ACMD

Advisory Council on the Misuse of Drugs

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Minister of State for Crime Prevention and ASB reduction
Baroness Browning
Home Office
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20th July 2011

Dear Minister,

Re: Phenazepam advice

I am writing to provide you with the Advisory Council on the Misuse of Drugs' (ACMD) consideration of the compound phenazepam (sometimes termed fenazepam) (7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one).

Phenazepam is a benzodiazepine drug, ('street' names include, *'Bonsai'* and '*Bonsai Supersleep'*) and it is being sold as a 'legal high' on the internet. The ACMD is aware that phenazepam is being sold in various ways: under its own name as a single substance; in combination with dimethocaine (one example 'brand' name is '*Dimethocaine Phenazepam Legal Powder')*; and, as a counterfeit for 'Valium' (diazepam) on line. Phenazepam is being sold in pure material in powder form and as a 1 mg per ml solution in dropper bottles.

Phenazepam acts as a depressant and was originally developed in the 1970s by the former Soviet Union, and is now produced in Russia and some CIS (The Commonwealth of Independent States) countries. There is no recognised use in the UK. In some countries it is used, although infrequently and not as routine, to treat neurological disorders and epilepsy, and as a premedication prior to surgery as it augments the effects of anesthetics.

The potency of phenazepam is around five times that of diazepam. Therefore, the risk of overdosing, if judging the dose by eye and using the powder form,

is significant as the human dose is 1-2mg. This is exemplified by some websites warning that an accurate analytical balance is required to weigh doses and the offer of a 1mg per ml solution. The ACMD is also concerned that phenazepam may potentially be more dangerous than other benzodiazepines due to the 60-hour half life of the substance. There is the potential for users to re-dose before the onset of the effects of the original dose, since peak effects are not reached until 2 to 3 hours after an oral dose has been taken, this increases the risk of overdose.

Some of the adverse effects associated with use of and overdose with phenazepam include: retrograde amnesia, loss of coordination, dizziness and drowsiness that can potentially proceed to coma with respiratory depression. In addition, as with other benzodiazepines, discontinuation after prolonged use can be associated with a withdrawal syndrome associated with symptoms including anxiety, insomnia, tremor and potentially convulsions.

The misuse of phenazepam was highlighted in Scotland (2010), by the Primary and Community Care Directorate – Pharmacy Division, when it issued a health warning in July 2010, highlighting reports of illicit use and subsequent overdose of phenazepam.

In December 2010, there were reports of 5 young people being hospitalised in the Scottish Borders after taking phenazepam. In January 2011, North Wales Police warned Anglesey residents that dealers were passing off large quantities of phenazepam as diazepam. A recent paper in the British Medical Journal (Maskell *et. al*, 2011[1]) cites nine cases from forensic toxicology testing in Dundee. Although death was not solely attributed to the use of phenazepam the authors suggest that the use of phenazepam is rising[2].

Guy's and St Thomas' NHS Foundation Trust have not seen any individuals presenting to the Emergency Department with self-reported phenazepam use in the last 5 years. However, it should be noted that individuals may not be aware of exactly which benzodiazepine they have used as they may have been mis-sold phenazepam instead of an alternative benzodiazepine. Additionally, medical and nursing staff who recognise that the individual has used a benzodiazepine, may not record the exact benzodiazepine that has been used (where the patient is able to reliably report this) and may simply record that the presentation is ‘benzodiazepine toxicity’.

A recent inquest into a UK death has shown that the deceased had taken an unknown quantity of phenazepam, believed to have been purchased over the internet, together with other prescribed medication (morphine, codeine, olanzapine and other benzodiazepines detected at post mortem). The cause of death was respiratory arrest, reported as a verdict of accidental overdose of drugs. Other than this fatality, the national Programme on Substance Abuse Deaths (np-SAD) have informed the ACMD that phenazepam has not

[1] Maskell, P. D., Paoli, G. D., Seetohul, L. N., Pounder, D. J. 2011. Phenazepam is currently being misused in the UK. *British Journal of Medicine.* **343**: 4207.
[2] The ACMD are aware that notification of a seizure of phenazepam in Germany has recently been made (12/07/2011) to the European Monitoring Centre for Drugs and Drug Addiction.

previously come to its notice either as being prescribed to the deceased, appearing in the post mortem toxicology, or appearing in the cause of death.

A fatality is reported in the peer reviewed literature from the US of acute oral ingestion of phenazepam and poppy seed tea (including ingestion of morphine, codeine and thebaine) (Bailey *et al.*, 2010[3]).

The ACMD is aware that phenazepam is being sold on the internet and there are numerous on-line suppliers. The Forensic Science Service (FSS) have received 118 cases of phenazepam from local forces in England and Wales in the last 2 years totalling 23,090 tablets. However, FSS has received no seizures from UK Borders Agency or HM Revenue and Customs in the same time period.

Phenazepam was first seen in a submission to LGC forensics (from its police customers) in August 2009, consisting of over 1,000 tablets, with two small seizures later that year. In 2010, there were 9 seizures, all in the second half of the year, with one consisting of over 3,700 tablets. In 2011 to date there have been six seizures. Most of the seizures have been in the form of tablets.

Phenazepam is not listed in the British National Formulary[4] and the ACMD is not aware that it is licensed in the UK for any clinical indications. A recent article in the British Medical Journal indicates it is currently only prescribed in the former Soviet Bloc[1] and we have no information that indicates that it is prescribed in the UK. Although it holds no marketing authorisation in the UK, phenazepam may still be imported and supplied for individual patients in accordance with The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789). The ACMD consider that this is unlikely as the Medicines and Healthcare products Regulatory Agency (MHRA) would object to importation if unable to satisfy a valid clinical need or adequate quality, due to the availability of equivalent licensed medicinal products in the UK and the safety and quality of the product with regards to its limited availability outside the UK and its misuse potential[5].

Phenazepam is not controlled under the Misuse of Drugs Act 1971. All controlled benzodiazepines are Class C drugs under the Misuse of Drugs Act 1971. Most benzodiazepines are placed in Schedule 4 Part 1 under the Misuse of the Misuse of Drugs Regulations 2001 (as amended) apart from temazepam, midazolam and flunitrazepam which are Schedule 3 (with increased regulatory requirements).

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[3] Bailey, K., Richards-Waugh., L, Clay, D., Gebhardt, M., Mahmoud, H., Kraner, J. C. 2010. Fatality involving the ingestion of phenazepam and poppy seed tea. *Journal of Analytical Toxicology*. **34**: 527-532.

[4] British National Formulary 61 (BNF). March 2011.

[5] MHRA. Medicines that do not need a licence (exemptions from licensing. Accessed at http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm on 11/07/2011).

Phenazepam is not scheduled in the 1971 United Nations Convention on Psychotropic Substances. In the USA, phenazepam is not classified as a controlled substance, so possessing it is not illegal. However, marketing phenazepam as a drug or for use in food products is illegal according to the FDA.

In considering its known harms, the ACMD recommends that phenazepam be controlled under the Misuse of Drugs Act 1971 as a Class C substance and scheduled as a schedule 3 substance under the Misuse of Drugs Regulations 2001.

In the interim and prior to control under the Misuse of Drugs Act 1971, the ACMD recommends that the Government should take immediate steps to curb the import of phenazepam thereby reducing the supply of this harmful substance as a public health measure. The ACMD recommends that an immediate ban is made on the import of phenazepam under the Open General Import Licence (OGIL). The prohibition on the import of phenazepam would provide powers to seize illegal imports of this substance to prevent harm to those in the UK.

Yours sincerely,

Professor Les Iversen FRS

cc: Anne Milton – Parliamentary Under Secretary of State, Department of Health