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INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA

1. Scheduling of Intranasal Steroids

The launch of a number of new intranasal steroid products with differing scheduling identification has prompted a number of calls from pharmacists. Sponsors of products appear to be tailoring each product to meet the requirements of Schedule 3 or 4 depending on the marketing strategy for that product. Should a pharmacist wish to supply a S4 manufacturer labelled pack as a S3 pack the pharmacist will need to take the following steps to comply with the requirements of the Poisons Regulations.

The current Schedule 3 entries are attached in the appendix. Please note that the entries are very specific in relation to dose, maximum daily dose, pack size, period of use (less than 6 months) and the age of the user (to be 12 years or older). Whilst the instance of side effects is low, there are concerns regarding the potential for serious adverse side effects such as growth suppression in children and nasal septum perforation. Use outside these indications warrants medical supervision and supply would therefore be as a Schedule 4.

The following requirements must be met for the provision of a Schedule 4 pack as a Schedule 3:

- ?? all conditions are met in relation to dose, maximum recommended daily dose, pack size and indication (including age restrictions).
- ?? The pharmacist labels the pack with directions that are consistent with the Schedule 3 dose and indications (as specified in the attached entries). The label must also include the name and strength of the substance and the name of the patient.
- ?? All references to Schedule 4 and Schedule 4 indications are removed from the pack or obscured so as to avoid confusion amongst clients.
- ?? Only a CMI consistent with the approved Schedule 3 indications should be provided.

2. RETURN OF NARCOTICS TO PHARMACIES

Pharmacists are reminded that when a narcotic drug is returned an entry must be made in the narcotic register. The two pharmacists (or pharmacist and health professional) who jointly destroy a narcotic substance are then required to complete an entry in the narcotic register which certifies details of the destruction (Reg 12). A health professional is

defined as a dentist, medical practitioner, pharmaceutical chemist, registered nurse or veterinary surgeon for the purposes of this regulation.

3. SUPPLY OF NARCOTIC DRUGS OTHER THAN ON PRESCRIPTION

A number of cases have been identified where pharmacists have supplied narcotic drugs directly to doctors, dentists or veterinary surgeons for professional use (other than on a prescription or a Doctor's Bag Order Form). All cases of supply of narcotic substances by pharmacists are required to be reported to this Department for monitoring purposes. Recording of the supply in the pharmacy dispensing system would ensure automatic electronic reporting. Please also note that an invoice is required to be issued relating to each supply.

4. RECORDING OF METHADONE MAINTENANCE PRESCRIPTIONS ON THE PHARMACY DISPENSING SYSTEM

Pharmacists are reminded that prescriptions for methadone maintenance or supervised tablets (e.g. methadone) must be recorded on the pharmacy dispensing system. The entry should be made when a new prescription is first dispensed. The keeping of written patient administration records does not negate the requirement for prescriptions to be entered on the dispensing system.

Please contact this Branch if you have any queries.

Jim Galloway,
Senior Pharmacist.

Pharmacy Managers- Please ensure that this newsletter is circulated to all pharmacists in your employment

(Please note that this and other circulars are available on the DHHS website at www.dhhs.tas.gov.au/publichealth/pharmaceuticals/)

APPENDIX

THE SCHEDULING ENTRIES- INTRANASAL STEROIDS

The following entries in the Tasmanian Poisons List are consistent with the national scheduling model.

1. BECLOMETHASONE

Schedule 3

BECLOMETHASONE in aqueous nasal sprays delivering 50micrograms or less of beclomethasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.

(Product in S3: Beconase Hayfever, Aldecin Aqueous Nasal Spray)

Schedule 4

BECLOMETHASONE **except** when included in Schedule 3
(No product in S4)

2. BUDESONIDE

Schedule 3

BUDESONIDE in aqueous nasal sprays delivering 50 micrograms or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the short term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over.

(Product in S3: Rhinocort Hayfever Nasal Spray 32 mcg)

Schedule 4

BUDESONIDE **except** when included in Schedule 3.

(Products in S4: Rhinocort Aqueous Nasal Spray 64mcg, Budamax Aqueous Nasal Spray)

4. FLUTICASONE

Schedule 3

FLUTICASONE in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no more than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.

(Product in S3: Beconase Allergy 24 Hour Fluticasone Aqueous Nasal Spray)

Schedule 4

FLUTICASONE **except** when included in Schedule 3
(No product in S4)

5. MOMETASONE

Schedule 3

MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over.

(Product in S3: Allermax Aqueous Nasal Spray)

Schedule 4

MOMETASONE **except** when included in Schedule 3
(Product in S4: Nasonex Aqueous Nasal Spray)