

Regulatory options for appropriate access and safety controls for alkyl nitrites

Submission to the TGA in response to calls for public feedback

Summary

I welcome the opportunity to provide feedback on the TGA's Consultation paper on options for appropriate access and safety controls for alkyl nitrites.

I believe that the ACMS has already made the correct decision with regards to these substances at its meeting in June 2018 and that this decision should stand regardless of efforts by a vocal minority to have this decision overturned.

As outlined in the TGA discussion paper these substances present a danger to public health and should not be available. According to the TGA discussion paper these substances are currently readily available illegally through adult shops and online for use in anal intercourse by homosexuals but the neither the TGA nor the ACMS should consider that this constitutes a valid clinical reason to make them available. State and Territory authorities should confiscate any of these products found for sale in these outlets as Health Canada inspectors currently do.

Background

I note that the ACMS considered the scheduling of alkyl nitrates at its June 2018 meeting and proposed to move currently schedule alkyl nitrites from Schedule 4 (Prescription only substances) to create a new Schedule 9 (Prohibited Substance) group entry for all alkyl nitrites and amend the Appendix A listing for lubricants.

It would appear that following this decision a number of public submissions (3 to be exact) and "several" presentations from external parties (number and identities unknown) at the November 2018 meeting the delegate has decided that further public consultation was "warranted" before making a final decision. One does have to wonder if the Delegate was forced to do so on the special pleadings of particular interests groups. As stated in the discussion paper these products have "significant use" (does this mean quantity of use or important clinical use?) among a "number of groups" (exactly how many "groups" is again unknown) in the Australian community. It would appear that the TGA has been "got at" but a small but vocal minority group intent on manipulating the regulatory system for their own benefit.

Response to issues raised in discussion paper

I note that on page 7 of the Discussion paper the following:

Therefore, the circumstances in which the proposed amendment to the Poisons Standard are being considered are quite serious, given that most access is currently not legal (and there are uncommon but very serious adverse events in some people from use alkyl nitrites). Presently those supplying, possessing and using alkyl nitrites without a prescription are contravening both the laws of their State or Territory as well as Federal laws (i.e. the Therapeutic Goods Act).

This does beg the question: why if this behaviour is contravening State and Territory laws as well as Commonwealth laws nothing has been done by State and Territory officials to enforce the laws?

One does have to wonder what is meant by “present options to regularise the situation in law”. Does this mean that if State and Territory officials can’t or won’t enforce the law because they “can’t be bothered” then it is simply a matter to change the law so they don’t have to enforce anything?

Also on page 7 of the paper the following:

From the [public submissions](#) it is clear that people that currently use alkyl nitrites want three main outcomes: a safe product to use; regulation that is proportional to the risks involved with their use and education on how to use alkyl nitrites safely.

Following the link to the ‘public submissions’ I would disagree with the assumption that “people that currently use alkyl nitrites want three main outcomes: a safe product to use, regulation that is proportional to the risks involved with their use and education on how to use alkyl nitrites safely”

There are 3 submissions in the link, and they, amongst other things, state the following:

Accord Australasia

Based on the background information provided, it appears that the intent of amending the Appendix A entry is to exclude personal lubricants. Feedback from our members at this stage indicates that this is not expected to impact their current products. Current feedback from those supplying industrial machinery lubricants did not identify any problems with the proposed new wording for the Appendix A entry. **To date, members have not identified any current use of alkyl nitrites, so are not expected to be impacted by the proposed Schedule 4 entry.**

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

ASCEPT agrees with the proposed changes

NSW Poisons Information Centre

We support tighter and more inclusive scheduling of volatile alkyl nitrites but advocate for a more restrictive schedule than Schedule 4 due to concerns over misuse and toxicity. At minimum we would recommend alkyl nitrites being Appendix D, but preferably Schedule 9 or Schedule 10 (rather than Schedule 4 or Schedule 8 since these substances do not have an established therapeutic value). In addition amending Appendix A to clarify exemptions from scheduling is supported.

Lack of established therapeutic value: Amyl nitrite has been used as a first aid measure to induce methaemoglobinaemia after cyanide exposure. However, current recommendations include sodium thiosulphate plus hydroxocobalamin, or sodium nitrite plus sodium

thiosulfate. Thus volatile nitrites have been superseded for this indication. Volatile nitrites were also historically used for angina, however have been replaced by nitrates. Thus, there is minimal therapeutic role for alkyl nitrites so we do not believe they need the widespread availability of Schedule 4. Alternatively, they could be made Schedule 4 for cyanide antidote kits under the Special Access Scheme, and Schedule 9 or 10 otherwise

Having read the submissions I make the following points:

- *“people that currently use alkyl nitrites”* - who are these people? According to NSW Poisons these substances do not have an established therapeutic value. They are not used in cyanide exposure and were used historically for angina but have been replaced by such products as Anginine® or Nitrolingual® Spray. Are you referring to paedophiles who administer it to children for anal dilation as noted by the NDPSC at its November 1993 meeting?¹
- *“A safe product to use”* – none of the 3 submissions stated that they wanted a “safe product to use”. In fact NSW Poisons Information Centre stated that these products are not safe and there is no human clinical use for these substances. Accord stated that there would be no problem with the changes to Appendix A for the only valid use of these substance which is in machinery lubricants.
- *“regulation that is proportional to the risks involved with their use”* – all the submissions stated that that they had no problem with the proposed changes to scheduling to make access restricted.
- *“education on how to use alkyl nitrites safely”* – I can find no reference to any submission mentioning education on how to use alkyl nitrites safely.

Again on Page 7:

For example, both evidence of, on the one hand, the potential for abuse, and on the other hand, the wide and largely safe use by a section of the community for sexual health purposes will be given considerable weight in the deliberations required by the decision-maker under section 52E(1) of the Therapeutic Goods Act.

I take issue with the phrase *“and largely safe use by a section of the community for sexual health purposes”*. What evidence does the Delegate have of “largely safe use” and what is really meant by the euphemism “sexual health purposes”? Since when does the use of a substance that is not TGA registered or even indicated for this use and sourced illegally under the guise of “a leather cleaner, video head cleaner, incense or room-odorising products” legitimise its use?

Let us not forget that in 2017 63% of HIV notifications were attributed to sexual contact between men². A figure that cannot be disputed by that certain “section of the community” because this statistic is from the Australian Federation of AIDS Organisations. Whilst I can understand you might have some sympathy for “this section of the community” I cannot understand why the TGA would venerate the activities of this community by claiming “largely safe use for sexual health purposes.”

¹ <https://www.tga.gov.au/book-page/13-alkyl-nitrites>

² <https://www.afao.org.au/about-hiv/hiv-statistics/>

The NSW Poisons Information quite clearly highlighted the risks of these substances in its submission (reproduced below for your benefit) and yet the discussion paper states “largely safe use” by a “section of the community”:

Toxicity and abuse potential:

In addition to this lack of therapeutic utility, alkyl nitrites have a potential for misuse, abuse and illicit use. Poisons centre experience indicates that alkyl nitrites are often used as party drugs. Harm can result as an adverse effect of inhalational use, or when accidentally swallowed or splashed in the eye. In addition, we have evidence of home use of alkyl nitrites for their euphoric properties and as sex aids. We have managed several cases of co-use with phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil), posing a risk of severe hypotension.

In addition to potential harms from misuse, use of volatile nitrites poses risks to the community (these sweet-smelling liquids are a child safety hazard). To avoid detection by authorities, alkyl nitrites are often labelled and sold as leather cleaner, video head cleaner, incense or room-odorising products. This can result in misidentification and impair the risk assessment. Toxicity of alkyl nitrites is primary due to vasodilatory actions. This includes tachycardia, hypotension, headache, flushing, dizziness, nausea, and syncope [2]. In addition, methaemoglobinaemia is a relatively uncommon but potentially life threatening consequence of alkyl nitrite exposure [3]. Any ingestion (even an accidental sip) can cause severe toxicity and warrants hospital assessment. Local splash contact with alkyl nitrites can result in mucosal, dermal and corneal injury. In addition, long term inhalation of alkyl nitrites has been associated with retinal damage and vision loss [4].

The poisons centre experience: evidence of increasing misuse and harms

Over an eleven-year period, 2004-2014 Australian PICs received 273 calls about alkyl nitrite exposures (note data was only available from May 2005 onwards from Victorian PIC and Jan 2009 for Queensland PIC). This includes 86 inhalational exposures, 169 ingestions, 18 dermal exposures and 36 ocular exposures (note that one case can have several routes). Over 96% of these calls (263) were regarding adults, with 10 calls (3.7%) regarding accidental paediatric exposures. There appears to be an increasing trend with time, with a 56% increase in exposures from 2009 (first year with nationwide capture) to 2014. In addition, a recent audit of NSW PIC (handles approximately half of national call volume) calls shows 30 unique calls in 2017, 28 in 2016, 27 in 2015.

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Prohibiting the use of alkyl nitrite substances through a Schedule 9 entry (as proposed by the interim decision) in order to protect public health will have legal consequences that vary between jurisdictions. It would criminalise the use of nitrite inhalants by gay and bisexual men, as well as an undetermined number of queer women, non-binary people, and heterosexual men and women who currently use nitrite inhalants

I take exception to the phrase “*it would criminalise the use of nitrite inhalants by gay and bisexual men...*”. Why is this an issue? It’s as if the TGA, ACMS and the Delegate don’t wish to alienate a “certain section” of the Australian community who are accessing a substance (currently illegally by purchasing substances ostensibly labelled as “machinery lubricants”) for use whilst engaging in

“insertive anal intercourse” (as the TGA so politely put it) as if this was a valid “sexual health” issue. As Abraham Lincoln said *“one cannot logically say that anybody has a right to do wrong”*.

I note that on the TGA’s website in the Scheduling history of the nitrites³ that when considering amyl nitride the NDPSC at its November 1993 meeting:

“considered a proposal to create new Appendix D (Possession of this drug without authority should be illegal) entries for amyl and butyl nitrites owing to their **reported use by paedophiles, who administer it to children for anal dilation**. The committee decided that due to the lack of precise information about widespread misuse by paedophiles, this proposal was not warranted at this time and that more attention should be paid to policing the illegal supply of a Schedule 4 substance.” (emphasis added)

I wonder if the current ACMS would consider that this reported use by paedophiles would now be considered a “sexual health” issue rather than an issue of child abuse. One would have to wonder if the TGA, ACMS and the Delegate be as considerate of an elderly group of CWA members in a sewing club wanting to purchase alkyl nitrates to lubricate their Singer Sewing Machines? I think not. It would appear that the Delegate has been put upon by the Alphabet People (ie the LGBTIQ or whatever acronym they currently use) to make an exception to the scheduling of a substance for which there is no clinical indication nor for which there is a TGA-registered product.

I also take exception to the term “non-binary” people. Please do explain what you mean. The “B” in LGBTIQ I was reliably informed by Wikipedia stands for “Bi-sexual” which I would assume means that there are only two genders ie male or female. Do you mean people with Turner’s Syndrome who have XO sex chromosomes and are not really male or female (or they were female but one X chromosome was lost)? Why all the confusion on gender identity⁴?

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More support could be provided to enable consumers to access education on how to use alkyl nitrites safely.

Regulatory responses might include changes in labelling of products to describe safe use, emphasise the risks, and provide advice about child-safe storage; mandating child-proof caps on packaging and other caps to prevent ingestion but not inhibit inhalation; educational messages about risk reduction; and point of sale restrictions such as minimum age limits for purchase or perhaps making them available via pharmacies where people could access quality advice and safety measures. Not all of these regulatory responses are within the powers of the TGA.

The above sentiments are equivalent to the argument that some people sniff petrol so we should accept that they do and provide advice on how to do it safely and effectively. As with cigarette smoking there is no amount of “safe tobacco” use. Public health policy is aimed at getting people to Quit. Remember the *“Every Cigarette is Doing you Damage”* Campaign launched in June 1997⁵. Likewise with the sniffing of alkyl nitrites – as suggested by the NSW Poisons Information Centre there is no safe use of these substances and their sale should be restricted. That is the purpose of the Scheduling framework and it should be followed without exception. Why would TGA consider a

³ <https://www.tga.gov.au/book-page/13-alkyl-nitrites>

⁴ <https://www.prageru.com/courses/political-science/gender-identity-why-all-confusion>

⁵ <http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-educat>

special pleading for those sections of the Australian community who believe that they are an exception to the scheduling policy on the basis that they are using it for “sexual health” purposes? Might it not be preferable to have a public campaign “*Every Act of Insertive Anal Sex is Doing you Damage*”? As outlined on the NSW Health website⁶:

In Australia, people at the highest risk of getting HIV infection are:

- men who have sex with men
- people who have sex with people from countries with a high rate of HIV infection
- people who inject drugs
- people who had tattoos or other piercings overseas using unsterile equipment
- people who have sex with a person with a high risk of HIV as listed here.

Even Wikipedia admits that HIV does not only affect homosexuals but can also infect anybody regardless of sex, ethnicity or sexual orientation, ... “**However**, HIV still severely affects MSM across the globe. MSM are only a small percentage of the US population, but they are consistently the population group most affected by the HIV/AIDS virus and are the largest proportion of American citizens with an AIDS diagnosis who have died”⁷

a) Risks and benefits of the use of the substance

Clearly the risk of the substances outweigh the benefits of the use of the substance as outlined in the TGA discussion paper.

Why this topic is the subject of further consultation beggars belief. One would have to wonder if this is an example of what Ben Shapiro talks about in his article “*When The Scientific Experts Abandon Science for Politics*”⁸. Has the virus of political correctness and woke sermonizing wormed its way into the TGA such that nothing can be decided on the basis of scientific evidence?

b) The purposes for which a substance is to be used and the extent of the use of a substance

As outlined in the NSW Poisons Information Centre there is no valid use of this substance. It is no longer used in cyanide poisoning and is no longer used for angina. The use recreationally to “induce the relaxation of smooth muscle and prevent the tearing of the inner sphincter during receptive anal intercourse” is not a TGA-approved indication for no product that is registered on the ARTG.

It’s not so long ago that sodomy laws were repealed in Australia according to Wikipedia ⁹. One has to wonder if such “progressive” changes to law were really so “progressive”. Just because a particular sexual activity is favoured by a section of the Australian community doesn’t mean that an exception has to be made to the scheduling laws to allow for the use of what is clearly a toxic substance whilst performing this act. The idea that it is “required” for “sexual health” is quite perverse and is not consistent with the Scheduling Policy Framework. It’s like a smoker arguing that they ‘need’ a cigarette for their ‘pulmonary health’ or an alcoholic arguing that they need a beer as a ‘liver tonic’.

⁶ <https://www.health.nsw.gov.au/Infectious/factsheets/Pages/HIV-infection.aspx>

⁷ https://en.wikipedia.org/wiki/HIV_and_men_who_have_sex_with_men

⁸ https://www.dailywire.com/news/41960/when-scientific-experts-abandon-science-politics-ben-shapiro?utm_source=facebook&utm_medium=social&utm_content=062316-podcast&utm_campaign=mattwalsh

⁹ https://en.wikipedia.org/wiki/Sodomy_law

Remember that 67% of HIV notifications in Australia were attributed to sexual contact between men. One would have to argue if the term “sexual illhealth” shouldn’t be used in this context.

c) Toxicity of a substance

As outlined in the discussion paper and the NSW Poisons Information Centre submission the substances in question are not without toxicity and have resulted in deaths. As also highlighted by Ophthalmologists there is an increase in cases of temporary and permanent macula damage caused by recreational drug use of alkyl nitrite compounds. *“None so deaf as those that will not hear. None so blind as those that will not see”*¹⁰

d) The dosage, formulation, labelling, packaging and presentation of a substance

The discussion paper clearly states that there is no TGA-registered alkyl nitrite substances listed on the ARTG. If there was one would assume that it would only be available for use in cyanide poisoning and angina, however both of these indications have been superseded by other medicines.

The discussion paper also clearly states that the substances that are available in Australia in “adult shops” and online are those products where suppliers are claiming that the substances are not captured by scheduling because they fall under the exemption for lubricants in Appendix A of the Poisons Standard. This is obviously a loop hole which State and Territory Health Departments have been remiss in policing. The substances are clearly not used as leather cleaner, video head cleaner or incense or room-odorising products. As mentioned in the discussion when found at retail outlets by Health Canada Inspectors, the products are seized. Perhaps Australian authorities could follow the Canadian example and enforce the law.

e) The potential for abuse of a substance

As stated in the discussion paper these products are being used for euphoric and muscle relaxant effects and their use has resulted in harm to the user due to adverse events. It would appear as if the TGA and the ACMS is having difficulty understanding its own discussion paper and has obviously been coerced by a “section of the Australian community” to engage in a pointless public consultation process at great time and expense. The public consultation appears to have been agreed to so as to placate the interests of this section of the community who believe that they have a special exemption to utilise these substances for so-called “sexual health” purposes. More than once in the scheduling policy history the phrase **“reported use by paedophiles, who administer it to children for anal dilation”** is used.

f) Any other matters that the Secretary considers necessary to protect public health

I agree that the amendments to the Appendix A entry will clarify its intent but this will of course be pointless unless the States and Territories act to enforce the law by confiscating all the “leather cleaners and video head cleaners” that are on sale at “adult shops” and the like.

Perhaps the Delegate should consider the issues raised in Robert R Reilly’s book *“Making Gay Okay: How Rationalizing Homosexual Behaviour is Changing Everything”*¹¹. Whilst written from an American perspective I would suggest that issues raised in the book are also relevant to the Australian setting. I would highly recommend members of the ACMS read this book before denouncing it as “politically incorrect” and rushing to the Bebelplatz to burn it.

¹⁰ https://en.wikiquote.org/wiki/Matthew_Henry

¹¹ <https://www.amazon.com/Making-Gay-Okay-Rationalizing-Homosexual/dp/1621640868>

A short extract from the review is telling in this case where the LGBTQ!etc have decided that a class of substances with no other valid clinical use should be allowed for use in "sexual health". If this group of Australians were anyone else e.g. a group of sewing grannys wanting lubricant for their overlockers, they would not be given the time of day.

Why are Americans being forced to consider homosexual acts as morally acceptable?

Why has the US Supreme Court discovered a constitutional right to same-sex "marriage", which until a decade ago, was unheard of in the history of Western or any other civilization?

Where has the "gay rights" movement come from, and how has it so easily conquered America?

The answers are in the dynamics of the rationalization of sexual misbehavior. The power of rationalization—the means by which one mentally transforms wrong into right—drives the gay rights movement, gives it its revolutionary character, and makes its advocates indefatigable. The homosexual cause moved naturally from a plea for tolerance to cultural conquest because the security of its rationalization requires universal acceptance. In other words, we all must say that the bad is good.

At stake in the rationalization of homosexual behavior is reality itself, which is why it will have consequences that reach far beyond the issue at hand. Already America's major institutions have been transformed—its courts, its schools, its military, its civic institutions, and even its diplomacy.

The further institutionalization of homosexuality will mean the triumph of force over reason, thus undermining the very foundations of the American Republic.