Pharmaceutical Society of Australia

National Medicines Policy Review

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About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 35,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
www.psa.org.au

Contacts:

Chris Freeman
National President

Mark Kinsela
Chief Executive Officer
ceo@psa.org.au

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Purpose

The Pharmaceutical Society of Australia (PSA) provides its views through this submission to the National Medicines Policy (NMP) Review Committee to support a refresh of the NMP as a high level policy framework with the primary aim of future-proofing the policy.

Appendix 1 of this submission includes PSA's views on specific healthcare activities and programs which are underpinned by current NMP principles and objectives, and are relevant to pharmacists' practice. These are intended to provide context of the interpretation and implementation of the current NMP.

Key issues

PSA firmly believes it is vital to the Australian healthcare system and Australian patients to preserve and promote the ongoing relevance, universality and impact of the NMP.

PSA highlights the following to the Review Committee as key issues for consideration in the refresh of the NMP to ensure future viability and impact of the policy.

- Continuing to have a robust, overarching principle-based framework is important. However, there is an urgent need for clear leadership in translating the refreshed NMP into an implementation plan with specific goals and activities, as well as the need to monitor outcomes and impact of the policy.

- There must be a commitment to continuous quality improvement through appropriate data collection, transparent reporting and evaluation to inform future iterations of the NMP.

- To achieve outcomes consistent with the NMP aims, strengthened accountability to design and deliver person-centred care will be important.

- Inclusion of the 10th National Health Priority Area of 'Quality Use of Medicines and Medicines Safety', as referred in the Discussion Paper, as a core tenet of the NMP must be a priority.

- Working towards national harmonisation of state and territory regulatory arrangements is long overdue and will be essential to support healthcare system efficiency, health workforce capacity and improve medicine access. The NMP can show leadership by supporting this intent.

- A refreshed NMP will not have meaningful impact without a dedicated and supported healthcare workforce. As such, there must be a core principle that healthcare practitioners are able to practise commensurate with their recognised competencies and scope of practice, consistently across all jurisdictions within Australia.

- In keeping with contemporary healthcare practice, supporting collaborative partnerships will ensure that the NMP is able to deliver on its core objective and remit. This will also require an understanding of the differing capabilities and capacity of each partner contributing to person-centred outcomes under the policy.

Responses to the Terms of Reference questions

In the following sections, PSA has addressed the NMP Review Terms of Reference with responses to the questions posed in the Discussion Paper.

Appendix 1 of this submission contains information on specific healthcare activities or aspects of particular programs based on feedback from pharmacists. These are intended to provide context of what impact the current NMP is having on the ground. PSA firmly believes a refreshed NMP can be designed in a way that strengthens current arrangements and improves on gaps or anomalies in healthcare service delivery to patients and the public.

Terms of Reference 1: *Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.*

Question A: *Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?*

The NMP holds a pre-eminent position as a pillar of professional pharmacy practice. Pharmacists work in roles that are fundamental to all four arms of the NMP with a particular focus on the quality use of medicines (QUM). Nevertheless, all principles and objectives are inextricably linked and need to be considered holistically and comprehensively to ensure they guide evidence-based policy-making which translates into sustainable implementation and beneficial person-centred outcomes.

PSA strongly supports the expectation that the NMP principles "should be evident in the planning, design and implementation of programs, systems and initiatives created".

PSA generally supports the five proposed principles.

Principle	PSA response
Equity	The proposed principle of 'equity' is inadequate. As drafted, it essentially focusses on 'access' but it must also include the notion that the outcomes of this access should be 'equitable'. It must be more explicitly acknowledged that some people with greater needs, or increased vulnerability, may require 'more' care to consider it to be equitable. In addition, the system or mechanism that is used to deliver care (or medicines) must have appropriate flexibility to facilitate equitable care as the intended goal of the NMP.
Consumer centred approach	PSA suggests consideration of an alternative term, 'person centred approach'. This would be consistent with the current proposal of the Australian Commission on Safety and Quality in Health Care to include an overarching principle of 'person-centred care' in the two revised documents on guiding principles for medication management.[1]
Partnership based NMP	PSA regards a 'partnership based' NMP to be essential in order to deliver meaningful outcomes. However, PSA believes there is substantial scope to improve on this with regards to implementation of the NMP. PSA expands on this view throughout this submission.

[1] Australian Commission on Safety and Quality in Health Care. Review of national quality use of medicines publications. At: **www.safetyandquality.gov.au/our-work/medication-safety/quality-use-medicines#review-of-national-quality-use-of-medicines-publications**

Principle	PSA response
Accountability and transparency	Although 'accountability' is an important principle, PSA queries how it would be demonstrated (and to whom) in the context of the NMP. For the pharmacy profession, 'accountability' is defined as "being answerable for one's actions, and the roles and responsibilities inherent in one's job or position" and that "accountability cannot be delegated".
Stewardship	PSA supports the intent of the proposed principle of 'stewardship', however, does not believe the term would be widely understood. All of the NMP principles must be clear and relatable to all stakeholders, including healthcare recipients, their families and carers.

Question B: *Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?*

Timely access to the medicines that Australians need, at a cost individuals and the community can afford

Australians, with access to a universal healthcare system, have come to expect that they can access essential medicines in a timely manner and at a price that is fair and affordable. The Pharmaceutical Benefits Scheme (PBS) continues to provide the framework for this to be delivered, via an effective and cost-effective framework evaluating safe and effective therapeutic products. This objective is critical and relevant for the updated NMP.

There are examples where improving access to medicines has resulted in reduced affordability. In April 2015 the Pharmaceutical Benefits Advisory Committee (PBAC) recommended[2] to the Minister for Health the de-listing of several over-the-counter medicines on the basis of: scheduling in the Poisons Standard, low ex-manufacturer price, evidence for subsidy is not overwhelming and products unlikely to be highly reliant on specialist prescribing and management. Whilst this recommendation improved access for some Australian citizens, affordability, and ultimately access, for others diminished. We particularly highlight those patients reliant on the PBS Safety Net arrangements and Aboriginal and Torres Strait Islander people, who were not able to access closing the gap co-payment support.

We request the Review Committee ensures that the principles of universal access, equity and affordability are clearly stated so that all three are able to be maintained. In the future, if examples such as that highlighted above are identified, PSA supports a review of elements of the policy in collaboration with partners, to find a way forward.

The NMP should be flexible and adaptable to allow exploration of innovative practices to advance healthcare service delivery in Australia. Where strong evidence exists, either through research or models of service delivery in other countries, the NMP needs to be flexible enough to support implementation in Australia. It is disappointing to see healthcare practice models involving pharmacists being successfully implemented in other like countries, but proposals to design and implement similar services in Australia meeting resistance or disinterest. Collaborative prescribing is one such area.

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[2] Recommendations made by the PBAC – April 2015 PBAC Special meeting. At: **www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-04/2015-04-removing-otc-medicines-from-the-pbs.pdf**

PSA has identified several issues which are currently impacting negatively on 'access' and 'timely access' for patients, which suggest one of the fundamental expectations of the NMP is not being met. Selected examples are provided in **Appendix 1** to help illustrate the impact, including: Serious Scarcity Substitution Instruments, Opiate Dependence Treatment Program, state and territory regulatory arrangements (Issues 1–3).

Medicines meeting appropriate standards of quality, safety and efficacy

This objective is fundamental to ensuring Australians have access to safe, high quality and efficacious medicines. PSA supports the vital role of the Australian therapeutic goods regulator and supports the retention of this NMP objective.

PSA also supports the health technology assessment process in place which complements the regulatory pathway and ensures appropriate subsidy (for most medicines) and reimbursement of medicinal products.

In **Appendix 1**, the impact of unapproved and unregistered medicines (Issue 4) is outlined.

Quality use of medicines

PSA strongly supports the retention of the QUM objective in the NMP. However, going forward, PSA strongly believes that there must be genuine and innovative considerations to ensure full potential of this objective can be achieved for the benefit of all Australians. **Appendix 1** outlines two examples where significant improvements are warranted – workforce capacity and sustainability (Issue 5) and contribution of medicine expertise to collaborative care services (Issue 6).

PSA believes the QUM objective of the NMP is well recognised by stakeholders but has generally been implemented only passively. This must change under the new NMP and, as the organisation representing medicine experts, PSA is ready to contribute to and lead this discussion.

QUM is a cycle of person-centred care. This is depicted in the Medicines Management Pathway[3] that includes the full scope of QUM activities namely: the decision to prescribe or deprescribe a medicine, issuing the medicine, provision of medicine information, administration of the medicine and monitoring for response. PSA believes the cycle of QUM and elements of this pathway are not necessarily well understood or articulated. This review of the NMP provides the opportunity to improve this understanding.

As outlined in the profession's competency standards,[4] pharmacists are committed to maintaining professional standards and applying medicines management expertise and the principles of QUM while recognising obligations to society and the profession. Important components of QUM include medicine safety, efficacious use and judicious use of medicines. Pharmacists engage with patients, their carers, colleagues, other healthcare professionals and the wider community to promote the judicious, appropriate, safe and effective use of medicines. In all professional roles and practice settings, pharmacists' practice is firmly underpinned by QUM principles.

The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population. Pharmacists support patients by providing advice on medicines

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[3] Stowasser DA, et al. Understanding the medicines management pathway. J Pharm Pract Res 2004;34:293–6. At: **www.shpa.org.au/sites/default/files/uploaded-content/field_f_content_file/56._understanding_the_med_management_pathway.pdf**

[4] National competency standards framework for pharmacists in Australia. Canberra: Pharmaceutical Society of Australia; 2016. At: **https://my.psa.org.au/servlet/fileField?entityId=ka10o000000QM4zAAG&field=PDF_File_Member_Content__Body__s**

and medication management, to ensure medication safety and to promote the optimal use of medicines. Pharmacists also have a role in promoting and supporting achievement of QUM within organisations or the community and in connection with other healthcare professionals.

In future, PSA suggests it is a priority to adopt a proactive, rigorous and innovative approach to expanding and implementing the QUM objective. PSA would welcome the opportunity to provide leadership in this space and to work with NMP partners to further the health and wellbeing of all Australians.

We also wish to highlight to the Review Committee that reference must be made within the NMP to the 10th National Health Priority Area, 'Quality Use of Medicines and Medicines Safety'. PSA raised this issue in a national conversation in 2016 that led to the declaration of this critical issue as a Priority Area in 2019. PSA led a consortium of NMP partners to host a medicine safety forum to help inform Australia's 10th National Health Priority Area. As outlined in the report,[5] the consortium partners have provided recommendations around whole-of-health system changes and identified priority areas for implementation. PSA would welcome the opportunity to further discuss the recommendations and priorities in the context of the revised NMP with the review team.

Maintaining a responsible and viable medicines industry

NMP objective. The current NMP states that the above three NMP objectives "require the continued existence of a responsible and viable medicines industry in Australia". PSA believes each objective in the NMP must be important in their own right but also complementary with other objectives.

While the intent of this objective is generally supported, PSA notes that it refers to a particular NMP partner or sector. As a person-centred policy, the NMP must be neutral and not focussed on one particular sector. PSA suggests this requires careful consideration going forward. We would request that an updated policy also includes "maintaining a responsible and viable health workforce" to ensure ongoing performance and sustainability of the NMP.

Pharmacovigilance activities. PSA supports the World Health Organisation's contention that the "management of the risks associated with the use of medicines demands close and effective collaboration between the key players in the field of pharmacovigilance".

While sponsors of medicines have post-market surveillance obligations, as newer and greater range of medicines become available in the future, PSA strongly suggests there should be an increased emphasis on pharmacovigilance through the NMP.

This issue is further outlined (Issue 7) in **Appendix 1**, together with other topics including: medicine shortages (Issue 8), section 19A approvals (Issue 9), QUM risk-share arrangements (Issue 10).

Sustainability and medicinal products including disposal of medicines. The NMP has an opportunity to include a statement about sustainable practices within the development, supply chain and disposal of medicinal products. Pharmacists have been contributing to one element of this process with the safe collection and appropriate disposal of expired or unwanted medicines. With increasing use of pharmaceuticals and development of new formulations, responsible disposal is part of the equation of safe and quality use of medicines.

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[5] Pharmaceutical Society of Australia. Medicine Safety Forum: informing Australia's 10th National Health Priority Area. 2020. At: **www.psa.org.au/wp-content/uploads/2021/06/Medicine-safety-forum.pdf**

To highlight this further as an example, PSA has received information that, despite the ongoing success of the National Return Unwanted Medicines program,[6] only a fraction of all unwanted medicines is collected. PSA suggests that the NMP is an appropriate vehicle to promote public awareness around issues associated with medicines generally, apart from taking/using them, as each person also has a responsibility for safe disposal.

Terms of Reference 2: *Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.*

Question A: *Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?*

Current definition. Pharmacists have been guided by the definition of "medicines" included in key professional publications,[4,7] viz. "a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental welfare of people. Includes prescription and non-prescription medicines, including complementary health care products, irrespective of the administered route". Vaccines are already captured under this definition.

Medical devices. Although medicines and medical devices are considered together as therapeutic goods and common regulatory principles and requirements apply, PSA believes medical devices should remain separate from medicines with respect to the NMP. (PSA acknowledges that some devices are intended to facilitate delivery of a medicine.) The main aim of this review should be to improve and strengthen the NMP rather than increase the complexity of the policy at this time.

Current and future therapies. PSA suggests there is a need to move beyond 'medicines' as a term. It is necessary to accommodate new and emerging technologies including those referred to by the TGA, FDA or European Union such as, gene therapies, immunotherapy products, regenerative medicine products, cellular and tissue based products and short-term transformative therapies. There is also mention of artificial intelligence-assisted medicines.

PSA is aware that the European Medicines Agency uses the term 'medicinal product' which is defined as "a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action". The EMA also uses the term 'advanced therapy medicinal products' to capture "medicines for human use that are based on genes, tissues or cells".

PSA suggests that the term "medicinal products" being sufficiently broad to include new therapies would be a reasonable term to evolve from "medicines" in the new NMP.

Digital health technologies. As outlined in PSA's 2019 report,[8] Connecting the dots: digitally empowered pharmacists, advances in digital health technologies are already impacting on health providers and health consumers and will continue to do so. It is vital that a refreshed NMP captures the anticipated growth in adoption of digital technologies in health care. In addition, the scope of the Policy must be adaptable to be able to include future innovation, as far as practicable.

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6 See **https://returnmed.com.au/**

7 Pharmaceutical Society of Australia. Professional practice standards. Version 5. Canberra: PSA; 2017. At: **https://my.psa.org.au/servlet/fileField?entityId=ka10o0000001DYHAA2&field=PDF_File_Member_Content__Body__s**

8 Pharmaceutical Society of Australia. Connecting the dots: digitally empowered pharmacists. Canberra: PSA; 2019. At: **https://www.psa.org.au/wp-content/uploads/2019/07/Connecting-the-dots-Digitally-Empowered-Pharmacists.pdf**

It is likely that the use of wearables and implants will continue to rise as they become more accessible and affordable. Consideration should also be given to, for example, nanomedicines and precision medicines, as well as 3D printed medicines. In addition, the use of apps will continue to increase and this is one example of where better data collection could be implemented to inform policy performance and outcomes. It will also be necessary to consider evolving issues such as the use of drones in the delivery of medicines and healthcare services.

In summary, PSA requests that the Review Committee include terminology sufficiently broad enough to capture known advances in care as well as continuing to maintain a view on as yet unknown innovations via ongoing horizon scanning.

Question B: *Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?*

As referred in the Discussion Paper, advances in digital and health technologies have evolved and will continue to impact on the design and delivery of medicines, healthcare service delivery and medication safety initiatives.

Terms of Reference 3: Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

Question A: *How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?*

Although the broad intent of the NMP remains relevant today, as outlined above, it does not comprehensively capture key changes to the health.

Well-considered high-level principles and consistent objectives that focus on person-centredness will be important for the future NMP. However, long term relevance and resilience of the NMP and its impact on the healthcare system will require critical changes, particularly around implementation, as outlined below.

Question B: *How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?*

Although this question and the Discussion paper refer to a "refresh" of the NMP, PSA suggests there is a need to provide broader consideration for a successful 'future' NMP framework. The current NMP has lacked an overarching implementation plan and has instead relied upon individual or sector stakeholders to interpret and develop activities. While there have been positive outcomes, often processes have been slow and activities not always well coordinated. It is critical that the 'new' NMP has a comprehensive framework with an implementation plan that supports research, collection of data, evaluation and reporting of performance measures, and importantly regular review and refinement of policies.

There is also a need to instil clear leadership around the implementation of the NMP. Although the NMP may already underpin Government decision-making, currently there is not a strong link between the policy itself and what health practitioners and patients experience, as well as what the public sees on the ground. The Policy needs to be translated into health system structures and activities generally and health professional practices in particular, and to result in meaningful health outcomes for Australians. This might be done, for example, by policy makers and regulators working collaboratively with Australian Government-funded health peak and advisory bodies to consistently and regularly embed NMP principles and objectives in respective activities and communications. This has been one of the key considerations of PSA in fulfilling its obligations as a health peak and advisory body for the

pharmacy profession.

Strong leadership and connecting with all stakeholders should facilitate greater opportunity for early identification and considered response to future health landscape changes.

Terms of Reference 4: Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

Question A: *How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?*

Every effort needs to be made to ensure all people or population groups are adequately and appropriately considered and captured by the NMP. Medicines are the most common intervention in health care and already impacts on many Australians and will continue to do so. Improvements in health literacy overall through NMP activities should also be a priority. There is also increasing focus on consumer or patient activation being necessary to improve the use of health and medicine information.

Consumer centricity or a person-centred approach must be a fundamental principle in the future NMP. In any NMP-related initiative, consumers and relevant patient groups must be part of the co-design process and have the opportunity to contribute to development, innovation and reform. In addition, an approach should be taken to facilitate consumers being informed, engaged and empowered about their own health and care.

PSA strongly advocates for the needs of high-risk and vulnerable population groups, for example, Aboriginal and Torres Strait Islander peoples, people with disability, the elderly, culturally and linguistically diverse people, members of the LGBTQIA+ community, people with low health literacy, people requiring mental health care, and others. It is particularly important that the needs, expectations and preferences of these individuals are considered carefully as they are generally likely to be more susceptible to medication-related harm.

Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

Question A: *What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?*

Implementation plan. The principles underpinning the NMP are solid and continue to resonate today. However, PSA believes that over the 20-plus years the NMP has been in place, as a nation, we have not maximised the benefits that could be derived from having a unique and universally endorsed policy. While recognising the importance of having a partnership approach to the implementation of the NMP, there has not always been maximal cross-sectoral collaboration to achieve best possible outcomes for individuals and communities.

To a large extent, each organisation, partner or sector has worked hard to "draw on their unique perspectives and abilities" and promote and implement the NMP objectives. However, those activities have not necessarily been coordinated as well as they could be to gain synergies and maximise efficiencies.

In primary health care, for example, Primary Health Networks may commission services to implement NMP-related activities through their role and responsibility for delivering and improving health outcomes within their respective networks.

PSA firmly believes that, on reflection, the absence of a specific implementation plan has limited progress and achievements under the current NMP. What is evident with most comprehensive

national health-related policies is that there is an associated implementation plan or framework. Thus, PSA suggests it is vital that an implementation plan is developed to support and operationalise the 'new' National Medicines Policy. An inclusive and successful implementation plan will require proactive action, including strong leadership and coordination; a commitment to monitoring and evaluation, and judicious use of data; embedding performance measures and associated accountabilities, promoting research to inform improved QUM, and facilitating mechanisms to refine programs and policies based on implementation outcomes.

Having a robust and inclusive implementation plan will also clarify responsibilities and intent and ensure there is less wasted effort in designing and implementing ad hoc programs or duplicating initiatives. We highlight three key areas below where an enhanced NMP policy would improve outcomes for patients across Australia.

Improving coordination across jurisdictions. At times, patients have not received clear, timely or consistent care due to jurisdictional differences in health service or medicine access arrangements. This is inconsistent with the remit of the NMP to provide equitable access to care. PSA has long advocated through pre-budget and other submissions for funds to establish a vital position of a Commonwealth Chief Pharmacist. PSA suggests this person would facilitate improvements in coordination between government departments and increase responsiveness to medicine safety and QUM within our complex healthcare system.

By way of example, pharmacists experienced and reported during earlier stages of the COVID-19 pandemic of inadequate coordination efforts by government departments and apparent lack of understanding of, or foresight into the flow-on effects and impacts on the profession. This extended to government advice provided to health practitioners which contravened state/territory poisons laws. PSA is confident that a Commonwealth Chief Pharmacist liaising with state and territory colleagues would improve coordination and communication, and importantly, prevent inappropriate or unacceptable decisions or actions being taken.

Improved transparency, coordination and collaboration. In 2019, PSA made a submission to the Review of the Quality Use of Medicines Program's Delivery by the National Prescribing Service Limited (NPS MedicineWise).

In the submission, PSA commented on two specific areas:

- **Rational use of antibiotics**. The antibiotic resistance campaigns by NPS MedicineWise reportedly delivered a 16% reduction in antibiotic dispensing for upper respiratory tract infections for concessional patients under PBS supply for July 2012 to July 2015 and PBS savings of over $75 million for 2015/16. Results of 2017 national antimicrobial prescribing surveys, however, included alarming figures relating to antimicrobial prescriptions in both hospital and aged care settings, such as:
    - prescriptions assessed as being non-compliant with clinical guidelines (26.2%) or inappropriate (22.4%; e.g. spectrum too broad; incorrect dose or frequency; antimicrobial not required; and incorrect duration)
    - over half (55.2%) of prescriptions were for residents with no signs and/or symptoms of infection in the week prior to the start date
    - for 26.9% of prescriptions, the start date was greater than six months prior to the survey date.

    These outcomes suggested to PSA that there was value in considering changes or improvements through, for example, more appropriate performance measures, partnering with

other organisations to enhance synergies, or investing in more innovative initiatives as clearly there was significant scope to improve QUM.

- **Quality Prescribing Incentive**. PSA acknowledges that some changes were implemented to the QPI under the Practice Incentives Program in 2019.

  The point that PSA made at the time was that contributions to the range of QUM activities for QPI purposes appeared to be limited to those developed by NPS MedicineWise. PSA had enquired about how it could contribute to the development or delivery of QUM activities which were consistent with the objectives of NPS MedicineWise. The QPI under the PIP appeared to be an appropriate avenue for pharmacists to assist general practitioners to achieve more effective, quality prescribing through a range of education, support and prescribing information, and to fulfil QPI requirements.

  Although NPS MedicineWise clarified that it was not the sole provider of activities eligible for inclusion in the PIP QPI, PSA discovered that 'suitable' activities were largely restricted to those provided by them. PSA firmly believed that the arrangement was overly restrictive and not necessarily in the best interests of supporting prescribers or meeting the overall objectives of NPS MedicineWise.

PSA's overarching message was that despite significant recurring Government funding, there was scope for substantial improvement for the NPS MedicineWise QUM Program to deliver on the QUM agenda. In addition, and disappointingly from PSA's experience, a partnership approach was not necessarily encouraged. These issues require attention and improvement.

The manner by which the Public Report of the review was released was also not timely and lacked transparency.

These issues re-affirm that, the outcomes from the current NMP review must lead to a commitment to invest in the development of an implementation plan, provide clarity around transparency and accountability, improve coordination and encourage partnerships through strong leadership.

Enhanced opportunities for QUM research. Evaluation of implementation activities broadly will be essential to gain an understanding of the impact of NMP goals and objectives, and to inform refinements and improvements in policies and programs. An important medium- to long-term enabler of the NMP and to guide and shape future health care will be QUM research. There will need to be direct investment into QUM research that will facilitate innovation in healthcare service delivery.

PSA would also re-iterate a priority of the NMP should be around the importance of translating research outcomes into practice. We do not want to see significant investments in research generating positive outcomes which are then not implemented in practice or used to inform future health or pharmacy policies.

Question B: *How can communication about the NMP be enhanced or improved?*

PSA strongly suggests that the NMP is highlighted to media organisations and journalists. Further, these stakeholders should be given the opportunity to work constructively with all NMP partners (as appropriate) so that they have a clear understanding of what the principles and objectives of the NMP are, what the implications are for everyday Australians, and what the best way to report on NMP-related initiatives is.

The media have significant reach and speed in disseminating messages to the public. When reporting on healthcare matters, they can influence decision-making by patients and carers, and shape the local or national response to health issues. Importantly, these reactions and responses have flow-on effects

for healthcare professionals and healthcare workers. Giving Australians access to evidence-based health messaging is critical, given the potential for inaccurate or mixed messaging available via online and social media sources.

Reporting on risks and benefits on medicines and in health care is always a balancing act. Unfortunately, it is often the case that media reporting content can be disproportionate to the actual scientific basis of a clinical outcome or finding. In many cases, media stories can appear to accelerate research progress or unduly emphasise potential clinical benefit. Stories with a negative slant can also have an exaggerated impact on individuals and the public. We have experienced these challenges in relation to COVID-19 vaccines.

It is important that a clear and balanced picture on a health topic can be provided to media outlets in a timely manner. It is always much harder to correct misinformation in people's minds than it is to not generate confusion in the first place. Mechanisms to provide clear and concise information and education about the NMP and health matters generally to the media will be important. It will help to ensure clear, accurate and realistic reporting to the public, and potentially improve health literacy of the general population.

Question C: *What would be effective mechanisms to support communication about the policy?*

There should be discussion about appropriate communication mechanisms as part of the development of an implementation plan for the NMP. As an example, PSA believes there should be joint media releases, where possible, between the Australian Government and relevant NMP partners for significant NMP-related announcements.

There should also be similar joint statements to warn the public when there is activity contrary to NMP principles (e.g. when misinformation about medicines and vaccines is being spread by high profile individuals during the COVID-19 pandemic).

Terms of Reference 6: Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

Question A: *How should the NMP's 'partnership-based' approach be defined?*

The NMP's strong 'partnership-based' approach is clear, as is the inherent "responsibility" of each partner to contribute to the achievement of the Policy's objectives. As referred earlier, PSA believes that better coordination of these respective contributions is much needed and this must be effected through strong leadership and an implementation plan.

Greater accountability can also be derived from having appropriate data collection arrangements and performance measures, and applying evaluation outcomes to further research, review and refinement of the initiative or policy.

PSA acknowledges the current NMP document outlines how partnerships could help to progress the NMP and provides an indication of which partners have prime carriage of work to advance the main NMP agendas. PSA believes each of these partners have a role and renewed responsibility to nurture a collaborative working relationship and work towards mutually beneficial outcomes.

Question B: *What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?*

Medicine use is relevant to people with disability and medication safety is particularly important and in urgent need of attention as revealed through the Disability Royal Commission. PSA suggests specific inclusion of this vulnerable population group is warranted.

As mentioned earlier, there is a range of vulnerable population groups that need to be considered. The NMP essentially impacts on any person who is taking or using a medicine.

Question C: *How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?*

PSA suggests this requires input from governance experts as well as reflection on governance arrangements of similar high-level national policies.

PSA believes identification of a clear leadership group to define priorities and progress coordinated activities according to an agreed implementation plan will be paramount. PSA as the peak professional body for pharmacists would seek to be part of such a group.

Question D: *How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?*

(No suggested response)

Appendix 1: Issues impacting on patient care and pharmacists' practice in the context of the National Medicines Policy

This section provides PSA's views on specific healthcare activities and programs which are underpinned by current NMP principles and objectives and are relevant to pharmacists' practice. The issues or topics are not suggested for direct inclusion in the refreshed NMP but are intended to provide context of the interpretation and implementation of the current NMP. These are selected examples based on reports to PSA by pharmacists through their professional practice experience in delivering care to patients, families, carers and the public.

A. Issues impacting on equitable access and timely access to medicines

Issue 1: Serious Scarcity Substitution Instruments

The SSSIs have been implemented to help address medicine shortages by allowing community pharmacists to substitute specific medicines without prior approval from the prescriber. It is considered to minimise delays and allow continuity of prescribed treatment for patients, and relieve workload pressure on prescribers and pharmacists.

While it is acknowledged that an appropriate substitution may depend on external factors (e.g. level of stock in the country), PSA contends that the SSSI arrangement remains cumbersome due to the need to formalise a legislative instrument for each scarce medicine.

More importantly, there should not be a need for a legislative instrument to permit pharmacists to supply an alternative medicine with the same active ingredient. These professional activities (e.g. change in dosage form, change in strength of medicine) are fundamental core competencies that pharmacists are already registered for. It is creating inefficiencies, and adversely affecting timely access and continuity of care for patients.

PSA strongly suggests implementation of NMP principles and objectives must reflect and be consistent with the scope and remit of relevant partners and their members and not create unnecessary hindrances to professional practice.

Issue 2: Opiate Dependence Treatment Program

People who access medicines under the PBS ODTP frequently cite cost and travel as barriers to access. Despite being an essential medicine and generally for chronic use, the funding and supply arrangements for these medicines are different to general PBS medicines. Some claim that the access arrangements are discriminatory and do not support best practice care for people with opioid dependence.

PSA suggests access arrangements to ODT medicines should be reviewed to ensure they meet NMP principles and objectives, including issues such as eligibility for PBS Safety net records and access to formal staged supply arrangements. A program structure that provides for fair and commensurate remuneration for pharmacists involved in the ODTP is also long overdue. Many pharmacists report that the current supply arrangements are not sustainable, but they continue to deliver the service due to their public health responsibilities and professional commitment to care.

Issue 3: State and territory regulatory arrangements

Australians are used to having different arrangements implemented across state and territory borders, even when one policy or recommendation has been issued at the national level. However, with

respect to health care, all Australians should have access to the same standard of care or access arrangements.

When the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* came into force, the supply of PBS-subsidised medicines to patients following a telehealth medical consultation was made safer and more convenient. However, implementation of this arrangement by state and territory governments were not coordinated and conducted at varying pace, with the last jurisdiction to enact the change almost eight weeks later. This resulted in confusion and inconvenience for patients and carers as well as confusion and significant additional workload for pharmacists.

The use and impact of therapeutic products will continue to increase. While PSA respects the sovereignty of Australian states and territories, it firmly believes it is time to harmonise state and territory legislative arrangements for the regulation of therapeutic products and associated services. Harmonising regulation across states and territories to achieve a single, national system is not new; it has been considered in the context of regulation of poisonous chemicals. Also, professional registration of health practitioners successfully transitioned to a national system and is operating well. Another example is the legislative arrangement to declare a Serious Scarcity Substitution Instrument at the federal level which allows a pharmacist to dispense a substitutable medicine even if state or territory legislation normally prevents this from occurring.

The implementation of a single, national regulatory framework for medicines will promote efficiency and effectiveness in the work of regulators, reduce effort and cost associated with multi-jurisdictional businesses and the professional practice of pharmacists and prescribers, and the experience of recipients of therapeutic care.

B. Issues relating to the quality, safety and efficacy of medicines made available to Australians

Issue 4: Unapproved and unregistered medicines

PSA notes there has been a recent trend towards an increasing number of arrangements to permit the supply of unapproved medicines in Australia to benefit patients, including, for example, medicinal cannabis and nicotine vaping products. These arrangements are designed to facilitate timely access to therapeutic products that Australians need.

However, these arrangements generally have specific administrative requirements for prescribers, pharmacists and patients. This, in effect, transfers or imposes some of the regulatory obligations onto health professionals, particularly prescribers and pharmacists. For example, arranging procurement, handling and dispensing unregistered and unapproved products may require the pharmacist to ensure conformance with product standards (e.g. Therapeutic Goods Orders), dealing with overseas suppliers, making Australian customs declarations, compliance with any additional advertising rules, or obtaining a retail licence. These additional administrative and professional requirements can increase the burden on health practitioners.

In addition, the use of unapproved medicines increases clinical and legal responsibility for health professionals, including in situations where there may be limited or lack of reliable information or evidence.

There must be careful consideration given to such arrangements, particularly as the range of available unapproved products increases. Appropriate mitigation and monitoring of risks associated with unapproved medicines are paramount and this responsibility should not fall disproportionately on health professionals and patients.

C. Issues impacting on quality use of medicines and patient care

Issue 5: Workforce capacity and sustainability

Currently, pharmacists undertake the same training as other health professional immunisers to become authorised immunisers. However, pharmacists are not permitted to administer the same range of vaccines as other health professional immunisers, and they also do not receive equivalent remuneration. These current anomalies and disparities must not persist as they are having a negative impact on timely access and QUM for patients. There are also flow-on negative impacts on pharmacist workforce sustainability as well as health workforce capacity more broadly.

Issue 6: Medicine expertise to boost collaborative care services

Pharmacists, within their scope of medicine and medication management expertise, should be included as eligible providers and remunerated as part of a team delivering collaborative care services under the Medical Benefits Schedule. Despite clear MBS Taskforce recommendations for pharmacists to be included as eligible allied health providers for specific items, they have not translated into the required legislative amendments, thus excluding opportunities to deliver on the Government's commitment to improve medication safety and QUM.

D. Issues relating to a responsible medicines industry

Issue 7: Pharmacovigilance activities

PSA has previously advocated for a holistic, nationally-coordinated and outcomes-focussed pharmacovigilance program. PSA strongly suggests that greater and better collection and use of post-market surveillance data will be vital going forward to improve medication safety, inform QUM decisions and guide improved health outcomes.

In particular, the fundamental role of pharmacists in improving medication safety should be recognised and opportunities created for formal involvement in these roles. A recent example is the new pharmacist-led real-time pharmacovigilance system that will monitor potential adverse events following vaccination with the Moderna *Spikevax* COVID-19 vaccine.

Issue 8: Medicine shortages

While it is accepted that medicine shortages cannot be eliminated completely, they can have significant impact on patients, pharmacists, prescribers and regulators.

In the interests of timely supply of medicines, continuity of patient care and seamless delivery of health care, efficient and innovative ways to minimise or address shortages must be developed. Early identification and notification of medicine shortages are fundamental to ensuring a resilient and responsive healthcare system, particularly as more medicines are expected to become available over the next decades.

PSA is aware there are several overseas examples of proactive potential shortage reporting mechanisms that we could gain insights from.

Issue 9: Section 19A approvals

Pharmacists are increasingly encountering section 19A approved medicines being sourced to address medicine shortages. These temporary arrangements are helpful but clearly they are not long term solutions. PSA suggests that the NMP should recognise the need to grow opportunities for sponsors

of therapeutic goods to apply for registration in Australia in order to increase the pool of approved medicines for Australian patients.

Issue 10: QUM risk-share arrangements

PSA believes that there is significant scope to improve the role, responsibility and contribution of the pharmaceutical industry in the context of the NMP. Generally speaking, mechanisms to promote timely access to medicines are well-established and have been the subject to recent and ongoing reforms.

It is generally the case that sponsors seek PBS listing of their medicines, and current assessment of suitability will be undertaken based on data, evidence and information relating to those medicines under clinical trials or other controlled conditions. It is a reality, however, that we gain experience and important additional information on safety and risk-benefit profile following market approval and wider clinical use.

PSA strongly believes that the pharmaceutical industry must also be responsible for implementing QUM measures – these activities should not just be the responsibility of health professionals, regulators or policy-makers. For example, they should fund appropriate interventions to promote judicious use. They should also work in partnership with professional bodies and clinical groups to develop QUM guidelines of their medicine, including 'protocols' on ceasing treatment where that is relevant and appropriate.

PSA would suggest and support the concept of risk-sharing arrangements coupled with, for example, PBS listing, with respect to 'costs' associated with adverse outcomes with specific medicines or groups of medicines. Industry contributions to costs associated with medicine overuse and treatment (e.g. for addiction treatment) could be factored in.