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Pharmaceutical Services Branch Newsletter

31 March 2020

COVID-19

Evidence is still emerging about how this new virus spreads, the disease it causes, approaches to prevention, and treatment. The latest information from the Commonwealth Department of Health can be found here. The Tasmanian Department of Health is frequently updating its *COVID-19 Frequently Asked Questions* webpage which can be found here. A suite of measures has been introduced by both the Commonwealth and Tasmanian governments to limit the spread of COVID-19 in our community. Such measures include physical distancing, self-isolation, and quarantine. Despite the challenges the COVID-19 pandemic has presented to all in the healthcare sector, PSB remains committed to providing timely and accessible high-quality advice to prescribers and pharmacists on matters relating to Tasmanian poisons legislation.

Signing of prescription by prescribers and telemedicine consultations

In response to COVID-19, the Commonwealth introduced new temporary Bulk Billing items, including certain telehealth consultations. As a result of these changes, Pharmaceutical Services Branch (PSB) have received increased reports of unsigned prescriptions being provided to pharmacists.

Prescribers are reminded they have an obligation to sign prescriptions at the time of issuing. A pharmacist cannot dispense a medicine to a patient from a prescription without the prescriber authorising the supply with his or her own signature. Should an electronic signature be used, prescribers are expected to maintain the security of this electronic signature, so they are the only person able to electronically authorise a prescription.

Electronic transmission of prescriptions

In response to COVID-19, the Commonwealth has announced measures to fast track the implementation of electronic transmission of prescriptions by select prescribing and dispensing software vendors over the next 8 weeks. If your prescribing or dispensing vendor advises you that electronic transmission of prescriptions is available, they must provide your pharmacy with a copy of their Tasmanian approval which should be retained by the pharmacy.

National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020

In the interim period before electronic transmission of prescriptions becomes available and in conjunction with the telehealth measures, the Commonwealth have issued the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*. This arrangement allows images or faxes of signed PBS prescriptions provided to a pharmacist to be claimed as PBS-subsidised benefits at the time of supply.

Please note these measures are inconsistent with state and territory legislative requirements for prescriptions. It is hoped that the Commonwealth Government will undertake appropriate consultation with the states and territories in the future to address this issue satisfactorily.

If there are any concerns regarding the Commonwealth's special arrangement, interested parties should direct enquires to the Commonwealth's Department of Health.

Continued dispensing in an emergency

The Tasmanian *Poisons Regulations 2018* were amended on 31 March 2020 (Regulation 53A) to enable the emergency supply of a restricted substance (excluding psychotropic substances) without prescription where there is an emergency order in declared under sections 14 or 53 of the *Public Health Act 1997* or sections 41A, 42 or 45 of the *Emergency Management Act 2006*. Similar provisions have or will be adopted by other states and territories. **Up to date information on current emergency orders can be located here**.

When a declaration under these powers is made, pharmacists may supply a restricted substance (excluding psychotropic substances) without prescription so long as they are satisfied on reasonable grounds that the person seeking the sale or supply of the restricted substance –

(i) has a valid prescription for the restricted substance to be sold or supplied but is unable to provide the prescription to the pharmaceutical chemist due to the emergency, to which the declaration relates; or

(ii) requires provision of the restricted substance and has previously had a valid prescription for the restricted substance to be sold or supplied but is unable to be issued with a new prescription for the restricted substance due to the emergency, to which the declaration relates.

If a restricted substance is supplied in these circumstances the maximum quantity of that substance that may be sold or supplied to a person is the PBS maximum quantity (if the substance is a PBS restricted substance); or, the quantity contained in the smallest package in which the substance is generally available if the substance is not a PBS restricted substance. The pharmacist must label the substance in accordance with Regulation 53(c) and must make an entry into in the patient record on their dispensing system in accordance with Regulation 53(d).

Pharmacists with limited registration

Regulation 82 has been amended to provide for immunisations to be conducted by intern pharmacists while under supervision from a pharmacist immuniser. This amendment was designed to support intern pharmacists gain experience in delivering immunisations while under the supervision of a pharmacist immuniser prior to becoming fully registered pharmacists. PSB reminds all health professionals who provide immunisation services to be aware of the requirements of the Tasmanian Vaccination Program Guidelines.

Dosing and staged-supply requirements for Section 59E authorities

The precautionary safety measures implemented due to COVID-19 to safeguard the health of our community may pose a logistical and safety challenge for patients who are prescribed high-risk medications (such as opioids) under Section 59E (s59E) of the *Poisons Act 1971*.

Of the measures introduced, mandatory self-isolation and quarantine will likely impact patients for whom staged-supply conditions have previously been implemented to protect their safety. A clinical safety challenge exists between minimising the public risk of COVID-19 transmission and ensuring high-risk medication-related harm to patients is minimised.

Where an authorised prescriber clinically assesses the risk of COVID-19 infection or transmission to be higher than the risk of medication-related harm to a patient on staged-supply arrangements, the prescriber will need to contact PSB. This may require variation from s59E authority conditions and prescribers will be expected to have undertaken and documented a thorough risk-benefit assessment supporting a change in the medication supply arrangements for the patient.

Pharmacists who receive requests from patients to supply increased quantities of Schedule 8 medicines subject to mandatory staged-supply conditions are required to seek confirmation from the authorised prescriber and should clearly document this on the patient's pharmacy record. Section 59E authority details can be confirmed on DORA.

For patients treated under the Tasmanian Opioid Pharmacotherapy Program, prescribers and pharmacists will need to contact the Alcohol and Drug Service for further advice on management strategies during the COVID-19 pandemic. The contact number for ADS is 1300 139 641, and their additional contact details can be found here.

Product shortages and therapeutic substitution

Demand for medicines increased markedly during early March 2020 in reaction to the COVID-19 pandemic. From 19 March 2020, pharmacists are being advised to limit the dispensing of certain prescriptions and sales of over-the-counter medicines. This is to ensure equitable access to medicines for all Australians. This measure is supported by the Commonwealth Department of Health, the Pharmacy Guild of Australia, the Pharmaceutical society of Australia, and the National Pharmaceutical Services Association, representing pharmaceutical wholesalers. More information about this can be found on the Therapeutics goods of Australia website here.

Where a significant product shortage exists, the Commonwealth Therapeutic Goods Administration have committed to lead and develop an approach to provide professional guidance on suitable alternative products where the Schedule 4 substance remains the same (e.g. strength or formulation unavailability).

Regulation 45 and 51 of the Tasmanian *Poisons Regulations 2018* are silent on the practice of a pharmacist substituting the strength or formulation of a Schedule 4 substance in the event of a serious product shortage; however, professional practice standards require a pharmacist to communicate this change to the prescriber.

Where a Schedule 4 substance is not available in any product formulation or strength, a patient would be required to obtain a new prescription, or a pharmacist would be required to receive an emergency order, from a prescriber for an alternative substance.

Poisons List amendments

This month, the Commonwealth Government introduced changes to the *Poisons Standard* (the *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) Instrument 2020)* which can be found here. 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 changes to the SUSMP include:

Hydroxychloroquine – added to Appendix D

Effective 24 March 2020, hydroxychloroquine will be added to Appendix D of the *Poisons Standard February 2019*. This will introduce additional controls to the prescribing of hydroxychloroquine, restricting the initial treatment of a patient to be authorised by specialists in dermatology; intensive care medicine; paediatrics and child health; physicians and emergency medicine specialists.

Salbutamol – Schedule 3 entry amended

Effective 24 March 2020, where salbutamol is the only therapeutically active substance:

a) in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose; or

b) in dry powders for inhalation delivering 200 micrograms or less of salbutamol per dose;

supply is limited:

c) to persons with evidence of a medically diagnosed lung condition; or

d) to persons with a record of previous supply from the pharmacist; or

e) to persons authorised under a law of a State or Territory to use or supply salbutamol in the practice of their profession; or

f) for use in institutional first aid; and

where paragraph (c) or (d) applies—supply is limited to one primary pack of salbutamol per person.

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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