ANTIHISTAMINES

Final proposal for harmonisation

At the 30th meeting in November 2003 the MCC postponed making a recommendation on the classification of antihistamines until the NDPSC had completed its review of the classification of these substances when combined with analgesics or when contained in products for travel sickness. The NDPSC has now agreed on the following classification levels:

Prescription medicine

- Antihistamines or combination products with the potential for serious abuse.

Restricted medicine

- Single-ingredient sedating antihistamines
- sedating antihistamines in combination with active ingredients other than a sympathomimetic decongestant except when in the bed-time dose of a day/night preparation.

Pharmacy-only medicine

- Non-sedating antihistamines in either single-ingredient preparations or in combination products containing other pharmacy-only or unscheduled ingredients.
- Sedating antihistamines in combination products when one of the active ingredients is a sympathomimetic decongestant and the product is indicated for the relief of symptoms of coughs colds or influenza.
- Sedating antihistamines in the bedtime dose of day/night combination preparations for the relief of symptoms of coughs colds or influenza. The bedtime dose is not required to contain a sympathomimetic decongestant.
- Meclozine and diphenhydramine in limited pack sizes for travel sickness.* Promethazine has already been reclassified to S2 (pharmacy-only) when in packs of 10 for this use.

It has also been agreed that each antihistamine should be evaluated separately in the light of its particular properties and uses.

*The NDPSC has not agreed to harmonise with the New Zealand exemption for sale of these packs at transport terminals or on boats or planes. There is currently no information which would cause the MCC to review the exemption from pharmacy-only status when sold from one of these outlets.