

**EXPLANATORY MEMORANDUM TO**  
**THE MISUSE OF DRUGS (AMENDMENT) (No.3) REGULATIONS 2005**  
**2005 No. 3372**

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

2. **Description**

This Statutory Instrument amends the Misuse of Drugs Regulations 2001 (the 2001 Regulations) by placing Ketamine into Part 1 of Schedule 4 to those Regulations. This makes Ketamine subject to the record-keeping, information and destruction requirements set out in regulations 22, 23, 26 and 27 of the 2001 Regulations and permits the production, possession and supply of Ketamine in certain circumstances under those Regulations. These controls are considered necessary due to the adverse impact of Ketamine on the user and to prevent its diversion.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

None.

4. **Legislative Background**

4.1 In recent years, enforcement agencies have become aware that the drug Ketamine, which is used in veterinary medicine as an anaesthetic and in hospitals as an analgesic, was being used illicitly. Her Majesty's Revenue and Customs reported in 2001/2 that large amounts of Ketamine were being intercepted from India, often in packages where Ketamine was in solution packaged as rosewater.

4.2 The Advisory Council on the Misuse of Drugs (ACMD) began a detailed consideration of Ketamine in 2003. An ACMD Ketamine working group called a wide range of experts to give evidence on the best way of controlling Ketamine based on its relative harm. In November 2004 the ACMD recommended that Ketamine be controlled as a Class C drug under the Misuse of Drugs Act 1971 and placed in Part 1 of Schedule 4 to the 2001 Regulations.

4.3 An Order in Council inserting Ketamine into Part 3 of Schedule 2 to the Misuse of Drugs Act 1971 (Class C drugs), was debated in both Houses and was made by the Privy Council on 15 November. It will come into force on 1 January 2006. The Misuse of Drugs (Amendment) (No. 3) Regulations 2005, which will also come into force on 1 January 2006, permit the production, possession and supply of Ketamine in certain circumstances in line with the recommendations of the Advisory Council on the Misuse of Drugs.

4.4 Persons already authorised by the Regulations (e.g. doctors and pharmacists) or by a written Home Office authority to produce, supply or possess those drugs which are listed in Part 1 of Schedule 4 to the 2001 Regulations will automatically be so authorised in respect of Ketamine. Regulations 22 and 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction) will also apply to

Ketamine. Drugs in Part 1 of Schedule 4 to the 2001 Regulations are not subject to safe custody requirements.

## **5. Extent**

This instrument applies to England, Wales and Scotland. Northern Ireland Department for Health, Social Services and Public Safety will make separate legislative arrangements.

## **6. European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy Background**

7.1 Ketamine is currently a Prescription Only Medicine (POM) and is controlled under the Medicines Act 1968. It is used primarily in veterinary medicine as an anaesthetic, but is also prescribed in hospitals as an analgesic to manage acute pain. Ketamine is a dissociative anaesthetic - it has hallucinogenic properties and can make the user feel detached from their body. It is mainly misused by clubbers by snorting but it can be taken in pill form and also be injected.

7.2 Ketamine can affect the memory and so may, if used over a prolonged period, have the potential to disrupt the personal and working life of users. There has been concern that Ketamine may lead to psychotic relapse or precipitation of schizophrenia in people who have a tendency towards these particular types of disorders. Mixing Ketamine and alcohol can be fatal. It also stimulates the cardiovascular system so that there is an immediate effect on the body of the user. There is an increase in heart rate, cardiac output and blood pressure, which makes it potentially dangerous to people with diseases of the cardiovascular system.

7.3 Her Majesty's Revenue and Customs identified in 2001/2 an emerging trend for large parcels of the drug being imported into the UK, concealed in solution in packages labelled "Rosewater". The ACMD carried out a formal study of Ketamine in 2003 and recommended that Ketamine should be controlled as a Class C drug under the Misuse of Drugs Act 1971 and placed in part 1 of Schedule 4 to the 2001 Regulations.

7.4 In February, the then Drugs Minister, Caroline Flint accepted these recommendations in principle that Ketamine should be a controlled drug, subject to views received in a public consultation that took place between March and June. The consultation was generally supportive of the measures.

**8. Impact**

A Regulatory Impact Assessment was prepared in relation to the classification of Ketamine as a Class C drug and the inclusion of Ketamine in Part 1 of Schedule 4 to the 2001 Regulations and is attached to this memorandum.

**9. Contact**

Jeremy Sare at the Home Office Tel: 0207 035 0461 or e-mail:  
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## **KETAMINE – FINAL REGULATORY IMPACT STATEMENT**

### **TITLE OF PROPOSAL**

The Misuse of Drugs Act 1971 (Amendment) Order 2005 makes the substance Ketamine a controlled Class C drug under the Act.

### **2. PURPOSE AND INTENDED EFFECT OF MEASURE**

#### a) Objective

2.1 The measure is intended to make it an offence to import and export, manufacture, supply, possess and possess with intent to supply Ketamine without lawful authority and thereby reduce its misuse and associated problems. The word 'Ketamine' will be inserted into part III of Schedule 2 of the Misuse of Drugs Act that lists the Class C drugs.

#### b) Background

2.2 Ketamine is a pain killing medicine used in hospitals and in veterinary surgery. There has been a history of supplies being diverted for illicit purposes although at low levels. In recent years enforcement agencies have reported increased imports of Ketamine and surveys show increased prevalence in the clubbing scene.

#### c) Rationale for Government Intervention

2.3 Ketamine is a dissociative anaesthetic that reduces body sensation. It is used legitimately in hospitals in cases of extreme pain (severe burns, amputation) and by veterinary surgeons for anaesthetising a variety of animal types. Those using it for illicit purposes have reported doing themselves serious injury without feeling any related pain. In addition, excessive doses of Ketamine can increase the risk of respiratory problems and heart failure. Ketamine is extremely dangerous when mixed with alcohol and/or other drugs. The long term effects of recreational use of Ketamine are not yet known, but there is some evidence that a minority of users could become psychologically dependent.

2.4 Ketamine use remains at a relatively low level; the Advisory Council on the Misuse of Drugs report (2004) indicates likely that it is used illicitly by less than 0.5% of the adult population. Data collected by the London Centre of the National Poisons Information Service (NPIS) shows that calls requiring information on Ketamine intoxication rose steadily from 10 per year in 1995 to over 100 in 2001. Ketamine related calls accounted for less than 0.02% of calls in 1995 and rose to 0.1% of calls in 2002.

2.5 Epidemiological information from annual self-reported postal surveys of Ketamine use amongst clubbers have shown a rise in regular users between 1999-2003 from 4% to 16%. A distinct epidemiological group of people also uses Ketamine -these people tend to be older, use Ketamine more by intravenous and intramuscular routes.

2.6 Seizures of Ketamine in England and Wales were first reported in 1990. HM R&C were unable to seize the Ketamine as a controlled drug nor as a medicine as it was not in a medicinal form. However they were able to carry out seizures as the packages were 'wrongly declared' as rosewater. Seizures increased during the early 90's reaching a peak of over 250 in 1998. Seizures have been relatively constant since with 195 reported seizures in 2003, which approximates to 150,000 doses in the last 5 years. HM Revenue and Customs reported an emerging trend of Ketamine importation in 2001. Ketamine brought in bulk in India was being covertly imported as a variety of products including rosewater and massage oils.

2.7 The potential for criminal groups to make substantial profits for little risk remains so long as Ketamine is not a controlled drug under the Act and importers are not penalised. Ketamine has been controlled under the Medicines Act 1968, but not the Misuse of Drugs Act 1971. The Advisory Council on the Misuse of Drugs (ACMD) an independent body that advises the Government on drug misuse issues recommended in November 2004 that Ketamine should be brought under the controls of the Misuse of Drugs Act 1971 as a

Class C drug and the Misuse of Drugs Regulations 2001 (schedule 4 part 1) as Ketamine has been shown to be a substance of misuse.

### **3. CONSULTATION**

3.1 A consultation was sent to approximately 100 trade organisations, medical bodies and other interested parties. Consultees had 12 weeks to respond between March and June 2005. Of the twenty-six responses all but two supported the measure to bring Ketamine under the Act.

3.2 Transform Drug Foundation's opposition to the measure was in line with its opposition to the prohibition of drugs - Transform advocates a Government regulated drug market. The Government has firmly rejected that position on a number of occasions. The Government's response to the Home Affairs Select Committee 2002 report on Government's Drugs Policy stated "We do not accept that legalisation and regulation is now, or will be in the future, an acceptable response to the presence of drugs".

3.3 The organisation Release opposed the measure of controlling Ketamine as they feared it could incriminate young people. They called for Ketamine to be placed in Schedule 4 part 2 of the 2001 Regulations along side anabolic steroids where there is no possession offence. This option was considered in correspondence between the Home Office, HMR&C and the Medicines and HealthCare Products Agency and rejected on the grounds that Ketamine users should not be able to claim personal use like steroid users. Steroids used in moderation can provide some benefits to individuals such as body building, Ketamine's medicinal use in humans is confined to alleviating acute pain so supply is controlled by the prescribing of it by doctors.

3.4 All respondents to the consultation will receive an official response.

### **4. OPTIONS**

4.1 Two options have been identified:

Option 1 – Do nothing

Option 2 – Allow the proposed controls on Ketamine (those with proven licit need for Ketamine will still have access although it will be regulated by licences and statutory exemptions for controlled drugs)

4.2 Option 1 – There are no economic, social or environmental benefits. The increasing importation and subsequent misuse of Ketamine would continue unchecked. There are certain health risks of taking Ketamine which would continue to rise if no controls were put in place. The health risks can be summarised as:

4.3 Ketamine impairs the performance of complex tasks that require sustained attention and muscle control. When these involve risks to self or others (such as driving or operating machinery) Ketamine has the potential to be dangerous.

4.4 There are few recorded fatalities as a direct result of Ketamine use alone. When Ketamine-related deaths are reported the usual co-intoxicants are opiates and alcohol. (There is no official figure for Ketamine related deaths – the figures are not collated centrally as it is not a controlled drug). Ketamine has some effects on mental health and functioning. Ketamine is misused orally and intranasally as a tablet and powder respectively. However, it can also be used in solution intramuscularly and intravenously and this route carries the risk of infection blood borne viruses (especially hepatitis and HIV).

4.5 Intoxication with Ketamine produces profound effects on memory. There is now some evidence to show that subtle memory deficits persist for longer than 3 days after use and that these deficits are worse for regular users of Ketamine. These memory problems have the potential to disrupt users personal and working life.

4.6 Option 2 – There will be no economic and environmental benefits. There will be a social benefit as listed above. Ketamine is currently subject to the provisions of the medicines legislation but is not subject to specific controls to combat its misuse (the Medicine’s Act 1968 includes no possession offence and supply is only an offence if the substance is in the form of medicinal product) . The misuse of drugs legislation will provide additional controls on the production, supply, possession, import and export of Ketamine in view of its potential for misuse. This measure will help to reduce the availability of Ketamine on the illicit UK drugs market.

## **5. COMPLIANCE COSTS AND BENEFITS**

### **Sectors and Groups affected**

5.1 Ketamine has legal and legitimate uses as a pain killer and anaesthetic. The main areas affected in increased costs of controlling Ketamine will be the manufacturers of Ketamine as well as hospital doctors and veterinary surgeons.

5.2 The direct economic cost to manufacturing will be extremely low. It is expected that only three businesses, Pfizer (NHS medicinal supplies) and (the two main veterinary medicine companies) will be affected by this change and it is predicted that there will be little or no additional costs involved. There are no specific record-keeping requirements in relation to the supply of Schedule 4 drugs except in respect of quantities imported and exported. There will be no increase in the way of additional costs for UK wholesalers.

5.3 The views of the business, including the small business sector and pharmaceutical trade organisations were sought as part of the consultation process who did not report any additional or indirect costs (recurring and non-recurring) that will arise for business in this sector.

5.4 Section 7 of the Misuse of Drugs Act 1971 sets out conditions whereby companies may produce, supply and/or possess a controlled drug if under a licence, issued by the Secretary of State. The proposed measure will require the companies, Pfizer, Fort Dodge and Vetoquinol having to obtain a licence or authority to produce, supply and/or possess Ketamine. A fee in the region of £124 will be payable annually by each firm to cover Home Office Licensing Section’s costs. In addition, if the company imports or exports Ketamine, it will also need to obtain import and export licences from the Home Office for each consignment of Ketamine imported or exported. Import and export licences are issued free of charge but there will be some administrative costs attached to applying for the licences. This should not be too onerous since exporters currently have to check for receiving country controls, many of which involve the prior issue of an import certificate by that country.

5.5 Section 7 of the Misuse of Drugs Act 1971 also sets out professions for whom it is not unlawful to prescribe, administer, manufacture, compound, supply or possess a controlled drug. These professions include doctors and veterinary surgeons. Hospitals already routinely keep Ketamine in their controlled drug cabinets. We have consulted the relevant veterinary organisation as well as Veterinary Medicines Directorate in DEFRA and they have indicated that any potential additional costs to veterinary practices are likely to be very limited.

5.6 The National Treatment Agency (NTA) does not currently offer treatment for Ketamine users. Any person with problem use or dependence requiring treatment could expect to receive comprehensive assessment and, as well as receiving support and advice on minimising risks of use, could expect to be offered care planned treatment, including appropriate psychosocial interventions to assist in reducing Ketamine use and achieving abstinence.

5.7 There will be a social/economic cost in that Ketamine will become a controlled drug and those persons not entitled to possess, supply, import and export it will be liable to prosecution under the Misuse of Drugs legislation. The measures will allow HMR&C to seize importations once it becomes a controlled drug and not only for ‘wrongly declared’ packages. This is likely to have a significant deterrent effect on importers who tend to be opportunists rather than organised criminal drug dealers.

## Possession Offences

5.8 As a Class C drug those caught in possession will not be liable for arrest under guidance set out in section 24 of PACE 1984. However there may be some prosecutions for possession when individuals are apprehended on other charges such as shoplifting. It is difficult to estimate the scale and nature of the offences in advance of a drug become controlled. Costs would be met from existing police budgets. It is unlikely that there will be any custodial sentences for possession offences.

## Supply/Importation Offences

5.9. Based on all the available data from HMR&C on numbers of imports, we estimate there could be about 50 prosecutions per year for possession with intent to supply, supply and importation offences Ketamine. The estimate is based on numbers of suppliers prior to its control which are reduced by the deterrent effect of it becoming a controlled drug.

5.10 The average cost to prison service per year of incarcerating one person is £35,000 (National Offender Management Service figure). The only Class B/C drug where average sentence received is captured is for cannabis which was 8 months (Drug Offender Statistics 2003). Current sentencing policy allows for release after half the sentence served if the original sentence was below 12 months. Assuming custody time of 4 months the total costs to prisons for implementing these measures are in the region of £583,333.

5.11 There will also be accompanying costs to court services. A non-contested crown court case cost can be assumed to be complete in 1 day incurring costs of £2,910. It is assumed a contested case would last 3 days at a cost of £9,915. A significant proportion (up to 50%) are likely to plead not guilty citing a personal use argument. The total court costs would be 25 x £2,910 added to 25 x £9,915 = £360,625.

5.12 There will be no environmental cost.

## **6. SMALL FIRMS IMPACT TEST**

The Small Business Service has been consulted and consider the impact on small businesses should be minimal.

## **7. COMPETITION ASSESSMENT**

There are no competition issues as the impact on business is small.

## **8. RACE EQUALITY IMPACT ASSESSMENT**

The control of Ketamine will not have any disproportionate effect any particular racial group.

## **9. HEALTH IMPACT ASSESSMENT**

The health effects of taking Ketamine are detailed in sections 2.3 and 4.3 -5 of the RIA. The main effects of Ketamine centre on impairing judgement from a general disassociation between mind and body. Serious harms to the individual can be derived from mixing Ketamine with other drugs particularly alcohol. Although intravenous use of Ketamine is rare this route carries the risk of blood borne viruses such as Hepatitis 'C' and HIV. Without detailed prevalence figures it is difficult to determine the full impact on health, but decreased access to Ketamine should yield some health benefits.

## **10. ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW**

10.1 The proposed controls on Ketamine will be enforced by the Home Office Drugs Branch Inspectorate. The Inspectorate will visit companies that apply for a production, supply or possession authority in respect of the drug. The proposed import and export controls will be enforced by the Home Office Drugs Branch and HM Revenue and

Customs. Unauthorised imports and exports will be liable to be stopped at border checkpoints by HMR&C officers.

10.2 Police forces and Courts will be informed of the change through a Home Office Circular. Police Forces will arrest and prosecute any individuals or groups of individuals attempting to supply Ketamine. The maximum penalty for unauthorised manufacture and supply is 14 years imprisonment and/or a fine. The maximum sentence for the offence of possession of Ketamine will be 2 years imprisonment.

10.3 The Advisory Council on the Misuse of Drugs will monitor the prevalence and impact of Ketamine use through British Crime Survey where Ketamine levels have been monitored since April 2005.

10.4. The main medium for communicating the dangers of drug taking, especially to young people, is through the Talk to Frank campaign. Ketamine is already included on the Frank website at [www.talktofrank.com/azofdrugs/K/Ketamine.aspx](http://www.talktofrank.com/azofdrugs/K/Ketamine.aspx) and the campaign's telephone operators are trained in giving advice on the harms of taking Ketamine. Drug information leaflets currently being developed by the Home Office are to include reference to Ketamine detailing the harms and the change in law of its status.

## **11. IMPLEMENTATION AND DELIVERY PLAN**

11.1 The Amendment Order is subject to the draft affirmative resolution procedure, which requires that they be debated in each House of Parliament and then signed by the Clerk of the Privy Council. It is intended that the Order be signed when the Privy Council meets on 15 November but if sufficient debating time cannot be found, an alternative Privy Council date would be 14 December.

11.2 The measure would not come into force until 5-6 weeks later to allow for the dissemination of information about the legal change to the enforcement agencies.

## **12. POST IMPLEMENTATION REVIEW**

The Home Office will continue to liaise closely with HMR&C in patterns of Ketamine imports. The issue of Ketamine prevalence is discussed at the ACMD's Technical Committee which meets bi-annually where HMR&C are represented. Other bodies represented with relevant knowledge on Ketamine seizures include Laboratory of the Government Chemist and Forensic Science Service. The National Criminal Intelligence Service provides wider intelligence on drug use patterns.

## **13. SUMMARY AND RECOMMENDATIONS**

It is intended that misuse of drugs controls should be introduced on the production, supply, importation, exportation and possession of Ketamine. The control on Ketamine is being introduced to combat its misuse and its potential for misuse. The new controls should reduce the scope for the diversion of the drug to the illicit drugs market, a reduction in its misuse and consequent benefits to public health.

### **Declaration and Publication:**

**I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.**

**Signed by the responsible Minister .....**

**Date .....**



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