

15 October 2015

Medicines.Scheduling@tga.gov.au

Re: Consultation: Delegate's interim decisions – ACMS meeting, July 2015

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practising in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA supports pharmacists to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians, as individuals, for the community as a whole and for healthcare facilities within our systems of healthcare.

SHPA believes that any changes to the scheduling of medicines should be driven and underpinned by the principles of patient safety. Our thoughts on three of the delegates' interim decisions are presented below.

Codeine

Given the evidence considered by the delegates, SHPA concurs that there are aspects related to codeine that do not meet the Scheduling Policy Framework (SPF) factors for inclusion in Schedule 3. In relation to this, it is criterion 2 which is critical and not satisfied: "The use of the medicine at established therapeutic dosages is not expected to produce dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimised through monitoring by a pharmacist."

The risks can be minimised through monitoring by a pharmacist, however this requires the implementation of a national Electronic Recording and Reporting of Controlled Drugs (ERRCD) system that includes codeine, irrespective of the schedule.

For this reason, SHPA concurs that the only option available within the current interpretation of the SPF, and the lack of agreed implementation of a national Electronic Recording and Reporting of Controlled Drugs (ERRCD) system, is to reschedule codeine as detailed in the interim decision.

However, we reiterate, that this decision would introduce considerable challenges and additional financial burden to both patients (as increased out-of-pocket costs) and the healthcare system as a whole, in particular Medicare payments, including:

- requiring multiple additional attendances to doctors for prescriptions with the associated increase in claims through Medicare
- potentially more prescriptions through the Pharmaceutical Benefits Scheme (PBS); this will be dependent upon separate decisions about whether these medicines remain on the PBS
- Preventing nurses from initiating analgesic treatment in emergency departments and during hospital admissions, particularly in hospitals without full time medical staff.

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SHPA believes that the option of continuing codeine as a Schedule 3 medicine should be considered with the following requirements:

1. these products are supplied as pharmacist only medicines and that all supplies of these products are dispensed, individually labelled and recorded by the pharmacist; and
2. are included in a national ERRCD system.

Irrespective of the scheduling of codeine, SHPA believes that a ERRCD system would mitigate many of the risks of the inappropriate use and diversion of products containing codeine. SHPA is a cosignatory to a letter sent to all health ministers highlighting the need for a national ERRCD. The letter notes that an ERRCD is a crucial clinical support and intervention tool to help practitioners manage the prescribing, supply and management of drugs of addiction, and to prevent harm from inappropriate use of prescription medicines. (<http://www.shpa.org.au/lib/pdf/whatsnew/20150909-Joint-letter-to-Health-Ministers-re-ERRCD.pdf>)

It is possible that in response to the interim decision, manufacturers may re-evaluate products containing codeine, which may lead to a decrease in the number of products. SHPA believes that manufacturers should communicate as early as possible if any product will be discontinued. Timely information will be crucial to educating consumers about their future treatment options and promoting non-pharmacological interventions in treatment plans.

Naloxone

SHPA supports the creation of a Schedule 3 entry for single use prefilled syringes for injection containing 400 micrograms/mL or less of naloxone.

Esomeprazole

As part of Choosing Wisely Australia the Royal Australian College of General Practitioners (RACGP) have flagged the long term use of proton pump inhibitors (PPIs) as one of the top five tests, treatments or procedures which should be questioned by GPs and their patients. That statement is based on the evidence that a high proportion of patients are kept on maximal doses long term when this should not be the case. (<http://www.choosingwisely.org.au/recommendations/racgp>)

In principle, SHPA does not support any Schedule 2 entries for PPI. Although the change would only apply to packs containing no more than 7 days' supply of the medicine, we believe that these medicines should be Schedule 3 to ensure appropriate consultation and review by a pharmacist to minimise the number of people who move to long term use of these medicines.

If you would like to discuss the issues raised in this submission or require further information, please contact us (shpa@shpa.org.au or 03 9486 0177)

Yours sincerely



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