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SUBMISSION

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Public consultation for the review of the accreditation standards for pharmacist prescriber education programs

Introduction

Health ministers have tasked the Pharmacy Board of Australia (PBA) with establishing a set of national standards and guidelines for pharmacist prescribing, which has led to the PBA's proposed scheduled medicines endorsement for pharmacists. The Australian Pharmacy Council (APC) is reviewing the accreditation standards for pharmacist prescriber education programs to support this endorsement. The Australian Medical Association (AMA) thanks the APC for the opportunity to provide feedback to this consultation.

The AMA has consistently highlighted the important role pharmacists play in our healthcare system. Pharmacists are experts in medicines, with capabilities encompassing pharmacology, drug interactions and medication safety, and they function as a critical safety checkpoint in the management of medicine use.

The PBA's proposal to enable pharmacists to autonomously prescribe scheduled medicines (up to and including Schedule 8 medicines, where authorised by jurisdictional legislation) would remove this key safeguard and jeopardise patient safety. It would also introduce serious issues that would place patients at further risk, including concerns around pharmacists' qualifications and training for autonomous prescribing, conflicts of interest, fragmentation of patient care, and unintended effects on the broader health system (such as contributing to the problem of opioid addiction and antimicrobial resistance).

In the absence of a robust, evidence-based, cost-risk-benefit analysis of the available options for pharmacy prescribing, the AMA has recommended that the PBA defer the proposed endorsement until these pertinent issues can be appropriately addressed.

The AMA acknowledges that the accreditation standards for pharmacist prescriber education programs are a key component of the PBA's proposed endorsement. They are a critical regulatory safeguard that helps ensure future pharmacist prescribers are sufficiently trained and qualified. Given

the endorsement itself has not been finalised, the AMA strongly recommends that the review of the accreditation standards be postponed until the scope of the endorsement is determined.

Revised pharmacist prescriber education programs accreditation standards

We recognise the effort the APC has undertaken to update the accreditation standards, including conducting literature reviews on the evidence for pharmacy prescribing, accreditation standards for non-medical prescribers in Australia, and international standards for pharmacy prescribing.

The AMA welcomes the following inclusions in the proposed standards:

- a minimum program requirement of AQF Level 8
- references to collaboration with other health professionals and the importance of team-based model of care
- a new domain outlining the requirements for cultural safety in relation to Aboriginal and Torres Strait Islander peoples
- clear acknowledgment of conflicts of interest
- the competencies required by the National Prescribing Competencies Framework.

The AMA also appreciates the changes made to the draft standards following the recommendations we provided during an earlier targeted consultation period, including:

- limiting enrolment in prescriber education programs to pharmacists who hold general registration (rather than the original proposal, which included applicants for general registration)

- including the qualifier that 'designated prescriber' supervisor must be suitably qualified, particularly given that the standards state that "at times, supervision may be delegated to other members of the healthcare team". However, the AMA maintains that only medical practitioners and nurse practitioners (acting within their scope of practice) are appropriately qualified to provide prescribing supervision

- clarifying that most of the international models reviewed as part of this consultation require a post-graduate qualification. More importantly, many of these overseas programs, including those in the United Kingdom and New Zealand, are not designed to train community pharmacists. Rather, they train pharmacists who would work within a highly defined scope of practice, often as part of a collaborative team within general practice. Australia has a strong, world-class healthcare system with its own distinct challenges, and we should avoid cherry-picking approaches from other countries, especially in the absence of any compelling supporting evidence.

Feedback on the consultation paper and proposed accreditation standards

The AMA, however, remains concerned with several aspects of the proposed accreditation standards, for which we have provided the following feedback.

1) In the consultation paper, the APC has stated its preferred option for the consultation (to revise and update the standards) and its rationale across two tables. The APC explains this approach

would support the PBA's endorsement and create a nationally consistent, safe and contemporary framework for pharmacist prescribing.

While the AMA agrees that pharmacist prescribing has occurred at different stages across jurisdictions, resulting in inconsistencies, this is primarily caused by the hasty expansion of pharmacists' scope of practice. Numerous trials and pilots have been implemented in quick succession before appropriate post-program evaluations could be undertaken.

Similarly, the current consultation recommends the accreditation standards be updated before the PBA's endorsement is finalised. The standards would need to include different requirements and competencies depending on the outcome and scope of the endorsement, particularly in relation to contentious aspects such as scope of practice, conflicts of interest, management of health records, and collaboration with other practitioners.

The AMA does not support the information presented in the options table (page 9). In our view, option 1 (status quo) would allow the discourse around pharmacist prescribing to play out and inform any endorsement for pharmacist prescribing. It would also allow all ongoing trials and programs to be properly evaluated. On the other hand, option 2 could be disadvantageous if the standards set through this consultation fall out of step with the endorsement outcome. In that case, the standards would not reflect contemporary pharmacist prescribing practice, and patient safety could be adversely affected if the requirements are not sufficiently rigorous.

2) While the AMA appreciates the literature review the APC has prepared, the results presented need to be interpreted with caution.

In its summary, the APC claims that the literature supports pharmacy prescribing as improving access to and convenience of care, achieving comparable clinical outcomes to doctor-led care, delivering effective safety outcomes, and being cost-effective. However, the literature review does not distinguish between models of pharmacist prescribing (collaborative, protocol-driven or independent) or between different types of pharmacist prescribing (for example between community- or hospital-based pharmacists).

A recent rapid review prepared by the Sax Institute focused specifically on autonomous pharmacist prescribing in the community pharmacy setting and selected recent peer-reviewed studies with quantitative outcomes. These distinctions are important because they reflect the PBA's proposed endorsement. The Sax review concluded that, while there is some evidence autonomous pharmacist prescribing in community pharmacies improves access, there is limited evidence demonstrating improvements in clinical, safety or health service outcomes. The studies that do provide data for these outcomes were assessed to be weak evidence. Additionally, the review concluded there is limited evidence to support this model of pharmacist prescribing in Australia, which is consistent with the AMA's feedback above.

Indeed, the APC's own review concludes that evidence supporting pharmacist prescribing is strongest in interprofessional teams and in models incorporating standardised protocols or

guidelines. Similarly, safety outcomes were most evident in these pharmacist prescribing models rather than in autonomous prescribing models.

Appraised in this context, the APC's review provides evidence against the autonomous pharmacist prescribing model proposed in the PBA's endorsement and instead supports the interprofessional, collaborative models of care that the AMA has advocated for.

3) The Health Professionals Prescribing Pathway (HPPP) states that it is critical for the registration standards of an endorsement for scheduled medicines to impose restrictions on the endorsement commensurate with the level of risk associated with the prescribing practice. It also highlights that safe prescribing requires health professionals to work within the boundaries of their scope of practice. This is clearly reflected in the recent joint open letter that the AMA and other key stakeholders wrote to the Board regarding the safe expansion of diagnostic authority and prescribing in Australia — expansion of prescribing authority must occur within a governance model with clearly defined roles and responsibilities.

   In contrast, the PBA's endorsement expands the classes of medicines pharmacist prescribers could prescribe to include Schedule 8 medicines and refrains from specifying their scope of practice. Instead, the proposal recommends pharmacist prescribers self-assess and determine their individual scope. In turn, the APC recommends future prescriber programs guide students in defining and documenting their scope of practice and ensure graduates have the foundational knowledge and competencies to prescribe within that scope.

   While the proposed accreditation standards include requirements for graduates to demonstrate competencies in comprehensive patient assessment, differential diagnosis, and the entire prescribing process (Criteria 5.7 and 5.8), it remains unclear how future programs would be structured to enable graduates to achieve them. Current pharmacist prescribing courses provide only 120–150 hours of supervised clinical experience. In comparison, medical practitioners gain these critical skills through extensive medical training, which includes a minimum 5,000 hours of clinical experience.

   More critically, it is unclear how future programs would accommodate differences in scopes of practice among graduates (for example, a pharmacist intending to prescribe Schedule 4 medicines versus one intending to prescribe Schedule 8 medicines). The conditions for which Schedule 8 medicines are prescribed are often more serious and complex. Importantly, Schedule 8 medicines are associated with risks of dependence and misuse. For this reason, medical practitioners prescribing Schedule 8 medicines are subject to additional requirements, including authority prescription approval, compliance with real-time prescription monitoring systems, and increased regulatory scrutiny. If the competencies outlined by the accreditation standards are intended to be "foundational", the standards should outline the additional competencies required for pharmacists intending to practise at the higher end of the proposed scope, as well as the associated educational programs and assessment requirements. The proposed one-size-fits all approach is not sufficiently robust to protect patient safety.

4) The AMA appreciates the inclusion of the Learning Domain document, which provides additional information on the knowledge, skills and competencies that pharmacist prescribers need to demonstrate upon completing the program. However, in addition to the issue raised in the previous section regarding scope of practice, the Learning Domain document should provide further details on the matters outlined below.

   There is a serious conflict of interest in allowing pharmacist prescribers to both prescribe and dispense a medicine. Having a colleague from the same premises dispense a prescription written by a pharmacist prescriber still constitutes a significant conflict of interest. While the proposed standards address conflicts of interest relating to program governance and delivery (Criterion 2.2), they do not outline the competencies required to manage the conflicts of interest that pharmacist prescribers would encounter as autonomous prescribers. The management of these conflicts of interest should be included in the Learning Domain document and independently assessed.

   The Learning Domain document outlines several important competencies related to professional practice that support safe and effective prescribing, including the management of chronic conditions, clinical governance, continuity of care, the use of AI technologies in practice, interprofessional collaboration and communication, and public health awareness. However, the document does not detail how these competencies would be effectively delivered, monitored and assessed within the prescriber programs.

Conclusion

The AMA has consistently asserted that non-medical prescribing should occur within a medically led, collaborative and delegated team environment in the interests of patient safety and quality of care. This would allow the implementation of appropriate safeguards to address the unintended consequences and unforeseen issues that non-medical prescribing has created overseas. The AMA remains committed to further discussions on the challenges facing our health system, as well as the potential solutions available, and to working with other key stakeholders towards a healthcare model that meets the needs of the community.

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