Director, Scheduling Project Management Regulatory Engagement and Planning Branch Regulatory Practice and Support Division Therapeutic Goods Administration PO Box 100 WODEN ACT 2606

10 January 2019

Dear Sirs

RE: Regulatory options for appropriate access and safety controls for alkyl nitrites

I make the following submission in response to the consultation paper regarding possible options for the future scheduling of alkyl nitrites. This is based on my own experience as a 55 year old gay man who has used "poppers" regularly for over 35 years. I am in a committed relationship with my long term same sex partner, I have had a successful professional career and I am a responsible member of my community, devoting much of my spare time to volunteering in my community. My story is not unique, it is representative of a great many other people who are not able to make such a submission.

Poppers have been a regular part of my sexual life for most of my life. I would be extremely reluctant to give up to up sexual activity I enjoy, which is facilitated by poppers. So much so that if the proposed schedule 9 listing were to proceed, I would seek to acquire poppers through illegal suppliers in the black market or import them illegally, in defiance of policy I know to be misguided and with full knowledge that I would be breaking the law and risking prosecution.

Risks and benefits of use of the substance

The risk of maculopathy from poppers use is significantly overstated. I understand that the main cause of vision loss is isopropyl nitrite, which was introduced as a substitute for isobutyl nitrite when it was outlawed in the EU in 2007. Isopropyl nitrite-based poppers are not generally available Australia. This change indicates the dangers of changing drug or poisons policy without properly considering how the legal and illicit market is likely to respond. There is a good case for schedule 9 listing of isopropyl nitrite, which I would fully support.

There is virtually no risk of addiction from poppers as they are not psychoactive and overdose is extremely rare from sniffing. Misuse through swallowing is comparable to swallowing bleech or other toxic household substances. The most significant side effect is nostril burns or headache which is a self-limiting temporary effect.

The benefits of poppers in facilitating receptive anal intercourse are significant. They enable sexual intimacy and fulfillment and reduce sexual anxiety. They prevent damage from tearing by relaxing the anal sphincter. Due to their long history of association with gay culture, it could also be argued that poppers have an enduring cultural significance for an oppressed minority. They are in many ways a symbol of our determination to stand up for our love rights.

The purposes for which the substance is used, and the extent of use

Like many other gay men, and other people, I use poppers to facilitate receptive anal sex including fisting. Evidence from the periodic survey and FLUX study suggests that the majority of users also use poppers monthly or less frequent. Gay and bisexual men have been using poppers since the 1970s for this purpose, virtually without incident. I have been using poppers regularly for over 35 years without incident. My sex life would be significantly diminished without access to poppers

The toxicity of the substance

Many household products available for sale in supermarkets are highly toxic if consumed incorrectly. Toxicity alone is not a reason to restrict the sale of any substance but I understand that legislators have a responsibility to ensure appropriate packaging and labelling is required. However, listing poppers in schedule 9 actively works against appropriate packaging and labelling. Already the restrictions on sale under the current schedule have meant that manufacturers are unable to advise sniffing, which could be seen is the most appropriate method of consumption. Schedule 9 listing will not reduce the availability or use of poppers, but it will force users like me to source it from the black market or to import it, preventing not only appropriate packaging and labelling, but also restricting the ability of LGBTI community organisations to provide education on proper use. There is a well established pattern of community education through friendship networks and our community organisations that was developed in response to HIV and continues to use harm minimisation principles to manage the health of LGBTI people. In particular, it would be helpful to provide warnings about using poppers in conjunction with Viagra.

The dosage, formulation, labelling, packaging and presentation of the substance

Current legislation which has driven the market to mislabel the poppers as video head cleaner, leather cleaner or other misleading descriptions, is unhelpful in ensuring the safe consumption by Australian consumers. Usage instructions which advise against sniffing are equally unhelpful and may imply that drinking is an appropriate method of use. The TGA should use this opportunity to mandate better packaging including: child proof caps and labelling that states the product should not be swallowed. A schedule 5 listing "caution" would be appropriate in this context. LGBTI health organisations should be commissioned to produce health information materials to support safe use under a harm minimisation framework. A schedule 9 listing would only force the supply into the hands of criminals, or encourage the substitution of more risky products and substances, without the capacity to regulate appropriate labelling, which would certainly increase the harms to the LGBTI community.

The potential for abuse of the substance

I would argue that the use of poppers by gay men and others is not abuse or misuse. Poppers are currently being used exclusively for the purpose they are specifically manufactured for. Facilitating anal sexual intercourse is a legitimate, legal application and arguing that this is misuse, denigrates the sexual practice of LGBTI people.

Other matters that are necessary to protect public health

I note that the TGA's own criteria for listing a substance in Schedule 9 requires that the substance have 'no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use'. This is most definitely not the case with poppers. The therapeutic value of the "poppers" in facilitating receptive anal sex without

injury or pain is unmatched my any other substance. By relaxing the anal sphincter, which is not able to be controlled voluntarily, "poppers" allow initial penetration and prevent tearing. In this way they prevent sexual anxiety and for many people they are only way they are able to enjoy receptive anal intercourse. Anaesthetic creams - the only alternative - may reduce pain but increase the likelihood of damage (as sensitivity to pain is reduced), while reducing sensitivity and pleasure. Poppers are not addictive as they work as a muscle relaxant rather than affecting brain chemistry. Cases of misuse are so rare they can be compared to the misuse of other commonly available toxic household products and I would argue that if misuse does occur it is primarily as a result of legislation which forces manufacturers to label the product incorrectly rather than providing sensible usage instructions and health warnings on the bottle.

I would be pleased to speak directly to this submission at the public consultation, if the TGA should wish it.

Yours faithfully,