

## TGA – Re Ibuprofen: Proposed amendments to the Poisons Standard

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### Background

- The TGA Secretary has received applications under section 52EAA of the Therapeutic Goods Act 1989 (the Act) to amend the current Poisons Standard.
- The Secretary invites public submissions to be made to the expert advisory committee by 29 September, for consideration at the November meetings of the Advisory Committees on Medicines and Chemicals Scheduling (ACMS).
- Ibuprofen (the only medicine on the list for the treatment of pain being considered by the TGA in this round) has been referred for scheduling advice. The proposal is to reschedule modified release ibuprofen from Schedule 3 (Pharmacist only medicine) to Schedule 2 (Pharmacy medicine).
- The change would apply to divided preparations containing 300 mg or less of ibuprofen, in a primary pack containing not more than 12 dosage units, when labelled with a recommended daily dose of 1200 mg or less of ibuprofen.
- This will enable patients over 12 years of age to access some preparations of modified release ibuprofen without prior consultation with a pharmacist.
- Ibuprofen has an equivalent or better risk profile than paracetamol and aspirin.

### SUBMISSION

Painaustralia welcomes the opportunity to provide input to the Therapeutic Goods Administration's (TGA) consultation on the proposed amendment to the current Poisons Standard to the meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS).

Painaustralia is Australia's leading pain advocacy body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain on individuals and the community.

Painaustralia and its members have been actively engaged on the issue of quality use of medicines for many years. Working with extensive consumer network and in-house consumers advisory group, Painaustralia is focused on developing balanced, practical and strategic solutions relating to the impact of medicines scheduling. As such, down-scheduling modified release ibuprofen of 300 mg or less to a Schedule 2 listing is important to our members and stakeholders.

The up-scheduling of Modified Release Paracetamol and broader reforms to opioids in recent years has created greater barriers for consumer in accessing affordable pain management treatments. Because of this, Painaustralia supportive of improving the availability of 300 mg ibuprofen by permitting self-selection as a Schedule 2 medicine, provided that consumers are adequately informed of these changes.

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Non-steroidal anti-inflammatory drugs (NSAIDs) are the most commonly used pharmacological agents worldwide to treat mild to moderate pain. Ibuprofen is one of the most used NSAIDs and many people living with chronic pain opt to self-medicate their condition with these drugs. Because of this, consumers need to understand the components of their medication, the dosage limitations and the risks associated with them.

Clear visibility of safety and quality use of medication information for commonly used medication is vital to ensuring consumers are aware of the risks and in aiding consumers to comply with their treatment and avoid adverse health outcomes. As summarised in the application, Ibuprofen 300 mg is appropriate for inclusion in Schedule 2 given its safety profile is at least equivalent or better than paracetamol and aspirin. However, without pharmacist advice prior to purchase, consumers may take more than recommended if they are accustomed to taking 2 of the widely available 200 mg tablets, unless the scheduling changes are communicated to them.

Painaustralia recommends that the down-scheduling be accompanied by a targeted education and awareness campaign around quality use of Ibuprofen, as well as an evaluation of the change and to support consumers who are considering changing to modified release preparations. The impact of down-scheduling particularly on the rates of reported adverse events and overall hospital presentations are also important factors that must be monitored as a part of the TGA's proposed change processes.

We submit these matters for the consideration by the TGA, ACMS-ACCS in finalising proposed amendments to the Poisons Standards and welcome the opportunity to discuss our submission with you further.

