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INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA

Changes to the Tasmanian Poisons List

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 that take effect from the 1st January 2005. Below are detailed the more notable changes.

1. Schedule 2- Amendment

NICOTINE for use as an aid in withdrawal from tobacco smoking in preparations for inhalation or sublingual use.

***Background:** The effect of this amendment will be to move nicotine sublingual tablets from Schedule 3 to 2. This change was made on the basis that the safety and adverse effect profile of the formulation for its intended use fulfills the criteria for an S2 medicine. There is significant overseas marketing experience that has indicated a low potential for misuse.*

2. Schedule 4- New entries

PIPER METHYSTICUM (Kava) in preparations for human use **except:**

- (a) in preparations for oral use containing dried whole or peeled rhizome or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome when labelled with a recommended daily dose of 250 mg or less of kavalactones:
 - (i) containing more than 25 mg of kavalactones per dose, labelled with the statement:

WARNING: Not for prolonged use. Not recommended for use by pregnant or lactating women. May harm the liver;
 - (ii) in tablet or capsule form containing 125 mg or less of kavalactones per tablet or capsule; or
 - (iii) in the form of a teabag when the amount of dried whole or peeled rhizome does not exceed 3 g;
- (b) in topical preparations for use on the rectum, vagina or throat containing dried whole or peeled rhizome or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome; or
- (c) in dermal preparations.

Background: *Kava and its extracts have been under review due to serious adverse reactions and a number of deaths worldwide. The Kava Evaluation Group (KEG) and the Office of Complimentary Medicines (OCM) of the TGA have made recommendations on the regulation of kava as an ingredient in medicines. The concern is due to the potential risk of liver toxicity from the use of non-aqueous extracts of kava plants at high doses. The NDPSC noted that the available information suggested that whole or peeled kava rhizomes and their aqueous preparations containing 250mg or less of kavalactones were acceptable for use in exempt medicines and that medical advice was necessary for safe use of other kava preparations.*

3. Schedule 4- Amendments

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use **except:**

- (a) in oral preparations containing 200mg or less but more than 50mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when labelled with the warning statement:

WARNING - this medication may be dangerous when used in large amounts or for a long time; or

WARNING - this product contains [insert pyridoxine, pyridoxal or pyridoxamine as applicable] which may be dangerous when used in large amounts or for a long time; or

- (b) in oral preparations containing 50mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

Background: *The NDPSC considered the outcomes of the reviews of the safety of pyridoxine and its congeners by expert committees in the UK, EU and the USA. The committee agreed that since there was sufficient evidence to clearly characterize a significant risk of neuropathy from prolonged use of pyridoxine at a dose of 200mg per day or greater in adults, such doses of pyridoxine should only be available on the prescription of a medical practitioner.*

Other important information:

4. Recording of certain Schedule 3 drugs

Pharmacists may be aware that the Galbally Review of State and Territory drugs, poisons and controlled substances legislation, carried out under the National Competition Policy (NCP), recommended that recording requirements in regulations applying to the supply of certain schedule 3 drugs should be removed. The basis of this recommendation is the fact that the purpose of recording of supply of medication is primarily to support appropriate professional practice and patient care. Consequently, any recording requirements should generally be addressed within codes of professional practice rather than drug control legislation.

To implement this Galbally recommendation, the Poisons Regulations 2002 were recently amended to remove Regulation 53. **Therefore, recording of each supply of the Schedule 3 substances acepifyline, aminophylline, dihydrocodiene in undivided preparations, salbutamol, terbutaline, and theophylline (the remaining "S3R" substances) is no longer required by regulation.** Pharmacists should look to professional practice guidelines for guidance on which over the counter medicines should be recorded and under which circumstances in order to ensure optimal patient care.

Please note that the supply of **pseudoephedrine** is a different issue (Also see attached circular). Several Australian jurisdictions require recording of supply of pseudoephedrine because it is a substance involved in criminal activity, misuse and abuse. The NCP accepts that certain drugs may need to be recorded under poisons legislation because of

these characteristics. Recording of sales of pseudoephedrine is still under consideration in Tasmania and is the subject of ongoing discussion with pharmacy bodies. Pharmacists will be advised shortly about possible enhancement to the arrangements for controlling the supply of pseudoephedrine.

5. The supply of salbutamol inhalers to schools, St. John Ambulance officers and persons trained by the Asthma Foundation of Tasmania

The Asthma Foundation of Tasmania has asked the Branch to remind pharmacists that salbutamol inhalers are accessible to certain approved persons under the Poisons Regulations. Salbutamol inhalers may be supplied:

- a) in accordance with the written authority of a school principal;
- b) to a St. John Ambulance Officer; or
- c) to the holder of a current relevant certificate issued on behalf of the Asthma Foundation of Tasmania.

In the latter two categories a pharmacist should request written evidence of authorisation.

6. Recording of methadone maintenance prescriptions on the pharmacy dispensing system

Pharmacists are reminded that prescriptions for methadone maintenance or buprenorphine 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 when each new prescription is received.

All narcotic prescriptions, no matter how supply occurs, must be recorded when a prescription is initially dispensed e.g. in the case of daily supervised dosing of tablets the total dispensed quantity is recorded on the dispensing system and not each days dose. The creation of a record on the dispensing system ensures that a report comes to this Branch when the narcotic returns disc is lodged each month.

7. Accessing the Tasmanian Poisons List

As previously advised the Poisons List is available online. The setup of the website has changed and below is given one way of readily accessing the List:

1. Go to www.thelaw.tas.gov.au
2. Select "Browse A-Z"
3. Tick the "Stat rules" box.
4. In the "Search box" type "Poisons List".
5. Click on the browse result "Poisons List 2001 (SR 2001, No 102)".
6. The consolidated poisons list is displayed in the left hand box by Schedule.
7. If you click on the "Poisons List Order 2001" (in bold) at the top of the left hand box, the full Poisons List will appear as one document and may be printed or copied to a floppy or disc.

8. Pharmacists "ready reference" for prescriptions

Please note that an updated ready reference and circulars are available on the DHHS website at www.dhhs.tas.gov.au/publichealth/pharmaceuticals/

PHARMACY MANAGERS- PLEASE CIRCULATE TO ALL PHARMACISTS IN YOUR EMPLOYMENT.

Jim Galloway
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