
Regulatory options for appropriate access and safety controls for alkyl nitrites - seeking public feedback

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afao.org.au | lgbtihealth.org.au

Contact

Heath Paynter

Level 1, 222 King Street
Newtown NSW 2042

T: +61 2 9557 9399
E: heath.paynter@afao.org.au
W: afao.org.au

Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response in Australia. AFAO works to end HIV transmission and reduce its impact on communities in Australia, Asia and the Pacific. AFAO's members are the AIDS Councils in each state and territory; the National Association of People with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); Anwernekenhe National HIV Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO's affiliate member organisations – spanning community, research and clinical workforce – share AFAO's values and support the work we do.

Contact

Nicky Bath

Level 1, 222 King Street
Newtown NSW 2042

T: +61 2 8568 1123
E: nicky.bath@lgbtihealth.org.au
W: lgbtihealth.org.au

National LGBTI Health Alliance

The National LGBTI Health Alliance (the Alliance) is the national peak health organisation in Australia for organisations and individuals that provide health-related programs, services and research focused on lesbian, gay, bisexual, transgender, and intersex people (LGBTI) and other sexuality, gender, and bodily diverse people and communities. We recognise that people's genders, bodies, relationships, and sexualities affect their health and wellbeing in every domain of their life.

Introduction

AFAO and the National LGBTI Health Alliance welcome the Therapeutic Goods Administration's (TGA) move to defer the final decision on possible amendments to the Poisons Standard for alkyl nitrites to accommodate further consultation with the community before a final decision is determined.

We also welcome the TGA's updated November Discussion Paper which acknowledges that alkyl nitrites have a therapeutic use and play an important role in the lives of many members of the LGBTIQ community and sex workers for sexual health as an aid to make sex less painful.

Our Position

As previously highlighted in an earlier [submission](#), AFAO and the National LGBTI Health Alliance oppose the listing of alkyl nitrites in Schedule 9 of the Poisons Standard.

The Interim Decision to list alkyl nitrites in Schedule 9 of the Poisons Standard:

- significantly overstates the toxicity of the substance and the potential for problematic use.
- is based upon limited and insufficiently available evidence of harm, together with anecdotes that do not reflect acceptable standards of evidence for a decision of this nature.
- was not informed by appropriate consultation or engagement with medical experts and the communities most affected by the Interim Decision, although we note that this consultation now provides the community with an opportunity to comment on the Interim Decision.
- will cause far more harm through the criminalisation of marginalised populations than any caused by the therapeutic use of alkyl nitrites.
- ignores the benefits associated with the therapeutic use of alkyl nitrites as a muscle relaxant to make sex less painful for gay and bisexual men and sex workers.

Regulatory Context

In April 2018, the Therapeutic Goods Administration (TGA) made an Interim Decision to move the entire class of volatile alkyl nitrites in the Poisons Standard from Schedule 4 (Prescription Medicines) to Schedule 9 (Prohibited Substances).

After receiving numerous public submissions on this Interim Decision and following a joint meeting of the Advisory Committee of Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS), it was decided that further public consultation was warranted prior to a final decision being made.

If the TGA endorse the Interim Decision volatile alkyl nitrites will be treated in a similar way to illicit drugs meaning that people who use, or possess them, will be exposed to serious criminal sanctions, in accordance with state and territory criminal codes.

Policy Context

The TGA's concerns in relation to alkyl nitrites focus on two factors:

- anecdotal and isolated instances highlighted by a small number of ophthalmologists; and
- unintentional misuse of alkyl nitrites due to ingestion or snorting of the substance (instances not associated with the therapeutic use of alkyl nitrites as an inhalant to make sex less painful).

AFAO and the National LGBTI Health Alliance acknowledge that there have been a very small number of reported cases of unintentional misuse of alkyl nitrites, however the level of misuse within the community does not warrant the proposed prohibition. The majority of calls received by the Australian Poisons Information Centre regarding alkyl nitrites occurred following accidental snorting or ingestion of the substance, indicating that ‘unintentional misuse’ was the primary cause of problematic exposures.

Widespread and beneficial use

Repeated cross-sectional surveys of Australian gay men report that almost 45% of gay men in Sydney and Melbourne have used alkyl nitrites in the last six months, with similar patterns of use in the other capitals¹². People who use alkyl nitrites for its therapeutic use do so safely, and without harm. As the TGA’s acknowledges in their Discussion Paper, alkyl nitrites are used for their therapeutic use as a muscle relaxant, which creates a therapeutic value of making sex less painful and, by extension, more enjoyable and pleasurable for a significant number of gay and bisexual men and sex workers.

Balancing the benefits of therapeutic use against the risks

AFAO and the National LGBTI Health Alliance acknowledge that the TGA is bound to arrive at a decision that balances the benefits of the therapeutic use of alkyl nitrites against the risks associated with the substance’s misuse.

From the information available in the TGA’s Discussion Paper there is a lack of quality evidence of significant harm when alkyl nitrites are used for their therapeutic use to make sex less painful. Placing alkyl nitrites into Schedule 9 would not necessarily reduce the substance’s availability but, rather, would likely drive the market underground and remove the opportunity to potentially regulate the formulation and packaging of alkyl nitrites. We are concerned that if alkyl nitrites were prohibited, unregulated formulations with unknown harms will become available.

Criminalisation of gay and bisexual men and sex workers

Listing alkyl nitrites in Schedule 9 of the Poisons Standard will criminalise use and possession of this substance. The potential criminalisation of alkyl nitrites will also disproportionately impact a large proportion of the LGBTIQ community. Considering this, there is a significant risk that the decision to place alkyl nitrites into Schedule 9 will be perceived by community members as targeted at the gay community. The announcement of the Interim Decision itself led to considerable public comment, distress, frustration and anger among our communities owing to fear among our communities that prohibiting the use of alkyl nitrites would criminalise the therapeutic use of this substance by gay and bisexual men and sex workers.

The legislative connection between the *Therapeutic Goods Act 1989*, the Poisons Standard and the State and Territory criminal codes could, inadvertently, increase the administrative demands on law enforcement agencies and judicial officers, without addressing concerns around misuse.

¹ Hull, P., Mao, L., Lea, T., Lee, E., Kolstee, J., Duck, T., Feeney, L., Prestage, G., Zablotska, I., de Wit, J., & Holt, M. (2017). *Gay Community Periodic Survey: Sydney 2017*. Sydney: Centre for Social Research in Health, UNSW Sydney. <http://doi.org/10.4225/53/59598c5643b4d>

² Lee, E., Mao, L., Broady, T., Bavinton, B., McKenzie, T., Batrouney, C., Malholtra, S., Manwaring, J., West, M., Prestage, G., & Holt, M. (2018). *Gay Community Periodic Survey: Melbourne 2018*. Sydney: Centre for Social Research in Health, UNSW Sydney. <https://doi.org/10.4225/53/5b2875d6780ec>

Consultation Process - Quality of evidence regarding the harms associated with their therapeutic use of alkyl nitrites

Despite a high proportion of gay men and others having used alkyl nitrites over a long period of time, there is no quality scientific or social research evidence to suggest alkyl nitrites are harmful when used for its therapeutic use and, unlike alcohol, cannabis or cocaine, volatile alkyl nitrites do not result in psychoactive or chemical dependence.

The TGA's Discussion Paper was developed to invite a public consultation on, among other things, the risks of alkyl nitrites. In the Discussion Paper a range of risks associated with the use of alkyl nitrites are identified to support public comment on the impact of community use of the substance. The information provided in the paper summarises these risks. However, we are unable to explore the veracity of these data and information as we have not been provided with sufficient access to the raw data and the systems and processes used to capture these data and information. For the consultation to fulfil its objective to invite informed public comment on the risks associated with alkyl nitrites we feel that it would not be rational for the TGA to make a decision informed by the public consultation process without providing the community with sufficient access to these data and information to properly analyse the purported risks of alkyl nitrites

Recommendations

AFAO and the National LGBTI Health Alliance recommend that the most appropriate way of managing uncertainty around alkyl nitrite use in the community is through health promotion activities to trigger increased discussion between healthcare professionals and community members in medical consultations, and child-proof packaging. This would reduce harms associated with unintended misuse and would be more cost effective than exposing individuals to the criminal justice system, which could increase the administrative demands on law enforcement and judicial officers, without addressing concerns around misuse.

AFAO and the National LGTBI Health Alliance's initial [submission](#) outlines our position and the evidence used to substantiate our position that alkyl nitrites should not be listed in schedule 9 of the Poisons Standard.