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2 March 2018

Advisory Committee on Medicines Scheduling
Department of Health
MDP 71
GPO Box 9848
Canberra ACT 2601
Email: *medicines.scheduling@health.gov.au*

Dear Secretary,

RE: Interim decision for substances referred to the November 2017 meeting of the Advisory Committee on Medicines Scheduling (ACMS)

The Pharmaceutical Society of Australia (PSA) takes this opportunity to provide further comment in relation to the interim scheduling decision on ibuprofen which was released on 5 February 2018.

The proposed amendment for ibuprofen (considered by the ACMS in November 2017) was to:

- amend the Schedule 2 (S2) entry to restrict to no more than 30 dosage units (down from 100 dosage units) when in divided preparations containing 200 mg or less of ibuprofen in a primary pack
- delete the exemptions in the S2 entry that currently allow general sale of up to 25 dosage units of 200 mg ibuprofen, and
- amend the Schedule 3 (S3) entry to allow up to 100 dosage units containing 200 mg or less of ibuprofen in a primary pack.

In response to the invitation to comment, PSA made a submission in which it recommended that ibuprofen should be rescheduled as proposed so that ibuprofen-containing products continue to be available over-the-counter (OTC) but restricted to a pharmacy setting. The rationale for this position is that it will provide the opportunity for pharmacist intervention, support a quality use of medicines approach to the use of ibuprofen, and contribute to enhanced patient care.

The delegate's interim decision (based on ACMS advice) announced in February 2018 was that the current S2 and S3 entries for ibuprofen remained appropriate i.e. the rescheduling proposal was not accepted.

Pharmacists understand that the well-established safety profile of ibuprofen for short term use means patients should have reasonable access for self-treatment. Regulatory measures such as labelling and packaging requirements are in place to help minimise potential risks of adverse events.

PSA suggests that such regulatory measures are appropriate in the context of risk management for the general population. However, as the health professional most accessible to patients, pharmacists routinely encounter scenarios where ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs) are being used inappropriately or sub-optimally by individuals.

Pharmacists are genuinely concerned that continued availability of ibuprofen-containing products for self-selection through non-pharmacy settings has the potential to further increase the risk of adverse outcomes and also disadvantage people who are not achieving optimal pain management. This is particularly relevant in the context of the recent upscheduling of codeine-containing products. Despite the considerable lead-in

time for implementation of the revised scheduling arrangements, some patients are still working out how best to adjust their pain management regimen and require access to pharmacist advice and intervention at point of supply. Pharmacists are aware that some of these patients are those with conditions such as cardiovascular disease, renal disease, gastrointestinal issues or asthma, for whom the risks of adverse outcomes are higher.

In the *interim decision report*, it was suggested that advice regarding the risk of toxicity from ibuprofen use (e.g. complications such as cardiovascular disease and renal impairment, and confusion in the elderly) is adequately covered by mandatory labelling requirements. The Australian Commission on Safety and Quality in Healthcare in their *National Statement on Health Literacy* noted that "only about 40% of adults have the level of individual health literacy needed to meet the complex demands of everyday life" and further, for example, "that only 40% of adults can understand and follow health messages in the way in which they are usually presented". Even with the best designed label on the product packaging, pharmacists frequently report of instances where the patient has not read, not understood, misunderstood or disregarded information relevant to them to take the medicine safely or effectively when this information is not reinforced by the intervention of a pharmacist.

PSA strongly suggests that it is in the best interests of patients for pharmacist advice to be available at the point of supply so that medicine information can be tailored based on health literacy levels of the patient to ensure safe and effective use of ibuprofen.

Pharmacists are also aware that some patient behaviours are not managed by regulatory measures such as labelling, for example, patients persisting with ibuprofen therapy beyond short term use and/or increasing daily dosages. PSA is now aware of a recent publication (Kaufman et al. Pharmacoepidemiol Drug Saf 2018;1-10. DOI: 10.1002/pds.4391) which *reported* that many users of OTC ibuprofen exceed the recommended maximum daily dosage.

In weighing up risks and benefits of ibuprofen use, the interim decision report concludes that "there are no new safety concerns". PSA notes there is, in fact, accumulating evidence that taking ibuprofen regularly, in any dose, increases the risk of having an acute myocardial infarction (AMI).

The interim decision report cites Bally et al. (*BMJ 2017;357:j1909*) but refers to the published evidence of potential cardiovascular risk being associated with OTC doses of ibuprofen as "not substantiated". The published study reported that the use of ibuprofen (and all traditional NSAIDs) increases the risk of AMI immediately with exposure. For ibuprofen use of one to seven days, the probability of this increased risk was 97%.

In addition, *a Danish study* (Sondergaard et al. Eur Heart J 2017;3(2):100-7) recently found that short-term treatment with non-selective NSAIDs, particularly ibuprofen and diclofenac, was associated with an increased early risk of cardiac arrest by about 30%.

Consistent with PSA's position, these studies highlight the importance of and need for appropriate professional guidance for NSAID therapy in the general population, including counselling and professional advice for OTC supply of ibuprofen. Without the advice of a pharmacist, use outside of the labelling requirements and warnings is very likely, especially in unregulated open-sale environments.

In summary, PSA re-iterates its support for the proposed amendment for ibuprofen and requests that the issues raised in this submission be given consideration.

Sincerely,

Dr Shane Jackson BPharm(Hons) PhD FPS AACPA AdvPracPharm
National President