

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Newsletter Number 44

INFORMATION CIRCULAR TO PHARMACISTS IN TASMANIA

1. Verifying prescriptions for narcotic substances

Recent presentations of forgeries of prescriptions for narcotic substances has reinforced the need for compliance with Regulation 23 of the *Poisons Regulations 2002*. That regulation requires a pharmacist to verify the authenticity of a prescription for a narcotic substance to which the regulation applies. Authentication is specified as familiarity with the handwriting of the prescriber or in the absence of that knowledge the pharmacist must verify with the purported prescriber that he or she wrote the prescription.

If the pharmacist is unable to verify that the prescription is authentic and there are no other reasons for concern, no more than is sufficient for 2 days' treatment may be supplied. Please ensure that proper attention is paid to this requirement given the substantial concern at the diversion and misuse of narcotic substances in this state.

2. Keeping of registers

Due to various scenarios that Poisons Inspectors have been encountering in pharmacies and other sites where registers are used, legal advice has been sought on who is permitted to complete the entries in a narcotic register under the Poisons Act and Regulations. Essentially the following advice was received:

1. It is important to note there is no basis in the Act or regulations for a power for a pharmacist to delegate to another person the **responsibility** of making the entries in the register. The pharmacist is the person required to keep the register and that person is legally responsible for ensuring that the register is kept in accordance with the regulations.
2. However, the entries in the register may be **made** by someone other than the pharmacist, other than the signing of the entry in column 6. Therefore a person may complete some particulars of entries in the register on behalf of the pharmacist provided the latter authorises them to do so.
3. The signature of the pharmacist is necessary to the entry.

Please also note that only the pharmacist acquiring or disposing of the narcotic substance is entitled to sign the register in column 6 (i.e. this signing function cannot be undertaken by another pharmacist).

3. Pharmaceutical Services webpage certificate

Most pharmacists would be aware that recently Pharmaceutical Services Branch developed a web portal for the forwarding of the monthly S8 (and other recordable drugs) report. This report was previously required to be downloaded onto a floppy disc and mailed to the Branch. This method of data transfer was both labour intensive, unreliable and insecure. The new web portal has addressed these issues successfully. Most pharmacies using the site have had very little trouble managing the change.

PSB has not formally announced the launch of the site as gaining a Microsoft secure website certificate has proved time consuming. The Branch has now been advised the certificate has been issued and will be installed by the end of September. Pharmacies unfamiliar with the web portal are invited to ring the Branch to get the login and password details and a copy of the user manual.

4. Continuation of inspection programme

The Branch is continuing its programme of the review of pharmacies for compliance with the Poisons Act and Regulations. The emphasis of inspections has been on the checking of narcotic recording, confirmation of balances, narcotic security and the correct storage of Schedule 2 and 3 medication.

To date the standard of narcotic records has been of some concern. Pharmacists are reminded that the legal requirements are put in place to protect all involved in the handling of narcotic substances. Please confirm your compliance with the Regulations in respect of record-keeping and storage. Poor security procedures and record-keeping may result in the referral of a complaint to the Pharmacy Board.

5. Scheduling changes

Consistent with the recommendations of the National Drugs and Poisons Scheduling Committee (NDPSC), a number of amendments have been made to the Tasmanian Poisons List this month and these have effect from the 10th September 2008. The consolidated Poisons List is available on the website www.thelaw.tas.gov.au. Items that may be of particular interest are detailed below.

5.1 Schedule 3 Amendments- Sedating antihistamines

BROMPHENIRAMINE, CHLORPHENIRAMINE, DEXCHLORPHENIRAMINE, DIPHENHYDRAMINE, DOXYLAMINE, PHENIRAMINE AND TRIPROLIDINE

Amend entries to read:

[SUBSTANCE] in oral preparations **except:**

- (a) for the treatment of children under 2 years of age; or
- (b) when included in Schedule 2

***Background:** The NDPSC conducted a review of the scheduling of non-phenothiazine type sedating antihistamines when in Schedule 3. The committee looked at the overall balance of risks and benefits of the use of these substances in children less than two years of age and was of the view that the paucity of evidence of benefit was outweighed by the potential risk. It was noted that there was an issue related to extrapolation to this age group of results of studies done in older children or reliance on adult data. There is lack of evidence of the efficacy of the relevant products, many of which contained combinations of substances. (Note: The Therapeutic Goods Administration acted separately in April 2008 and considered that products containing antihistamines, antitussives, expectorants and decongestants should not be administered to children less than 2 years of age. That authority has asked that pharmacists advise all customers requesting OTC cough and cold product that these medicines should not be used in infants and children less than 2 years of age).*

5.2 Schedule 2,3 and 4 amendments- Fluorides for human use

Fluoride

The scheduling of fluoride, including toothpastes and mouthwashes, has been revised in an attempt to update and simplify requirements. The aim was to maintain public health and safety from the point of view of both toxicity from acute ingestion and the potential for the development of fluorosis. The NDPSC also considered current recommendations for prevention of dental caries and the exposure of the Australian population to fluoride via drinking water.

Fluoride scheduling is summarised in the table in Attachment 1¹. The full details are available at the www.thelaw.tas.gov.au website. Please contact the Branch if clarification is required regarding particular products.

¹ This table was adapted from the original developed by Jane Carpenter, Pharmaceutical Services Branch, Department of Health, Western Australia.

5.3 Schedule 3- New entry

PANTOPRAZOLE in oral preparations containing 20mg or less of pantoprazole for relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days of supply.

***Background:** Please note that this change was effective from the 1st May 2008 but was not notified due to a joint circular being issued with the Pharmacy Board at that time. The scheduling committee was satisfied that the available efficacy and safety data supported pantoprazole as a 14 day treatment as a schedule 3 medicine. Please note that pantoprazole has not been included in Appendix H and therefore has not been approved for advertising.*

Please contact the Branch if you have any queries.

Jim Galloway
Deputy Chief Pharmacist
11th September 2008

Fluoride Scheduling Changes- September 2008

Preparation	Schedule
Tablets (and other preparations for ingestion), up to 0.5 mg fluoride ion per tablet	Schedule 2 Note: The maximum strength of oral preparations at S2 has now been halved (previously maximum was 2.2 mg of sodium fluoride per dosage unit which is equivalent to 1 mg of fluoride ion).
Mouthwashes (and other liquid preparations for topical use), concentration of 15 mg/kg or less of fluoride ion	Unscheduled
Mouthwashes (and other liquid preparations for topical use), concentration of 220 mg/kg or less of fluoride ion (but more than 15 mg/kg)	Unscheduled if in a <i>small bottle</i> (maximum total fluoride ion content of pack is up to 120 mg), with a child resistant closure (CRC), labelled with warnings: "Do not swallow" and "Do not use in children 6 years of age or less".
Mouthwashes (and other liquid preparations for topical use), concentration of 1000 mg/kg or less of fluoride ion (but more than 15 mg/kg).	Schedule 2 Must be in a container with a CRC and labelled with warnings: "Do not swallow" and "Do not use in children 6 years of age or less".
Mouthwashes (and other liquid preparations for topical use), concentration \leq 5500 mg/kg but > 1000 mg/kg of fluoride ion	Schedule 3 Must be in a container with a CRC.
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), \leq 1000 mg/kg fluoride ion	Unscheduled
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), \leq 1500 mg/kg but > 1000 mg/kg fluoride ion	Unscheduled provided have warning labels to indicate they must not be swallowed and must not be used in children aged 6 or under. Otherwise these preparations are in <i>Schedule 3</i> . Note: this change raises the concentration of fluoride ion that may be used in toothpastes which may be exempt from scheduling (with certain warning labels) from 1000 mg/kg to 1500 mg/kg.
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), \leq 5500 mg/kg but > 1500 mg/kg fluoride ion	Schedule 3
Other preparations for human use (unless included in or expressly excluded from S2 or S3)	Schedule 4 Note: fluoride does also appear in Schedule 5 and Schedule 6 for non-human uses



Please note: Preparations that would normally be included in Schedule 2, 3 and 4 are exempt from scheduling if they are supplied to a registered dental professional (this includes a dentist, dental therapist or dental hygienist).