

Thursday, 11 October 2018

Dear Sir/Madam,

I am greatly concerned about the TGA's recent interim decision at ACMS #24 to schedule Alkyl Nitrites as schedule 9. I do not support this decision and outline my reasoning below.

Key concerns I have are:

- Impact on the gay male population.
- Potential to generate crime
- Lack of evidence of significant harm.
- Potential for increased harm due to product substitution.
- A failure to consider 'off label' uses.

Alkyl Nitrites have been used therapeutically for over 100 years and their use long predates the establishment of the TGA and its predecessors. Historically the main uses were to aid the treatment of angina and cyanide poisoning however for the last 50 years the primary use has been by gay men who use the muscle relaxant properties to aid sexual intimacy with their partners.

A recent survey found that 40% of Australian gay men have used Alkyl Nitrites in the last six months this is 89,600 Australians, when their partners are accounted for this is an impact on 170,000 Australians.(Ref 1) It may be argued that this is an unscheduled use and should not be considered as part of the decision but when we account for the historical attitudes towards homosexuality and the taboos associated with sex, especially gay sex it is discriminatory not to properly address this usage as part of a scheduling decision.

Applications to schedule a new therapeutic use are generally submitted by commercial entities looking to sell and market a product. This has never happened for Alkyl Nitrites for use by gay men as the product cannot be patented as it is not novel and has been known and marketed for over 100 years, this is also due to the perceived reputation damage a company would receive for marketing a "gay sex drug". The recent marriage equality debate shows how homophobic attitudes are still prevalent in society and the need for the TGA to account for this when assessing Alkyl Nitrites and their past scheduling decisions. For these reasons sales of Alkyl Nitrites to the gay community have remained in a legal grey area, marketed as leather cleaner or room odorisers, accepted and allowed for over 30 years but never legal nor illegal.

In scheduling all Alkyl Nitrites as S9 this loophole will be closed and sale and possession could become crimes. The potential of this decision to criminalise 40% of the gay community cannot be overstated.

The Sex Discrimination Act, 1984, Section 5A prohibits discrimination on the grounds of sexual orientation, Section 26 extends this obligation to the administration of commonwealth laws and programs. I am greatly concerned that the TGA are in breach of this act by not acknowledging and discussing the impact of this decision on the gay community. The interim decision describes use as "*sex aids due to their muscle relaxant properties*" as "*the potential for abuse of a substance*". It is hard to see how banning a substance because it is used by gay men to aid painless sexual intimacy with their partners as anything other than discrimination. The current decision does not openly acknowledge this usage and fails to properly consider the impact on the gay community verses the perceived threat to public health. Subsection 52E (1)(f) of the *Therapeutic Goods Act 1989* section provides an opportunity for these impacts to be assessed, which has not been conducted under the current interim decision.

Rescheduling will create social harms:

I am concerned about the potential for this decision to generate crime. Currently S9 consists primarily of opiates, amphetamines, cannabinoids, psychoactive compounds and their many analogues. All of these have thriving black markets constantly dodging law enforcement efforts. The wider distribution of these is limited by the need for smuggling, clandestine laboratories and clandestine horticultural facilities.

Production of Alkyl Nitrites does not require specialised apparatus and requires no special precursor chemicals. Someone with high school chemistry skills can produce a batch of Alkyl Nitrites using five chemicals available from hardware stores, supermarkets and food suppliers in their own kitchen. With such a simple synthesis it is impossible to see how supply could be controlled. Refer to Appendix 1 for information which demonstrates how the simple production could be performed in a kitchen.

Banning Alkyl Nitrites will create a boon for organised crime and harm the legitimate tax paying businesses that currently sell the product. If rescheduled Alkyl Nitrites will be the easiest to produce schedule 9 substance by a large margin. This mirrors the thoughts of former Australian Federal Police commissioner Mick Palmer who said in a recent press release on the issue "I don't think that a ban would be effective" (Ref 2).

Clandestine production by organised crime would expose users to impure and potential contaminated product exposing them to far greater health risks than the current commercially produced product.

Criminalisation of Homosexuality by stealth:

Alkyl Nitrites are widely used amongst homosexual makes with estimates of 40% having used them in the last six months, with many reliant on them for painless sexual intercourse with their partners (Ref 1). In the past poppers have been a target for restrictions due to their associations with homosexuality. In the absence of concrete evidence of social and physical harm greater than other commonly available substances such as alcohol a ban will be viewed by the community as a direct attack on homosexuality.

In the event of rescheduling to S9 possession, sale and possession and usage will be illegal. Will previously law abiding men now be branded criminals and drawn into the legal system? For many gay men persecution at the hands of the law for their sexual preferences is an all too recent memory and will have a profound impact on their mental health

Prevalence in Society

Alkyl Nitrite use is incredible prevalent in society with many millions of users worldwide.

Most surveys provide a figure of 35-40% of gay men use Alkyl Nitrites across a wide range of countries. A sample of usage statistics from comparable nations is included below.

Australia – 35-40% of the Australian gay male population, over 89,000 people. (Ref 1)

United Kingdom - Two million bottles are sold annually by the country's two largest manufacturers. (Ref 3)

United States – In 1982 250 million doses of alkyl nitrites were consumed annually. (Ref 6)
Canada – 30% of the gay male population. (Ref 4)

With such extensive usage over a period of more than 40 years covering tens of millions of people any significant social or physical harms would have become apparent by now.

Physical Harms

The interim decision references a small number incidents and adverse reactions related to Alkyl Nitrites. A key factor when assessing these is the population size and frequency of use, this has not been discussed in the interim decision. The adverse events can be divided into three categories

Incorrect usage and access: These can be addressed by labelling and child proof packaging.

Methemoglobina: Reports are rare, this is generally associated with incorrect use by ingestion and could be addressed by labelling.

Poppers maculopathy: This is a new problem and has only been observed in the last ten years, cases have been discussed in case notes and medical literature. Around 30 cases have been identified worldwide, given the millions of users of Alkyl Nitrites worldwide this is a very small rate of incidence. A key question that has been raised by researchers is why we are only observing this outcome now, despite decades of widespread use of Alkyl Nitrites. One area of research is a possible link to one specific Alkyl Nitrite, Isopropyl nitrite. Up until ten years ago most 'poppers' sold worldwide were Amyl Nitrite or Butyl Nitrite, these have had decades of widespread use without problems. Due to bans on these formulations driven by homophobia and a now discredited theory that they caused AIDS most suppliers worldwide switched to Isopropyl Nitrite it was at this point that isolated cases of Poppers maculopathy started being reported. Research into the possible link with Isopropyl nitrite has been conducted by Rewbury R, Hughes E, Purbrick R, et al and published in the British journal of Ophthalmology. In their research they conducted chemical analysis on the brands of poppers used by 10 cases of poppers maculopathy, they found that all brands strongly connected with popper maculopathy contained Isopropyl Nitrite. They also noted that cessation of symptoms and recovery was observed when patients ceased using the products.

It is also worthy of note that [REDACTED] and Glycerol Trinitrate which have similar uses to Alkyl Nitrites and all affect Nitric Oxide within the body and have reports of ocular side effects, none of these compounds are being banned because of this effect.

Development of a black market is likely in the event of a blanket S9 listing. This was observed in Canada where a ban only led to a 3% drop in usage. (Ref 4) Black market sales and production of Alkyl Nitrites will invariably be Isopropyl Nitrite, the Alkyl Nitrite which is most strongly associated with Poppers maculopathy. This will occur as of the precursor alcohols suitable for manufacturing Alkyl Nitrites, Isopropyl Alcohol is the cheapest and the only one available at hardware stores and supermarkets.

Bans in comparable nations:

Alkyl Nitrites are available for retail sale in most major developed nations including the United States, United Kingdom and all major European Nations. The key exception is Canada where a ban was enacted in 2013. After five years the ban has little positive impact, usage amongst the Canadian gay community has only reduced 3% to 30%. Due to the ban, retail sales have been replaced with clandestine production, cross border smuggling and importation by post. Due to the loss of licit sales

a number of retailers have closed or downsized resulting in job losses. Concerns have also been raised regarding the safety of clandestinely produced products. Overall the ban has been completely ineffective and generated significant social harms. (Ref 4)

United Kingdom

The United Kingdom recently considered banning Alkyl Nitrites as part of a blanket ban on psychoactive substances, the issue was widely covered in the media and debated in parliament. A decision was made to exclude Alkyl Nitrites from the ban as they are not psychoactive and “not seen to be capable of having harmful effects sufficient to constitute a societal problem”

A submission to the UK enquiry from the (UK) National Aids Trust stated that a ban will “simply drive retail and use ‘underground’. It argued that this would take the use of alkyl nitrites outside any regulatory regime which might successfully protect gay men from particular compounds, leading to an increased risk of health harms, and even possibly deaths. In addition, if the sale of ‘poppers’ is displaced to drug dealers, there could be a further risk of migration to the use of other drugs. The Gay Men’s Health Collective stated that banning ‘poppers’ would result in increased class A and B drug use, and increased transmission of STIs.” (Ref 7) These outcomes are equally likely in an Australian context and consideration should be given before a decision is made.

Alternatives to Alkyl Nitrites:

No equivalent products providing a rapid, short acting muscle relaxant effect are available on the market.

Glycerol Trinitrate (Nitroglycerine) is the most likely alternative to Alkyl Nitrites but come with a number of disadvantages. Its action is slower than Alkyl Nitrites taking 1 to 4 minutes to induce muscle relaxation, which is not conducive to passionate lovemaking. It is generally provided as an ointment which is applied directly to the muscle that requires relaxing. This introduces a significant hazard, ointments are oil based and rapidly destroy condoms. This makes it impossible to combine nitroglycerine with safe sex and could lead to a significant increase in transmission of sexually transmitted diseases.

I have included below an extract of the delegates decision under ACMS #24 where the assessment under the criteria from subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate were listed. I have listed my response to a subset of these criteria in the table.

Delegates Criteria	Response
<i>A. the risks and benefits of the use of a substance:</i>	
<p>There are numerous risks of harm associated with alkyl nitrites.</p> <p>Risks associated with the use of alkyl nitrites include illicit use for euphoric (perceived due to dilation of blood vessels in brain and periphery), analgesic and muscle relaxant effects.^[21]</p>	<p>Use as a muscle relaxant to enable painless intimacy with their partners is not a risk. Alkyl Nitrites are not known to have an analgesic effect so this is not a risk. There are no reports in medical literature of an analgesic effect.</p>

Increased risk of cardiovascular harm when used in conjunction with other vasodilators.	
Alkyl nitrites are sweet-smelling liquids and pose a risk to child safety through cases of accidental ingestion.	Accidental ingestion by children is a risk common to all medications and cleaning products and is easily controlled by childproof packaging.
There are no therapeutic benefits associated with the use of alkyl nitrites other than amyl nitrite, which may be used as an alternative antidote for cyanide poisoning in the event that IV access or first line antidotes are not immediately available	Alkyl nitrites are used by 40% of Australian gay men to enable painless intimacy with their partners, this is an important therapeutic benefit.
Industry stakeholders have not identified any current use of alkyl nitrites and have indicated that the proposed changes to the Poisons Standard with respect to alkyl nitrites and lubricants will therefore not impact their current products.	The current list of industry stakeholders excludes the 170,000 gay men who use alkyl nitrites, the retail and wholesale businesses that supply them and the government and non-government organisations that examine LGBTI health and social issues.
<i>B. the purposes for which a substance is to be used and the extent of use of a substance:</i>	
Alkyl nitrites have little to no therapeutic use. There are no products on the Australian Register of Therapeutic Goods (ARTG) that contain alkyl nitrites. There are no agricultural products or veterinary medicines containing any nitrite listed on the Australian Pesticides and Veterinary Medicines Authority's PubCRIS database.	Alkyl nitrites are used by 40% of Australian gay men to enable painless intimacy with their partners, this is an important therapeutic use.
<i>C. the toxicity of a substance:</i>	
Inhalation of alkyl nitrites can lead to methaemoglobinaemia and even death, with significantly increased risk if ingested. Methaemoglobinaemia is potentially life threatening if not treated appropriately. ^[23]	The toxic effects listed are primarily theoretical with case notes and reports in medical literature difficult to find. When the millions of users of alkyl nitrites worldwide are taken into account significant adverse effects are extremely rare. Methaemoglobinaemia is primarily associated with ingestion and only isolated case notes associated with inhalation can be located.
Alkyl nitrites can cause chemical burns to the skin and eyes on direct contact. Other risks of alkyl nitrites include maculopathy and skin lesions.	The risk of chemical burns and subsequent lesions is common to countless consumer and pharmaceutical products and is successfully addressed in these products by safety warnings and child proof packaging.

	Association with lesions is generally a reference to a now disproven association with Kaposi Sarcoma which was later found to be caused by a virus.
<i>D. the potential for abuse of a substance:</i>	
<p>There is a high potential for misuse and abuse of alkyl nitrites for euphoric properties, and as sex aids due to their muscle relaxant properties.</p> <p>The misuse and abuse of alkyl nitrites appears to be in particular sections of the community rather than widespread.</p>	<p>Alkyl nitrites are widely used by the gay community as a short acting muscle relaxant to enable painless sexual intimacy with their partners.</p> <p>Assisting painless sexual intimacy is not abuse. ██████████ are currently listed by the TGA for use as “sex aids” to aid in the treatment of erectile dysfunction. Alkyl nitrites are the gay male equivalent of ██████████ and the consideration of use as “sex aids” as abuse cannot be seen as anything other than homophobia.</p>
<i>E. any other matters that the Secretary considers necessary to protect public health:</i>	
	This section allows special issues to be discussed. Items that should have been covered are the impact on the gay population and the risk of clandestine production.

Before a decision on scheduling decision is made there is a need to do a new assessment under section 52E of the Therapeutic Goods Act ensuring that widespread usage by the gay community is acknowledged and the impact on this community properly assessed.

Input should be sought from a wider range of affected parties to properly gauge the impact on the gay community, these should include public health organisations, gay health organisations and law enforcement groups.

An outcome which would avoid adverse impacts on the gay community and reduce the risk of poppers maculopathy would be to only add Isopropyl Nitrite to Schedule 9 due to its association with poppers maculopathy. To avoid the development of a black market and the social harms associated with a blanket ban this would need to be combined with removal of Amyl Nitrite from the schedule. This would allow the current retail sale of Isopropyl Nitrite to be replaced with Amyl Nitrite which has a more favourable safety profile.

References

1. The Centre for Social Research in Health *Annual Report of Trends in Behaviour* (2016) reports that among gay men,

Amyl nitrite is the most commonly used drug by gay men in the GCPS (Gay Community Periodic Survey, a yearly survey conducted in capital cities since 1996). The proportion of men reporting the use of amyl nitrite has remained stable over the last decade, and was used by around 35%-40% in the six months preceding the survey. (CSRH 2016 p8)

The Australian Study of Health and Relationships (ASHR2) study reported 3.2% of adult male respondents identified as gay or bisexual (ASHR2 2015 p5). Assuming the adult population at 8,000,000 (IndexMundi 2018), approximately 89,600 adult gay and bisexual men may have used poppers products in the past 6 months.

2. <https://www.theguardian.com/politics/2018/sep/25/making-amyl-nitrite-an-illegal-drug-would-be-ineffective-warns-former-afp-chief>
3. <https://www.theguardian.com/society/2016/mar/07/poppers-ban-uk-april-liquid-gold-john-addy>
4. Schwartz C. POPPERS: THE BAN ON ALKYL NITRITES IN CANADA AND ITS IMPACTS ON GBMSM HEALTH, CBRC Community-Based Research Centre for Gay Men's Health 2018.
5. Rewbury R, Hughes E, Purbrick R, et al
Poppers: legal highs with questionable contents? A case series of poppers maculopathy
British Journal of Ophthalmology 2017;101:1530-1534
6. Thomas P. Lowry, M.D.
Journal of Psychoactive Drugs; Jan-Jun, 1982; Vol. 14(2): 77-79
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7. (UK) House of Commons
Home Affairs Committee
"Psychoactive Substances"
First Report of Session 2015-2016
Home Affairs Committee, Psychoactive Substances (report), London: Stationery Office, 23 Oct 2015, p. 14

Appendix 1: Clandestine production of Alkyl Nitrites:

This section briefly describes the process for clandestine production of Alkyl Nitrites. By describing the commonly available chemicals required and their wide availability it attempts to highlight why clandestine production by organised crime is inevitable in the event of a ban. [REDACTED]

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