AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission – TGA proposals regarding the scheduling policy framework and advertising of Schedule 3 medicines

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.

Therefore the AMA supports, or has no objections to, most of the TGA's proposals to enhance the scheduling framework and processes outlined in its consultation paper. A table at the end of the submission summarises our response to each proposal.

However there are a small number of proposals about which the AMA has concerns or comments, and these are detailed below.

The AMA also has an additional proposal to improve medicines scheduling decisions, for the TGA to consider.

Public summary of the scheduling submission

The AMA strongly supports the publication of scheduling applications, and is disappointed that the TGA proposes that only a summary of the application would be made public.

The AMA has previously raised concerns about the applicants' submissions being kept confidential, and the difficulty this causes in framing an informed and relevant submission.

Given this, the AMA is particularly concerned that the applicant will be responsible for crafting a summary of their own application. This approach risks allowing the applicant to slant the summary to support their own views – emphasising factors that support their application and ignoring those that do not. The applicant may also omit important information.

If the full application is not made public, then the TGA should play a more proactive role by determining the information which must be included in the public summary, and also assessing its accuracy.

New controls for certain medicines that have been down-scheduled to S3

In principle, the AMA does not oppose the enhancement of the poisons standards to enable additional controls or requirements for certain S3 medicines to be specified.

However, the AMA is apprehensive that the availability of these apparent 'controls' will give false assurance that it is therefore safe to down-schedule S4 medicines to S3.

For example, in the last two and a half years there have been two applications for S4 medicines to be down-scheduled - oral contraceptives and Vardenafil – where it has been argued that patient questionnaires at the point of supply could minimise risks to patients.

The AMA still strongly opposes the down-scheduling of these medicines on the basis that it would both risk patient safety and contravene quality use of medicine principles, even if extra 'controls' and 'requirements' were available to impose on pharmacists at the point of supply.

Prescription of the combined oral contraceptive pill provides an opportunity to consider the benefits of changing to a Long-Acting Reversible Contraceptive (LARC), offer opportunistic screening for sexually transmissible infection or cervix cancer, blood pressure measurement and unrelated health prevention activity.

Prescription of Vardenafil provides an opportunity to screen for Diabetes Mellitus and sexually transmissible infection, as well as unrelated health prevention activity.

Relying on pharmacists to control the use of low-dose codeine products did not stem the increase in codeine-related deaths post 2010.

Market incentives to down-scheduling medicines

The TGA consultation paper does not explain what possible benefits there would be for Australian consumers of providing market incentives to sponsors to apply for their product to be down-scheduled. In the absence of any examples, facts or evidence supporting the benefits to public health, the AMA does not support this proposal.

Advertising of S3 medicines

The AMA considers there is little benefit in relaxing the regulation of S3 medicines.

Direct to consumer advertising (DTCA) of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines. While DTCA may potentially increase awareness of certain health conditions and medicines, its primary purpose is to increase demand and sales for the advertiser's product.

The information provided to consumers/patients through DTCA is designed to persuade, rather than inform. DTCA may not provide the necessary balance and objectivity required for consumers/patients to make informed choices.

It is difficult for the AMA to make any further comment without seeing more detailed proposals for how a framework for limited and controlled advertising of S3 medicines might work. Without seeing further specific proposals and understanding how they would be implemented, the AMA cannot support reforms which would reduce current controls.

Membership of the Advisory Committee on Medicines Scheduling

The AMA urges the mandatory inclusion of a clinically active general practitioner to the membership of the Advisory Committee on Medicines Scheduling (ACMS). The AMA has written to the relevant Minister and directly to the TGA on this issue several times over the last two years.

The legislative and regulatory changes that will be required to update the scheduling framework provide the perfect opportunity to redress this gap.

The AMA proposes that an amendment be made to the *Therapeutic Goods Regulations 1990* Part 6, Division 1A, clause 35B, which prescribes ACMS membership, to include a requirement for a member to be appointed who is a practising general practitioner.

The current ACMS membership comprises 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 S4 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 advise 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 by real-life patients.

This risk will increase substantially if proposed changes lead to more S4 medicines being down-scheduled to S3.

Summary of AMA responses

Proposal	AMA response
Policy recommendations	
1. Split SPF into policy document and guidance handbook	No objection
2. Establish informal working group to advice on possible amendments to poisons standard	No objection
3. Amend regulations to allow general public consultations of the interim decision and extend consultation period	Support
4. Explore options for a chemicals scheduling delegate in APVMA to streamline scheduling and market authorisation	Not relevant to AMA
5. Create new appendix in the poisons standard to enable additional controls or requirements for S3 medicines, especially for down-scheduled medicines from S4	Refer detailed comments
Business improvements	
1A Clearer explanation of cascading principle	Support
1B Revision of Committee advice and delegate reasons	Support
2A Public summary of application	Refer detailed comments
2B Early alert for stakeholders	Support
2C Communication and application tracking	Support
3 Equal consideration of benefits and risks	No objection
4 Explain legislative nature of scheduling decisions	No objection
5A Explain jurisdictional requirements	No objection
5B Provide early alert of scheduling decisions	Support
5C Information sharing between APVMA and Secretariat	Not relevant to AMA
6 Improve poisons framework clarity	No objection
Ongoing improvements and guidance materials	
1 Trial of applicants presenting to committees	No objection
2 Explore utility of risk/benefit tree methodology	No objection
3 Proactively identify substances for rescheduling	No objection
4A Aligning scheduling process with market authorisation	No objection
4B Market incentives for rescheduling	Refer detailed comments
Advertising S3 medicines	
1 Change advertising regulations for S3 medicines	Refer detailed comments

APRIL 2017

Contact
Georgia Morris
Senior Policy Advisor
Medical Practice Section
02 6270 5466
gmorris@ama.com.au