Publication of interim decisions proposing to amend, or not amend, the current Poisons Standard, September 2018

10 October 2018
**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.

**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.
The Proposal

The Therapeutic Goods Administration (TGA) has made an Interim Decision to include the entire class of volatile alkyl nitrites in the Poisons Standard, and to move these substances from Schedule 4 (Prescription Medicines) to Schedule 9 (Prohibited Substances).

A potential result of this decision is that these substances may be treated in a similar way to currently illicit drugs meaning that the people who use them, or possess them, will face criminal sanctions. The actual penalties on the manufacture, possession, sale or use will be dependent on laws in each State and Territory.

Our Position

AFAO and the National LGBTI Health Alliance do not support the listing of alkyl nitrites in Schedule 9 of the Poisons Standard.

The Interim Decision:

- significantly overstates the toxicity of the substance and the potential for abuse
- is based upon limited evidence of harm including inconsistencies, 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 alcohol and other drugs experts and the communities most affected by the Interim Decision
- will cause far more significant harm through the criminalisation of marginalised populations than that caused by the use of alkyl nitrites

Use in Australia is Relatively Stable

The use of alkyl nitrites within sub-populations of the Australian population, particularly gay and bisexual men, is ongoing, however, the rationale for the proposed escalation in the regulatory control is based on weak evidence.

Various forms of alkyl nitrites have been widely used in some sections of the community for over four decades. Initially used in both recreational settings and during sexual activities, current use appears to be primarily as an aid to sex, particularly for gay men having anal sex and by some sex workers with their clients.

The interim decision indicates increasing use however this is not supported by the reference listed, the Ecstasy and Related Drugs Reporting System (EDRS). In this sample, the use of amyl dropped from 27% (2016) to 25% (2017). Instead the Delegate chose to cite older data showing an increase between 2015 and 2016. Additionally, the EDRS Report states:

“Frequency of amyl nitrite use was generally low, with participants reporting a median of three days of use in the last six months (range: 1–100 days). Over two-thirds (68%) of participants who had recently used amyl nitrate (n=197) had used less than once per month in the preceding six months. No participants reported daily use.”
Information from Gay Community Periodic Surveys indicates that the use of amyl has been stable in the last decade.\(^1\)

**Poor Evidence of Harm**

The justification of the Interim Decision on evidence that is of such inadequate quality not only obviates the basis of the decision but is manifestly inadequate with respect to the standards of evidence expected to the applied by the TGA in exercising its regulatory functions.

There is very little evidence of harm despite use by a high proportion of gay men over a long period of time, and to a lesser extent among lesbian, bisexual and queer women.\(^4\) Multiple assertions of high rates of harm from the use of these alkyl nitrites are listed in the reason for the change, however, almost no substantive evidence of this harm is provided beyond rare instances of vision problems, methaemoglobinaemia and a small number of calls to the poison hotline.

The Delegate indicates a hospital has reported 14 deaths across a 35-40 year period in London, however, this appears to be taken from an old flyer from the internet from another organisation, with no attempt to check or confirm this reference (http://www.re-solv.org/wp-content/uploads/2011/12/Poppers.pdf).

While the reports of a small number of people with short term deterioration in vision are concerning, the evidence of significant harm is inconsistent. While one quoted source indicates that some vision loss could be permanent, another indicates that this appears to be rectified quickly on consultation with medical professionals and the cessation of use of the substance (although the delegate failed to note this in their decision).\(^5\)

In the articles that are quoted, evidence primarily takes the form of anecdotes and case studies rather than systematic evidence of harm. Many of the anecdotes provided relate to unusual circumstances, such as rare pre-existing conditions and highly excessive use, both of which are best managed through health service engagement and not the criminal justice system.

The one reference that attempts to look at broader scale harms (Davies et al., 2016), found that 2.2% of respondents believed that poppers had affected their eyesight, with a further 9.8% indicating that it was possible that it had. However it did not quantify the scale or longevity of the eye symptoms and is based upon self-report by consumers with no clinical confirmation. It should be noted that this report draws a link between the change in substance being used and the apparent appearance of symptoms. That is to say, the regulation of a less harmful alkyl nitrite caused a new version to be used that had more (albeit still limited) risks associated with it.

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Given the use of these substances has been occurring for decades, it is illuminative that there is so little evidence of significant harm. It also suggests a pattern of use that, for most people, is low risk.

Unlike substances such as alcohol, cannabis or cocaine, volatile alkyl nitrites are not psychoactive and there is no evidence that they are chemically addictive. In 2008, a review of volatile substance misuse, conducted by the Department of Health and Ageing, excluded nitrites as they do not affect the central nervous system.

In 2016 there was an attempt to ban alkyl nitrites (street name ‘poppers’) through a Psychoactive Substances Act in the United Kingdom. This failed because in the opinion of the Advisory Council on the Misuse of Drugs (ACMD):

“The ACMD’s consensus view is that a psychoactive substance has a direct action on the brain and that substances having peripheral effects, such as those caused by alkyl nitrites, do not directly stimulate or depress the central nervous system.”

Additionally, while the delegates’ Interim Decision quotes the ACMD’s report in support of the change of schedule, the ACMD report states:

“misuse [of poppers], within the terms of section 1 of the Act, is not seen to be capable of having ‘harmful effects sufficient to constitute a social problem.’”

‘Amyl’, Community Norms and the Criminal Justice System

There have been previous unsuccessful attempts to restrict community access to these substances and this interim decision is seeking to change a sub-cultural norm that has developed over many decades. It would be incumbent on the TGA to undertake significant community education and engagement on this issue if it were to make this change.

As noted above, ‘poppers’ are used by a large proportion of gay men and by few outside LGBTI communities, other than some sex workers. Considering this, there is a significant risk that the TGA’s Interim Decision, and any subsequent change to the schedule, will be perceived by some community members as targeted at the gay community. The Interim Decision has already proved to be controversial, attracting considerable public comment and leading to community distress, frustration and anger.

Given the ubiquity of use within parts of the gay community, it is likely that demand for alkyl nitrites would continue and be met through unregulated supply or, in the alternative, chemical variations that have unknown harms.

Scarlet Alliance, Australian Sex Workers Association, the peak body representing their membership of sex workers, sex worker organisations, collectives and projects, has expressed concern about the impact on sex workers of the proposed listing of alkyl nitrites in Schedule 9 of the Poisons Standard. Although alkyl nitrites are not commonly used by all sex workers, anecdotal reports indicate that the substance is widely used in some subsections of the sex industry. The criminalisation of alkyl nitrites will unnecessarily criminalise a work practice that has been used in a safe and controlled manner by some clients and sex workers with little to no significant harm or serious misuse. Sex workers are a community disproportionately impacted by criminalisation and stigma. There is significant evidence that demonstrates criminalisation creates significant barriers to occupational health and safety and access to health promotion and justice. Further criminalising an already marginalised population for a practice with low risk of harm will be significantly more damaging.

Criminalising sex-related behaviour exposes communities at risk of HIV and a range of other sexually transmitted infections (STIs) to increased risk and compromises the public health investment in HIV prevention, testing and treatment.

Given the legislative connections between the Therapeutic Goods Act, the Poisons Standard and State and Territory laws that criminalise the sale, possession and use of Schedule 9 substances, this decision has major implications for the criminal justice system.

It is likely that the criminalisation of a behaviour with little associated health risk will cause far greater harm than the substance itself. It is within this context that our primary concern that this will further criminalise and stigmatise already marginalised populations is situated. There are significant risks that large numbers of people will be subsequently classified as engaging in criminal behaviour when no substantive harm to personal or public health has been articulated.

The impact on the criminal justice system is potentially significant. This includes the increased administrative burden on police, the judicial system, border security and corrections associated with charging and prosecuting – as well as the possibility of a criminal record and a prison sentence – for significant numbers of gay and bisexual men, lesbian and bisexual women and some sex workers.

These concerns were recently profiled by Former Australian Federal Police Commissioner, Mick Palmer, who was reported as saying “I don’t think that a ban [on alkyl nitrite] would be effective”.7

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 and through healthcare professionals discussing use with individuals in medical consultations. This would be significantly more effective, from a cost and public health perspective, than regulatory changes leading to a criminal justice response.