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# AMA submission to the National Medicines Policy Consultation Draft

The AMA supports the review of the National Medicines Policy (NMP) as an important long-term process. In the initial submission on the review, the AMA noted that the objectives of the NMP are still relevant, however many were going unmet. The AMA recommended developing set of Key Performance Indicators to ensure Australia is meeting these objectives. Other key recommendations included reinstating a national medicines advisory body to ensure the NMP remains relevant, and to monitor NMP policies and programs, and introducing new objectives that recognises how Australia's broader health environment influences medicines use in Australia.

While positive developments were made, in general the lack of meaningful governance and reporting mechanisms mean this policy is not yet ready. The AMA supports the calls to complete this policy review after the upcoming Federal Election to ensure it is not rushed.

This document presents the AMA's responses to questions asked in the format of an online survey.

> **Aim: The Policy's aim is to create the environment, in which appropriate structures, processes and accountabilities enable medicines and medicines-related services to be accessible in an equitable, safe, timely, and affordable way and to be used optimally according to the principles of person-centred care and the quality use of medicines, so that improved health, social and economic outcomes are secured for individuals and the broader community.**

The AMA agrees with the aim of the NMP.

While the aim encapsulates the important components of the purpose and intent of the NMP, the discussion paper does not adequately provide for assessment or evaluation of the aim. The AMA's initial submission to the NMP review advocated for the introduction of performance indicators to measure how well Australia is upholding NMP objectives and future principles to achieve better health outcomes, noting this would also support identification for areas for reform.

The current document does not provide meaningful indicators for the aim, the pillars (formerly objectives) and the principles to be measured against. These are important as they ensure the Policy remains fit for purpose and is achieving its aim.

**Scope: The Policy's scope refers to the term 'medicine' covers a broad range of products that are used to prevent, treat, monitor or cure a disease. These products include prescription medicines, over-the-counter medicines and complementary/traditional medicines and encompass biologic and non-biologic medicines, including gene therapies, cell and tissue engineered products and vaccines.**

The AMA would like to see the scope extended to include which "prescribers" are also included under the NMP. This should be accompanied by a definition of "health practitioner" which is a specific term used to define professions that are 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. Professions such as naturopaths and homeopaths that are not registered under Ahpra may recommend that their clients consume "complementary/traditional medicines" for health purposes. These alternative professions must recognise that they are also responsible for ensuring the QUM and other NMP objectives.

**Principles:**

The AMA is generally supportive of the principles, noting the expansion in the most recent draft. The AMA appreciates the elaboration of the action relating to "equity" to align with AMA feedback.

The AMA also strongly recommends that the "Person-centred" principle specific note that the patient safety and access should be paramount. This can be achieved by including the following:

- The line between prescribing and dispensing must be maintained. Commercial interests are separated from professional values and decision-making.
- Medically-led oversight of patients must be maintained to ensure that patients initiate their course of medication as directed.
- Improving patient access to vital medications must be prioritised over individual profits.
- Patient choice must be guaranteed.

The AMA would like the "accountability and transparency" principle to include in the action that all stakeholders are responsible for managing and reducing real, perceived, or potential conflicts of interest when advancing the NMP's central pillars.

The AMA would still like the principles to include medicines regulation consistency and communication. As noted in our initial submission, Australia's medicines regulation is very complex because of the overlapping Commonwealth and State/Territory requirements. These do not always align with each other, for example, prescription requirements and Real Time Prescription Monitoring.

**Enablers: The NMP influences, and is also influenced by, related policies, programs, and initiatives of the wider health system. Seven enablers are identified in the Policy as being critical to the Policy's success.**

The AMA welcomes the inclusion of enablers to the NMP. While these enablers are generally positive, the AMA is concerned with the wording of the "health workforce" enabler. The issue with the term "full scope of practice" is that despite only medical practitioners being trained to make a complete diagnosis, monitor the ongoing use of medicines and to understand the risks and benefits inherent in prescribing receiving the appropriate training, many non-medical health professionals advocate to expand their scope as a method to increase medicines access.

These proposals rarely consider the impact on patient safety, QUM and conflicts of interest. Increased access to medicines on the basis of convenience may compromise QUM.

The AMA does not support independent prescribing by non-medical 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.

The AMA recommended including the improvement of health literacy to improve QUM and health outcomes as an objective, but including it as an enabler is appropriate.

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.

The AMA would like to see specific mention of the need to combat the spread of medicines misinformation. While this has a long history, it has been particularly concerning during the COVID-19 and the rampant spreading of misinformation online.

The AMA welcomes the inclusion of "interoperability" as a component of the "Technology" enabler.

**Governance Arrangements:**

The AMA does not support the Governance framework as it is currently proposed. While "co-ordination", "shared problem solving" and "accountability" are important aspirational goals for governance of such an important piece of policy, it is unclear who, what or how this will occur in practice.

It states that "Each partner is responsible and accountable for achieving the NMP's aim and intended outcomes", yet it is unclear what this accountability would constitute and how behaviour deemed to contravene the principles and pillars of the NMP would be managed.

The AMA is concerned that the Commonwealth has not led "collaborative action on problems that cannot be solved by any one partner." Case in point is the Community Pharmacy Agreement (CPA) which is an important avenue for initiating NMP objectives, yet is determined almost exclusively by the Pharmacy Guild of Australia and 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.

In fact, the CPA is in direct contravention to many of the principles and pillars of the draft NMP.

The *Review of Pharmacy Remuneration and Regulation*[1] 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 CPA[2] without this level of transparency and 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.

The AMA's concern here is that without a genuine governance body to monitor the implementation of and adherence to the NMP, Australia will continue to see NMP objectives carried out without appropriate transparency or collaboration. As such, we propose the establishment of an independent national medicines advisory body that would monitor NMP objectives and ensure the NMP remains relevant to today's medicines system.

The AMA also reiterates the recommendation from our original submission: 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.

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

[1] King et al (2017) *Review of pharmacy remuneration and regulation.*
[2] Department of Health (2020) *Pharmacy Trial Program*

response[3] to the WHO *Global Patient Safety Challenge: Medication without harm*, and the QUM indicators for hospital settings[4] would be good reference points for developing NMP KPIs.

**Pillar 1: "Timely, equitable and reliable access to needed medicines at a cost that individuals and the community can afford".**

The AMA welcomes the inclusion of "equitable" in the "pillar". 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. Reform in this space should be evidence-based, independent and transparent.

In the initial submission, the AMA noted that 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 that the PBS Safety Net Threshold eligibility is achievable and easy to track. These should be KPIs that the NMP is measured against.

The AMA also reiterates the key reconditions that Australia should abolish pharmacy location and ownership rules to reduce consumer costs and increase access to medicines and pharmacists.

Reform to these rules 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.[5,6,7] 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.

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 chains.[8] 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.

[3] Australian Commission on Safety and Quality in Healthcare (2020) *Medication without harm: Australia's response.*
[4] Australian Commission on Safety and Quality in Health Care (2014) *National Quality Use of Medicines Indicators for Australian Hospitals: indicator summary.*
[5] Harper et al (2015) *Competition policy review: final report.*
[6] Productivity Commission (2015) *Efficiency in health.*
[7] Australian Government (2015) *Government response to the Competition Policy Review.*
[8] KordaMentha (2018) *Pharmacy: an industry at a crossroads.*

The current location rules[9] 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 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.

An independent national medicines advisory body overseeing the NMP could call for a review of these rules and ensure that it abide by the principles and pillars of the NMP. This should be an outcome of Pillar 1.

This body could also ensure that continued efforts of non-medical health professionals to prescribe medicines are considered transparently in line with NMP principles and pillars including patient safety, QUM and conflicts of interest. Increased access to medicines on the basis of convenience may compromise QUM.

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,[10,11] 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 standards,[12] is more detailed, and requires Ministerial Council approval. As such, an initial objective could be to ensure policies for expanding non-medical practitioner scope of practice are consistent across Ahpra Boards.

**Pillar 2: "Medicines meet appropriate standards of quality, safety and efficacy."**

The AMA is generally supportive of "Pillar 2". Noting that the second intended outcome is "Australia's medicines regulatory processes are efficient, protect health and safety, and are trusted by the community", the AMA reiterates the recommendation that: 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.

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.

Listed medicines are not evaluated for compliance or efficacy before they are included on the Australian Register of Therapeutic Goods (ARTG).[13] 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

[9] Department of Health (2020) *Pharmacy location rules: applicant's handbook.*
[10] Optometry Board of Australia (2018) *Registration standard: endorsement for scheduled medicines*.
[11] Optometry Board of Australia (2019) *Guidelines for the use of scheduled medicines*.
[12] Podiatry Board of Australia (2018) *Registration standard: endorsement for scheduled medicines.*
[13] Therapeutic Goods Administration (2021) *Listed medicines.*

determined, 74 per cent of reviews were cancelled by sponsors after the TGA requested information.[14] In 2020, 29 products were cancelled from the ARTG following a review by the TGA.[15]

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 mean that sometimes these are not identified at the rate they should. Only 195 post-market reviews were completed in 2019-20.[16] 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.

Noting the frequent calls for stronger collaboration and acknowledgement of the need to respect the expertise of others within the NMP, the AMA reiterates the recommendation that 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.

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 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 pharmacists.[17] 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.

**Pillar 3: "Quality use of medicines and medicines safety."**

The AMA welcomes the addition of “medicines safety” to this “pillar”. This pillar is well formulated. However, given the importance of this section and the direction of its content, it is

[14] Therapeutic Goods Administration (2020) *Annual performance statistics report: July 2019 to June 2020.*
[15] Therapeutic Goods Administration (2020) *Complementary medicines: cancellations from the ARTG.*
[16] Therapeutic Goods Administration (2020) *Annual performance statistics report: July 2019 to June 2020.*
[17] Therapeutic Goods Administration (2021) *Advisory Committee of Medicines Scheduling (ACMS).*

regrettable that there are now KPIs included nor any overarching body that will ensure all partners are abiding by the pillar or its elements.

While the AMA welcomes the focus on a person-centred approach and recognises the role interoperable digital health solutions can play, this section omits key recommendations on the impact of the working environment on the quality use of medicines. As explained in the AMA's initial submission, the extent to which QUM guidelines can be implemented is heavily influenced by the working environment. This pillar should recognise the importance of adequately resourced prescribing environments to support QUM, including to reduce the risk of preventable medication harm.

It is recognised that fatigue, poor working conditions, and workforce shortages are all factors increasing the risk of medication errors.[18] 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 18.[19] Recent, shocking research has found that one-in-ten doctors had thoughts of self-harm during the pandemic.[20] The relationship between poor performance and fatigue also extends to nurses who are crucial to medicines administration.[21] This is also widespread in under-resourced aged care settings, where medication management issues are linked to understaffing and under-skilled staff.[22]

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-threatening.[23]

The AMA notes that "polypharmacy" is mentioned as a particular focus of the pillar, particularly in relation to transitions of care, however we would like to see the NMP take a stronger guiding position in addressing issues such as polypharmacy. The AMA continues to call for a national strategy on polypharmacy to be developed.[24] This should be developed under the NMP, as should evidence-based guidelines for prescribing for older people should be developed.

> **Pillar 4: "Responsive and sustainable medicines industry and research sector with the capability, capacity and expertise to meet current and future health challenges."**

The AMA supports and welcomes the expansion of this pillar to align with a more person-centred approach.

[18] World Health Organization (2017) *WHO Global Patient Safety Challenge: medication without harm.*
[19] Australian Medical Association (2017) *2016 AMA Safe Hours Audit*.
[20] Bismark M, Scurrah K, Pascoe A, Willis K, Jain R, Smallwood N. Thoughts of suicide or self-harm among Australian healthcare workers during the COVID-19 pandemic. Australian & New Zealand Journal of Psychiatry. February 2022. doi:10.1177/00048674221075540
[21] Garrubba and Joseph (2019) *The impact of fatigue in healthcare settings: a scoping review.* Centre for clinical effectives, Monash Health.
[22] Royal Commission into Aged Care Quality and Safety (2020) *Final report.*
[23] Hodkinson (2020) *Preventable medication harm across health care settings: a systematic review and meta-analysis*. BMC Medicine.
[24] Australian Medical Association (2020) *AMA submission to the Royal Commission into Aged Care Quality and Safety.*

The AMA remains concerned with the prospect of medicines shortages in the short and long-term. Medicine shortages may increase the risk of medication errors, delayed care and an increase in health care costs.[25,26,27]

The strategic agreements between Strategic Agreements between the Commonwealth and the medicines industry put into place late last year are a step in the right direction, but have not yet been tested and lack clarity on key issues the obligations on suppliers to hold four to six months stock of 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, the AMA has also been informed by suppliers that this will be challenging to meet these requirements. Medicines supply in Australia is largely market-based, and medicines can be discontinued if they are financially unviable.

Genuine, wide-ranging consultation between all key stakeholders around an overarching, comprehensive strategy for medicines supply is required. The AMA recommends this include a comprehensive review into the practicality and feasibility of domestic medicines manufacturing. 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.

**Implementation:**

The AMA is dissatisfied with the implementation plan in the draft NMP. As stated in our initial submission, the AMA supports the existing objectives as currently outlined, however we do not believe that these objectives have been met. Now, with the refinement of the objectives to pillars and a stronger person-centred focus, there is a real opportunity with the revised NMP to build in genuine KPIs and reporting structures that ensure all partners abide by the principles and pillars.

The AMA strongly advocates for a review to be conducted into determining how well Australia is achieving NMP objectives by developing a set of Key Performance Indicators. This could be an ongoing review built into the structures of the NMP.

As outlined in the section on governance, this will require the Government reinstating a national medicines advisory body to ensure the NMP remains relevant, and to monitor NMP policies and programs.

**Evaluation:**

The discussion paper does not adequately provide for assessment or evaluation of the aim. The AMA's initial submission to the NMP review advocated for the introduction of performance indicators to measure how well Australia is upholding NMP objectives and future principles to

[25] Morris (2018) *Medicine shortages in Australia – what are we doing about them?*
[26] Tucker et al (2020) *The drug shortage era: a scoping review of the literature 2001-2019*. Clinical Pharmacology and Therapeutics.
[27] Mazer-Amirshahi et al (2014) *Critical drug shortages: Implications for emergency medicine*. Academic Emergency Medicine.

achieve better health outcomes, noting this would also support identification for areas for reform.

In the initial submission on the review, the AMA noted that the objectives of the NMP are still relevant, however many were going unmet. The AMA recommended developing set of Key Performance Indicators to ensure Australia is meeting these objectives. It also recommended reinstating a national medicines advisory body to ensure the NMP remains relevant, and to monitor NMP policies and programs.

As noted in the section on Governance, 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 response to the WHO Global Patient Safety Challenge: Medication without harm, and the QUM indicators for hospital settings would be good reference points for developing NMP KPIs.

The establishment of an independent national medicines advisory body that would monitor NMP objectives and ensure the NMP remains relevant to today's medicines system.

**General Comments:**

The AMA shares the concerns of many stakeholders in this process that the review is being conducted hastily and more consultation and refinement is required. The AMA supports the review process as fundamental to ensuring the NMP is appropriate and fit for purpose. This process cannot be rushed. As such, we would prefer the consultation process is concluded after the upcoming Federal Election.

The AMA is encouraged by the direction that the NMP review is headed, with strong improvements in person-centredness and good principles and enablers identified. We welcome ongoing engagement in the continued refinement of the draft to ensure the final product is fit for purpose. It would be disappointing to see this positive progress wasted by presenting a rushed, unfinished document guide medicines policy over the coming years.

**March 2022**