

Thank you for this additional opportunity to voice a view in opposition to the rescheduling of alkyl nitrites and in support of alternative regulatory responses.

As my original submission pointed out, the TGA must:

Before making a final decision, consider the matters to be taken into account in section 52E of the *Therapeutic Goods Act 1989*, including not not exclusive to: the dosage, formulation, labelling, packaging and presentation of a substance

The TGA's decision to make illegal all sale, distribution and possession of alkyl nitrites is such an extreme affront to gay males and the culture of male homosexual practice that it is little wonder that the TGA's initial decision failed to even begin to address issues surrounding dosage, formulation, labelling, packaging and presentation of a substance.

My previous submission placed the TGA on notice that any affected person, myself included, has a right to seek a merits or judicial review (most appropriately handled in that order) of the TGA's final decision to 'ban poppers'.

It was therefore inevitable that the TGA would have to comment at least somewhat on how (i) no attempt has ever been made (or lobbied for by those health practitioners claiming to be so concerned for our health) to use labelling of poppers bottles to educate consumers and (ii) any harmful effects of alkyl nitrites do not apply equally to each sub-category of nitrite.

The TGA has now further commented in a manner that makes an extraordinary admission at the end of the following statement:

"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 Therapeutic Goods Administration Consultation on appropriate access and safety controls via the Poisons Standard for alkyl nitrites V1.0 November 2018 Page 9 of 22 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 TGA still does not make it clear what regulatory response can be applied to how things are now: The purchase of this substance by mainly gay male clientele in sex shops and gay male-only venues.

If the TGA has known for so long that it lacks a comprehensive regulatory response within its own powers, what evidence can it produce that it consulted with other regulatory bodies that do have that regulatory response?

The TGA is putting the cart before the horse by not addressing labelling on bottles first, before it does anything else at all. More to the point, this issue should have been sincerely dealt with by whichever government statutory authority has the regulatory response to do so in consultation with the TGA as far back as 2010 with Australian Consumer Law requiring bottles of poppers to be labelled in compliance to the law, particularly in reference to general consumer protections applicable to product labelling.

Concerns about child safety, including the mandating of child safety caps, is an issue that should be handled separately to the question of whether or not to make poppers use illegal.

Concerns about other users of poppers besides gay males should not obfuscate the fact that most users, if not almost every user, is a gay male.

To truly consider the health issues around poppers, there needs to be frankness about exactly what this product is and exactly who uses it most.

The TGA's admission that it "lacks regulatory response power" effectively is an admission it alone can't be trusted with responding to the big picture of poppers use in Australia – that being made up of its sale, distribution and possession.

It makes me appropriately angry that those health practitioners that purport to be so concerned about our health couldn't be bothered with getting first things done first.

That it "lacks regulatory response power" is the most frank statement the TGA has made throughout this otherwise coy and rushed decision that my LGBTI community has been so right to attempt to undermine.

So please TGA – stop being so coy and label these products accurately and educationally. Then stop being in such a rush – instead monitoring what change in health outcomes that one change alone brings.

This would amount to a similar, cautious and incremental change taken to the harm reduction of cigarettes – a far greater substance of addiction and death (as is alcohol).

Please do not obfuscate from the language of discrimination. For the health practitioners to go so soft and slowly on the harm reduction of cigarettes and alcohol, despite all that cancer from cigarette smoking and all the road toll deaths and domestic and street violence arising from binge drinking of alcohol, then to go fast and furious against poppers use, which affects mostly gay males and lacks the same history of drug addiction and adverse affects on broader society, IS discrimination.

A ban on poppers IS an attack on gay males, their culture and sense of being. A ban on poppers is a trigger for legal challenge, including merits review and judicial review and possibly a review in the legal field of human rights.