



Wellington  
20 September 2004

To all Pharmaceutical Companies and Pharmaceutical Wholesalers

## **EPHEDRINE AND PSEUDOEPHEDRINE TO BECOME CONTROLLED DRUGS**

From 15 October 2004 all ephedrine and pseudoephedrine containing products will become controlled drugs in New Zealand.

This means that ephedrine and pseudoephedrine will be controlled under the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977.

Ephedrine will be scheduled as a Class C Part V controlled drug.

Pseudoephedrine will be scheduled as a Class C Part III (partially exempted) controlled drug if it is a cough/cold/flu or decongestant preparation where the package in which the preparation is sold or supplied contains not more than 1.8 grams of pseudoephedrine.

If the pseudoephedrine preparation is not described above then it will be scheduled as a Class C Part V controlled drug.

Preparations of pseudoephedrine that are in a modified or sustained release formulation that deliver no more than 240mg of pseudoephedrine in a 24 hour period will be scheduled as Class C Part V but will be defined as “partially exempted drugs” (and thus still be able to be sold as Class C Part III preparations).

## ***Why change the law?***

Both ephedrine and pseudoephedrine pose a risk to the public of New Zealand as principal ingredients in the manufacture of the Class A controlled drug methamphetamine, rather than as drugs in their own right.

The classification of ephedrine and pseudoephedrine under the Misuse of Drugs Act will:

- increase legislative controls against the supply and use of these precursor substances;
- give Customs wider powers to investigate importation syndicates, including the ability to conduct controlled deliveries;
- allow for penalties that would be a genuine deterrent to their importation;
- retain the availability of these substances as prescription and pharmacy-only-medicines for legitimate use by the public.

The classification of ephedrine and pseudoephedrine as controlled drugs is considered necessary to tighten up border controls and provide further domestic controls.

## ***How does this affect you as a Pharmaceutical Company?***

- Pharmaceutical companies supplying ephedrine and pseudoephedrine must comply with the licensing sections of the Misuse of Drugs legislation.

- **Licences to Deal in Controlled Drugs**

If the company already has a licence to deal in controlled drugs and wishes to continue supplying ephedrine and pseudoephedrine, then the current licence to deal will need to be amended. Please forward to your local Medicines Control Office the original copy of your Licence to Deal in Controlled Drugs together with a letter stating that you wish ephedrine and/or pseudoephedrine be added to your licence.

If the company does not hold a Licence to Deal in Controlled Drugs, and wishes to continue supplying ephedrine and/or pseudoephedrine, then an application must be made for a Licence to Deal in Controlled Drugs. Please contact your local Medicines Control Office for advice on how to apply.

Manufacturers of controlled drugs must submit a list of all controlled drugs that they intend to manufacture in the licensing period. This list must now include the manufacturing quantities of ephedrine and/or pseudoephedrine. This submission will be made with their application for a Licence to Deal in Controlled Drugs.

- **Licences to Import/Export Controlled Drugs**

A licence to import or export controlled drugs must be issued by the Ministry of Health for every consignment containing controlled drugs (including ephedrine and/or pseudoephedrine) that crosses the New Zealand border. Import and export licences are required for all consignments entering or leaving New Zealand from **15 October 2004**.

Application forms for Licences to Import/Export Controlled Drugs and information is available from Tracy Dear, Advisor - Controlled Drug Licensing on telephone 04-496-2438 or via email on [tracy\\_dear@moh.govt.nz](mailto:tracy_dear@moh.govt.nz). There is a licence fee of \$11.25 including GST for each application.

If you already have ephedrine and/or pseudoephedrine on order for delivery after **15 October 2004**, you are still required to have a licence to import controlled drugs for each individual consignment. Please apply for a licence(s) to import controlled drugs immediately.

- **Labelling Requirement**

Where the pharmaceutical company is the New Zealand sponsor of an ephedrine and/or pseudoephedrine product, then that company is responsible for amending the labelling of the container to reflect the product being rescheduled as a controlled drug. The words "CONTROLLED DRUG C5" or "CONTROLLED DRUG C3" must appear in the upper part of the principal display panel and be printed in conspicuous block capital letters on the label, depending on the product scheduling. (Section 25 of the Misuse of Drugs Regulations 1977)

As this will result in a change in the approved label for the product a Changed Medicine Notification (CMN) must be submitted. **There will be no fee charged for these CMN's. The regulations allow a total of 6 months for a change of classification statement of medicines to be in place at all levels. It has been agreed that all ephedrine and pseudoephedrine products are to be labelled as C3 or C5 controlled drugs by 15 April 2005.**

- **Storage**

Class C Part III and Part V controlled drugs **do not** require storage in a controlled drug safe/cabinet. Therefore ephedrine and pseudoephedrine containing products do not need to be kept in a safe. However, secure storage is recommended.

- **Records**

Transactions involving Class C Part III and Part V controlled drugs **do not** require recording in a controlled drug register. Therefore ephedrine and pseudoephedrine containing products do not need to be recorded in a controlled drug register.

- **Medical Representatives/Hawkers**

Medical Representatives or Hawkery employed by your company will no longer be able to supply samples of ephedrine and pseudoephedrine containing products.

- **Advertising**

Class C Part V controlled drugs may be advertised solely to practitioners and pharmacists. They may not be advertised to the public. However, Class C Part III controlled drugs and other defined “partially exempted” controlled drugs (eg. Over The Counter (OTC) products containing pseudoephedrine) may be advertised to the public.

## ***The Benefits***

- Scheduling of ephedrine and pseudoephedrine as controlled drugs ensures tighter control is maintained over internal distribution within New Zealand.
- Rescheduling aims to reduce the extent to which ephedrine and pseudoephedrine are diverted into illicit channels within New Zealand.
- Heavier penalties for illicit use and supply as controlled drugs will help the New Zealand Police and Customs better control the illicit trade in ephedrine and pseudoephedrine.
- Information gathered from import and export licences will provide annual statistical reports to the International Narcotics Control Board, of the United Nations. These reports establish the movement of ephedrine and pseudoephedrine into and out of New Zealand, and will be used to monitor the amount of the controlled drugs consumed by New Zealanders each year.

For further information or clarification on how this change will affect you, please contact your local Medicines Control Office.

Yours sincerely

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