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NSW Poisons Information Centre
www.poisonsinfo.nsw.gov.au

The Children's Hospital at Westmead
Locked Bag 4001
Westmead, NSW 2145
Sydney, Australia

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15th January 2019

Director, Scheduling Project Management
Regulatory Engagement and Planning Branch
Regulatory Practice and Support Division
Therapeutic Goods Administration

Re: Comment on Regulatory options for appropriate access and safety controls for alkyl nitrites

The NSW Poisons Information Centre (PIC) has previously submitted detailed information regarding extent of and trends in poisoning exposures due to alkyl nitrites.

The NSW PIC remains concerned at the alarming rate of increase in poisoning exposures to alkyl nitrites in recent years, however we recognise the concerns raised around criminalisation of use, particularly for populations using alkyl nitrites with therapeutic intent to enable receptive anal intercourse. It must be noted that however common this practice is, currently there is no data available on what constitutes safe and effective use of these products for that purpose.

Information regarding risks of retinal maculopathy linked to alkyl nitrite use shows positive correlation, but unfortunately the unorthodox use of non-pharmaceutical products means details of product components and clear statistics on usage is unclear. This makes assessment of the risk very difficult. Although association between changing regulations internationally resulting in increased isopropyl nitrite use and increases in maculopathy have been seen, further research is required.

Organisations lobbying to maintain access to alkyl nitrites for special interest groups would be perfectly placed to recruit/conduct clinical trials for specific products of identified ingredients in safe dosage forms. If this much needed data proved the safety which is being claimed, the NSW PIC would be keen to support a reconsideration of the scheduling of alkyl nitrites.

In the meantime, the NSW PIC feels placement of alkyl nitrites in schedule 9 would be most appropriate, with the exception of amyl nitrite, which has evidence of safety from historical therapeutic use and could remain in schedule 4. This would ensure appropriate advice on usage and monitoring to minimise adverse outcomes. This schedule 4 listing for amyl nitrite should be conditional on provision in a formulation which will deliver a metered/single dose, prevent accidental ingestion, and access to the liquid, as well as having a maximum number of dosages available. Investigation into, development and approval of such a dosage administration system for amyl nitrite would minimise risks of accidental and intentional poisoning significantly and allow safe prescribing to patients.

A product has been available internationally in the form of amyl nitrite inhalant ampoule 0.3ml, pack of 12, but newer technologies are likely to offer superior formulation options. Development of

patient information appropriate for the intended use of the specific product would also support safe use and minimise the risk of poisoning.

Regards