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## Newsletter Number 40

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### INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA

#### **1. Changes to the Tasmanian Poisons List**

Consistent with the recommendations of the National Drugs and Poisons Scheduling Committee, a number of amendments will be made to the Tasmanian Poisons List that take effect from the 1<sup>st</sup> September 2006. The consolidated Poisons List is available on the website [www.thelaw.tas.gov.au](http://www.thelaw.tas.gov.au)

##### **1.1 Schedule 2- Amendment**

**FLUTICASONE** in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.

***Background:** The maximum daily dose limit for fluticasone has been reduced from 400mcg to 200mcg. This entry is now consistent with the limitations imposed on the potency of other inhaled nasal corticosteroid products included in Schedule 2.*

##### **BECLOMETHASONE, BUDESONIDE, FLUTICASONE, MOMETASONE AND TRIAMCINOLONE in aqueous nasal sprays**

***Background:** The pack size restriction (200 actuations or less) imposed by poisons scheduling has been removed on these products. Limits may still be placed on manufacturer's pack sizes by the product registration authority, the Therapeutic Goods Administration, where appropriate.*

##### **1.2 Schedule 3- New entries**

**AZELASTINE** in topical eye preparations containing 0.05% or less of azelastine.

***Background:** Azelastine is a histamine H-1 antagonist approved for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis. It has also been included in Appendix H to the Standard for the Scheduling of Drugs and Poisons (SUSDP) and therefore may be advertised. Given time and more Australian experience, this compound may be considered for inclusion in Schedule 2, consistent with the scheduling of other topical antihistamines.*

**KETOTIFEN** for ophthalmic use in preparations containing 0.025% or less of ketotifen

***Background:** Ketotifen is a histamine H-1 antagonist with mast cell stabilizing properties. It is approved for the symptomatic short-term treatment of seasonal allergic conjunctivitis in adults and children 3 years and older. The product may be advertised.*

**IBUPROFEN** in divided preparations, each containing 400 mg or less of ibuprofen, in a primary pack containing not more than 50 dosage units when labelled:

- (a) with a recommended daily dose of 1200 mg or less of ibuprofen;
- and
- (b) not for the treatment of children under 12 years of age

**except** when included in or expressly excluded from Schedule 2.

### **1.3 Schedule 4- New entry**

**POTASSIUM CHLORIDE** in slow-release oral preparations for human therapeutic use except when containing 100 mg or less of potassium chloride per dosage unit.

***Background:** A recommendation for restrictive scheduling was made by a NSW coroner investigating the death of a young child that had been administered slow-release potassium tablets. The committee considered the many issues around this matter and concluded that the toxicity of this formulation is consistent with a Schedule 4 listing. The NDPSC will be giving further consideration to other unscheduled products that contain large amounts of potassium.*

### **1.4 Scheduling of chlorhexidine**

The committee has conducted a review of the toxicology of chlorhexidine, a substance that is widely used in medical and agricultural settings. The decision to schedule was made on the basis of severe eye irritation at higher concentrations. Chlorhexidine scheduling is given in summary in the following table:

<b>Schedule</b>	<b>Concentration</b>
Unscheduled	1% or less, and all solid preparations
Schedule 5 (CAUTION)	>1% to 3%
Schedule 6 (POISON)	>3% to 7%
Schedule 7(DANGEROUS POISON)	>7%

### **1.4 Orlistat- Approval for advertising**

Orlistat when in Schedule 3 has been included in Appendix H and is therefore permitted to be advertised.

## **2. Other important information for pharmacists**

### **2.1 Pharmacist assistance to Tasmania Police**

Tasmania Police has expressed its appreciation to pharmacists for assistance with investigations regarding the purchasing of pseudoephedrine and prescription forgery. Whilst at times review of your records may represent an imposition, information has been very useful in pursuing charges against those involved in criminal activity.

### **2.2. Attention: Codeine Linctus is included in Schedule 8**

A requirement for a codeine formulation to be included in Schedule 4 is that the substance “is compounded with one or more therapeutically active substances”. The NDPSC examined the scheduling of Codeine Linctus APF and noted that no other therapeutically active substance is included. Therefore the advice of the committee is that Codeine Linctus APF is included in Schedule 8.

Pharmacists are asked to ensure that the normal Schedule 8 storage, recording and supply arrangements are applied as soon as possible to any stock of Codeine Linctus APF or formulations where codeine is the only therapeutically active ingredient.

## **2.3 Supply by Country Stores of S2 Medicines under licence (Section 27 of the Poisons Act 1971)**

Consistent with national recommendations, Tasmanian “country stores” at a prescribed distance from a pharmacy may sell products from a restricted list of Schedule 2 medicines. In Tasmania that distance is 10 kilometres. A licence must be first issued by this Branch to a particular applicant to obtain and sell or supply these products.

The licence strictly limits the products to those that are in schedule 2 and not listed in an exclusion list (see Appendix 1 below). The exclusion list is updated from time to time.

Whilst in the past a number of stores have purchased products from pharmaceutical wholesalers, these companies, in some instances, have now found it commercially unfavorable to continue accounts with country store-holders. As a result a number of store-holders have sought medicines from pharmacies.

Store-holders have been advised of the importance of when obtaining stock for sale or supply that the limits of the licence are complied with. It is recommended to store-holders, that when seeking stock from a pharmacy, a copy of the licence is taken with them. The store-holder may then discuss with the pharmacist what products may be obtained. This Branch may be contacted if there is any uncertainty as to what may be purchased and supplied.

### **Appendix 1**

In 2006/2007 the following may be supplied by country stores licenced pursuant to Section 27 of the *Poisons Act 1971*:

SCHEDULE 2 SUBSTANCES **EXCEPT** THE FOLLOWING: -

1. ASPIRIN in:
  - a) products containing more than 25 tablets or capsules; and
  - b) products including aspirin and codeine in combination when containing more than 25 tablets or capsules.
2. Products containing DICYCLOMINE for infants.
3. Products containing HYDROCORTISONE.
4. IBUPROFEN in:
  - a) products containing more than 25 tablets or capsules;
  - b) in liquid products for the treatment of pain in children containing more than 100ml; and
  - c) products including ibuprofen and codeine in combination when containing more than 25 tablets or capsules.
5. PARACETAMOL in:
  - a) in products containing more than 25 tablets or capsules;
  - b) in liquid products for the treatment of pain in children containing more than 100ml; and
  - c) products including paracetamol and codeine in combination when containing more than 25 tablets or capsules.
6. Products containing PHENIRAMINE for travel sickness.

Please contact this Branch if you have any queries.

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