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AMA submission – Medicines Scheduling Policy review

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The AMA supports reforms to the medicines scheduling framework which will improve the consistency and quality of decision-making; address the current lack of transparency in the scheduling process; and make more detailed information available on which to comment on scheduling proposals.

The AMA's comments on specific areas of the discussion paper prepared by the Queensland University of Technology are provided below.

In relation to improving the risk-benefit balance, it seems sensible to ensure that benefits, not just risks, are considered. However we would be cautious of implementing an overly rigid methodology that precludes some flexibility.

Regarding the improvement of decision-making transparency, we agree it would be helpful to develop an application template that clarifies requirements and incorporates a risk-benefit framework which would also allow decisions to be published in a logical manner against template headings. The template could be 'front-loaded' with threshold criteria for scheduling so that proposers for down-scheduling medicines, in particular, would see immediately the minimum requirements for change. This may deter unrealistic applications.

Regarding the options proposed relating to information availability and input to decision-making, the AMA strongly supports the publication of scheduling applications (section 2.4, option e). The AMA has previously raised concerns about the unacceptability of proposers' submissions being kept confidential, and the difficulty this causes in framing an informed and relevant submission.

We have no other concerns with the current public consultation process, including: the public consultation period; the limiting of further submissions following the Secretary's interim decision; and the non-reviewable nature of the Secretary's final decision.

However the AMA wishes again to raise the composition of the Advisory Committee for Medicines Scheduling (ACMS). The AMA does not accept that this is outside the scope of this review.

In fact the Minister responsible for therapeutic goods regulation wrote to the AMA President on 13 May 2015 stating that "any changes to the TGA's statutory advisory committees and their composition in the near future are subject to the outcomes of the Government's Expert Review of Medicines and Medical Devices Regulation" and encouraged the AMA to raise this issue as part of the Review process.

Given the Minister's direction, the AMA again urges that the ACMS membership includes a practising general practitioner.

The current membership is made up of three pharmacists (none currently working in community pharmacy) and one medical practitioner (a consultant physician).

Decisions about medicines scheduling are not just about the pharmacology and toxicology of a drug. Just as important is how the drug is used in the real world.

General practitioners are uniquely placed to see the effects of scheduling on the public. They prescribe the vast majority of Schedule 4 and 8 medicines and through their whole-of-patient consultations, also understand how patients use non-prescription medicines.

ACMS decisions impact heavily on general practice. It is vital to ensure that general practitioners' practical experience is available to advice on safety and implementation issues common in a family practice. Scheduling changes primarily affect GPs and community pharmacists in relation to safety, abuse, misuse or diversion.

The AMA considers that without the benefit of general practitioner expertise, the ability of ACMS to make well-rounded decisions is significantly compromised. The risk is that decisions will be based on 'text-book' assessments of medicine use rather than how medicines are used in contemporary clinical practice.

The AMA proposes that an amendment should be made to the *Therapeutic Goods Regulations 1990* Division 3A, which prescribes ACMS membership, to include a requirement for a member to be appointed who is a practising general practitioner.

Apart from the above areas, the AMA does not have strong views on other matters raised in the discussion paper. These are of more relevance to sponsors and the government agencies that will need to implement and comply with the reforms.

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