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Pharmacist prescribing discussion paper

AMA submission to the Pharmacy Board of Australia

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The AMA is pleased to respond to the discussion paper – *Pharmacist prescribing* – released by the Pharmacy Board of Australia regarding expanding the scope of practice of pharmacists to the prescribing of Schedule 4 (S4) and Schedule 8 (S8) medicines.

The AMA places a high value on the professional role of pharmacists in working with medical practitioners and patients to ensure medication adherence, improve medication management, and provide education about medication safety. We have been working collaboratively with the Pharmaceutical Society of Australia to better integrate pharmacists' expertise within general practice.

We support models of care that fully utilise pharmacists' training and expertise, within their scope of practice.

The AMA also strongly supports nationally consistent approaches to prescribing by non-medical health practitioners, and therefore the national framework for non-medical health practitioner prescribing approved by the Council of Australian Governments (COAG) and administered by the Australian Health Practitioners Regulation Agency (AHPRA).

Within this context, the AMA supports collaborative models of health care where non-medical health practitioners may prescribe within their scope of practice in a medically-led and delegated team environment.

This submission details the AMA's policy regarding prescribing of S4 and S8 medicines by non-medical practitioners; its views on different models of prescribing; and the requirements that should be met, and the processes that should be followed, by non-medical health practitioner national boards seeking to prescribe.

The submission highlights gravely worrying assumptions by the Pharmacy Board, including: the proposal to bypass the nationally agreed process for applications to prescribe; the denial that

the proposals represent a significant expansion of pharmacists' scope of practice; and a lack of acknowledgement that its proposals will impact on the broader health workforce.

The AMA also challenges the Board's evidence that patients in Australia do not have appropriate access to medicines, and the rationale that a solution to this claimed inadequate access is expanding prescribing rights to non-medical health practitioners.

Finally, the submission emphasises the role of medical practitioners, particularly general practitioners, in providing holistic care for patients, well beyond a simple 'prescription transaction'.

In this submission, 'prescribing' refers to the prescribing of S4 and S8 medicines. Pharmacists are currently authorised and expert in dispensing and supplying S2 and S3 medicines.

National governance framework for non-medical health practitioner prescribing

The discussion paper suggests that pharmacist prescribing of S4 and S8 medicines under protocol or supervision could be pursued without any additional Pharmacy Board regulation or Ministerial Council approval.

It is true that, legally, each state and territory can independently amend its regulations to allow pharmacists to prescribe S4 and S8 medicines with no concern for national consistency, core national standards of prescribing practice, workforce mobility, impact on other health professions, patient out-of-pocket costs, patient safety, and so on.

However this would represent a fundamental undermining of the years of development, consultation, negotiation and agreement that culminated in Australian Health Ministers agreeing in 2016 to introduce a national governance framework and process for non-medical health practitioners to apply to prescribe or expand their prescribing of medicines.

This agreement by Health Ministers acknowledged the risk to patient safety highlighted in the *Health Professionals Prescribing Pathway Project Final Report* (HPPP) of 2013¹. The final report described the ever-increasing ad hoc and inconsistent practices and approaches to education, practitioner competence and prescribing occurring across various non-medical health professions and within various jurisdictions. The primary objective of the HPPP project was to address these critical concerns.

The final report made several recommendations to address this problem, including that:

- National Boards publish applicable standards, codes or guidelines to support the endorsement of health practitioners to prescribe including recency of practice and continuing professional development requirements;

¹ Health Workforce Australia, *Health Professionals Prescribing Pathway Project Final Report*, November 2013.

- Accreditation Councils develop education and training standards for approval by National Boards, and assess education providers and programs against education and training standards and the *National Prescribing Competencies Framework*;
- AHPRA and National Boards develop and implement consistent inter-professional guidelines to support standards; and
- State and Territory governments commit to the development of national inter-government governance arrangements for the conferring of prescribing authorities on health practitioners.

The last two recommendations have been implemented in the form of the Health Ministers agreement to adhere to the AHPRA-developed *Guidance for National Boards* – to which all National Boards contributed. Other National Boards, such as the Nursing and Midwifery Board of Australia (NMBA), are conscientiously complying with the Guidance, in order to implement the first two recommendations. The Pharmacy Board should refer to the NMBA's work to develop, and consult on, an endorsement for registered nurses to prescribing under supervision.

The AMA cannot comprehend why the Pharmacy Board is contemplating pursuing prescribing rights for its health practitioners outside this transparent, robust, and nationally consistent process.

As stated in the AHMAC *Guidance for National Boards*, the objectives of Health Ministers in agreeing to a national process, are to:

- ensure robust, evidence-informed development and assessment of proposals for the use of scheduled medicines;
- promote the safe and effective use of scheduled medicines;
- facilitate common standards across professions for training and clinical practice with respect to the use of scheduled medicines; and
- facilitate nationally-consistent, core schedule medicines authorities to enable innovation in health service delivery.²

The AHPRA/COAG framework ensures a nationally consistent and transparent process for non-medical health practitioners to prescribe or expand their prescribing.

² Australian Health Ministers' Advisory Council, *Guidance for National Boards: Applications to the Ministerial Council for approval of endorsement in relation to scheduled medicines under section 14 of the National Law*, 2016, page 1.

If the Pharmacy Board supports its practitioners to pursue a jurisdiction-by-jurisdiction authority to prescribe it will lead to inconsistent and ad hoc practices and approaches to education and training, standards and prescribing practices, practitioner competence and

continuing professional education requirements. At a minimum it creates confusion for health practitioners and patients moving interstate, as highlighted in the Board's own discussion paper when referring to pharmacist prescribing in Canada (page 4). At worst, this poses a risk to patient safety.

From a workforce perspective, it will limit pharmacist mobility across jurisdictions and possibly within jurisdictions, and its impact on other registered health practitioners, for example, nurse practitioners and registered nurses endorsed to prescribe, cannot be adequately assessed and addressed.

Jurisdictions and health practitioners working in silos is not an appropriate way to design the health care system to meet the future needs of the community.

The primary reason the AMA opposed the introduction of pharmacist vaccinations in community pharmacies in 2013-14 was because its initial introduction in Queensland was not underpinned by a national approach to education, training, standards or guidelines.

The Pharmacy Board will recall that the AMA wrote to it on 20 February 2014 about the lack of adequate and appropriate accredited training for pharmacists to prescribe and administer vaccines or deal with adverse events arising from vaccinations. The Pharmacy Board itself stated in a 5 December 2013 communique that work on competencies and training was required before vaccination by a pharmacist should occur. And yet the Queensland government implemented pharmacist vaccinations without requiring that pharmacists prescribing and administering vaccinations had completed an accredited education and training program approved by the Board.

Instead, the Pharmacy Board had to 'play catch-up', with appropriate accredited training only developed and implemented after several jurisdictions had already introduced pharmacist vaccinations.

Does the Pharmacy Board really want to encourage a return to this kind of 'model' for prescribing S4 and S8 medicines?

The Pharmacy Board has a critical role in ensuring that: competencies and standards are established; commensurate training programs are developed and accredited; programs of study are approved; and a registration standard for endorsement for scheduled medicines is set.

The AMA urges the Board to embrace its leadership role and insist that its members pursue any model of pharmacist prescribing within the governance of the national approach administered by AHPRA and approved by Health Ministers in 2016.

Prescribing standards and training

Safe, high quality patient care depends on multidisciplinary teams of health practitioners, led by a medical practitioner, working together within their scopes of practice.

Medical practitioners are currently the only health professionals trained to fully assess a person, initiate further investigations, make a diagnosis, and understand the full range of clinically appropriate treatments for a given condition, including when to prescribe and, importantly, when not to prescribe medicines.

The NPS MedicineWise *Prescribing Competencies Framework*³ provides the benchmark for safe, appropriate and quality prescribing. The Framework sets high standards of competencies for independent diagnosis and prescribing and requires that the prescriber is responsible and accountable for their prescribing decision.

Independent prescribing of S4 and S8 medicines should only be practised by health practitioners whose core training fully and comprehensively achieves the competencies set out in the Framework.

Currently only medicine and dentistry core education and training programs deliver the full set of required competencies and therefore meet the 'autonomous prescribing category' described in the *Health Professionals Prescribing Pathway*. Only medical practitioners have training and skills which encompass prevention, pre-symptomatic detection of disease, early diagnosis, diagnosis of established disease, management of disease, management of disease complications, pathology/imaging interpretation, rehabilitation, terminal care and counselling.

Prescribing under supervision and prescribing under protocol, while not carrying the same risks to patients as autonomous prescribing, still require non-medical health practitioners to undertake additional accredited education and training specific to their scope of practice, which ensures practitioners meet consistent and measurable standards and competencies.

It is therefore very concerning that the discussion paper suggests that this type of prescribing is already within pharmacists' scope of practice and very little additional training would be required.

Pharmacist prescribing of these medicines is clearly a dramatic change to the practice of pharmacists in Australia. There is no pharmacist prescribing in Australia beyond very recent, isolated trials within a closely medically-supervised environment.

To suggest prescribing of S4 and S8 medicines under supervision or under protocol is already within the scope of pharmacists' practice is false and an insult to medical practitioners, and all non-medical health practitioners endorsed to prescribe who have undertaken additional,

³ NPS MedicineWise, *Prescribing Competencies Framework*, 2012

nationally consistent, accredited education, training and assessment, and met the further prescribing standards and competencies set by their Boards.

Models of non-medical health practitioner prescribing

Commonwealth and state/territory legislation effectively restricts non-medical health practitioners from prescribing autonomously, recognising the limitations of scopes of practice and in support of the quality use of medicines. The exception is dentists, as noted above, and a small number of non-medical health practitioners able to prescribe from a limited formulary, for example, optometrists may prescribe certain antibiotics in specific, limited circumstances.

Otherwise, non-medical health practitioners must be in a collaborative arrangement with a supervising medical practitioner in order to prescribe S4 and S8 medicines. For example, privately practising midwives and nurse practitioners may only prescribe PBS subsidised medicines if they are in a collaborative arrangement with a medical practitioner, and midwives and nurses who are salaried or working in the public system must also practice and prescribe within collaborative arrangements with medical practitioners and in line with proscribed protocols.

The AMA supports collaborative models of health care where non-medical health practitioners work as part of a medically-led team.

The AMA supports non-medical prescribing underpinned by the following principles:

- Non-medical prescribing occurs in a medically led and delegated team environment.
- Non-medical prescribing occurs in the context of 'role delegation' not 'task substitution'.
- There must be formally documented, collaborative arrangements that ensure:
 - diagnosis, ongoing monitoring, and evaluation of adverse events by a medical practitioner
 - clear lines of accountability and responsibility
 - separation of prescribing and dispensing (with limited exceptions as appropriate in rural/remote circumstances).
- Non-medical health practitioners must have core skills and appropriate competencies for safe prescribing attained by completing high quality, accredited education and training courses.
- Course curriculum must meet core competencies in determining when not to prescribe and/or when to refer patients to a medical practitioner.
- As occurs for medical practitioners, non-medical health practitioners should be closely supervised during their first years of prescribing practice.

- Non-medical health practitioner prescribers must bear some risk for their prescribing decisions.

Models of non-medical prescribing supported by the AMA include:

- prescribing by a protocol or limited formulary;
- initiating therapy according to protocol or symptoms; and/or
- continuing, discontinuing and maintaining therapy according to a pre-approved protocol.

The examples of pharmacist prescribing provided in the discussion paper are medical practitioner-led and supervised.

The AMA does not support independent or autonomous prescribing of S4 and S8 medicines by non-medical health practitioners, with the exception of dentists.

As detailed above, medical practitioners are currently the only health professionals trained to fully assess a person, initiate further investigations, make a diagnosis, and understand the full range of clinically appropriate treatments for a given condition, including when to prescribe and, importantly, when not to prescribe medicines.

A general practitioner, for example, has undertaken 10-14 years of training compared to pharmacists who have four years of training in a specific, focused area. Using their training, a general practitioner holistically assesses, examines, investigates, diagnoses, refers and coordinates multidisciplinary teams for patients.

A consultation between a general practitioner and a patient is not just a simple transaction about prescribing a medicine; every general practitioner visit includes opportunistic discussions with patients about a range of health care needs, including evidence-based prevention and screening services.

The Pharmacy Board's paper indicates that 'access' is the primary driver of need. The AMA considers that safe, high quality patient care depends on multidisciplinary teams of health practitioners, led by a medical practitioner, working together within their scopes of practice.

It relies not only on 'access' but on a patient-centred 'medical home' which provides continuity, coordination, comprehensiveness and accountability. Fragmentation of care decreases the patient experience, increases risks and increases costs. Any 'savings' from fewer GP consultations would be short-term as savings would be undermined by a reduction in preventive health care and subsequent downstream costs resulting from later presentations of established illnesses.

Conflicts of interest

As indicated above, the AMA maintains there should be a clear separation between the prescribing and dispensing of medicines.

This removes any real or potential or perceived conflict of interest in deciding the most appropriate treatment for patients, for example, which medicine to prescribe, or not to prescribe, any medicine.

If pharmacists can both prescribe and dispense it represents a fundamental conflict of interest as they derive a direct income from the sale of medicines. In addition, there is the opportunity and motivation within a retail pharmacy setting to 'upsell' additional products that may not be necessary for the patient.

Pharmacists both prescribing and dispensing also compromises medicine safety. The Pharmacy Guild itself states in its guide on the dispensing process that the 'separation of prescribing and dispensing medicines provides a safety mechanism as it ensures independent review of a prescription occurs prior to the commencement of treatment'⁴.

The AMA therefore opposes any prescribing of S4 and S8 medicines by pharmacists working in, employed by, or associated with, a retail pharmacy.

Evidence and rationale

In the interests of supporting patient safety and cost-effectiveness for the health care system, the AMA's view is that any expanded scopes of practice by non-medical health practitioners must be underpinned by a process that ensures:

- there are no new safety risks for patients;
- the change to scope of practice is rationally related to the practice of the profession and to core qualifications and competencies of their profession;
- the change in scope of practice is consistent with the evolution of the healthcare system and the dynamics between health professionals who work in collaborative, medically-led healthcare models;
- the training opportunities for other health practitioner groups is not diminished; and
- the cost to the health care system will be lower than the current service offering, taking account of supervision costs.

⁴ Pharmacy Guild of Australia, *Dispensing your prescription medicine: more than sticking a label on a bottle*, https://www.guild.org.au/__data/assets/pdf_file/0020/5366/the-dispensing-process.pdf

In addition, processes for expanding scopes of practice should also ensure that:

- the required competencies are predetermined, and accredited training and education programs are available to deliver those competencies; and
- there are documented protocols for collaboration with other health practitioners.

The *Guidance for National Boards* is closely aligned with these criteria.

The Guidance requires that non-medical health practitioner national boards must address a range of matters in their applications, including whether:

- the service need is well documented;
- an evidence-based approach has been adopted;
- an integrated, cross-profession approach has been applied including qualification requirements, clinical practice standards, training and curriculum;
- adverse views of stakeholders have been adequately addressed; and
- the proposal is compatible with the *National Medicines Policy* and the *Quality Use of Medicines*.⁵

The Pharmacy Board must do considerably more work to adequately address the above matters in its discussion paper.

For example, the Pharmacy Board will find it challenging to find relevant evidence for an Australian context that pharmacist prescribing will meet an unmet public need. International models are difficult to extrapolate to an Australian setting where access to quality health care in the primary and acute care setting is generally high, where most general practitioner consultations are bulk-billed, and where registered nurses, nurse practitioners and aboriginal health care workers already complement and supplement care provided by medical practitioners.

It will be particularly difficult to argue that prescribing by pharmacists in the primary health care and acute care setting will be more effective and cost-effective than prescribing by nurses.

The cost effectiveness of non-medical prescribing as a replacement or adjunct to medical prescribing is also uncertain.

⁵ Australian Health Ministers' Advisory Council, *Guidance for National Boards: Applications to the Ministerial Council for approval of endorsement in relation to scheduled medicines under section 14 of the National Law*, 2016, pages 5-6.

A recent Cochrane review⁶ of non-medical prescribing for acute and chronic disease management in primary and secondary care found mixed levels of evidence around a range of health management outcomes. The review includes 20 studies with pharmacists and is included in the discussion paper's own references.

The review indicates that there appeared to be moderate to high levels of evidence that with appropriate training and support, non-medical prescribers were able to prescribe medicines as part of managing a range of conditions.

The majority of studies focused on chronic disease management with moderate certainty of evidence supporting positive outcomes for managing – specifically –high blood pressure, diabetes, and high cholesterol. Importantly, in these studies non-medical prescribers frequently had medical support available in a collaborative care practice model.

However, overall there was poor level evidence for prescribing outcomes in relation to avoiding adverse events and achieving health economic (cost effectiveness) outcomes. In addition, in the majority of studies reporting medication use, non-medical prescribers prescribed more drugs, intensified drug doses and used a greater variety of drugs compared to usual care medical prescribers.

The expansion of prescribers therefore risks increasing PBS expenditure without necessarily leading to any better health outcomes for patients.

Increased prescribing is also of particular concern considering that Australia is currently seeking to reduce overprescribing, e.g. antibiotics and opioids. Promoting patient discussions about non-pharmacological solutions should be a priority rather than expanding the range of prescribers. This is not compatible with the *Quality Use of Medicines* policy.

The discussion paper also states that prescribing by pharmacists will improve access to medicines. Our view about 'access' being a primary driver is already detailed above. In any case, the sources used to back up this statement have become out-of-date.

Australian Bureau of Statistics (ABS) and Department of Health data indicate instead an improvement in patient access to medical practitioners over the last 10 years or so.

The number of medical practitioners per 100,000 of the Australian population – both specialists and general practitioners – is substantially higher now than it was in 2008-09.

The number of general practitioners has increased substantially over the last ten years particularly in outer regional, remote and very remote areas. This data show increases, whether it is for the total number of GPs, number per 100,000, full service equivalents (FSE), or FSE per 100,000. For example, across Australia, in 2017-18 there were 102.2 FSE GPs per 100,000

⁶ *Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care (Review)* Weeks G, George J, Maclure K, Stewart D, The Cochrane Collaboration 2016, www.conchanelibrary.com

population compared to 79 in 2008-9; and in very remote areas of Australia, there were 70.5 FSE GPs per 100,000 population in 2017-18 compared to 38.8 in 2008-9.⁷

The most recent ABS survey of patient experiences in Australia also shows an improvement in 'people waiting longer than they felt acceptable' to see a GP – falling from 23% in 2013-14 to 19% in 2017-18⁸.

As well as numbers of medical practitioners increasing, technological solutions have also rapidly evolved to improve access to more convenient, immediate and higher quality health care.

In any case, the issues and underlying reasons behind any maldistribution of medical practitioners also apply equally to pharmacists. It is highly likely that an area with shortages of general practitioners will also have limited access to pharmacists.

The AMA agrees that there are: 'many ways in which pharmacists could ... reduce medicine-related misadventures and improve the efficiency and cost effectiveness of the use of medicines' (page 5, discussion paper). However, not necessarily through prescribing.

Summary

The AMA's key points are as follows.

The AMA supports non-medical practitioner prescribing within collaborative models of health care where non-medical health practitioners work as part of a medically-led team.

Models of non-medical prescribing supported by the AMA include:

- prescribing by a protocol or limited formulary;
- initiating therapy according to protocol or symptoms; and/or
- continuing, discontinuing and maintaining therapy according to a pre-approved protocol.

The AMA does not support independent or autonomous prescribing of S4 and S8 medicines by non-medical health practitioners, with the exception of dentists.

The AMA opposes any model of prescribing by pharmacists employed by, or working in, or associated with, a retail pharmacy.

⁷ <http://www.health.gov.au/internet/main/publishing.nsf/Content/General+Practice+Statistics-1>

⁸ Australian Bureau of Statistics *Patient experience in Australia: summary of findings 2017-18*
<http://www.abs.gov.au/ausstats/abs@.nsf/mf/4839.0>

The AMA opposes any expansion of pharmacist prescribing to S4 and S8 medicines outside the COAG/AHPRA governance framework agreed by all Health Ministers in 2016.

In order to pursue pharmacist prescribing, the Pharmacy Board must provide sound evidence that:

- there is a clear, demonstrated service need;
- there are no new safety risks for patients;
- the change in scope of practice will not impact on other health professionals; and
- the cost to the health care system will be lower than the current service offering, taking account of supervision costs.

This evidence has not been provided.

APRIL 2019

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