



## DEPARTMENT of HEALTH and HUMAN SERVICES

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### **Newsletter Number 42**

23<sup>rd</sup> August 2007

#### **INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA**

##### **1. New restrictions on the prescribing of alprazolam**

Many pharmacists have now attended the seminars hosted by the Divisions of General Practice regarding the misuse of alprazolam and the regulatory changes that will be applied to its prescribing from the 1<sup>st</sup> September 2007.

There is concern at the abuse and diversion of alprazolam. Serious injury and death have resulted in Tasmania from the practice of injecting alprazolam alone or with drugs such as methadone to produce a heroin like "high". The Tasmanian Coroner's Office has expressed serious concerns about the disturbing incidence of polysubstance-related deaths occurring in relation to the injection of prescription opioids and alprazolam.

The prescribing of benzodiazepine medication in Tasmania is 140-300% above the national average. Tasmanian intravenous drug users have belied the national downward shift in benzodiazepine injection since the removal of temazepam gel capsules in 2002-03.

The recommendation of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) is that alprazolam has a limited role in the treatment of panic disorder and anxiety. The initial approach should be psychological measures such as cognitive behavioural therapy. First line therapy is stated to be the newer antidepressants particularly paroxetine and sertraline. Benzodiazepines are listed as second line therapy along with tricyclic antidepressants and the MAOI's. This approach is supported by the PBS approval which is "for the treatment of panic disorders where other treatments have failed or are inappropriate".

##### ***Current Regulatory Status***

Alprazolam is listed as a declared restricted substance under the Tasmanian Poisons (Declared Restricted Substance Order 1990) commonly referred to as a S4D. This requires:

- Prescriptions dispensed in Tasmania must be written only by prescribers registered in Tasmania.
- Repeat interval must be stated on prescriptions.
- Prescriptions are valid for 6 months only from the date of writing.
- There is no provision for emergency supply by a pharmacist without a prescriber's authority.
- Possession without authority is illegal unless in accordance with a legal prescription.

- Patients declared as drug dependent can only be prescribed a S4D by their authorised opioid prescriber.

### *Changes as of 1 September 2007*

All the above requirements remain and in addition:

- All prescriptions dispensed for alprazolam will be added to the currently required monthly reporting of dispensed schedule 8 substances from Tasmanian pharmacies. (Note: alprazolam remains S4D)
- The prescribing of alprazolam for more than 4 weeks in conjunction with any opioid will require the prescriber to obtain an authority to prescribe. Authorities will be issued in a similar manner to the opioid authorities.
- Alprazolam prescribing to patients on the Opioid Pharmacotherapy Programme **will not** be legally authorised unless endorsed by the Clinical Director of the Alcohol and Drug Services. This is also a requirement of the Tasmanian Pharmacotherapy Policy.
- Prescribers will be notified not to prescribe alprazolam if a patient is already under the care of another medical practitioner who is also prescribing benzodiazepines and/or opioids. (This is consistent with the requirement that where an authority for opioids is given under the Alcohol and Drug Dependency Act 1968, prescribing of all drugs of dependence must remain with the one practice).

Please note that pharmacists are not required to monitor whether an authority has been issued. This is a matter between a patient's doctor and Pharmaceutical Services Branch.

## **2. Restricted supply and the supervised dosing of patients**

Dr. Adrian Reynolds, Clinical Director at Alcohol and Drug Services has encouraged pharmacists to take a continuing role in dealing with risk taking behaviour involving drugs:

'As a primary contact point for health service delivery, pharmacists frequently exercise their skills in the management of drug dependence. Through diligent supervision of medication consumption for patients identified as being at high risk of misuse or diversion of their medication, pharmacists have the potential to reduce the significant harms associated with non-clinical use of these substances. Pharmacists are well skilled in recognising high risk patient behaviour and the information they pass onto GPs is vital for appropriate clinical risk management.'

At the July seminars on the alprazolam changes Dr. Reynolds made a number of recommendations to pharmacists in respect of safe practice. Many of the points were made in relation to the Opioid Pharmacotherapy Program (OPP) but also have applicability where patients are dosed with opiates under supervision:

- Daily dispensing should be considered as part of supervised ambulatory withdrawal management when there is evidence of poor compliance and/or safety concerns for the patient or others
- Contracting the patient to behave in specific ways can also be useful
- Emphasise to the patient that you are concerned about their safety and that you are required to adhere to your legal and professional obligations
- If a patient on pharmacotherapy presents exhibiting signs of being alcohol or drug affected don't dose. (This would also apply to supervised opioid dosing)

- When clients exhibit high risk behaviour or poor treatment compliance, it is imperative that the prescriber assess the patient the same day or as soon as possible to discuss the reasons and what can be done to assist the client reduce risk
- Reject any attempt at emotional blackmail
- The Opioid Pharmacotherapy Program aims to assist patients progressively reduce risk of serious harm (it is a drug treatment program, not a drug supply program)

### **3. Dispensing of interstate Schedule 8 prescriptions**

Please note that the Tasmanian *Poisons Act 1975* only allows for a Schedule 8 drug be dispensed on the prescription of a medical practitioner registered in this state. Pharmacy monthly reports are indicating that some pharmacists are dispensing prescriptions from practitioners that are not locally registered. The registration status of a prescriber with an interstate address must be confirmed before dispensing.

### **4. Electronic prescribing**

The *Poisons Regulations 2002* have been amended to provide a mechanism for evaluating and approving electronic prescribing schemes. Prescribing may be for either Schedule 4 or Schedule 8 drugs. Any person or organization wishing to develop or implement an electronic prescribing scheme should contact this Branch early in the planning stage.

### **5. Meeting cold chain requirements**

Please note that the wholesaler Symbion has taken on new a technology for the delivery of products requiring cold chain distribution. Temperature sensitive products will not be delivered in polystyrene boxes with freezer blocks and therefore pharmacists should develop a procedure that ensures that the relevant items are placed in the refrigerator immediately upon delivery.

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

Consistent with the recommendations of the National Drugs and Poisons Scheduling Committee (NDPSC), a number of amendments will be made to the Tasmanian Poisons List that take effect from the 1st September 2007. The consolidated Poisons List is available on the website [www.thelaw.tas.gov.au](http://www.thelaw.tas.gov.au)

#### **6.1 Schedule 2- Amendments**

**RANITIDINE** in preparations supplied in the manufacturer's original pack containing not more than 14 days supply **except** in divided preparations for oral use containing 150mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 14 dosage units.

***Background:** The effect of the amendment will be to allow unscheduled packs of up to 14 doses of ranitidine in a manufacturer's original pack with a dose of no more than 150mg. Similar packs have been available in the UK, US and Canada for a number of years. The committee accepted the well established safety profile of this substance, that the safety information provided on the packet and the CMI are adequate and the indication is an accepted indication for unscheduled products.*

**SELENIUM** in preparations for human therapeutic use **except:**

- for topical use containing 3.5 per cent or less of selenium sulfide;
- when included in Schedule 4; or
- for oral use with a recommended daily dose of 150 micrograms or less.

***Background:** The dosage limit in schedule 2 has been revised upward substantially. One study (Clark et al) has shown that supplementation trials of 200mcg for 10 years did not result in the toxic accumulation of selenium (selenosis). Please note that selenosis is associated with intake of selenium in adults of more than 910mg per day and consequently the upper daily dose limit of products in Schedule 2 has been set at 300 microgram so as to allow an adequate safety margin. Higher dose products are included in Schedule 4(see entry below).*

## **6.2 Schedule 4- Revised entries**

### **SELENIUM:**

- (a) for human oral use with a recommended daily dose of more than 300 micrograms; or
- (b) for the treatment of animals **except**:
  - (i) when included in Schedule 6 or 7;
  - (ii) in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium per dosage unit;
  - (iii) in other divided preparations containing 30 micrograms or less of selenium per dosage unit;
  - (iv) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or
  - (v) in feeds containing 1 g/tonne or less of selenium.

### **VITAMIN A** for human therapeutic or cosmetic use **except**:

- (a) in preparations for topical use containing 1 per cent or less of vitamin A;
- (b) in preparations for internal use containing 3000 micrograms retinol equivalents or less of vitamin A per daily dose; or
- (c) in preparations for parenteral nutrition replacement.

**Background:** *The permitted unscheduled daily dose of vitamin A for internal use has been revised upward consistent with the current recommended daily intake established by the NHMRC.*

Please contact this Branch if you have any queries.

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