

19 October 2010

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Dear Sir/Madam

Proposed classification of norephedrine as a Schedule 2, Part 2 Controlled drug and a Schedule 4 (Precursor substance) in the Misuse of Drugs Act 1975

As you may be aware, following advice from the Expert Advisory Committee on Drugs, the Associate Minister of Health with responsibility for drug policy matters, Hon Peter Dunne, has agreed to proceed with a proposal to classify norephedrine as a Schedule 2, Part 2 (Class B2) controlled drug and a Schedule 4 precursor substance in the Misuse of Drugs Act 1975 (“the Act”).

The Ministry of Health is conducting a targeted consultation to seek your comment on the impact of the proposed classification of norephedrine. Your comments will contribute to the Ministry’s advice to Cabinet and the Regulatory Impact Statement about anticipated fiscal costs.

Reason for proposed regulation

Norephedrine is a psychoactive substance of the phenethylamine and amphetamine chemical classes. Norephedrine, or phenylpropanolamine as it is sometimes referred, is currently available in a veterinary medicine and is also used illegally as a precursor substance in the manufacture of amphetamine, a Class B1 controlled drug in the Act. The Expert Advisory Committee on Drugs has considered norephedrine and agreed that controls should be placed on norephedrine to prevent its diversion for illegal use. New Zealand also has obligations under United Nations drugs conventions to control the manufacture, importation and supply of norephedrine.

Norephedrine has previously been used in the treatment of nasal congestion and has been included in several over-the-counter decongestants and prescription pharmaceuticals, as well as in some appetite suppressants. However, there are no pharmaceutical preparations containing norephedrine for human medical conditions currently available in New Zealand.

The only known current use of norephedrine in New Zealand is in the veterinary medicine Propalin®. Propalin® is an animal remedy and is registered under the Agricultural Compound and Veterinary Medicines Act 1997 as a renal and urinary tract modifier and is imported and distributed to veterinarians by one supplier. Propalin® is the trade name for phenylpropanolamine hydrochloride, which is described as a synonym for norephedrine in scientific literature from the United States. ESR has advised that phenylpropanolamine is a non-systematic name with two stereo isomers: norephedrine and norpseudoephedrine. Phenylpropanolamine is listed as a prescription medicine under the Medicines Act 1981 and norpseudoephedrine is controlled under the Misuse of Drugs Act.

Regulation of Schedule 2 Controlled Drugs

Classification under Schedule 2, Part 2 of the Act provides for: a maximum of 14 years imprisonment for unlawful importation, manufacture, sale or supply; up to 10 years imprisonment for conspiracy to commit an offence; and, up to three months or a \$500 fine for possession. The same penalties apply for amphetamine for which norephedrine is a potential precursor substance.

A Class B2 classification would likely require the concurrent removal of norephedrine (listed under the name of phenylpropanolamine) as a prescription medicine from the Medicines Act. Consideration would also be required on the continued status of phenylpropanolamine as a registered animal remedy under the Agricultural Compound and Veterinary Medicines Act.

Regulation of Schedule 4 Precursor Substances

A Schedule 4, Part 1 classification in the Act would make it an offence to supply, produce, or manufacture norephedrine knowing it would be used to commit an offence, such as producing or manufacturing a controlled drug.

It is also an offence to import a precursor substance for the purposes of producing or manufacturing a controlled drug. The maximum penalty for an indictable offence under section 12AB of the Act is seven years imprisonment and one year imprisonment, or a fine of \$1,000.00 for summary convictions. Section 12AC of the Act sets out the lawful purposes for which a precursor substance may be imported into New Zealand, which include agricultural, commercial or industrial purposes.

A Schedule 4, Part 1 classification would allow for the continued availability of norephedrine for therapeutic purposes should this be prescribed by a registered New Zealand medical practitioner or veterinarian.

Feedback

Your feedback is invited on the following:

- the extent of your current supply
- use or regulation of norephedrine, and any significant regulatory costs, systems or impacts (a 'picture' of norephedrine use currently)
- any estimated consequential costs or system amendments to current regulatory systems to address Class B2 and Schedule 4 regulation of norephedrine in the Act (e.g. monitoring of use/users, collecting and recording information about movement of norephedrine/reporting thefts etc.).

Your comments will be incorporated into feedback and recommendations by the Ministry of Health when the proposal seeks Cabinet approval later this year.

Please direct your responses to this proposal to:

Norephedrine Consultation
National Drug Policy Team
Ministry of Health
PO Box 5013
WELLINGTON

Email: bronwen_hicks@moh.govt.nz

Please provide these responses by 19 November 2010.

Yours sincerely

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