# MEDICINES

## 2021

### 1. Introduction

1.1. This document outlines the AMA position on timely access to affordable medicines and the safe, efficient, and quality use of medicines in Australia.

1.2. The term 'medicine' includes prescription, over-the-counter and complementary medicines, and vaccines. Further policy specific to complementary medicines is provided in the AMA position statement *Complementary Medicine – 2018*.

### 2. Medicines policy development

2.1. The AMA supports the National Medicines Policy[1].

2.2. The AMA supports the maintenance of an independent national medicines advisory body, with membership from groups who have an interest in the safe, efficient and quality use of medicines and medicines policy in Australia. This forum is important to discuss and debate changes in the medicines environment and to promote, influence and assist in the implementation of the National Medicines Policy in Australia.

### 3. Quality use of medicines

3.1. The AMA supports the National Strategy for the Quality Use of Medicines[2].

3.2. Medical practitioners have a responsibility to:

a) select management options wisely by considering all treatment options which will best, and most cost-effectively, manage a patient's health care needs
b) choose the most suitable medicines when medicines are considered appropriate, taking into account the potential for self-harm, and the ability of the patient to adhere to the dosage regimen
c) ensure medicines are used safely and effectively, and that patients are fully informed of the relevant side effects of medicines as well as the relevant interactions between medicines
d) report any adverse reactions to the TGA.

3.3. Patients have a responsibility to:

a) advise their prescriber about any other medicine they are taking, including over-the- counter and/or complementary medicines
b) take their medicines as directed
c) report any adverse event associated with medicines to their prescriber.

3.4. The AMA supports the activities of NPS MedicineWise to provide independent, accurate, balanced, evidence-based information on the quality use of medicines.

### 4. Access to medicines

4.1. The AMA supports the development of policy and infrastructure that improves access to medicines, improves population and individual health outcomes, and reduces the disparity in health outcomes for vulnerable groups.

[1] Commonwealth of Australia (2019) *National Medicines Policy.*
[2] Commonwealth of Australia (2002) *National Strategy for Quality Use of Medicines.*

4.2. Recognising that medicines shortages have become increasingly common in Australia and present a serious risk to patients, the AMA supports comprehensive strategies to address these, including the domestic manufacturing of medicines, to:

a) Reduce negative impacts and risks to patients posed by shortages of imported medications
b) Create sovereign industrial capability to manufacture medications to ensure the adequate security in times of serious disruption to overseas supply chains
c) Enhance Australia's medicine and vaccine research and development capabilities.

4.3. The AMA supports the principles of the Pharmaceutical Benefits Scheme (PBS) to provide universal access to appropriate medicines through registered medical practitioners in an effective, efficient and equitable manner, and encourages the development of PBS policy that contributes to optimal patient care.

4.4. The PBS safety net plays a vital role in improving access to medicines by limiting the out of pocket expenses for people who use a large number of prescribed medicines within a calendar year. The Government has an obligation to ensure any policy changes to the PBS safety net do not impact on timely access to affordable medicines for all Australians.

4.5. The AMA supports the independence and transparency of PBS listing and pricing functions through the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC plays a fundamental role in ensuring that the PBS subsidises safe, effective and affordable medicines and must be allowed to make decisions independently and free from political interference and sectional interests. The PBAC process is an evidence-based and equitable system for providing affordable, sustainable access to cost-effective medicines for all Australians.

4.6. The AMA upholds that medical practitioners must maintain clinical independence in order to make the best treatment recommendations for patients, based on current evidence. It is vital that the medical profession remains independent to make their own clinical judgments regarding treatment recommendations.

4.7. The AMA encourages medical practitioners to offer generic or biosimilar medicine choices when it is safe and appropriate to do so, and to discuss these options with patients. The AMA opposes any compulsion on medical practitioners to prescribe a generic or biosimilar medicine. There are good clinical reasons why generic or biosimilar medicines are not appropriate for some patients.

4.8. 'Off-label prescribing' is the prescription of a registered medicine for a use that is not included in the product information approved by the TGA, including when the medicine is prescribed or administered for another indication, at a different dose, via an alternate route of administration, or for a patient of an age or gender outside the registered use.

4.9. Off-label prescribing may be clinically appropriate, but there are clinical, safety, ethical, medico-legal and financial issues related to off-label use. The AMA supports the guiding principles for the quality use of off-label medicines developed by the Council of Australian Therapeutic Advisory Groups for public hospitals[3]. These principles should also guide private practice where relevant, in particular:

a) off-label use of a medicine should only be considered when other options are unavailable, exhausted, not tolerated or unsuitable
b) the patient/carer must be involved in decision-making
c) outcomes, effectiveness and adverse events should be monitored and reported to facilitate evidence-based decisions.

[3] Council of Australian Therapeutic Advisory Groups (2013) *Rethinking Medicines Decision-making in Australian Hospitals: guiding principles for the quality use of off-label medicines.*

4.10. There are certain situations where a face-to-face consultation in order to prescribe medicines may be impractical e.g. rural and remote areas. In these situations, the AMA supports the prescription of medicines related to clinical care by telehealth and electronic prescribing means where the medical practitioner has determined it is clinically safe to do so, a face-to-face consultation is not immediately required, and where systems are in place to record this communication in the patient record. Further policy specific to these kinds of consultations is provided in the AMA position statement *Technology-based patient consultations - 2013*[4].

## 5. Prescribing regulation

5.1. In the interests of patient safety, the AMA supports measures to control access to certain medicines that are prone to addiction and misuse.

5.2. The AMA supports the introduction and funding by governments of electronic systems to collect and report real-time prescribing and dispensing data relating to these medicines as an effective means of addressing problems of forgery, dependency, misuse, abuse and prescription shopping.

5.3. The AMA also accepts the need for measures to ensure high cost pharmaceuticals are used appropriately in the interests of effective PBS expenditure.

5.4. However, prescribing regulations and measures, such as the PBS Authority policy, should not pose a barrier to medical practitioners treating their patients or impose an administrative burden without evidence that they are effective and necessary.

5.5. Alternative approaches such as audit mechanisms, should be explored before additional regulation is imposed.

## 6. Prescribing rights

6.1. Only medical practitioners are trained to make a complete diagnosis, monitor the ongoing use of medicines and to understand the risks and benefits inherent in prescribing.

6.2. The AMA does not support independent prescribing by non-medical health practitioners outside a collaborative arrangement with a medical practitioner. Prescribing by non-medical practitioners should only occur within a medically led and delegated team environment in the interests of patient safety and quality of care. Further, the AMA recommends a system of mandatory referral to a registered medical practitioner where appropriate clinical criteria and outcomes are not achieved within a specific time frame.

6.3. The AMA's *10 minimum standards for prescribing* outlines the minimum standards that must be required of all prescribers authorised to prescribe Schedule 4 and 8 medicines[5].

6.4. The AMA supports the high standards required by the NPS MedicineWise Prescribing Competency Framework in order to safely prescribe independently[6].

6.5. When Commonwealth, State and Territory authorities allow limited prescribing (including access to PBS medicines), non-medical practitioners must have core skills and appropriate competencies for safe prescribing attained by completing nationally consistent and high quality accredited education and training courses that meet the high standards of the NPS MedicineWise *Prescribing Competencies Framework*. The AMA supports the *Health Professionals Prescribing Pathway*[7] endorsed by the Standing Council on Health in

[4] Australian Medical Association (2013) *Technology-based patient consultations – 2013.*
[5] Australian Medical Association (2019) *AMA 10 minimum standards for prescribing.*
[6] NPS MedicineWise (2021) *Prescribing Competencies Framework – 2nd edition.*
[7] Health Workforce Australia (2013) *Health Professionals Prescribing Pathway.*

November 2013 which sets out the five steps that a non-medical health practitioner must undertake to safely prescribe medicines.

6.6. The AMA supports the national inter-governmental arrangements for the conferring of prescribing authorities on non-medical health practitioners which were endorsed by the Council of Australian Governments in 2016, proscribed under the National Law, described in Guidance for National Boards, and are administered by the Australian Health Practitioners Regulation Agency[8]. These arrangements ensure nationally consistent approaches to prescribing by non-medical health practitioners that are transparent, robust and informed by evidence. They also ensure common standards across professions for training and clinical practice, and support the safe and effective use of prescription medicines. Any expansion of non-medical practitioner prescribing should only occur within this national framework.

6.7. The AMA supports independent prescribing by dentists. Dentists are trained to prescribe medicines for dental conditions and prescribe within their scope of practice.

## 7. Medicines regulation

7.1. The AMA supports the role of the Therapeutic Goods Administration (TGA), as the regulator of medicines in Australia, to ensure that medicines meet appropriate standards for quality, safety and efficacy.

7.2. Activities that allow the TGA to better pursue the quality use of medicines should be publicly funded. Cost recovery should only apply to the regulatory processes associated with supplying a medicine or device in Australia.

7.3. The TGA needs to be appropriately funded and resourced to ensure the safety of the system is maintained.

7.4. The AMA recommends medicines should only be up or down scheduled where there is strong evidence it is safe to do so, where there is demonstrated patient benefit and safety in dispensing the medication by this method, and where it would not adversely affect appropriate access to medicine.

7.5. The AMA supports a comprehensive product vigilance system in line with international best practice, and the development of proactive product vigilance strategies that improve data linkage and enhance the robustness of post market surveillance processes.

7.6. Adverse medicine events are in themselves a significant public health problem. The AMA supports improvements to adverse medicine event reporting systems. To reduce the risk of adverse events associated with prescription medicines, post-market monitoring must occur from the time a medicine first comes to market, complemented by the TGA's early warning system.

7.7. Where evidence supports a change in clinical practice, medicine product information must be updated in a timely manner in consultation with relevant medical craft groups and pharmaceutical manufacturers.

7.8. Government systems should ensure that medicine product information and consumer medicines information is in line with best practice in the interests of patient safety. These documents should not be allowed to become out-of-date because the patent period for a medicine has expired and generics have come on market.

[8] Australian Health Ministers' Advisory Council (2016) *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*

7.9. The Australian approved name of the active ingredient should be the primary identifier for all medicines and be given pre-eminence on the medicines label in the interests of safeguarding public health and safety.

7.10. The AMA supports a system of mandatory notifications which requires pharmaceutical suppliers to advise the TGA of potential and actual medicine shortages in Australia so that critical shortages can be identified early and effectively managed. The TGA should have primary responsibility for assessing the clinical risk of potential shortages in consultation with medical, pharmaceutical and other experts and working with the industry to mitigate risks.

7.11. All health practitioners should have access to evidence-based, up-to-date medicines information that is easily accessed from all health care settings.

## 8. Community pharmacy

8.1. Community Pharmacy plays an important role in providing medicines information to consumers and ensuring that all Australians have access to medicines in a timely and safe manner.

8.2. The AMA supports cost-effective models of Community Pharmacy that maintain professional, quality and safety standards. The AMA also supports government funded pharmacy programs which contribute to a sustainable PBS and a viable retail pharmacy industry irrespective of where a pharmacy is located.

8.3. It is important for patient safety and continuity of care that there is timely, clear and consistent communication between the medical practitioner and the pharmacist.

8.4. Pharmacists should dispense medicines in accordance with the patient's prescription unless the pharmacist has discussed and agreed changes with the patient's medical practitioner.

8.5. Dispensing decisions should primarily be driven by consideration of the benefit to the patient[9].

8.6. Patients should be aware that medication prices vary between pharmacies, including for items dispensed under the PBS.

8.7. Noting the various payment and brand options under the PBS, community pharmacy has a responsibility to dispense in a manner which is the most cost effective to the patient.

## 9. Pharmaceutical industry

9.1. The AMA believes that an efficient, financially viable, responsible and innovative pharmaceutical industry producing safe products of high quality will ensure Australia has access to new medicines at a price the patient, taxpayer and industry can afford.

9.2. The AMA supports an appropriate balance between patent periods that reward originators for innovation and the entry of generic pharmaceuticals into the market to increase affordability and access.

9.3. The AMA supports international harmonisation of the medicines industry, where access to a safe supply of medicines, and Australian standards for medicines regulation and therapeutic practice, are maintained.

[9] See Australian Medical Association (2016) *AMA Code of Ethics*.

9.4. The AMA supports pharmaceutical industry self-regulation through codes of conduct, of industry activities to promote prescription medicines. Codes of conduct should set out standards of ethical behaviour that must be adhered to by pharmaceutical companies and their representatives in relationships with health practitioners and patients. Codes of conduct should be regularly reviewed and updated in collaboration with relevant stakeholders including the medical profession.

**See also:**

*AMA Position Statement on Technology-based patient consultations - 2013*

*AMA Position Statement on Complementary Medicine – 2018*

*AMA Position Statement on the Doctor's Role in Stewardship of Health Care Resources – 2016*

*AMA Guidelines on 10 minimum standards for prescribing – 2019*