



SHPA response to public consultation on proposed amendments to the Poisons Standard - ACMS, ACCS & Joint ACMS-ACCS, March 2023 - Substance 1: Celecoxib

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA convenes speciality practice groups comprised of pharmacists who specialise in areas such as Pain Management, Women's and Newborn Health, Medication Safety as well as Surgery and Perioperative Medicine.

In reference to proposed amendments referred for scheduling advice to ACMS meeting #41, 2.1 Celecoxib, SHPA supports in principle:

- the applicant's proposal for a new Schedule three entry for celecoxib for oral use in capsules containing 200 mg or less per capsule when in packs containing not more than ten dosage units.
- the indication for short-term treatment of period pain in adults and for the short-term treatment of acute pain in adults with muscle and joint injuries.

The Australian Medicines Handbook entry for celecoxib¹ states that patients with moderate hepatic impairment should start treatment at half the recommended dose, that being 200mg instead of 400mg for period pain and postoperative, musculoskeletal or soft tissue pain. In addition, doses higher than 200mg a day are associated with cardiovascular events such as acute myocardial infarction², thus SHPA proposes that consideration is given to appropriate package labels and warnings, as well as dosage instructions on the package that suggest no more than 200mg per day dosage to those with history of thrombosis or cardiovascular event risk. These consumers may need to be referred to their GP for more appropriate treatment.

SHPA does not consider celecoxib to pose further risk to consumers than other pharmacist only medicines already available for the treatment of acute pain. At celecoxib doses ≤ 200 mg a day, cases of cardiovascular events are similar to other Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – with the exception of diclofenac, which is already available without prescription and is associated with higher rates of cardiovascular toxicity.¹ Celecoxib is also thought to present the lowest risk of renal impairment when compared to other NSAIDs.¹

Pharmacists are well placed to have discussions with consumers around acute pain management and may or may not recommend celecoxib as the most appropriate treatment. Sale of this medicine should require the pharmacist to ascertain any contraindications that the consumer may have with this medication such as cardiovascular, renal, or gastrointestinal risk factors. Furthermore, discussion around signs of an allergic reaction may be required given that the most reported adverse event for celecoxib is related to allergic reactions.³

Celecoxib product labelling should clearly state the clinical indications as well as reiterate the Pharmacist Only Medicine is for short term relief (maximum five days treatment) of acute pain only. SHPA anticipates that repeated purchases or inadequately controlled pain will prompt pharmacist referral to the consumer's GP for further pain assessment and management.



If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on yyik@shpa.org.au.

References

¹ Australian Medicines Handbook. (2023). Celecoxib. Available at:

<https://amhonline.amh.net.au/chapters/rheumatological-drugs/drugs-other-musculoskeletal-conditions/nsaids/celecoxib>

² Bally M., Dendukuri N., Rich B., Nadeau L., Helin-Salmivaara A., Garbe E., Brophy J.M. (2017). Risk of acute myocardial infarction with NSAIDs in real world use: bayesian meta-analysis of individual patient data. British Medical Journal. doi: 10.1136/bmj.j1909

³ Therapeutic Goods Administration. Database of Adverse Event Notifications - Medicines. Celecoxib. Available at: <https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx>



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