THE EXPERT ADVISORY COMMITTEE ON DRUGS (EACD) ADVICE TO THE MINISTER OF HEALTH ON:

PSEUDOEPHEDRINE

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ADVICE TO THE MINISTER OF HEALTH ON PSEUDOEPHEDRINE

Executive Summary

This paper considers pseudoephedrine (PSE) a key precursor chemical used in the illicit production of methamphetamine.

PSE has a number of legitimate uses, including as an ingredient of pharmacy cough and cold products.

A classification suggested for the EACDs consideration of PSE is that of Schedule 3 (Part 3).

Recommendations

After considering all of the information put to the Committee and the classification criteria in the Misuse of Drugs Act 1975, the EACD makes the following recommendations to the Minister of Health:

(a) Pseudoephedrine should be classified in Part 3 of the Third Schedule of the Misuse of Drugs Act 1975 (ie, C3).

(b) This paper should be made publicly available (eg, posted on the National Drug Policy website www.ndp.govt.nz).

Identifying the Problem

Although PSE is rarely a drug of abuse or addiction it is the key ingredient in methamphetamine production in New Zealand. Thirty tablets of Sudafed (60g), for example, could produce at least 1 gram of methamphetamine (worth $1000 - 1200 on the street).

Customs (Auckland Mail Centre) recorded an increase of stopped products (suspected ephedrine or pseudoephedrine) from 3 in 1999 to 30 in 2001 (until October). From November 2001 till 13 December 2002, improved record keeping noted 45 stops/referrals to the Health team at the Mail Centre and 12 at the Inspections Base. They also show a steady increase in the size of stopped products, with examples of parcels containing 1800, 2400, and 20,000 tablets in single imports.

Police and Customs are also observing the following trends in the acquisition of large quantities of products containing PSE:

a) "pharmacy hopping/ doctor shopping" for cough and cold pharmacy products that contain PSE;
b) theft (sometimes with intimidation or violence) of products from pharmacies;
c) importation of large quantities through overseas-based internet pharmacies, particularly China; and
d) involvement of organised crime/ gangs, and links with gun possession, violent behaviour, "turf wars" etc.

In recent years there has been a marked increase in the manufacture of methamphetamine by clandestine laboratories ("clanlabs") in New Zealand, using PSE as a key ingredient. The number of clan-labs detected in New Zealand has increased from fewer than two per year before 1998, to nine in 2000, to 42 clan-labs in 2001. As at 31 October 2002, a further 98 clan-labs had been detected.

Concerns have also been raised over the ability of legal controls in New Zealand to regulate the illicit use of products containing PSE, under the Misuse of Drugs Act (MODA), Medicines Act, and Customs and Excise Act (C&E) 1996. In particular:

a) police lack warrantless search and seizure powers under the MODA for precursor substances – the s 18(2) powers apply only to A, B1 and C1 "controlled drugs";
b) customs lack any powers in their own right to seize imported precursor substances, under the MODA or C&E Act. Instead they must work closely with Health's Medicines Control team, ESR and Police officials to use other powers/ means of border control; and
c) products containing PSE are regulated primarily as medicines, within a classification system that is based on availability criteria without regard for their potential misuse, e.g. "pharmacy-only" medicines are available over-the-counter at pharmacies.

For options A and B an amendment to the Act is being proposed to deal with these. For option C the classification of PSE as a C3 substance will help alleviate these problems whilst maintaining access to PSE products for legitimate users

Substance identification

PSE is a decongestant. It can help relieve nasal or sinus congestion (stuffiness). Extended-release PSE tablets can give day-long relief.

PSE works by constricting (shrinking) blood vessels (veins and arteries) in the nose, lungs, and other mucus membranes. PSE is used to treat congestion associated with allergies, hay fever, sinus irritation, and the common cold.

Illicit use

PSE, a common over-the-counter cold remedy, is a precursor chemical for manufacturing methamphetamine. Thirty tablets of Sudafed (60g), for example, could produce at least 1 gram of methamphetamine (worth $180-1000 on the street).

Pharmacies and pharmaceutical suppliers have noted problems with theft of PSE. Pharmacies are also subject to “shoppers”, those purchasing large amounts of PSE for use in illicit methamphetamine production.

Licit use

PSE is most commonly used to relieve nasal and sinus congestion and produces little or no rebound congestion, unlike topically applied sympathomimetics. It is available commercially in a variety of products either alone or in combination with other drugs. PSE is also effective in reducing air-travel-related otalgia in adults.

Apart from its use against nasal congestion, it is also useful for reducing congestion of the Eustachian tube (the tube connecting the middle ear with the cavity at the back of the nose). This congestion often occurs with inflammation and infection of the middle ear.

PSE is less likely than other decongestants to cause anxiety, tremor, and restlessness by stimulating the central nervous system. But in common with other drugs in this group, it may cause rebound congestion (worsening of congestions after prolonged use).

PSE is also used occasionally in the control of urinary incontinence.

As outlined PSE has a wide range of therapeutic uses, and is an effective treatment for a range of ailments.

Similarity to Known Substances

PSE is an orally administered sympathomimetic agent with structural similarity to ephedrine. Compared to ephedrine, PSE has practically no bronchodilatory properties and is ineffective in relieving bronchospasm (www.cp.gsm.com).

PSE appears to have a lower propensity to cause hypertension and potential sequelae (e.g., hemorrhagic stroke, hypertensive crisis) than ephedrine or phenylpropanolamine.

Current Classification under the Act

PSE is classified in the first schedule of the Medicines Regulations 1984, as a Prescription Medicine and also as a Pharmacy Medicine when used in cough or decongestant preparations in either slow release form or in preparations containing not more than 60 milligrams per dose, and when the recommended daily dose is not more than 240 milligrams (Medicines Regulations 1984).

The Ministry of Health has received correspondence from pharmacists concerned about the growing methamphetamine abuse. The Pharmaceutical Society of New Zealand supports the proposal to make PSE a Controlled Drug (although with a slightly different classification - single ingredient products as Class C Part V and combination products as Class C VI exempted drugs). The Society recommends pharmacists insist on, verify and record the photo-ID of all purchasers that are unknown to them to assist in identifying possible "shoppers". While Pharmacists are aware of the problem and have developed techniques to assist in identifying potential "shoppers", they have identified a need for the support and assistance of a classification of PSE.

Currently the only effective way to control the illicit use of products containing PSE is to:

a) use cross-referenced statutory powers under Medicines legislation to allow Customs and Police to intercept imported packages that exceed a three month medical supply/ lack a prescription;
b) build on cross-agency memoranda of understanding and cooperation to target suspected clan-labbers, pharmacy shoppers;
c) use general statutory powers in relation to theft of goods from doctors and pharmacies; and
d) use search and seizure powers in relation to raided clan-labs, and argue in Court about the intended illicit use of precursor substances for the manufacture of methamphetamine.

International classification and experience

A paper from Australia entitled "The Diversion of Pharmaceutical Drugs onto the Illicit Market" (November 2002) identified the following strategies for controlling PSE from an Australian perspective:

a) Doctor Shopping Programme 1997 – detection of doctor shoppers;
b) rescheduling of medicines;
c) cooperative programmes with manufacturers, wholesalers and pharmacies;
d) codes of Practice for pharmacy bodies, chemical and scientific industries; and
e) locally based initiatives, e.g. voluntary registers of drug misusers, doctor/ pharmacist networks.

United States Congress enacted the Methamphetamine Control Act of 1996 to curb the production and abuse of methamphetamine by controlling the key chemicals (PSE, red phosphorous and iodine) necessary to produce the drug and by increasing criminal sentences for its possession and distribution (www.kci.org).

References

Medicines Regulations 1984

Meetings of PSE working group (including officials from Medsafe, Ministry of Health, Customs, Police and NDIB).

Clinical Pharmacology – "Pseudoephedrine" – http://cp.gsm.com/direct/getmono.asp?caller=hill&cpnum=526&monotype=full

Drug Information on family doctor.org – "Pseudoephedrine" - www.familydoctor.com

Koch Crime Institute website – "Manufacturing of Methamphetamine" - www.kci.org/meth_info/making_meth.htm