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 consultation on proposed regulation of Schedule 8 opioids

The AMA welcomes the opportunity to comment on the TGA's consultation paper exploring a number of potential measures within its regulatory remit which could be used to improve the use, and reduce the misuse, of Schedule 8 opioids.

The AMA has the following overarching comments to make before addressing each option in turn.

First, the AMA fully supports safe and effective prescribing of opioids. Opioids are high risk medicines and it is appropriate that additional regulatory measures are in place in the interests of patient safety.

Second, as the TGA points out, strong opioids play a critical role in many forms of cancer treatment and other conditions so it is important that medical practitioners can continue to prescribe them when clinically required without additional, unnecessary red tape.

Third, a regulatory approach should always be a last resort, after alternative, non-legislative approaches have been ineffective.

There is considerable scope to enhance and implement: targeted education and training; monitoring of prescribing and provision of feedback; and auditing and compliance activities. This is all within the scope of responsibilities of the Department of Health, of which the TGA is just one part.

Fourth, and related to the above point, the regulatory options proposed should be considered in the context of the full suite of measures available to government. It makes no sense to consider the specific and narrow regulatory approaches only with the remit of the TGA in isolation of other activities already underway.

For example, several States and Territories already have in place additional restrictions and requirements that must be met before medical practitioners can prescribe Schedule 8 opioids to their patients.

Further, the AMA is aware that, concurrent to the release of the TGA's consultation paper, the Provider Benefits Integrity Division of the Department of Health issued invitations to non-government stakeholders to attend a meeting on opioid prescribing, to provide advice and work with the Department on improving prescribing of opioids under the PBS.

The debate about further measures to improve the quality use of opioids would benefit from the Federal Department of Health demonstrating internal collaboration by issuing a whole-of-portfolio consultation paper so that the full range of potential options can be seen within the whole context of Federal responsibilities.

Finally, the AMA has been calling on all State and Territory governments to implement real time prescription monitoring of all Schedule 8 medicines since 2013. As noted in the TGA's consultation paper, this alone should effectively reduce misuse, illness and death related to strong opioids.

Within the context of the above points, the AMA's comments on each of the TGA's options are provided below.

Remove highest dose products from the market, or restrict them to specialist/authority prescribing

The AMA acknowledges that, in the interests of patient safety, additional measures are sometimes required to control access to certain medicines that are prone to addition and misuse. However, prescribing regulations and other measures should not pose a barrier to medical practitioners treating their patients or impose an administrative burden without evidence that they are effective and necessary.

As noted in the TGA's consultation paper, removing higher dose S8 opioid products from the market would prevent patients who need higher doses for clinically appropriate reasons from accessing these medicines altogether. Therefore this option appears excessive.

Similarly, preventing general practitioners from prescribing these medicines would pose considerable hardship in situations where patients live in rural/remote areas or have other difficulties accessing specialist doctors, palliative care and/or pain clinics. In addition, many general practitioners work within or with recognised palliative care services.

As flagged above, some State and Territory governments, for example Western Australia and the ACT, have already introduced restrictions on general practitioner prescribing of certain Schedule 8 medicines. The restrictions include requiring general practitioners to apply for an annual approval and/or specialist approval/support before they may prescribe above certain doses.

AMA general practitioner members report these systems are working well and provide clear support and guidance for doctors as well as their patients.

Similar restrictions could also be effectively implemented nationally via the Medicare/PBS framework given that the vast majority of prescriptions written in Australia are PBS prescriptions. The PBS is already used in this way, for example, general practitioners must be 'accredited' to prescribe HIV/AIDS medicine under the highly specialised drugs scheme but can then independently treat and manage their patients.

If this type of approach was favoured, then the AMA would be keen to work with the Department of Health and with State/Territory governments on exploring a national approach to improve consistency across jurisdictions – an approach that is clinically rational and evidence-based,

allows general practitioners to effectively manage patients who need S8 opioids, and at the same time provides safeguards for doctors and their patients.

However the AMA considers that prior to introducing these kinds of regulatory barriers, the Department of Health should first enhance alternative approaches.

As flagged above, there is considerable scope to increase educational activities. This includes strategies already planned by the Department of Health which involves using PBS and Medicare data to identify medical practitioners prescribing S8 opioids in a different way to the majority of their peers, followed up by advisory letters to influenced prescribing behaviour.

Use of Poisons Standard appendices to provide additional regulatory controls

The use of regulations to control prescribing by particular types of medical practitioners is discussed above.

The AMA would support exploring the benefits of additional safety directions, label warning statements or specific dispensing labels aimed at reducing unintended misuse or overdose by health practitioners and patients.

Require the availability of smaller pack sizes for treatment of patients with acute pain as well as larger pack sizes for people with cancer-related chronic pain

The AMA supports the availability of smaller pack sizes, as long as larger pack sizes are still available. Smaller pack sizes would also be useful in preventing waste in the treatment of end stage palliative care patients. AMA members report that a patient may sometimes only require one or two doses at end of life, but only the larger pack size is available for prescription.

Review the indications for strong opioids

The AMA supports a Department of Health review of indications for strong opioids products with the aim of potentially aligning them with current clinical guidelines. It would be helpful for doctors and patients if the indications described in the Product Information align with current clinical guidelines. However it will be important to ensure the reference clinical guidelines are nationally regarded and clinically accepted, and that any changes are based on extensive consultation.

Increase prescriber awareness of opioid alternatives to manage chronic pain

The AMA supports stronger Department of Health engagement in education activities aimed at improving appropriate management of chronic pain.

Require risk management plans for opioid products

The AMA notes that the TGA considers ‘health care professional education and training’ could be one of the risk minimisation strategies required in an opioid medicine’s risk management plan. However, while acknowledging that professional education and training activities that meet the requirements for CPD points are generally conducted at arms-length from the sponsor, the AMA considers this option would add little value.

The AMA fully supports the independent and evidence-based educational material and activities delivered by NPS MedicineWise.

Review warning labels and revise Consumer Medicine Information

The AMA supports exploring additional measures to warn patients about the risks of dependence, overdose and lack of efficacy in treating long-term chronic non-cancer pain. It may also be helpful to include links to reputable patient education websites in the CMIs.

Expedited TGA review of improved products for pain relief and opioid antidotes

The AMA previously supported the TGA's priority review pathway because the evaluation of novel medicines submitted for registration is underpinned by the usual standards of evidence. On this basis, the AMA supports this option.

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Contact

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