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PSB Newsletter 52

Supply by pharmacists of Schedule 4 or Schedule 8 substances without a (hard copy) prescription

Pharmaceutical Services Branch (PSB) wishes to notify pharmacists that during the course of planned inspections, supplies that are made by a pharmacist without hardcopy prescriptions may be checked in order to ascertain compliance with the *Poisons Regulations 2008* (Regulations).

PSB would like to remind pharmacists of the circumstances under which supply of prescription substances can be made when the patient does not have a (hard copy) prescription. A copy of PSB's Ready Reference for Prescriptions is attached to this newsletter and can be found at www.dhhs.tas.gov.au/psbtas/guidelines.

Only these provisions apply and the Regulations allow for no other arrangements.

The following scenarios summarise the relevant Regulations. Pharmacists should refer to the Regulations for complete information on each of the supply mechanisms described below.

Schedule 4 (Restricted substances)

Four provisions apply:

1. *Regulation 43*. Emergency prescribing and dispensing of restricted substances

Regulation 43 authorises a pharmacist to supply a Schedule 4[i] (including Schedule 4D substances[ii]) substance to a patient 'on the instruction of a prescriber'. This could, for example, take the form of a verbal, faxed or emailed order from a prescriber. Other forms of communication may also be utilised provided the legitimacy of the order can be verified. When a pharmacist makes a supply in this way it is the responsibility of the prescriber to forward a hard copy prescription to the pharmacist within 24 hours. Where prescribers fail to comply with this requirement, pharmacists should make every effort to obtain the prescription and record the details of each attempt to do so.

2. *Regulation 43A*. Continued dispensing without prescription in specified circumstances

Regulation 43A authorises a pharmacist to supply up to, and including, the maximum single Pharmaceutical Benefit Listed quantity of an eligible Schedule 4 substance (oral hormonal contraceptives and HMG-CoA reductase inhibitors) on the basis of a previous prescription if a valid prescription is unavailable; and the supply is in accordance with the circumstances specified in the

[i] Defined in the Regulations as a 'restricted substance'
[ii] Defined in the Regulations as a 'declared restricted substance'

National Health (Continued Dispensing) Determination 2012 issued under section 89A(3) of the *National Health Act 1953* of the Commonwealth for that eligible restricted substance.

3. *Regulation 48*. Emergency supply of restricted substances other than specified psychotropic substances

Regulation 48 authorises pharmacists to make a supply of three (3) day's treatment of a Schedule 4 substance to a patient where the patient is already taking the substance and "the continuation of that treatment is essential to the wellbeing of the patient." In the case of a product where the primary container contains more than three (3) day's treatment, for example a cream, metered dose inhaler or eye drop, the primary pack may be supplied.

Please note that Schedule 4D substances cannot be supplied in this way.

4. *Regulation 49*. Supply of restricted substance in a medical institution

Regulation 49 authorises pharmacists to make one supply of a Schedule 4 substance to a resident of an aged care facility provided the substance is on the drug therapy chart of the resident. When supply under Regulation 49 is made a hard copy prescription authorising the supply must be sent to the pharmacist by the prescriber responsible for preparing the drug therapy chart within 24 hours. Where prescribers fail to comply with this requirement, pharmacists should make every effort to obtain the prescription and record the details of each attempt to do so. Further Regulation 49 supplies cannot be made for the patient and drug in question until this hard copy prescription is provided to the pharmacist.

Please note there is no mechanism for supply in this manner for Schedule 4D nor Schedule 8[iii] substances.

Schedule 8 (Narcotic substances)

Only **one** provision applies:

5. *Regulation 18*. Emergency prescribing and dispensing of narcotic substances

Regulation 18 authorises a pharmacist to supply a Schedule 8 substance to a patient on the basis of an order communicated to the pharmacist other than by hard copy prescription. This could, for example, take the form of a verbal, faxed or emailed order from a prescriber. Other forms of communication may also be utilised provided the legitimacy of the order can be verified. When a pharmacist makes a supply in this way, it is the responsibility of the prescriber to forward a hard copy prescription to the pharmacist within 24 hours. Where prescribers fail to comply with this requirement, pharmacists should make every effort to obtain the prescription and record the details of each attempt to do so.

Regardless of the supply mechanism, pharmacists should make a detailed record of the circumstances of each supply in the patient history.

DORA

PSB has been in the process of rolling out DORA, a website that allows medical practitioners and pharmacists access to Tasmanian real time dispensing data and regulatory information including patient's Schedule 8 dispensing history and current circular information. DORA is currently available in approximately

[iii] Defined in the Regulations as a 'narcotic substance'

50% of Tasmanian pharmacies. It is recommended that all pharmacies arrange for DORA access and that all pharmacists become registered users. Please contact PSB to arrange for access.

When do Pharmaceutical Services Branch circulars expire?

The Pharmaceutical Services Branch (PSB) frequently distributes 'circulars' to pharmacies asking pharmacists to assist in the clinical management of specific patients. These circulars concern patients who may be drug seeking, doctor shopping or misusing scheduled medicines.

Where it has been necessary to restrict a patient's access to scheduled medicines in the interests of patient safety, circulars should remain in force unless PSB advises otherwise. Accordingly, pharmacies should be aware that circulars **do not** expire unless PSB issues a follow up circular advising that the original circular is no longer applicable. Pharmacists are reminded that circulars are available on DORA.

Repeat intervals on Schedule 4D and Schedule 8 medicines

PSB continues to receive reports of Schedule 8 and Schedule 4D substances being supplied from pharmacies 'early' in circumstances that contravene Regulations 23 and 46 of the Regulations.
Previous newsletters have highlighted these substances are subject to significant levels of misuse & diversion. Early supply may in some cases present a major patient and/or public safety risk.

Under Regulations 23 and 46, prescriptions for Schedule 8 substances and Schedule 4D substances respectively may not be dispensed other than in accordance with the repeat interval specified by the prescriber or, if the prescriber does not specify a repeat interval, more frequently than allowed for by the directions on the prescription.

The Regulations allow for a supply to be made up to four (4) days early in some circumstances; however safety and quality use of medicine considerations would dictate this would not be a regular event for a particular patient with a particular drug. This ensures a patient is not cumulatively supplied Schedule 8 or Schedule 4D substances more than four (4) days 'early'.

Many medical software programs stipulate a repeat interval of 20 days automatically to align with the Pharmaceutical Benefits Scheme (PBS) 'Safety Net 20 Day Rule'. Please be aware that checking the correct interval with the prescriber may be indicated from a safe practice perspective. As specified in Regulation 15 of the Regulations, all directions for Schedule 8 substances must be handwritten, including the repeat interval. If you would like to discuss these issues with a PSB pharmacist please call 6166 0400.

Identifying Prescribers of Schedule 8 Prescriptions

PBS regularly receives Schedule 8 prescription records from pharmacies where the prescriber has been identified as 'casual', 'unknown', 'hospital doctor' or a name that resembles what has been signed on the prescription.

Pharmacists are reminded it is their responsibility to verify a prescription is a *bona fide* prescription before dispensing – if there is any doubt, the dispensing pharmacist should contact the prescriber to verify the prescription. This is an important measure to stop the obtaining of Schedule 8 substances by fraudulent means.

The use of PBS Prescriber Numbers for identification purposes has been proposed by some as a solution. There are 2 issues with this proposal:

1. DHHS is not permitted by the Australian Government to access the PBS database that would enable identification of the prescriber; and

2. The use of this number would not free the pharmacist of their responsibility to verify the authenticity of the Schedule 8 prescription under the Regulations.

Regulation 24 requires pharmacists to authenticate the identity of the prescriber for every Schedule 8 prescription before it is dispensed by one of the two specified options or, alternatively, to only supply a sufficient quantity for 2 day's treatment until the prescriber can be correctly identified.

A useful, practical tool that some pharmacies utilise is to keep a photocopy of de-identified Schedule 8 prescriptions from different prescribers. This tool provides a pharmacist with samples of different prescribers handwriting and further verification options to ensure safe supply. This is particularly valuable for any pharmacy that employs locum, part-time or after-hours pharmacists.

Regulation 24. Restriction on dispensing narcotic substances

(1) A person who is unable to verify that a prescription for a narcotic substance is authentic must dispense no more of that substance than is sufficient for 2 days' treatment if it is used in accordance with the instructions on the prescription.

(2) For the purposes of subregulation (1), a person is to be taken to have authenticated a prescription if that person –

> *(a) is familiar with the handwriting of the purported prescriber and is satisfied that the prescription is in that handwriting; or*
>
> *(b) verifies with the purported prescriber that he or she wrote the prescription.*

Poisons Regulations 2008 amendments

Recent amendments to the Regulations pharmacists should ensure they are aware of include:

Regulation 15(7). Prescribing and supply of narcotic substances

Regulation 15 authorises the legal prescribing and supply of Schedule 8 substances by certain persons. Subregulation (7) specifies the conditions which must be met when a prescription is written or issued.

In order to provide clarity with regard to the prescribing of Schedule 8 substances in the context of including only one Schedule 8 preparation on a single prescription the following paragraph has been included in Regulation 15(7):

> *(ab) he or she is not to include in that prescription more than one preparation which is or includes a narcotic substance;*

For example, a prescriber can only write or issue a prescription for a one Schedule 8 preparation per prescription e.g. morphine sulfate 30mg. A prescriber cannot write or issue a prescription for multiple strengths of the same Schedule 8 substance e.g. morphine sulfate 30mg CR-tablets and morphine sulfate 5mg CR-tablets on the same prescription. This example includes two Schedule 8 preparations and therefore would not be a legal prescription.

Regulation 64. Prescribed persons for section 38(1)(i) of Act - Pharmacist Immunisation

Regulation 64(ca) now allows a pharmacist, who has met certain educational requirements and who have been approved by the Director of Public Health to administer certain vaccines as listed in Schedule 4; provided they are the approved vaccines (according to the particular immuniser's health speciality) against the diseases listed in Appendix 1 and 2 of the Tasmanian Vaccination Program Guidelines and the vaccines are administered in accordance with a vaccination program approved by the Director of Public Health. The

Guidelines may be sourced from:
www.dhhs.tas.gov.au/publichealth/communicable_diseases_prevention_unit/immunisation/information_for_immunisation_providers

For further information regarding the practical outcomes of this amendment please contact:

Clinical Nurse Consultant (Immunisation)

Public Health Services

Department of Health and Human Services

GPO Box 125

HOBART TAS 7000

Telephone: 1800 671 738

Codeine

PSB has received enquiries from pharmacists regarding the scheduling status and monitoring of over-the-counter (OTC) codeine products. The scheduling status of codeine has not changed. Amendment of the scheduling status of codeine is currently under consideration by the Therapeutic Goods Administration (TGA). When a patient requests OTC codeine, pharmacists are encouraged to use DORA to ascertain any Schedule 8 prescribing and/or circular details relating to that patient.

PSB is considering the potential application of e-health technology solutions such as Tasmania's DORA System or other proprietary software to help monitor the supply of codeine and reduce the public health harms associated with misuse.

Pharmacists are reminded of their legal responsibilities specifically under Regulation 53(1)(b) when supplying Schedule 3[iv] substances to patients which notes:

***Regulation 53(1)(b)*. Supply of potent substances by pharmaceutical chemists**

(1) A pharmaceutical chemist must not supply a potent substance unless –

(b) the pharmaceutical chemist, or a pharmaceutical chemist or pharmacy trainee employed by that pharmaceutical chemist –

(i) participates personally and directly in the supply of the substance; and

(ii) on consideration of the condition, disease or symptoms of the person for whom, or the animal for which, the substance is supplied (in this regulation referred to as "the patient") forms the opinion that the use of that substance in the treatment of the patient is justified;

Poisons List amendments & labelling exemptions

The full version of the SUSMP is available online at: www.tga.gov.au/publication/poisons-standard-susmp

Selected recent changes to the SUSMP include:

LANSOPRAOLE, OMEPRAZOLE & RABEPRAZOLE

SCHEDULE 2 – NEW ENTRY

[iv] Defined in the Regulations as a 'potent substance'

LANSOPRAZOLE in oral preparations containing 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

SCHEDULE 3 – AMENDMENT

LANSOPRAZOLE in oral preparations containing 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

SCHEDULE 4 – AMENDMENT

LANSOPRAZOLE except when included in Schedule 2 or 3.

OMEPRAZOLE except when included in Schedule 2 or 3.

RABEPRAZOLE except when included in Schedule 2 or 3.

PARACETAMOL

SCHEDULE 2 - AMENDMENT

a) recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing not more than 12 dosage units per pack.
b) in other preparations except:

i) when included in Schedule 3 or 4.

ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules.

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels.

(C) not labelled for the treatment of children 6 years of age or less.

(D) not labelled for the treatment of children under 12 years of age when combined with phenylephrine and/or guaifenesin. Or

iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure.

(B) in a primary pack containing not more than 20 tablets or capsules.

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels.

(D) not labelled for the treatment of children 6 years of age or less, and

(E) not labelled for the treatment of children under 12 years f age when combined with phenylephrine and/or guaifenesin.

SCHEDULE 3 – CURRENT ENTRY

PARACETAMOL when combined with ibuprofen in a primary pack containing 30 dosage units or less except when included in Schedule 2.

SCHEDULE 4 – AMENDMENT

a) when combined with aspirin or salicylamide or any derivative of these substances except when separately specified in the Schedules;
b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;
c) in slow release tablets or capsules containing more than 665 mg of paracetamol;
d) in non-slow release tablets or capsules containing more than 500 mg of paracetamol;
e) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol; or
f) for injection.

LABELLING EXEMPTION

Naloxone Injection (*Narcan®)*

Narcan® ampoules, labelled as a Schedule Four restricted substance (Prescription Only Medicine) may be supplied in Tasmania even though it is a Schedule Three (Pharmacist Only Medicine). This exemption applies until the stock of containers of the product that are incorrectly labelled are exhausted and, in any case, no later than 31 January 2017.

A copy of this newsletter is available at www.dhhs.tas.gov.au/psbtas

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Deputy Chief Pharmacist
7 July 2016