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Pharmaceutical Services Branch Newsletter

December 2019

This edition of the Pharmaceutical Services Branch (PSB) newsletter provides health professionals with information on PSB's new fax number details, Tasmanian Opioid Pharmacotherapy Program requirements, electronic transmission of prescriptions, an outline on prescriber name requirements, relevant scheduling changes and labelling exemptions.

PSB fax number update

In March 2019 PSB's fax number changed to **(03) 6173 0820**. If you have not already done so, could you please update this number in your records. Please note other PSB contact details have not changed.

Tasmanian Opioid Pharmacotherapy Program (TOPP)

Prescribers and pharmacists are reminded that patients who are enrolled on the TOPP may only be prescribed schedule 4 declared restricted substances (S4Ds), by their authorised TOPP prescriber.

Additionally, the *TOPP Policy and Clinical Practice Standards* allow only TWO take-away doses (TAD) per week for *stabilised* patients. Should a prescriber consider it clinically appropriate to allow more than two TADs per week the TOPP requires prior approval from the Clinical Director of ADS.

Pharmacists are reminded that prescriptions for opioid pharmacotherapy treatment must be recorded on the pharmacy dispensing system. Patient administration records (dosing sheets) do not negate the requirement for prescriptions to be recorded on the dispensing system when each new prescription is received.

All prescriptions for Schedule 8 substances must be dispensed in accordance with Regulation 23 of the *Poisons Regulations 2018*. The creation of a record on the dispensing system is a legislative requirement and ensures reporting to Tasmania's real time prescription monitoring system, DORA. The accuracy of DORA records is vital, so that prescribers and pharmacists are able to make safe and fully informed clinical decisions regarding the supply of high-risk prescription substances.

Electronic transmission of prescriptions

From 1 November 2019, the Commonwealth Government introduced legislative changes to the *National Health Act 1953* to enable the electronic transmission of prescriptions for medicines subsidised by the Pharmaceutical Benefit Scheme. In 2008, the Tasmanian poisons legislation was amended to enable the use of electronic transmission of prescriptions by approved software in Tasmania. The *Poisons Regulations 2018* require software systems to receive an approval by the Secretary for Health for use in Tasmania. Please see PSB's website for further information on electronic transmission of prescriptions.

Reporting of required information to DORA

Health professionals supplying *relevant substances* are required to report the full name of the prescriber to the Department of Health consistent with Regulation 124 of the *Poisons Regulations 2018*. The Tasmanian Department of Health is not authorised to collect and use Commonwealth issued PBS prescriber numbers to identify prescribers in DORA. Health professionals providing inaccurate prescriber information are not meeting their reporting obligations. Where the prescriber name cannot be identified, the health professional is required to clarify or identify the correct name for reporting to the Department.

The Australian Health Practitioner Regulation Agency's *Register of practitioners* or the Veterinary Board of Tasmania's *Veterinary Register of Tasmania* are useful resources to confirm accurate prescriber name details. Entries such as 'Casual', 'Vet' and 'Locum' do not meet the health professionals reporting requirements.

Poisons List amendments

A number of scheduling changes have come into effect in Tasmania during 2019. The full version of the SUSMP is available online at www.tga.gov.au/publication/poisons-standard-susmp while details regarding scheduling decisions are available at www.tga.gov.au/scheduling-delegates-final-decisions. Recent relevant changes to the SUSMP include:

Paracetamol – modified release products

From 1 June 2020, the Therapeutics Goods Administration (TGA) will change the scheduling of modified release paracetamol products from the current status of Schedule 2 ('Pharmacy Medicines') to Schedule 3 ('Pharmacist Only Medicine').

The TGA's review of modified release paracetamol was initiated in August 2018 following the decision by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee to suspend all modified release paracetamol products in the European Union in September 2017. The EMA decision was based on increased risks to people who overdosed on modified release paracetamol compared to immediate release paracetamol. Rather than taking the same approach as the EMA, the TGA decided to take a more measured approach and initiate the scheduling review.

More information can be found on the TGA website here and here.

Labelling Exemptions

Prenoxad® prefilled syringes for injection (each containing 1mg naloxone in 1mL) - Exemption for naloxone for the treatment of opioid overdose in Schedule 3 from labelling with the signal words 'PHARMACIST ONLY MEDICINE' and the warning 'KEEP OUT OF REACH OF CHILDREN' in accordance with the relevant provision of the current Poisons Standard. This exemption expires on **31 March 2020**.

EllaOne® 30mg tablet – Exemption for ulipristal for the treatment of emergency contraception in Schedule 3 from the labelling requirements of Schedule 3 in accordance with the Poisons Standard, when labelled as a Schedule 4 poison. This exemption expires on **22 March 2020**.

If you have questions regarding the content of this newsletter please contact PSB on (03) 6166 0400 or via pharmserv@health.tas.gov.au. This newsletter is available at www.dhhs.tas.gov.au/psbtas/publications.

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23 December 2019