ANTIHISTAMINES FINAL PROPOSAL FOR HARMONISATION

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.
- Sedating antihistamine products for children under two years of age.

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 for children 2 years of age or more.
- Sedating antihistamines in the bedtime dose of day/night combination preparations for the relief of symptoms of coughs colds or influenza for children 2 years of age or more. The bedtime dose is not required to contain a sympathomimetic decongestant.
- Meclozine, promethazine and dimenhydrinate (=diphenhydramine theoclate) in pack sizes of 10 tablets or less for travel sickness

The NDPSC has not agreed to harmonise with the New Zealand exemption for sale of travel sickness 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.

PRESCRIPTION MEDICINE

ACRIVASTINE ANTAZOLINE; except for ophthalmic use AZATADINE; except for oral use AZELASTINE; except for nasal use BAMIPINE BROMPHENIRAMINE; except when specified elsewhere BUCLIZINE; except for oral use CETIRIZINE; except for oral use CHLORCYCLIZINE CHLORPHENIRAMINE; except for oral use CLEMASTINE; except for oral use CLEMIZOLE

CYPROHEPTADINE; except for oral use DESLORATADINE; except for oral use DEXCHLORPHENIRAMINE; except for oral use DIMENHYDRINATE; except when specified elsewhere DIMETHINDENE; except for oral use DIPHENHYDRAMINE; except for oral use DIPHENYLPYRALINE; except for oral use DOXYLAMINE; except when specified elsewhere LEVOCABASTINE; except for ophthalmic or nasal use LORATADINE; except for oral use **MEBHYDROLIN** MEPYRAMINE; except for oral use METHDILAZINE; except for oral use PHENIRAMINE: except for oral or ophthalmic use PHENYLTOLOXAMINE; except for oral use PROMETHAZINE; except when specified elsewhere **TERFENADINE** THENYLDIAMINE; except for oral use TRIMEPRAZINE; except for oral use TRIPROLIDINE; except for oral use

RESTRICTED MEDICINE

BROMPHENIRAMINE; for oral use except when specified elsewhere BUCLIZINE: for oral use CHLORPHENIRAMINE; for oral use except when specified elsewhere CLEMASTINE: for oral use CYPROHEPTADINE; for oral use DEXCHLORPHENIRAMINE; for oral use except when specified elsewhere DIMENHYDRINATE; for oral use except when specified elsewhere DIMETHINDENE; for oral use DIPHENHYDRAMINE; for oral use except when specified elsewhere DIPHENYLPYRALINE; for oral use except when specified elsewhere DOXYLAMINE; for oral use except when specified elsewhere **MEPYRAMINE**; for oral use METHDILAZINE; for oral use PHENIRAMINE; for oral use except when specified elsewhere PHENYLTOLOXAMINE: for oral use PROMETHAZINE; for oral use except when specified elsewhere THENYLDIAMINE: for oral use except when specified elsewhere TRIMEPRAZINE: for oral use in solid dose form or in liquid form containing 10 milligrams or less of trimeprazine per 5 millilitres TRIPROLIDINE; for oral use except when specified elsewhere

PHARMACY-ONLY MEDICINE

ANTAZOLINE; for ophthalmic use AZATADINE; for oral use AZELASTINE; for nasal use BROMPHENIRAMINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing brompheniramine in the bedtime dose; and
- in preparations for adults or children two years of age or more CETIRIZINE; for oral use

CHLORPHENIRAMINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing chlorpheniramine in the bedtime dose; and
- in preparations for adults or children two years of age or more DESLORATADINE; for oral use

DEXCHLORPHENIRAMINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing dexchlorpheniramine in the bedtime dose; and
- in preparations for adults or children two years of age or more

DIMENHYDRINATE; in packs containing not more than 10 tablets for the prevention or treatment of motion sickness except when sold at a transport terminal or aboard a ship or plane

DIPHENHYDRAMINE; in packs containing not more than 10 tablets for the prevention or treatment of motion sickness except when sold at a transport terminal or aboard a ship or plane; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing diphenhydramine in the bedtime dose; and
- in preparations for adults or children two years of age or more

DIPHENYLPYRALINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing diphenpyraline in the bedtime dose; and
- in preparations for adults or children two years of age or more

DOXYLAMINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing doxylamine in the bedtime dose; and

• in preparations for adults or children two years of age or more

LEVOCABASTINE; for ophthalmic or nasal use

LORATADINE; for oral use

PHENIRAMINE; for ophthalmic use; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing pheniramine in the bedtime dose; and
- in preparations for adults or children two years of age or more

PROMETHAZINE; ; in packs containing not more than 10 tablets for the prevention or treatment of motion sickness except when sold at a transport terminal or aboard a ship or plane; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing promethazine in the bedtime dose; and

• in preparations for adults or children two years of age or more THENYLDIAMINE; for nasal use; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing thenyldiamine in the bedtime dose; and

• in preparations for adults or children two years of age or more TRIMEPRAZINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing trimeprazine in the bedtime dose; and
- in preparations for adults or children two years of age or more

TRIPROLIDINE; when combined with one or more other therapeutically active substances in oral preparations for the treatment of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day/night pack containing triprolidine in the bedtime dose; and
- in preparations for adults or children two years of age or more