

# Alkyl Nitrites

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## What is the issue?

Alkyl nitrites are currently purchased for use as a sexual aid during receptive anal sex due to the smooth muscle relaxant effect, specifically on sphincter muscles. These items are “consumed” via nasal inhalation of vapours eluted from the liquid products.

Multiple alkyl nitrites are purchased in Australia, each with different schedules, toxicity, and effectiveness.

Alkyl nitrites that are currently purchased in Australia are labelled erroneously for use as “leather cleaners” or similar industrial purposes. Lack of standardised labelling has lead to people purchasing these items for the purposes of receptive anal sex without correct instructions or advice from peers, especially in instances where heterosexual couples are accessing these products.

Lack of labelling and advice has contributed to an increase in issues such as methaemoglobinaemia; eye damage; and ingestion of the liquid with associated mucosal membrane chemical burns.

Amyl nitrite is the agent most associated with safe use and user preference. Amyl nitrite is currently schedule 4 in Australia.

## Proposal to improve safety of access

While it is acknowledged that the Therapeutic Goods Administration is considering a change in schedule for all alkyl nitrites to schedule 9, this may lead to criminalisation of people who use these products for receptive anal sex, especially men who have sex with men and gay men. These groups already experience a high burden of sexual health inequality and stigma; criminalising access to or possession of these items is likely to disproportionately affect these populations and contribute to significant risks through further restricting access to safe and reliable information about the use of these products.

## Health product or social product?

A consideration in this discussion is whether the use of alkyl nitrites is a “health intervention” product or a social product.

While there are health benefits to the use of alkyl nitrites during receptive anal sex due to reduced chance of injury and STI transmission, most people who access these products consider them to be a social product that should not *require* the intervention of a health professional to access.

Changing these agents to schedule 9 is likely to lead to criminalisation of the purchase and possession of these products by an already marginalised group. Similarly, making these agents schedule 2, 3, or 4 is likely to lead to *medicalisation* of sexual activity between gay men and men who have sex with men.

Doubt was expressed by individuals during the consultation process about the need to access a health professional to purchase these products. Given that amyl nitrite is already schedule 4, yet is rarely accessed on prescription, it is likely that a medical model (prescription only) or pharmacy model (schedule 2 or 3) will not be utilised, with access through existing vendors – and associated legal risks – likely to persist. Regulatory change should acknowledge this, and focus on reducing risks rather than reducing access.

## Scheduling Options

### Unscheduled amyl nitrite with restricted criteria for sale

As the greatest risk from use of amyl nitrite is due to lack of safety labelling/precautions, it is recommended that amyl nitrite be regulated in a manner similar to other items that have a greater social utility than medical utility, such as tobacco or alcohol.

It is proposed that amyl nitrite should be available for sale from existing vendors with regulated labelling requirements for safe use as a sexual aid, as an unscheduled poison.

Vendors should undergo accreditation to ensure knowledgeable and responsible sale without an expectation for health advice to be provided. Age restrictions may be contemplated as part of this model, based on the existing age of sexual consent in each state.

Governments should tender for an organisation to develop and implement an accreditation framework, fee structure, and inspection/compliance process.

A sponsor will need to apply for importation and labelling of amyl nitrate for the Australian market, with consideration of TGA listing, adequate labelling, and safety/poisoning instructions. This would be required in all models that allow for ongoing access

Other alkyl nitrites with poorer safety profiles may also be considered for access via this method, or restricted from access under this model, based on risk.

#### Strengths of this option

- Avoids criminalisation of the use, possession, or sale of these products
- Avoids medicalisation of the use of these products
- Utilises existing socially accepted models of accessing agents used for social purposes
- Allows for age restriction to match the age of consent in each state

#### Weaknesses of this option

- Requires a third party to develop and implement an accreditation framework

### **Schedule 2**

In the instance where *unscheduled amyl nitrite with restricted criteria for sale* is not accepted as a suitable model for accessing these agents, it is likely that schedule 2 would be the most appropriate schedule for amyl nitrite.

#### Strengths of this option

- Avoids criminalisation of the use, possession, or sale of these products
- Lowest possible level of medicalisation of the use of these products where scheduling is implemented

#### Weaknesses of this option

- Requires existing vendors to cease all sales of these products
- Requires pharmacies to range these products, which may be delayed or inconsistent due to a lack of previous sales to guide demand
- Doubts expressed by people who utilise these agents now about access via a pharmacy, especially in a small community.
- Age restrictions cannot be applied

### **Schedule 3**

In the instance where *Schedule 2* is not accepted as a suitable model for accessing these agents, it is likely that schedule 3 would be the most practical option.

#### Strengths of this option

- Avoids criminalisation of the use, possession, or sale of these products

#### Weaknesses of this option

- Requires existing vendors to cease all sales of these products

- Requires pharmacies to range these products, which may be delayed or inconsistent due to a lack of previous sales to guide demand.
- Doubts expressed by people who utilise these agents now about access via a pharmacy, especially in a small community.
- Significant medicalisation of receptive anal sex.
- Unlikely to be accepted, resulting in the same situation that currently occurs, with inappropriately labelled “industrial” products being purchased.

### **Schedule 4**

Amyl Nitrite is currently schedule 4, yet access via prescription is rare or non-existent. This schedule remains inappropriate as access through other methods is likely to persist. This schedule has already failed.

### **Schedule 8**

This schedule is not appropriate.

### **Schedule 9**

This schedule would lead to significant harms due to criminalisation of the use of agents for a normal and accepted form of sexual activity.

## **Transition Period**

A transition period will be required (likely 18 months) while federal and state jurisdictions implement regulations appropriate for the preferred proposal. Labelling and safety instruction implementation; accreditation framework development and implementation; and importation/approval of an appropriately labelled and packaged product will be required. This implementation period will ensure there are no restrictions to current access in a manner that may cause an increase in harms as changes are implemented.

## **Summary**

A framework should be developed wherein amyl nitrite is available through accredited vendors as an unscheduled product, with adequate labelling and packaging fit for purpose. An implementation period of 18 months is proposed to ensure uninterrupted access during the implementation of this model.