

ACMD

Advisory Council on the Misuse of Drugs

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Rt Hon Chris Philp MP
Minister of State for Crime, Policing and Fire
2 Marsham Street
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11 August 2023

Dear Minister,

RE: ACMD Advice on Scheduling and Lawful Access to Nitrous Oxide

Thank you for the Government's responses to the ACMD 2023 Nitrous Oxide report and the subsequent commission of 9 June 2023. As they set out, following the Government's decision to control nitrous oxide as a Class C drug under the Misuse of Drugs Act 1971, there is a statutory duty for the Government to consult the ACMD on changes to the Misuse of Drugs Regulations 2001 to enable legitimate use of nitrous oxide.

Advice was sought from the ACMD on two aspects of the Misuse of Drugs Regulations 2001: i) appropriate scheduling of nitrous oxide to enable use for medical, dental, veterinary, healthcare and some scientific purposes (hence referred to below as 'medical-related uses') and ii) how to enable legitimate non-medical-related, lawful uses, including industrial uses.

The ACMD is grateful to Home Office officials for providing a preliminary analysis of the recent public consultation on legitimate uses of nitrous oxide to the ACMD's Technical Committee. As demonstrated by responses to the consultation, appropriate scheduling of nitrous oxide under the Misuse of Drugs Regulations 2001 presents several challenges. Compared to other substances controlled under the Misuse of Drugs Act 1971, nitrous oxide has a vast range of legitimate medical-related and non-medical-related uses, including industrial processes, catering and activities such as rocketry, automobile racing and amateur baking. Many responses to the consultation did not consider there to be viable alternatives to nitrous oxide. Furthermore, there is no precedent for scheduling gases under the Misuse of Drugs Regulations 2001 as nitrous oxide is the first gas to be controlled under the Misuse of Drugs Act 1971.

The Home Office have considered that possession of nitrous oxide for non-legitimate use should be unlawful. The ACMD has concluded that none of the existing schedules in the Misuse of Drugs Regulations 2001 are entirely appropriate to enable medical-related and non-medical-related uses of nitrous oxide without potential unintended consequences.

Medical-related uses

Nitrous oxide is used as an anaesthetic and analgesic in medical and dental settings and can also be used for cryosurgery. Nitrous oxide is available in cylinder forms of different sizes for medical uses and cylinders may be used in medical gas piping systems in hospitals.

Nitrous oxide is also used as an anaesthetic in veterinary contexts.

Non-medical-related uses

The Home Office public consultation identified numerous legitimate uses of nitrous oxide, however, there are potentially more. After reviewing the public consultation results, the ACMD is unable to conclude with certainty the breadth of non-medical-related uses of nitrous oxide, or the potential unintended consequences for non-medical-related uses of any scheduling recommendation under the Misuse of Drugs Regulations 2001. These unintended consequences include potentially legitimate uses not falling within an exemption and therefore businesses operating illegally. Also, individuals who use nitrous oxide for legitimate purposes who are aware of the possession offence may not be able to find a financially viable alternative. Further consultation is necessary with stakeholders to determine the implications of scheduling for non-medical-related uses and the feasibility of any non-medical-related exemptions. Schedule 2 of the Psychoactive Substances Act 2016 describes exempted activities in healthcare and approved scientific research, and the Government may wish to adopt a similar approach when considering the scheduling of nitrous oxide.

Conclusion 1: The ACMD is unable to conclude with certainty the breadth of non-medical-related uses of nitrous oxide, or the potential unintended consequences of scheduling under the Misuse of Drugs Regulations 2001 for these uses.

Enabling legitimate use

Defining legitimate use is an extremely important first step. The Home Office public consultation defined legitimate use as “*uses of nitrous oxide which are not for its psychoactive effect in a recreational capacity*”. Although most responses to the public consultation considered the proposed definition to be appropriate, it is essential that the definition used in legislation is legally robust and sufficiently comprehensive that it does not have unintended consequences.

Responses to the public consultation considered that a licensing requirement for possession and use would be too burdensome. To permit continued legitimate uses, the ACMD agreed that a licensing system would be inappropriate. The ACMD considered that exemptions for type of use would be more appropriate than exemptions based on specific forms, sizes of canister or groups of people. The

ACMD proposes that exemptions for type of legitimate use could be grouped into two categories: medical-related and non-medical-related.

Conclusion 2: The ACMD considers that a licensing regime for nitrous oxide would be disproportionate, complex and have an undesirable impact on legitimate uses.

Conclusion 3: If exemptions were to be applied to nitrous oxide, the ACMD considers that these should be based on type of use grouped into two categories: medical-related and non-medical-related.

Factors considered in the scheduling decision

The ACMD has followed its Standard Operating Procedure¹ for scheduling decisions and considered the factors below relevant to nitrous oxide:

- *Status as a medicine:* Nitrous oxide is used as an analgesic in medical and dental settings. Nitrous oxide is also used as an anaesthetic in veterinary contexts.
- *Use in industry, agriculture, and cosmetics:* Nitrous oxide has many commercial and industrial uses, as identified in the ACMD 2023 Nitrous Oxide report and the Home Office public consultation.
- *Classification under the Misuse of Drugs Act 1971:* Following the ACMD 2023 Nitrous Oxide report, the Government has decided to control nitrous oxide under Class C of the Misuse of Drugs Act 1971.
- *Safety:* Nitrous oxide has an established safety profile in a medical setting.
- *Controls on importation and exportation:* Based on the Home Office public consultation, there is limited evidence on the scale of the import or export of nitrous oxide.
- *Prevalence of prescribing:* Nitrous oxide is predominately used in urgent care settings and anaesthesia, so needs to be accessed easily.

The ACMD 2023 Nitrous Oxide report contains further information on: toxicity, behavioural effects, dependence potential, chemical structure, and pharmacological action of nitrous oxide. The ACMD 2015 Nitrous Oxide report contains further information on the diversion potential of nitrous oxide.

Appropriate scheduling under the Misuse of Drugs Regulations 2001

The ACMD understands the short timeframe for implementing legislative change by Government means the creation of a bespoke schedule under the Misuse of Drugs Regulations 2001 for nitrous oxide is unlikely to be feasible. Additionally, any scheduling decision needs to consider the impact on all legitimate uses of nitrous oxide, which will require further discussion with relevant stakeholders. Given the

¹ [Standard Operating Procedure for using evidence in ACMD reports - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/68121/Standard_Operating_Procedure_for_using_evidence_in_ACMD_reports.pdf)

Government's intended timescale for implementing legislative change, the ACMD's consideration of appropriate scheduling has consequently been limited to the existing framework under the Misuse of Drugs Regulations 2001.

A further consideration is that the Misuse of Drugs Regulations 2001 contain a list of persons specified who are authorised to possess, supply or offer to supply controlled drugs. Due to the range of medical-related and non-medical-related uses of nitrous oxide, it would be unfeasible to amend the list of persons to include all legitimate uses without creating significant unintended consequences. For example, it may be difficult to describe these persons in a way to cover all uses or there may be unknown legitimate users who would then be operating illegally.

In the ACMD 2023 Nitrous Oxide report, the health and social harms of nitrous oxide were assessed as being lower than for other drugs controlled under the Misuse of Drugs Act 1971. Therefore, the ACMD considered the health and social harms of nitrous oxide as being lower than other drugs with legitimate uses which are enabled by the Misuse of Drugs Regulations 2001.

Schedules 1, 2 and 3 in the Misuse of Drugs Regulations 2001 were deemed inappropriate as they would impose significant burdens on legitimate use. Schedule 4 Part 2 was also deemed inappropriate due to its specific application to performance enhancing drugs, principally anabolic steroids.

As such, the ACMD considered Schedules 4 Part 1 and Schedule 5 of the Misuse of Drugs Regulations 2001 to be the most appropriate options as they offered the lowest burdens on legitimate use. A comprehensive comparison of the controls to activities applied by Schedules 4 Part 1 and 5 can be found in Table 1, attached at the end of this letter.

Placing nitrous oxide in Schedule 4 Part 1 would introduce the need for licences for import and export. Only named persons (for example doctor, dentist and pharmacist) could possess nitrous oxide. Nitrous oxide could only be destroyed by these named individuals. There would also be the requirement to preserve registers, books and documents for two years, and keep a record of quantities of drug imported, exported or supplied. The ACMD considered these requirements would present significant burdens to medical-related and to legitimate non-medical-related uses.

Placing nitrous oxide in Schedule 5 would not introduce a licensing requirement for import and export. There would be no restriction on possession for legitimate use and limited record keeping for production, obtaining or supplying stock. There would also be no restrictions on the persons who could destroy nitrous oxide. The ACMD has concluded as Schedule 5 has the fewest controls, it is, therefore, the most appropriate Schedule and would enable medical-related and non-medical-related uses with fewest burdens. However, the ACMD considers modification of Schedule 5 is required to ensure all activities required for medical-related and legitimate non-medical-related uses are enabled while non-legitimate non-medical uses are controlled.

The ACMD recognises the Home Office consideration that possession of nitrous oxide for non-legitimate use should be unlawful. Schedule 5 could be amended

specifically for nitrous oxide to remove the exemption for possession to satisfy this consideration.

The ACMD understands it is too soon to learn from evaluations of recent international developments such as the controls introduced in the Netherlands, but, once available, any lessons learned should be reviewed and incorporated to minimise unintended consequences. Furthermore, the ACMD emphasises the need for ongoing review and an evaluation of the classification and scheduling decisions for nitrous oxide to review whether the legislative change is having the desired effect.

Conclusion 4: None of the current schedules under the Misuse of Drugs Regulations 2001 are wholly appropriate for nitrous oxide. Schedule 5, with modifications, would offer the most suitable controls while enabling medical-related and non-medical-related uses with fewest burdens.

Recommendations

Recommendation 1

The ACMD recommends that:

- i) Nitrous oxide be inserted into Schedule 5 of the Misuse of Drugs Regulations 2001.
- ii) Schedule 5 of the Misuse of Drugs Regulations 2001 be amended specifically for nitrous oxide to enable all activities required for legitimate uses.
- iii) Schedule 5 of the Misuse of Drugs Regulations 2001 be amended specifically for nitrous oxide to enable control of import and export, production, possession, and supply for non-legitimate uses.

Lead– Home Office.

Measure of outcome– Change to the Misuse of Drugs Regulations 2001.

Recommendation 2

The ACMD recommends that further consultation is needed with other Government departments and stakeholders to:

- i) Agree a legally robust definition of legitimate use of nitrous oxide, ensuring coverage of legitimate non-medical-related uses.
- ii) Determine any unintended implications or consequences of the proposed definition.

Lead– Home Office.

Measure of outcome– Further consultation completed; definition of legitimate use agreed, and any unintended consequences identified.

Recommendation 3

The Home Office should review international evaluations as soon as they become available, and where applicable apply lessons learned.

Lead– Home Office.

Measure of outcome– Changes made to the legislative framework based on international experiences.

Recommendation 4

The Home Office should design a framework for the assessment and evaluate the impact of classification of nitrous oxide under the Misuse of Drugs Act 1971 and scheduling under the Misuse of Drugs Regulations 2001. This review should take place after legislative changes are implemented and once sufficient data are available.

Lead– Home Office.

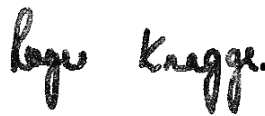
Measure of outcome– Framework for the assessment of the impact of the control and scheduling of nitrous oxide; formal evaluation of actions after implementation.

Yours sincerely,



Prof Owen Bowden-Jones

Chair of the ACMD



Prof Roger Knaggs

Chair of the ACMD Technical Committee

Table 1– Controls on activities applied by Schedule 4 Part 1 and Schedule 5 in the Misuse of Drugs Regulations 2001 relevant to nitrous oxide

Activities	Schedule 4 Part 1	Schedule 5	Comments
Import and export	By licence only	No restriction	Licence requirements in Schedule 4 Part 1 would apply to both medical-related and legitimate non-medical-related uses
Production	License holders, pharmacists, practitioners and persons lawfully conducting a retail pharmacy business	License holders, pharmacists, practitioners and persons lawfully conducting a retail pharmacy business	
Possession	Authorised persons as defined in the Misuse of Drugs Regulations 2001 (for example a doctor, dentist and pharmacist)	No restriction	Authorised persons in Schedule 4 Part 1 do not cover legitimate non-medical-related uses
Supply	Authorised persons as defined in the Misuse of Drugs Regulations 2001 (for example a doctor, dentist and pharmacist)	Authorised persons as defined in the Misuse of Drugs Regulations 2001 (for example a doctor, dentist and pharmacist)	Authorised persons do not cover non-medical-related uses
Emergency supply	Yes	Yes	Not relevant to legitimate non-medical-related uses
Additional requirements for prescription	Do not apply	Do not apply	Not relevant to legitimate non-medical-related uses
Prescription valid for	28 days	6 months	Not relevant to legitimate non-medical-related uses
Register	No register, but some classes of persons are required to keep records or invoices	No register, but some classes of persons are required to keep records or invoices	

Record keeping	Requirement to preserve registers, books and documents for 2 years, and keep a record of each: <ul style="list-style-type: none"> - quantity of drug produced, imported or exported - for supply, each quantity imported or exported 	Invoices to be retained for 2 years. Limited record keeping for production, obtaining or supplying stock.	Record keeping requirements are greater for Schedule 4 Part 1 compounds. Record keeping requirements would apply to both medical-related and legitimate non-medical-related uses.
Administration	To a patient by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber, supplementary prescriber (acting in accordance with a clinical management plan) or by any person in accordance with the directions of a person who is entitled to prescribe controlled drugs	No restriction	Not relevant to legitimate non-medical-related uses
Destruction	No, except in the presence of, and in accordance with any directions given by an authorised person	No restriction	Schedule 4 Part 1 destruction requirements would have significant implications for medical-related and legitimate non-medical-related uses.
Safe custody requirements	No	No	
Requisition necessary	No	No	
Requisition to be marked by supplier	No	No	