The interim decision's conclusion that alkyl nitrites have "little to no therapeutic use" rests on this conclusion.

¹ Australian Health Ministers' Advisory Council, Scheduling Policy Framework for Medicines and Chemicals (version 1.0, 2018).

“Therapeutic use” is defined under s3 of the Act as including:

- a) ‘preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- b) influencing, inhibiting or modifying a physiological process in persons; ...

We note that the definition of therapeutic goods is not limited to those listed on the Australian Register of Therapeutic Goods.

As detailed in the NAG submission, alkyl nitrites have the effect of relaxing the sphincter, making anal penetration easier and reducing the likelihood of tearing, which can otherwise be a problem for a significant proportion of gay men. We contend that the delegate has erred in failing to consider the benefits, purpose and extent of use of nitrites to facilitate receptive intercourse, as required by s 52E(1)(b).

As a result, poppers have a legitimate use and a relevant therapeutic benefit.

We suggest that, given that it flows from a failure to give the required statutory consideration to the benefits and purposes of use, any analysis of the potential for abuse for the purpose of S52(1)(e) that relies on this assertion is necessarily flawed.

The LGBTI Legal Service acknowledges that there have been some risks associated with the use of some alkyl nitrites, however in accordance with our submissions, this would be better addressed by:

- mandating for better packaging, including child-proof caps and labelling that clearly states the product should not be swallowed. This could be done in collaboration with state governments, or by amending the Act to include alkyl nitrates under Schedule 5 (‘Caution’) or 6 (‘Poison’) instead of Schedule 9; and
- rescheduling some poppers products in a way that would allow them to be sold in pharmacies or restricted premises (e.g. adult shops) with more appropriate packaging, labelling and with guidance about correct use.

Other matters necessary to protect public health

The LGBTIQ Legal Service share the concerns of the NAG about the potential health consequences of increased exposure to the criminal justice system among the men who have sex with men as a result of this decision. The interim decision would, on NAG estimates, effectively criminalise the conduct of approximately 90,000 Australian men who have sex with men, exposing them to various levels of criminal liability depending on the jurisdiction – e.g. up to five years imprisonment in the Australian



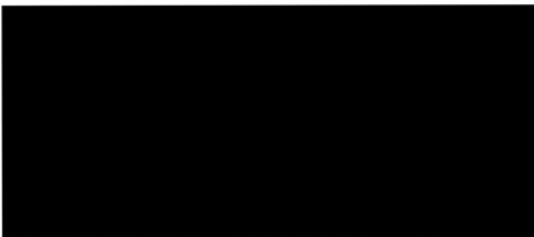
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Capital Territory. The interim decision does not assess any impact on public health that may stem from criminalising such a common practice or engage with research on this topic.

We express particular concern about the impact of the proposed decision on the capacity of men who have sex with men to receive informed advice about the health consequences of nitrate inhalant use. We suggest that the interim decision may lead to men who have sex with men being fearful of consulting health professionals about the use of nitrite inhalants, as opposed to the status quo, which poses no such barriers.

Contact for enquiries

If you have any queries, please contact Sam Elkin on 0490 086 090 or by email to sam@skls.org.au.



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