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PSB Newsletter 53

Codeine (3-methyl morphine) Rescheduling

Background

From 1 February 2018, all over-the-counter codeine-containing medicines for pain relief, cough and colds will be available by prescription only. This decision was formalised in December 2016 by the Commonwealth Government on the advice of the Therapeutic Goods Administration (TGA) as the Australian national medicines regulator. The TGA undertook a comprehensive review of the clinical evidence available for these products, as well as significant consultation with key stakeholders.

There are safer, more effective treatments available over the counter, and there is also strong evidence of ongoing health risks associated with codeine use without supervision by a doctor. Further information about the TGA decision on codeine can be found at the TGA Codeine information hub at www.tga.gov.au/codeine-info-hub.

The Tasmanian Codeine Rescheduling Implementation Group

The Tasmanian Department of Health and Human Services (DHHS) convened the Codeine Rescheduling Implementation Group (CRIG) in January 2017 to prepare Tasmania for the rescheduling of over-the-counter codeine-containing medicines and maximise the public health benefits of the decision. The CRIG consists of stakeholders from DHHS and relevant professional clinical organisations in Tasmania. More information is available from the Tasmanian Codeine Rescheduling hub at www.dhhs.tas.gov.au/psbtas/codeine_rescheduling.

Relevant regulatory changes for Pharmacists

The CRIG made some key recommendations to DHHS regarding the monitoring of codeine and related substances in Tasmania in order to provide more timely and accurate information to pharmacists and prescribers via DORA to reduce the ongoing harms from these substances. These recommendations were supported by both the Tasmanian branches of the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia.

Key regulatory changes

1. **Including all Schedule 4 opioid analgesics (codeine, tramadol and dextropropoxyphene) as *relevant substances* via real time reporting (RTR) and therefore required to be reported to DHHS.**

Why?

There is published evidence supporting the real time prescription monitoring of non-S8 substances which are subject to misuse. S4 opioid analgesics are substances subject to misuse and their unsanctioned use has contributed to many deaths. There is a strong quality and safety argument supporting medical practitioners and pharmacists having a more complete history of the supply of all opioid analgesics to their patients in Tasmania.

When?

The soft rollout date for software vendors implementing this change is 1 February 2018 with a final date for implementation by 1 April 2018. DHHS has been actively engaging dispensing system software vendors through the Medical Software Industry Association (MSIA) since August 2017. The scale of this change is significant and has involved collaboration between the MSIA, the Digital Health Agency and the Commonwealth Department of Health.

What?

Pharmacists should engage with their dispensing software vendor and be aware of progress in your pharmacy with respect to this recommendation. Pharmacists are reminded that where a patient is receiving treatment from an authorised prescriber with a Schedule 8 substance, Section 59E of the *Poisons Act 1971* restricts the supply of Schedule 4 Declared Restricted Substances (S4Ds) to the authorised prescriber (or their practice colleagues) only.

2. **Amending Regulation 93 of the *Poisons Regulations 2008* to ensure reporting *relevant substances* via RTR is the required practice by all Tasmanian pharmacies.**

Why?

RTR has been implemented in the majority of pharmacies in Tasmania since 2009 with over 95 per cent of Tasmanian community pharmacies reporting via RTR to DHHS. This legislative amendment is removing the outdated requirement to provide dispensing data regarding *reportable substances* within three days of the end of each month. Having all pharmacies reporting in real time ensures more accurate data is available for pharmacists and prescribers when considering supply of these substances. The amendment will improve the ability of DORA to support the judicious use of these substances.

When?

This amendment came into force on 13 December 2017; however, DHHS will be applying a 'business as usual' approach to continue working with pharmacies and software vendors who are not reporting in real time to implement this change.

What?

It is expected that pharmacies not currently reporting via RTR will work with PSB and their software vendor over the coming months to implement RTR. Please note that the amendment includes a provision '*unless otherwise authorised by the Secretary*' to allow for the possibility that IT issues may on occasion prevent reporting in real-time.

3. Amending the *Poisons Regulations 2008* to ensure the date of birth of a patient is present on prescriptions for Scheduled 8 substances and the date of birth reported to DHHS.

Why?

The addition of a patient's DOB to a prescription can only improve the patient's safety. Routine recording of a patient's DOB assists both pharmacists and PSB in accurately identifying the patient as well as providing an important clinical detail.

When?

From 1 February 2018 pharmacists will be required to ensure when dispensing prescriptions for Schedule 8 substances written from this date that all details on the prescription comply with the requirements of Regulation 15 of the *Poisons Regulation 2008* therefore include the date of birth of the patient.

What?

From 1 February 2018 prescribers are required to include a patient's date of birth on prescriptions for Schedule 8 substances.

Where a prescriber has not included the date of birth on a prescription for a Schedule 8 substance Regulation 23(15A) allows a pharmacist to write the date of birth for that patient onto the prescription.

Pharmacists are required to report the date of birth to DHHS via RTR when dispensing these substances. In practice, once the date of birth has been entered and saved on a patient record in the dispensing software it will automatically be provided to DHHS along with all other relevant information required under law for each subsequent dispensing event. This means that the date of birth will not be required to be entered into the dispensing software for every dispensing event.

In circumstances where the date of birth has not been provided on a prescription for a narcotic substance for a patient who is not known to the pharmacy, pharmacists should make every effort to obtain the date of birth through the usual avenues available to them e.g. the patient, patient's carer, prescriber, prescriber's practice, DORA or Pharmaceutical Services Branch.

4. Making the details of prescribers and pharmacies available when the DORA website is utilised to ensure more efficient clinical outcomes with respect to the substances subject to misuse.

Why?

DORA previously withheld prescriber and dispensing pharmacy details from registered users if they are not known by PSB to be associated with those businesses. Medical practitioners and pharmacists alike have noted this information is potentially lifesaving as it facilitates timely discussion between treating health practitioners. Additionally, PSB receives frequent requests to provide these details. This enhancement will significantly improve DORA's ability to support the judicious use of these drugs.

When?

This change has been implemented by DHHS.

What?

Pharmacists and prescribers can now view dispensing pharmacy and prescriber details when viewing patient dispensing and authority events on DORA.

5. Amending the Schedule 4 *Declared Restricted Substances Order* (S4D List) to include tramadol.

Why?

Tramadol has not previously been included in the Schedule 4 *Declared Restricted Substances Order 1990*. As tramadol is an opioid analgesic subject to misuse as with other S4D opioids, it has been a technical oversight this substance not be included in the S4D list.

When?

From 1 February 2018 pharmacists will be required to ensure when dispensing prescriptions for tramadol written from this date that all details comply with the requirements of the *Poisons Regulations 2008*.

What?

Pharmacists and prescribers can now view dispensing pharmacy and prescriber details when viewing patient dispensing and authority events on DORA.

Other frequently asked questions

Are there any changes to the scheduling of dihydrocodeine (Rikodeine®)?

No. The TGA reviewed the scheduling of dihydrocodeine after the final decision was made to reschedule codeine containing combination analgesics. Based on the limited data available regarding the reported misuse of this substance, the decision was made that the current Scheduling remain appropriate. Reports of misuse with this substance in particular population groups have been documented and pharmacists are reminded of their professional responsibilities under Regulation 53(1) of the *Poisons Regulation 2008* with respect to the appropriate supply of Schedule 3 substances. This includes participating personally and directly in the supply of the substance and on consideration of the condition, disease or symptoms of the person for whom, or the animal for which, the substance is supplied forms the opinion that the use of that substance in the treatment of the patient is justified.

What will the labelling requirements be for products that were previously OTC codeine-containing medicines?

Any stock remaining on community pharmacy shelves of OTC codeine-containing medicines can be dispensed after 1 February 2018 on prescription as a Schedule 4 prescription medicine in a community pharmacy for a maximum period of nine months (ie until 31 October 2018) or until the end of the shelf life, whichever is earlier, provided:

- the stock is stored in the dispensary
- there is a valid prescription
- the stock is supplied with a dispensing label in line with the *Poisons Regulations 2008*.

If you have any questions regarding the content of this newsletter please call Pharmaceutical Services Branch on (03) 6166 0400 or email pharmserv@dhhs.tas.gov.au

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