



AMA submission to the Department of Health – National Medicines Policy Review

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Summary of recommendations

Recommendation 1: A new objective must be made that recognises how Australia's broader health environment influences medicines use in Australia, and that the health system as a whole must be supported to achieve NMP objectives.

Recommendation 2: The current system is not upholding principles of equity or affordability of medicines and new policy should be developed to ensure:

- *there is no significant price variability of PBS or RPBS medicines across Australia, and*
- *The PBS Safety Net Threshold eligibility is achievable and easy to track.*

Recommendation 3: abolish pharmacy location and ownership rules to reduce consumer costs and increase access to medicines and pharmacists.

Recommendation 4: Implement the PBAC recommendation to dispense two months' worth of prescribed medicine at a time.

Recommendation 5: Initiate a review into improved models of dispensing in Australia that maintains important person-centred principles.

Recommendation 6: 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. Policies for expanding non-medical practitioner scope of practice should be consistent across Ahpra Boards.

Recommendation 7: The TGA should be appropriately resourced and supported to enhance its compliance monitoring functions, including to ensure that compliance for safety, quality, and efficacy occurs before listed medicines are available for supply.

Recommendation 8: The TGA Advisory Committee for Medicines Scheduling should consist of a wider range of experts in medicines, including a larger representation of independent medical practitioners.

Recommendation 9: NMP objectives should recognise the importance of adequately resourced prescribing environments to support QUM, including to reduce the risk of preventable medication harm.

Recommendation 10: The NMP objectives should recognise the importance of accessing non-pharmacological services from health practitioners to support QUM. Non-pharmacological services should be adequately supported and resourced to increase access.

Recommendation 11: Pharmacists should be supported to work under innovative, evidence-based care models that increase communication between transition of care points and improve QUM. This includes supporting an increase in general practice pharmacists.

Recommendation 12: NMP objectives must recognise and support enhanced communication between healthcare settings to reduce the risk of medication errors during transitions of care and support QUM.

Recommendation 13: A national strategy on polypharmacy should be developed under the NMP.

Recommendation 14: Medication reviews should be increased on an annual and as-needed basis for populations with high risk of polypharmacy such as older people.

Recommendation 15: Evidence-based guidelines for prescribing for older people should be developed.

Recommendation 16: The ‘maintaining a responsible and viable medicines industry’ must be re-focused to a person-centred approach.

Recommendation 17: The AMA calls on the Federal Government to develop and fund a comprehensive strategy to address medicine shortages, including domestic manufacturing of medicines, to:

- *reduce negative impacts and risks to patients posed by shortages of imported medications,*
- *create sovereign industrial capability to manufacture medications to ensure the adequate security of supply in times of serious disruption to overseas supply chains, and*
- *enhance Australia’s medicine and vaccine research and development capabilities.*

Recommendation 18: medicines approval processes should remain independent from stakeholders with direct conflicts of interest.

Recommendation 19: The AMA broadly supports the proposed NMP principles and believes medicines regulation consistency and communication should also be included as important principles.

Recommendation 20: Medical devices and other health technologies should have a separate national policy to medicines. Vaccines should be considered under the NMP.

Recommendation 21: Interoperability is integral to ensuring digital health solutions that support QUM are trusted and used and should be a key standard in any digital health regulation.

Recommendation 22: Digital health developers should be seen as key stakeholders under the NMP so they are accountable and responsible to uphold NMP objectives.

Recommendation 23: An independent national medicines advisory body should be implemented to carry out NMP objectives and to ensure the NMP remains relevant to today’s medicines system.

Recommendation 24: NMP objectives should recognise the different needs of Australia’s population groups, taking into account cultural background and social determinants of health.

Recommendation 25: Shared decision-making and informed consent are integral concepts to ensure a person-centred NMP.

Recommendation 26: The NMP objectives should promote improvement of health literacy to improve QUM and health outcomes.

Recommendation 27: A set of Key Performance Indicators should be developed to ensure the NMP is achieving its goals and to ensure NMP projects and policies are guided and remain accountable to the NMP.

Recommendation 28: Alternative health professionals should be included as NMP stakeholders so they are accountable to providing ethical, evidence-based, safe, efficacious, and high quality care.

Recommendation 29: Services that aim to meet NMP objectives (such as the Community Pharmacy Agreement) should be accountable, transparent, and evidence-based in the context of wider health system services and public health.

Introduction

The existing National Medicines Policy (NMP) outlines important objectives to achieve a high-quality medicines system in Australia and the AMA has long been a supporter of the NMP. While the objectives are still relevant to today's medicines environment, there are several additions that could improve the implementation of the NMP and ensure it remains relevant into the future. The objectives should remain high-level but should include underlying guidance and monitoring processes, so they are more easily implemented and tracked. The AMA would also support a review using performance indicators to measure how well Australia is upholding NMP objectives and future principles to achieve better health outcomes. This will help to identify key areas for reform.

It is important to consider Australia's broader public health environment when considering improvements to the NMP. While Australia is lucky to have one of the best health systems in the world, we also have a growing, ageing population¹ with an increase in the prevalence of multiple chronic, complex diseases². This warrants a focus on the social determinants of health, preventative care and reform to ensure the health system keeps pace with this fundamental shift. Polypharmacy is increasing in Australia, and those most at risk are people with multiple chronic conditions and older people. Approximately two thirds of older Australians (aged 75 years and over) take five or more medicines³. Medication errors cost the health system \$1.2 billion each year, with approximately 2-3 per cent of hospital admissions being medicines-related⁴. A lack of health literacy and the spread of misinformation in Australia increases the risk of medication errors, prevents patients from utilising evidence-based care and therapeutics, while reaching for non-evidence-based alternatives that may make their condition worse. Innovative models of care that would assist in reducing these risks are stifled by the current rules and regulations. Public hospitals⁵ and general practice⁶ are consistently underfunded and over-stretched, despite the quality care they provide and their potential to vastly improve the quality use of medicines (QUM). The health system can do better to achieve the NMP objectives if they have the right environment, funding, and support to do so.

Recommendation 1: A new objective must be made that recognises how Australia's broader health environment influences medicines use in Australia, and that the health system as a whole must be supported to achieve NMP objectives.

The existing objectives remain as relevant today as they did when first created. However, the AMA recognises that the medicines environment has changed significantly in this time. The NMP Review should identify key areas for improvement that should be reviewed and updated every ten years.

¹ Australian Institute of Health and Welfare (2018) [Older Australia at a glance](#).

² Australian Bureau of Statistics (2018) [Chronic conditions](#).

³ Australian Commission on Safety and Quality in Health Care (2021) [Fourth Australian Atlas of Healthcare Variation 2021. 6.1 Polypharmacy, 75 years and over](#).

⁴ Australian Commission on Safety and Quality in Health Care (2017) [Australia joins international push to halve medication errors](#).

⁵ Australian Medical Association (2020) [AMA public hospital report card](#).

⁶ Australian Medical Association (2020) [Delivering better care for patients: The AMA 10-year framework for primary care reform](#).

The following submission explores how well Australia's health system is meeting the NMP objectives and recommends changes to both the NMP and the health system itself.

Current objective: timely access to the medicines that Australians need, at a cost individuals and the community can afford

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. The main issues affecting patients' access to medicines include, affordability, current pharmacy ownership and location rules, and medicine shortages (see the section on maintaining a responsible and viable medicines industry for medicines shortages). Reform in this space should be evidence-based, independent and transparent.

Affordability

While Australia has important policies in place to reduce the cost of medicines in Australia such as the Pharmaceutical Benefits Scheme (PBS), price is still a major barrier to some patients accessing medicines⁷. In 2019-20, cost was the reason why 6.6 per cent of the Australian population either delayed filling or did not fill a prescription in the past 12 months⁸. A lack of medicine adherence can result in worse health outcomes and larger downstream costs for the health system^{9,10}. Price can vary across medicine brands, location, and pharmacies. The patient out-of-pocket cost is largely up to the discretion of the pharmacy up to the PBS co-payment of \$41.30 (general) or \$6.60 (concessional)^{11,12}, plus the potential for a brand price premium. This co-payment and the PBS Safety Net continue to increase annually to the Consumer Price Index while the Wage Price Index continues to decline¹³.

Generally, PBS-listed medicines are cheaper in metropolitan areas, creating further inequities between these areas and rural, regional and remote Australia¹⁴. A 2019 survey commissioned by Chemist Warehouse conducted in five regional towns in Victoria revealed that 65 per cent of respondents had travelled to pharmacies in other towns, 40 per cent of whom stated that price was the main factor for this decision. The survey also found that 77 per cent supported a change in pharmacy location rules to allow more competition in small towns¹⁵. The Competition Policy Review in 2015 suggested a range of methods to secure access to medicines, including tendering for service provision in underserved locations such as rural, regional and remote areas, community service obligation funding, or other obligations on pharmacies¹⁶. This submission explores changes to pharmacy ownership and location rules below.

⁷ Searles et al (2013) [The affordability of prescription medicines in Australia: are copayments and safety net thresholds too high?](#) CSIRO publishing.

⁸ Productivity Commission (2021) [Report on government services 2021: Health: Primary and community health.](#)

⁹ Organisation for Economic Co-operation and Development (2018) [Investing in medication adherence improves health outcomes and health system efficiency.](#)

¹⁰ Ortiz (2013) [Are prescription copayments compromising patient care?](#)

¹¹ King et al (2017) [Review of pharmacy remuneration and regulation.](#)

¹² Department of Health (2021) [Pharmaceutical benefits: Fees, patient contributions and safety net thresholds.](#)

¹³ Australian Bureau of Statistics (2021) [Wage Price Index, Australia.](#)

¹⁴ King et al (2017) [Review of pharmacy remuneration and regulation.](#)

¹⁵ Australian Journal of Pharmacy (2019) [The great pharmacy debate.](#)

¹⁶ Harper et al (2015) [Competition policy review: final report.](#)

The PBS Safety Net is underutilised. Some patients cannot afford to fill enough PBS prescriptions to reach the Safety Net Threshold¹⁷. The Safety Net also has complex eligibility and administrative requirements that leave patients confused. Currently, patients need to request a record form which is filled out by the pharmacist and the patient, and their eligibility is reset at the start of each calendar year¹⁸. The government should invest in digital health strategies for patients to more easily keep track of their PBS and Repatriation PBS (RPBS) spending to ensure they can access the PBS Safety Net Scheme when they become eligible.

Recommendation 2: The current system is not upholding principles of equity or affordability of medicines and new policy should be developed to ensure:

- *there is no significant price variability of PBS or RPBS medicines across Australia, and*
- *The PBS Safety Net Threshold eligibility is achievable and easy to track.*

Pharmacy ownership and location rules

The current pharmacy ownership and location rules must be relaxed given the anti-competitive nature of the pharmacy sector, to increase access for patients and allow non-pharmacists to own pharmacies. Reform has been a recommendation from a number of reviews, pharmacy groups, the Productivity Commission, research institutes, consumers and other organisations representing doctors, and even the Federal Government^{19,20,21}. These reviews identified that pharmacy was an area in need of immediate reform and the ownership and location rules essentially result in increased costs for consumers and should be abolished. These rules do not meet the NMP objectives as they limit access to medicines (financially and geographically) and inhibit access to pharmacists who are crucial in communicating the QUM. Bafflingly, despite numerous quality reviews and recommendations, these rules are still in place.

Defenders of these rules say that they are essential to keep pharmacies owned by the community. Unfortunately, that is no longer the case. In 2011, 81.5 per cent of pharmacies were independently owned or owned by smaller chains. In 2018, this was less than 27 per cent, the other 73 per cent being owned by one of four major retail pharmacy chains²². Doctors cannot own pharmacies unless they are also a pharmacist. The AMA believes that patient access and convenience in obtaining medications that they require can be improved by non-pharmacists being permitted to own pharmacies provided such ownership is managed ethically, addresses conflicts of interests and maintains the clear distinction between prescribing and dispensing.

The current location rules²³ make it particularly difficult for a pharmacy to be opened in a medical centre, despite the increased access this would provide for patients and the increased opportunities for collaboration it would create within the centre. The AMA believes that

¹⁷ Essue et al (2014) [Out-of-pocket costs of health care in Australia: submission to the Senate Standing Committee on Community Affairs.](#)

¹⁸ Department of Health (2021) [The Pharmaceutical Benefits Scheme: the Safety Net Scheme](#)

¹⁹ Harper et al (2015) [Competition policy review: final report.](#)

²⁰ Productivity Commission (2015) [Efficiency in health.](#)

²¹ Australian Government (2015) [Government response to the Competition Policy Review.](#)

²² KordaMentha (2018) [Pharmacy: an industry at a crossroads.](#)

²³ Department of Health (2020) [Pharmacy location rules: applicant's handbook.](#)

vulnerable patients such as those with severe mental health conditions would particularly benefit from being able to receive their medicines from the same area they receive their medical care.

Recommendation 3: abolish pharmacy location and ownership rules to reduce consumer costs and increase access to medicines and pharmacists.

Limited dispensing rules

In 2018, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended that pharmacies should be allowed to dispense up to two months' worth of the prescribed medicine at a time, for patient convenience and affordability, if it is deemed safe by the doctor²⁴. The AMA supports the independent decisions of PBAC and believes that it should not be interfered by political or sectional interests. However, that is exactly what happened²⁵. Pharmacy peak bodies lobbied the government to halt this recommendation due to concerns about the impact on pharmacy revenue, a move that put profits before patients. The AMA believes that this recommendation is still needed and considers that PBAC may wish to extend the quantity of medicines past two months in the future if deemed appropriate.

Recommendation 4: Implement the PBAC recommendation to dispense two months' worth of prescribed medicine at a time.

While a further discussion is required into improved models of medicines dispensing in Australia, the following principles must be maintained:

- The primary purpose is for the benefit of the patient in terms of improved access, quality of care and patient safety.
- It is important to ensure that the line between prescribing and dispensing is maintained. Commercial interests are separated from professional values and decision-making.
- GP oversight of patients must be maintained to ensure that patients initiate their course of medication as directed.
- This is about improving patient access to vital medications, not about profits for the owners of retail chemist shops.
- Any model must be value-based, demonstrating appropriateness, effectiveness, and efficiency.
- Patient choice is guaranteed.
- Transparency regarding prescribing, dispensing and patient outcomes is vital.

Recommendation 5: Initiate a review into improved models of dispensing in Australia that maintains important person-centred principles.

²⁴ Department of Health (2018) [August 2018 PBAC outcomes – other matters.](#)

²⁵ Paola (2020) [60-day dispensing, dollar discount 'gone in the agreement'.](#) Australian Journal of Pharmacy News.

Prescribing scope of practice

It is internationally recognised that GPs are the cornerstone of a successful primary healthcare system, and countries with a strong general practice have better health outcomes²⁶. Almost 85 per cent of patients see a GP each year and GPs remain the most common health service professional visited²⁷. Fragmentation of care is becoming more common as health system pressures grow. Poorly coordinated patient care within the health system and inadequate links between health and social services results in poorer health outcomes and increased health care costs²⁸. Ill-considered cost reduction strategies, like task substitution of non-medical health professionals for GP-led patient care, are increasingly proposed as a solution to these pressures. However, this further fragments patient care and results in poorer health outcomes and increased costs long-term²⁹.

Expanding prescribing scope of practice is commonly proposed by non-medical health professionals as a method to increase medicines access. However, it is important that these proposals are very carefully considered in the contexts of the patient safety, QUM and conflicts of interest. Increased access to medicines on the basis of convenience may compromise QUM.

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. The AMA therefore does not support independent prescribing by non-medical practitioners outside a collaborative arrangement with a medical practitioner³⁰. 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.

The AMA has developed 10 minimum standards for prescribing that should apply to all authorised prescribers³¹.

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 Pathway³² endorsed by the Standing Council on Health in November 2013 which sets out the five steps that a non-medical health practitioner must undertake to safely prescribe medicines.

²⁶ The World Health Organisation (2008) [The World Health Report 2008 - primary Health Care \(Now More Than Ever\)](#).

²⁷ Australian Bureau of Statistics (2020) [Patient experience in Australia: summary of findings](#).

²⁸ Frandsen BR, et al (2015) [Care fragmentation, quality, and costs among chronically ill patients](#). Am J Manag Care 2015;21:355–62

²⁹ Australian Medical Association (2020) [Delivering better care for patients: the AMA 10-year framework for primary care reform](#).

³⁰ Note: The AMA supports independent prescribing by dentists. Dentists are trained to prescribe medicines for dental conditions and prescribe within their scope of practice.

³¹ Australian Medical Association (2019) [AMA 10 minimum standards for prescribing](#).

³² Health Workforce Australia (2013) [The Health Professionals Prescribing Pathway](#).

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 Practitioner Regulation Agency (Ahpra)³³. Generally, 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.

However, the AMA is concerned with the inconsistent processes for non-medical health practitioners to obtain their endorsement for scheduled medicines (ESM). For example, if the Optometry Board of Australia amends their list of scheduled medicines^{34,35}, this does not require Ministerial Council approval. Conversely, the Podiatry Board of Australia's endorsement and list of scheduled medicines is outlined in its ESM registration standards³⁶, is more detailed, and requires Ministerial Council approval.

The AMA believes that the approval process should be consistent across the non-medical health professions and Ministerial Council approval should be required for any change to the list or ESM, even if the change is to add only one medicine to the list. This is the safest option for non-medical health practitioners wishing to prescribe while ensuring the objectives of the NMP are maintained.

Recommendation 6: 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. Policies for expanding non-medical practitioner scope of practice should be consistent across Ahpra Boards.

Current objective: medicines meeting appropriate standards of quality, safety, and efficacy

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. However, there are some changes that should occur to enhance the TGA's role. Activities that allow the TGA to better pursue QUM and appropriate quality, safety, and efficacy standards, should be publicly funded. The TGA needs to be appropriately funded and resourced to ensure the safety of the system is maintained.

Complementary medicines

Approximately 8 million Australians take two or more complementary medicines a week³⁷. While listed medicines (unscheduled medicines with well-known ingredients, including most

³³ Australian Health Minister's Advisory Council (2016) [Guidance for national boards: applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law.](#)

³⁴ Optometry Board of Australia (2018) [Registration standard: endorsement for scheduled medicines.](#)

³⁵ Optometry Board of Australia (2019) [Guidelines for the use of scheduled medicines.](#)

³⁶ Podiatry Board of Australia (2018) [Registration standard: endorsement for scheduled medicines.](#)

³⁷ NPS MedicineWise (2019) [Complementary medicines: reveal all to your pharmacist to stay safe.](#)

complementary medicines) are considered 'low risk' by the TGA's priority system³⁸, there is still potential for harm. There is limited efficacy evidence regarding most complementary medicine and some have the potential to cause adverse reactions or interact with conventional medicine³⁹. Unproven complementary medicines and therapies can also pose a risk to patient health either directly through misuse or indirectly if a patient defers seeking medical advice. Consumer investment in unproven medicines and therapies also risks patients being unable to afford necessary, evidence-based treatment, particularly where there are out-of-pocket costs.

Listed medicines are not evaluated for compliance or efficacy before they are included on the Australian Register of Therapeutic Goods (ARTG)⁴⁰. Post-market monitoring for listed medicines find high rates of non-compliance, raising concerns around patient safety, efficacy, and the quality of these products. In 2019-20, 74 per cent of listed medicines whose compliance status could be determined had compliance breaches. Where compliance status could not be determined, 74 per cent of reviews were cancelled by sponsors after the TGA requested information⁴¹. In 2020, 29 products were cancelled from the ARTG following a review by the TGA⁴². Pharmacies stock and advertise complementary medicines with questionable and limited evidence that they work, while some members of the public have limited health literacy to know this and may rely on advice from pharmacy staff. The TGA occasionally fines pharmacies for breaches against the advertising code for this reason. However, competing priorities and resources means that sometimes these are not picked up on at the rate they should. Only 195 post-market reviews were completed in 2019-20⁴³. While post-market monitoring should continue, it should be adequately resourced and listed medicines should be adequately assessed for safety, quality, and efficacy pre-market.

Recommendation 7: The TGA should be appropriately resourced and supported to enhance its compliance monitoring functions, including to ensure that compliance for safety, quality, and efficacy occurs before listed medicines are available for supply.

Medicines scheduling

Another area for improvement is to ensure that medicines are only 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. It is also important that scheduling decisions are made independently of political interests and based on reliable scientific evidence, despite the push from some interest groups to down-schedule medicines. Occasionally, medicine scheduling decisions do not adequately reflect or consider real-world implementation. For example, some cannabidiol products were recently downscheduled to become an over-the-counter medicines, despite the fact that there is insufficient evidence to use medicinal cannabis products more broadly and the evidence base varies across conditions. Further, changes to nicotine vaping products to become

³⁸ Therapeutic Goods Administration (2021) [Listed medicines](#).

³⁹ NPS MedicineWise (2010) [Drug interactions with complementary medicines](#).

⁴⁰ Therapeutic Goods Administration (2021) [Listed medicines](#).

⁴¹ Therapeutic Goods Administration (2020) [Annual performance statistics report: July 2019 to June 2020](#).

⁴² Therapeutic Goods Administration (2020) [Complementary medicines: cancellations from the ARTG](#).

⁴³ Therapeutic Goods Administration (2020) [Annual performance statistics report: July 2019 to June 2020](#).

prescription only, did not adequately consider the evidence-based and complex implementation and logistical issues before it was quickly implemented.

Decisions about medicine scheduling is not just about the pharmacology and toxicology of a drug, nor just about dispensing a medicine. Just as important is how the drug is used in the real world. Medical practitioners are uniquely placed to see the effects of scheduling on the public via patient consultations, through monitoring patients throughout their health condition and the duration of medicine use, assessing outcomes, and treating adverse events. Medicines accessibility is important, however it is more important that the safety and quality of medicines is not compromised for convenience. Currently, the majority of Advisory Committee on Medicines Scheduling (ACMS) members are pharmacists⁴⁴. The TGA should have a larger representation of independent medical practitioners on their ACMS to ensure that it captures the broader experience and understanding that medical practitioners can bring to scheduling decisions.

Recommendation 8: The TGA Advisory Committee for Medicines Scheduling should consist of a wider range of experts in medicines, including a larger representation of independent medical practitioners.

Current objective: quality use of medicines

The AMA supports the National Strategy for the Quality Use of Medicines⁴⁵. This document will also need to be updated in line with the NMP Review outcomes. The World Health Organization's *Global Safety Challenge: medication without harm* focuses on three priority areas: high-risk areas, polypharmacy, and transitions of care⁴⁶.

High-risk areas and medicines - The impact of the working environment on the quality use of medicines

There are several useful resources that guide the health system on how to implement the QUM in different settings^{47,48,49}. However, the extent to which QUM guidelines can be implemented is heavily influenced by the working environment. It is recognised that fatigue, poor working conditions, and workforce shortages are all factors increasing the risk of medication errors⁵⁰. In 2016, the AMA's Safe Hours Audit identified that one in two doctors are working unsafe hours (i.e. hours that put doctors at higher risk of fatigue), and the average number of hours worked in a shift was 18⁵¹. The relationship between poor performance and fatigue also extends to nurses who are crucial to medicines administration⁵². This is also widespread in under-resourced aged

⁴⁴ Therapeutic Goods Administration (2021) [Advisory Committee of Medicines Scheduling \(ACMS\)](#).

⁴⁵ Commonwealth of Australia (2002) [National strategy for the quality use of medicines](#).

⁴⁶ World Health Organization (2017) [The third global patient safety challenge: tackling medication-related harm](#).

⁴⁷ Department of Health (2020) [Quality Use of Medicines](#).

⁴⁸ Australian Commission on Safety and Quality in Health Care (2019) [Quality Use of Medicines](#).

⁴⁹ Australian Commission on Safety and Quality in Health Care (2020) [Medication without harm WHO global patient safety challenge – Australia's response](#).

⁵⁰ World Health Organization (2017) [WHO Global Patient Safety Challenge: medication without harm](#).

⁵¹ Australian Medical Association (2017) [2016 AMA Safe Hours Audit](#).

⁵² Garrubba and Joseph (2019) [The impact of fatigue in healthcare settings: a scoping review](#). Centre for clinical effectiveness, Monash Health.

care settings, where medication management issues are linked to understaffing and under-skilled staff⁵³.

Demand for health services in hospitals is outstripping supply with an ageing population with chronic co-morbidities in addition to a pandemic. The AMA's *Public hospital report card*⁵⁴ analyses the pressures that Australia's public hospitals face and shows a decline in public hospital performance since 2013-14. For example, in 2018-19, more than three million emergency patients required urgent care, but only 63 per cent were treated on time. The number of emergency patients who require a subsequent admission after their emergency treatment rose between 2013-14 and 2018-19 at nearly twice the rate of overall emergency presentations, and 3.5 times the rate of population growth.

AMA members report that time pressures are a common cause of medication errors, where a doctor has to see a large amount of patients in a short timeframe. A recent international meta-analysis showed that up to 1 in 30 patients is exposed to preventable medication harm in medical care, with over a quarter considered severe or life-threatening⁵⁵. AMA junior doctor members report that they are often left to write medication charts even though they have the least experience and are likely to be dealing with complex medication lists in the context of patients with complex health conditions. While writing medication charts is an essential learning experience, more support from more senior doctors is required. However, this can be difficult to obtain due to capacity constraints, as previously discussed. Education around new high-risk medicines should be delivered to junior doctors and other prescribers in a more consistent manner throughout different institutions. Prevention of medication errors and regular medication reviews should be prioritised to prevent complicated medicine regimens and worse health outcomes.

Recommendation 9: NMP objectives should recognise the importance of adequately resourced prescribing environments to support QUM, including to reduce the risk of preventable medication harm.

To enable non-pharmaceutical care, there must be appropriate resourcing and support for these services. For example, weaning chronic non-cancer patients off opioids and implementing alternative pain treatments is encouraged due to the finding that opioids are not suitable for this patient cohort⁵⁶. Deprescribing requires the right settings, resources and aids. Guidelines around pain management encourage the use of non-opioid therapies across a range of disciplines such as alcohol and drug services, pain specialists, palliative care, physiotherapy, psychiatry, psychology, and dietetics. These strategies are important for acute and chronic patients who have received care in the community and in hospital. However, at present, many of these services are not accessible to patients. For example, most pain management services are located in major capital cities, leaving a significant gap in rural and remote areas. Up to 80 per cent of patients

⁵³ Royal Commission into Aged Care Quality and Safety (2020) [Final report](#).

⁵⁴ Australian Medical Association (2020) [AMA Public Hospital Report Card](#).

⁵⁵ Hodkinson (2020) [Preventable medication harm across health care settings: a systematic review and meta-analysis](#). BMC Medicine.

⁵⁶ NPS MedicineWise (2020) [Opioids, chronic pain and the bigger picture](#).

with chronic pain are not receiving treatment to improve their quality of life⁵⁷. Some regional areas prescribe opioids at ten times the rate of other areas⁵⁸.

Similarly, allowing adequate mental health care by increasing the accessibility of a well-trained and collaborative mental health workforce in the community, hospitals, and aged care, would help to prevent the need for antipsychotics. In a given year, 1 in 5 Australians aged 16-85 will experience mental illness⁵⁹ and many know family or friends experiencing mental illness. Despite this, mental health care in Australia continues to be chronically under-funded and under-resourced⁶⁰.

Strategies such as increasing prescribing restrictions are essentially treating the symptoms without addressing the cause – a lack of preventative and early treatment measures. Health care settings must be adequately resourced and supported to ensure the optimal QUM.

Digital health strategies are integral to medication safety in high-risk settings. Its use is discussed in a separate section below.

Recommendation 10: The NMP objectives should recognise the importance of accessing non-pharmacological services from health practitioners to support QUM. Non-pharmacological services should be adequately supported and resourced to increase access.

Transitions of care

A Global challenge in improving QUM is the risk of medication errors during transitions of care events. This may occur in and between primary care, aged care, hospitals, and other healthcare facilities.

Transition of care points are the source of major error risk and involving pharmacists in hospital discharge summary preparation has been explored as a potential way to improve this⁶¹. Medical practitioners value pharmacists as highly trained experts in the safe and effective use of medicines and reform should occur so they can continue this role in environments that foster this central role, working within a medical practitioner-led multidisciplinary team.

One of the AMA's models of healthcare innovation is the pharmacists in general practice program which has proven highly successful in its initial phases. Under the AMA's plan, pharmacists working in general practices assist in areas such as medication management, patient education, and by supporting GP prescribing with advice on medication interactions and newly available medications. Economic modelling by Deloitte Access Economics demonstrated that for every \$1 invested in the program, \$1.56 in savings is delivered to the health system⁶². General practices are now supported to employ pharmacists under the Workforce Incentive Program. Practices employing pharmacists have reported improved patient outcomes and high levels of provider

⁵⁷ Department of Health (2019) [National strategic action plan for pain management](#).

⁵⁸ Ibid.

⁵⁹ Australian Institute of Health and Welfare (2021) [Mental health services in Australia](#).

⁶⁰ Australian Medication Association (2018) [Mental Health](#).

⁶¹ Tong et al (2017) [Reducing medication errors in hospital discharge summaries: a randomised controlled trial](#).

⁶² Deloitte Access Economics (2015) [Analysis of non-dispensing pharmacists in general practice clinics](#).

satisfaction⁶³. General practice pharmacists would be crucial to medicines reconciliation after a patient is discharged from hospital where their medicines may have changed considerably. Post-hospital medicines reconciliation is important to reduce the risk of adverse events, medication errors, and extend the time between hospitalisations⁶⁴. General practice pharmacists could also communicate with hospital and community pharmacists when appropriate to coordinate patient medication information.

Recommendation 11: Pharmacists should be supported to work under innovative, evidence-based care models that increase communication between transition of care points and improve QUM. This includes supporting an increase in general practice pharmacists.

My Health Record

My Health Record is intended to provide treating clinicians with essential clinical information that is otherwise unavailable at the time the patient presents in an Emergency Department or other healthcare facilities. However, the patient's My Health Record will only be as good as the information that has been uploaded by other treating healthcare providers. Wherever the medicines information uploaded to the patient's My Health Record is complete, it should make a positive contribution to best practice prescriptions in hospitals.

However, reliance of information in a patient's My Health Record will not be a silver bullet to achieving best practice prescribing because the Record is patient controlled. The patient can request a prescriber and a pharmacist that dispenses the medicine to not upload the script details to their My Health Record, or a patient can effectively remove a dispensed medicine from the My Health Record. Only the healthcare provider that uploaded that clinical document will be able to see that the document has been removed. The patient-controlled nature of the My Health Record is one of the consumer facing features of the Record.

Therefore, adequate communication with the patient's usual general practitioner (GP) and a comprehensive discharge summary is crucial to ensuring the patient does not have issues with their hospital-prescribed medication. The AMA's position statement on *General Practice/Hospitals Transfer of Care Arrangements* outlines the requirements for appropriate and effective transfer of care⁶⁵.

Recommendation 12: NMP objectives must recognise and support enhanced communication between healthcare settings to reduce the risk of medication errors during transitions of care and support QUM.

Polypharmacy

As mentioned, polypharmacy is increasing in Australia, and patients most at risk are those with multiple chronic conditions and older people. Approximately two thirds of older Australians (aged

⁶³ Rio, I (2019) [General practice and pharmacists working together.](#)

⁶⁴ Australian Commission on Safety and Quality in Health Care (2020) [Medication without harm WHO global patient safety challenge – Australia's response.](#)

⁶⁵ Australian Medical Association (2018) [General Practice/Hospitals transfer of care arrangements.](#)

75 years and over) take five or more medicines⁶⁶. There is wide polypharmacy rate variation across Australia's jurisdictions and socioeconomic status⁶⁷.

The AMA continues to call for a national strategy on polypharmacy to be developed⁶⁸. Having a strategy and guidelines may reduce adverse events, hospitalisation and PBS costs. Crucial to reducing polypharmacy is increasing the use of medicine reviews (including Home Medicine Reviews (HMRs) and Residential Medication Management Reviews (RMMRs)). The AMA has called for medication reviews to occur annually, and then on an as-needed basis to ensure medications are appropriate for older people. Pharmacists who work with doctors have an important role in assisting with medication adherence; improving medication management; and providing education about medication safety. The AMA welcomed the Government's announcement following the Royal Commission's interim report⁶⁹, introducing up to two follow up reviews for both HMRs and RMMRs⁷⁰. The AMA is also aware that the seventh Community Pharmacy Agreement includes funding for medication reviews⁷¹. However, a study conducted in 2021 showed that MBS claims for RMMRs are lodged for only a small number of residents who enter residential care, even though the program has significant potential for identifying and resolving medication-related problems in residential aged care facilities⁷².

The AMA supports any framework that allows for medication reviews to happen routinely for all recipients of aged care services (as above) that can be initiated by either the GP, the aged care provider or the pharmacist.

Evidence-based guidelines for prescribing for older people should be developed. Currently, studies focus on younger cohorts which do not take into account multiple co-morbidities or health issues specifically experienced by older people. This will assist prescribers to improve QUM for older patients.

Recommendation 13: A national strategy on polypharmacy should be developed under the NMP.

Recommendation 14: Medication reviews should be increased on an annual and as-needed basis for populations with high risk of polypharmacy such as older people.

Recommendation 15: Evidence-based guidelines for prescribing for older people should be developed.

⁶⁶ Australian Commission on Safety and Quality in Health Care (2021) [Fourth Australian Atlas of Healthcare Variation 2021. 6.1 Polypharmacy, 75 years and over.](#)

⁶⁷ Australian Commission on Safety and Quality in Health Care (2021) [Fourth Australian Atlas of Healthcare Variation 2021. 6.1 Polypharmacy, 75 years and over.](#)

⁶⁸ Australian Medical Association (2020) [AMA submission to the Royal Commission into Aged Care Quality and Safety.](#)

⁶⁹ Prime Minister of Australia (2020) [Response to Aged Care Royal Commission Interim Report](#)

⁷⁰ Australian Government (2020) [Response to the Senate Community Affairs Committee report for the Inquiry into the effectiveness of the aged care quality assessment and accreditation framework for protecting residents from abuse and poor practices, and ensuring proper clinical and medical care standards are maintained and practised](#)

⁷¹ Australian Government, Department of Health (2020), [7th Community Pharmacy Agreement](#)

⁷² JK Sluggett et al (2021) [Medication Management Reviews Australian Residential Aged Care](#)

Current objective: maintaining a responsible and viable medicines industry

This objective currently focuses on industry profitability and market challenges which does not reflect a person-centred approach. The medicines industry is an essential stakeholder in ensuring Australia achieves the other NMP objectives, however the ultimate reason behind this objective is to ensure patients can access their medicines to achieve better health outcomes. A shift to a person-centred approach under this objective is essential.

Recommendation 16: The ‘maintaining a responsible and viable medicines industry’ must be re-focused to a person-centred approach.

Medicine shortages

Medicine shortages is a long-term issue affecting patients in Australia that has increased in frequency over time⁷³. At the time of writing, there were 280 medicine shortages, 32 of which were listed as critical shortages by the TGA, and there were 45 anticipated shortages⁷⁴. Reports of shortages or increases in demand may have the effect of panic buying and stockpiling, making the situation even worse. Medicine shortages may increase the risk of medication errors, delayed care and an increase in health care costs^{75,76,77}.

Ninety per cent of Australia’s medicines come from overseas⁷⁸, primarily from Europe and the United States, who themselves rely on active pharmaceutical ingredients (APIs) manufactured in India and China⁷⁹. This makes Australia vulnerable when it comes to medicine shortages caused by a multitude of reasons such as market demand, manufacturing issues, geopolitical interventions, and global crises such as pandemics.

The AMA remains supportive of the work being conducted through Government, including through the TGA Medicine Shortages Working Party, to address medicine shortages. However, current methods are largely reactive, short-term, piecemeal and vulnerable. Medicines supply in Australia is largely market-based, and medicines can be discontinued if they are financially unviable. The TGA cannot compel pharmaceutical companies to add their medicines on to the ARTG, leaving Australia’s health in the hands of pharmaceutical business strategies.

Medicine supply chains can be extremely complex, long, and non-transparent due to commercial in confidence requirements. The Productivity Commission⁸⁰ labels three risks that make a market-level supply chain vulnerable: Limited flexibility, geographic clustering, and length. Supplementing Australia’s overseas imports with domestic manufacturing of essential medicines

⁷³ Morris (2018) [Medicine shortages in Australia – what are we doing about them?](#)

⁷⁴ Therapeutic Goods Administration (2021) [Medicine Shortages Information Initiative](#).

⁷⁵ Morris (2018) [Medicine shortages in Australia – what are we doing about them?](#)

⁷⁶ Tucker et al (2020) [The drug shortage era: a scoping review of the literature 2001-2019](#). Clinical Pharmacology and Therapeutics.

⁷⁷ Mazer-Amirshahi et al (2014) [Critical drug shortages: Implications for emergency medicine](#). Academic Emergency Medicine.

⁷⁸ Therapeutic Goods Administration (2019) [Reforms to the generic medicine market authorisation process](#).

⁷⁹ Productivity Commission (2021) [Vulnerable supply chains – Productivity Commission interim report](#).

⁸⁰ Productivity Commission (2021) [Vulnerable supply chains – Productivity Commission interim report. Page 36](#)

will decrease the risk of a vulnerable supply chain in terms of all three factors. Domestic manufacturing provides Australia with the *flexibility* to pivot to increase locally sourced manufacturing if overseas shortages occur or countries decide to implement export bans (which is increasingly being considered⁸¹). Domestic manufacturing also avoids the risk of *geographic clustering* by having a mix of locally made and imported products as appropriate. Supply chain *length* for locally manufactured products would also be shortened, minimising the number of points a disruption can occur along the supply chain. The AMA was pleased to see the announcements for funding domestic manufacturing through the Modern Manufacturing Strategy⁸². However, medicines manufacturing projects require more investment and to be part of an overarching, more comprehensive strategy to mitigate against the risk of medicine shortages.

The government could do more in terms of working with industry to achieve person-centred outcomes and the other NMP objectives and principles by considering initiatives that do not rely on the market. The recently developed Strategic Agreements between the Commonwealth and the medicines industry obligating suppliers to stockpile medicines is an important development to securing medicines supply in Australia and if done well will be an important strategy to avoid shortages of essential medicines. However, there needs to be a more wide-ranging consultation between all key stakeholders around an overarching, comprehensive strategy for medicines supply. Further, review and assessment processes for new health technologies such as the Pharmaceutical Benefits Advisory Committee and the Medical Services Advisory Committee should remain independent without representation from pharmaceutical industry stakeholders with direct conflicts of interest. Government should also investigate ways to incentivise the pharmaceutical industry to research and develop medicines in need, such as new antibiotics to reduce the prevalence of antimicrobial resistance⁸³.

Recommendation 17: The AMA calls on the Federal Government to develop and fund a comprehensive strategy to address medicine shortages, including domestic manufacturing of medicines, to:

- *reduce negative impacts and risks to patients posed by shortages of imported medications,*
- *create sovereign industrial capability to manufacture medications to ensure the adequate security of supply in times of serious disruption to overseas supply chains, and*
- *enhance Australia's medicine and vaccine research and development capabilities.*

Recommendation 18: medicines approval processes should remain independent from stakeholders with direct conflicts of interest.

⁸¹ Vogler and Fischer (2020) [How to address medicine shortages: findings from a cross-sectional study of 24 countries](#). Health Policy

⁸² Department of Industry, Science, Energy and Resources (2021) [Medical products national manufacturing priority road map](#).

⁸³ World Health Organization (2020) [Antimicrobial resistance](#).

NMP Principles

The AMA believes that if the NMP is too high level its intentions will be lost or unclear and therefore agree that it should include principles under each objective. The AMA broadly supports the proposed principles outlined in the discussion paper:

- *Equity – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of background or personal circumstance*
 - The AMA would suggest re-wording this objective to recognise the importance of background and personal circumstance in accessing medicines. Equity is about meeting needs that adapt to background and personal circumstance such as meeting cultural and socio-economic status needs. It is not about ignoring them.
- *consumer-centred approach – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy’s objectives.*
- *partnership based – establish and maintain active, respectful, collaborative, and transparent partnerships, to harness stakeholders’ skills, experience, and knowledge.*
- *accountability and transparency – all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of the policy’s objectives, within a transparent framework.*
 - This principle should include that all stakeholders are responsible for managing and reducing real, perceived, or potential conflicts of interest when achieving NMP objectives.
- *stewardship – all stakeholders have a shared responsibility to ensure that the policy’s objectives are met in an equitable, efficient, and sustainable manner, as stewards of the health system.*

Another principle worth considering is medicines regulation consistency and communication. Australia’s medicines regulation is heavily complex because the Commonwealth has a specific set of regulations (for example, Pharmaceutical Benefits Scheme, prescription requirements, and the TGA), while each State and Territory have their own requirements that do not necessarily align with each other (for example, prescription requirements, and Real Time Prescription Monitoring). This environment can produce difficulties and uncertainties that cause administrative burden on prescribers, especially if they change their practice location. This can also affect the patient if regulation changes are not clearly communicated to prescribers. For example, recently, several changes to PBS requirements for opioids caused mass confusion and distress for prescribers and patients because the changes were not adequately communicated in a timely manner and many patients with a legitimate need for opioids (such as palliative care patients) had their access delayed or denied.

Recommendation 19: The AMA broadly supports the proposed NMP principles and believes medicines regulation consistency and communication should also be included as important principles.

The definition of medicines and whether the NMP needs to be expanded to include health technologies.

The AMA believes that medicines and medical devices should have separate national strategies. While the NMP objectives can apply to both therapeutics, it is important not to lose focus, and the task to measure outcomes of the NMP objectives over time will become too large, potentially resulting in it not occurring as often as it should. While medicines and medical devices are both regulated by the TGA and the Department of Health, they have distinctly different regulatory and policy mechanisms. Therapeutic goods that blur the line between medicines and medical devices should be considered on a case by case basis in terms of which national policy is suited to it, as it is difficult to include these in such high level objectives.

Vaccines are considered medicines and therefore should be considered under the NMP.

Recommendation 20: Medical devices and other health technologies should have a separate national policy to medicines. Vaccines should be considered under the NMP.

Digital health

Expanding digital health has an important role to play in meeting NMP objectives and should be recognised in the future NMP. This has been particularly highlighted by the rollout of electronic prescribing and telehealth through the pandemic, allowing patients to access their medicines and medical care remotely to reduce the risk of virus transmission. The AMA considers digital health technology as a powerful enabler to optimise clinician workflow, achieve healthcare delivery efficiencies, and communicate to patients and the public. It is also essential in gathering data important to monitor medicines use, safety, quality, and efficacy, research new medicines, and track health outcomes.

While Australia's National Digital Health Strategy has been integral to implementing important digital health reform in Australia, there have been barriers to improvement. Software vendors are not necessarily obligated to adhere to Australian Digital Health Agency (ADHA) standards which creates inconsistency across platforms, reducing reliability of patient information such as medicines lists and reducing its usability. Interoperability between systems is an essential feature to ensure digital health products important for the QUM are used and are trusted. For example, secure messaging is a great technology, well targeted to meet healthcare provider needs and designed with ease of use from the clinician desktop – when it works. The actions of some messaging vendors to abandon interoperability standards after compliance approval, is a salient lesson that setting standards in and of itself, does not lead to standards implementation. Clinicians in some jurisdictions still cannot access this technology.

Further, digital health solutions are being developed rapidly and Australia's regulation is not keeping pace. For example, health apps have existed for some time but regulation and policies to ensure they are safe and efficacious are only now being explored.

Real time prescription monitoring

The AMA supports the introduction and funding by governments of electronic systems, such as real time prescription monitoring (RTPM), 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.

While States and Territories have produced their own RTPM systems, there needs to be as much national consistency as possible for it to work. Any system must be integrated with the national data base to ensure people do not avoid detection by crossing a State or Territory border. RTPM systems require seamless interoperability with clinical software used in hospitals and practices. The AMA understands that the Federal Department of Health has developed a National Data Exchange (NDE) that State and Territory RTPMs can feed into⁸⁴.

Recommendation 21: Interoperability is integral to ensuring digital health solutions that support QUM are trusted and used and should be a key standard in any digital health regulation.

Recommendation 22: Digital health developers should be seen as key stakeholders under the NMP so they are accountable and responsible to uphold NMP objectives.

Rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

Currently, while there are several initiatives that carry out NMP objectives, the NMP itself has been stagnant for some time. The AMA would support the maintenance of an independent national medicines advisory body, with membership from groups who have an interest in the safe, efficient QUM 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 NMP in Australia. Reinstating an advisory body (like the Australian Pharmaceutical Advisory Council) would assist in keeping NMP current while maintaining collaboration between NMP stakeholders. This advisory body should be coordinated by the government.

Recommendation 23: An independent national medicines advisory body should be implemented to carry out NMP objectives and to ensure the NMP remains relevant to today's medicines system.

A person-centred NMP

The AMA agrees that the current NMP requires a greater focus on the consumer. The NMP must recognise that Australians are diverse and therefore have different needs in terms of medicines and the health system. This includes health outcomes as a result of the social determinants of health.

Recommendation 24: NMP objectives should recognise the different needs of Australia's population groups, taking into account cultural background and social determinants of health.

⁸⁴ Department of Health (2021) [National Real Time Prescription Monitoring](#).

Shared decision-making and informed consent

The role of shared decision-making between the prescribing doctor and the patient and/or carer and informed consent needs to be included in the NMP to ensure it is person-centred. Shared decision-making includes discussing needs, goals, and preferences, risks and benefits, and encouraging patients and/or carers to ask questions about their medicines. Having a thorough conversation with patients takes time and the health system should be appropriately resourced and supported to do this (see section on the prescribing environment above).

Recommendation 25: Shared decision-making and informed consent are integral concepts to ensure a person-centred NMP.

However, shared decision making and informed consent depends on whether patients (and/or their carers) understand the medicines they are taking, and the medical condition/s in the context of the patient's own health journey. Health literacy is integral to bringing them along and ensuring they take control of their health and the safe use of medicines.

Health literacy

A major barrier to achieving the NMP objectives is misinformation and a lack of health (including medicines) literacy in Australia. Generally, poor health literacy influences poor health outcomes⁸⁵. Poor health literacy has been linked to low medication adherence, with higher rates of medication errors and difficulties interpreting medication label warnings and assessing the risks and benefits of taking medicines⁸⁶.

Doctors, and health systems more generally, have a vital role to play in improving health literacy by communicating effectively and sensitively with patients, encouraging discussion, and providing information that is understandable and relevant.

Health literacy is a society-wide issue that requires a multi-sector response. Governments, schools, businesses, the media, researchers, industry, health providers, and individuals can all make meaningful contributions to improving health literacy.

Low levels of health literacy are associated with other measures of social and economic disadvantage⁸⁷. Efforts to improve health literacy must respond appropriately to the varying needs of diverse population groups, including older people, Culturally and Linguistically Diverse (CALD), and Aboriginal and Torres Strait Islander populations.

The spread of misinformation is particularly concerning in achieving quality use of medicines. 17.2 per cent of respondents to the National Health Survey self-reported the inability to adequately appraise health information⁸⁸. Medicines misinformation has been particularly concerning during

⁸⁵ Australian Commission on Safety and Quality in Health Care (2014) [Health literacy: taking action to improve quality and safety](#).

⁸⁶ Choudhry et al (2019) [Health literacy studies conducted in Australia: a scoping review](#).

⁸⁷ Australian Commission on Safety and Quality in Health Care (2014) [Health literacy: taking action to improve quality and safety](#).

⁸⁸ Australian Bureau of Statistics (2019) [National health survey: health literacy](#).

the pandemic with more people than ever focusing on emerging research around COVID-19, its treatments, and vaccines, without the ability to correctly interpret it and subsequently spreading misinformation online, with disastrous consequences.

NPS MedicineWise and Health Direct are important health literacy tools and should be more widely promoted to Australians. Currently, they are not highly prioritised on Google Search and therefore would not be used by many people looking for Australian medicines content.

While some important initiatives exist to improve health and medicine literacy, it remains an underestimated problem. The AMA has called on several stakeholders to take action to improve health literacy and misinformation accountability⁸⁹ in Australia and it is important that this issue is also raised under the NMP.

Recommendation 26: The NMP objectives should promote improvement of health literacy to improve QUM and health outcomes.

The NMP's governance, communications, implementation (including enablers) and evaluation.

The AMA is aware that medicines stakeholders, policies and projects consider the NMP throughout their development and implementation processes. However, there has not been an overarching review into how well these initiatives implement NMP and there are no measures to do this. The current NMP does not clearly explain how stakeholders should be using the objectives to guide their work. The AMA believes that a set of Key Performance Indicators (KPIs) should be developed and there should be a comprehensive and overarching review of how well Australia is achieving NMP objectives on a regular basis. In addition, different stakeholders will be able to refer to the KPIs to assess their individual projects. KPI reporting would also provide some accountability and identify any gaps in Australia's medicines policy. The Action and Metrics sections in Australia's response⁹⁰ to the WHO *Global Patient Safety Challenge: Medication without harm*, and the QUM indicators for hospital settings⁹¹ would be good reference points for developing NMP KPIs.

Recommendation 27: A set of Key Performance Indicators should be developed to ensure the NMP is achieving its goals and to ensure NMP projects and policies are guided and remain accountable to the NMP.

NMP partners and options for building greater accountability

Additional stakeholders

It is important that the NMP define health practitioners, as it is a very specific term used to define professions that are registered under the Australian Health Practitioner Regulation Agency (Ahpra). However, NMP also includes complementary medicines that may be 'prescribed' or

⁸⁹ Australian Medical Association (2021) [Health literacy 2021 – AMA position statement](#).

⁹⁰ Australian Commission on Safety and Quality in Healthcare (2020) [Medication without harm: Australia's response](#).

⁹¹ Australian Commission on Safety and Quality in Health Care (2014) [National Quality Use of Medicines Indicators for Australian Hospitals: indicator summary](#).

recommended by other health professions such as naturopaths and homeopaths that are not registered under Ahpra. The AMA does not support the use of medicines that have not been thoroughly tested for safety, quality, and efficacy, however in reality this still occurs. These alternative health professions should recognise that they are also responsible for ensuring the QUM and other NMP objectives.

Recommendation 28: Alternative health professionals should be included as NMP stakeholders so they are accountable to providing ethical, evidence-based, safe, efficacious, and high quality care.

As previously mentioned, digital health is rapidly evolving and is increasingly used in the health system and in medicines work. However, regulation and accountability is not keeping pace. Digital health providers should also be considered stakeholders under the NMP. See recommendation 22.

Community Pharmacy Agreement

The Community Pharmacy Agreement is an important avenue for initiating NMP objectives. However, its mechanisms for accountability and avoiding conflicts of interest are in need of improvement. An agreement between the government and the Pharmacy Guild of Australia – an organisation representing businesses who have a direct commercial conflict of interest when negotiating community pharmacy funding, is not necessarily representative of Australia's pharmacists/pharmacies, nor is it necessarily representative of other medicines stakeholders. The AMA recognises that the Pharmaceutical Society of Australia was a co-signatory on the seventh Community Pharmacy Agreement. The details of the Agreement are not known until they are published publicly and as such stakeholder forums held prior to this, without this knowledge, are tokenistic.

The *Review of Pharmacy Remuneration and Regulation*⁹² amongst several reviews have highlighted that the Community Pharmacy Agreement is not fit for purpose (see section on the current NMP objective of timely access). For example, this review could not thoroughly determine the costs of dispensing services in community pharmacies. This does not provide accountability and transparency in how public funds are spent and whether services are effective and cost-effective. The AMA agrees that the pharmacy profession should be supported and resourced to carry out their important work. However, any funding should be transparent and go towards programs that have been evaluated for effectiveness and cost-effectiveness.

The AMA agrees there are benefits in future Agreements being limited to remuneration for the dispensing of Pharmaceutical Benefits Scheme (PBS) medicines and associated regulation. This would allow pharmacy programs, such as medication adherence and management services currently funded under the Agreement, to be funded in ways that are more consistent with how other primary care health services are funded. Given these programs are about providing health services, rather than medicines dispensing per se, it makes sense for them to be assessed, monitored, evaluated and audited in a similar way to medical services under the MBS. \$1.26 billion was provided to pharmacies under the Sixth CPA⁹³ without this level of transparency and

⁹² King et al (2017) [Review of pharmacy remuneration and regulation.](#)

⁹³ Department of Health (2020) [Pharmacy Trial Program](#)

accountability. The current MSAC process for the Pharmacy Diabetes Screening Trial is the first time evaluations of pharmacy programs under the Agreement have been made (relatively) public. Moving pharmacist health services outside of the Agreement would also open the way for more flexible models of funding, for example, support for pharmacists working within a general practice team and other innovative, patient-focused models of care.

Recommendation 29: Services that aim to meet NMP objectives (such as the Community Pharmacy Agreement) should be accountable, transparent, and evidence-based in the context of wider health system services and public health.

Conclusion

The NMP's objectives remain as current today as when they were developed. However, the AMA does not believe that these objectives have been met. There should be a review into determining how well Australia is achieving NMP objectives by developing a set of Key Performance Indicators. The Government should reinstate a national medicines advisory body to ensure the NMP remains relevant, and to monitor NMP policies and programs. A new objective must be made that recognises how Australia's broader health environment influences medicines use in Australia, and that the health system as a whole must be supported to achieve NMP objectives. The AMA regards this NMP Review as an important long-term process and welcomes further involvement to improve Australia's medicines environment and ultimately Australian's health outcomes.

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