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RACP Submission on the Discussion Paper on the National Medicines Policy Review

October 2021

About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 18,863 physicians and 8,830 trainee physicians, across Australia and New Zealand. The RACP represents a broad range of medical specialties including clinical pharmacology, general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, infectious diseases medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients.

Executive Summary

The College welcomes the opportunity to contribute to the National Medicines Policy (NMP) Review commissioned by the Minister for Health and Aged Care, the Hon Greg Hunt MP. The following comments relate to the Discussion Paper released as part of the Review. Opinions and themes included in this submission reflect a variety of views of RACP members on the matters raised in the Paper.

As a College representing thousands of physicians with specific and extensive expertise on this subject we are pleased to provide this submission to the Expert Advisory Committee.

The regulation of medicines and medical devices is of great importance to the RACP:

- Medicines' prescribing is a core aspect of physician science, physicians are key health professionals in the use of medicines and many engage with therapeutic devices.
- The RACP oversees clinical pharmacology training in Australia.
- Many members are involved with hospital and community-based therapeutics committees.
- Physicians work across all health care sectors and are aware of disparities and inconsistencies in practice regarding medicines.

As noted by the World Health Organisation, health system leaders and expert practitioners need to be involved in producing guidance and action plans relating to the many domains that contribute to the administering of medicines.[1] Of particular interest to physicians is the role of specialised expertise in optimising medicines and therapeutics research, regulation, education and practice.[2] Clinical and Experimental Pharmacologists and Toxicologists have key leadership roles in the design and implementation of national medicines policies.[3] They are involved in the critical evaluation of new and old therapies, therapeutic drug monitoring, clinical drug toxicology and pharmacovigilance and the work of Drug and Therapeutics Committees.

To benefit Australians, the NMP must:

- be written in such a way as to be actionable and translatable
- define and communicate its elements so that they can be consistently implemented in an integrated manner
- be applicable across currently siloed health care sectors, and
- clearly designate responsibilities for leadership and accountability.

It is equally important that consumers, whose health care experiences typically require navigating across several parts of the health system, receive seamless, consistently high-quality care and clear and reliable information about medicines and therapeutics.

Key points of this submission cover:

- Need for regular reviews. The NMP must be reviewed on a regular and structured basis to ensure currency, promote quality use of medicines (QUM) and provide relevant measurements of health outcomes which then impact decision making.

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[1] Medication Without Harm - Global Patient Safety Challenge on Medication Safety. Geneva: World Health Organization, 2017. Licence: CC BY-NC-SA 3.0 IGO https://www.who.int/initiatives/medication-without-harm [accessed 24/09/2021]

[2] Council for International Organisations of Medical Sciences (CIOMS); World Health Organisation (WHO), International Union of Basic & Clinical Pharmacology (IUPHAR), 2012: "Clinical Pharmacology in Health Care, Teaching and Research"

[3] Medication Without Harm - Global Patient Safety Challenge on Medication Safety. Geneva: World Health Organization, 2017. Licence: CC BY-NC-SA 3.0 IGO https://www.who.int/initiatives/medication-without-harm [accessed 24/09/2021]

- Ongoing Specialist Physician involvement. Physicians in general and Clinical Pharmacologists in particular should be included in the NMP development, implementation and evaluation at all levels.
- Fostering interconnectedness and integration. Stakeholders and partners must work to address the interconnectedness of the proposed principles and objectives with each other and with other components of the NMP and the broader health system. The challenge is to design and implement the NMP for all Australian consumers and across all health care settings and systems, noting we do not operate as "one health care system".
- Identifying and working to address the needs of different population groups. A proactive, data-informed mechanism for identifying the needs of different population groups will assist in the operationalisation of the NMP by directing resources and meeting requirements in an efficient and targeted way.
- Building the workforce. The NMP should reflect a commitment to ensuring the currency and sustainability of the specialty clinical pharmacology workforce to enable safe, effective and quality use of medicines.
- Improving medication safety. We recommend the policy go beyond minimising errors and acknowledge the importance of all harms. There is a difference between errors and harms and harms can occur without error. A focus on errors alone will not prevent all harms, and a failure to investigate harms whenever they occur is a lost opportunity for risk mitigation.
- Securing supply chains. The NMP must ensure there is effective policy for the handling of supply chain issues and of rapid approval of medicines in certain circumstances. The medicines shortage taskforce created during the pandemic is one way to deal with such issues.
- Safeguarding environment. As a comprehensive national policy, this document should address the environmental impact of medicines through the manufacturing process, human metabolic processes, and the disposal of unused drugs.[4]

We look forward to ongoing College engagement with the Expert Advisory Committee as the NMP is progressed and finalised.

Specific comments on the NMP

Consistent with the goals of minimising harm and promoting a preventative approach to health care, the NMP should recognise the need to routinely consider if medicines are the best response to a condition. Such an approach can work to reduce unnecessary medicine use in favour of prevention as part of a "one health system" philosophy of health care. The judicious use of medicines is mentioned on page 8 of the Discussion Paper in discussing quality use of medicines; however, more attention should be paid in the document to this important principle.

We welcome the emphasis on ensuring the document is clear and relevant to consumers. This goal can be furthered by introducing several improvements discussed throughout this submission. The Committee should also reconsider the use of the term "consumer" where a more positive and holistic substitute might exist to refer to people, their carers and the community. Carers and supporters should be included in policy discussions more often in recognition of their integral involvement in the lives of patients, people with disabilities, children and older people.

Clinical medicine incorporates a full range of information about individuals, their genetics, their biochemistry, their physiology, their anatomy, their culture, their beliefs, their diseases, their other medicines, their capacities. The NMP should foster care of individuals as a partnership based on the goals of the individual using all information available

[4] https://dualdiagnosis.org/the-environmental-impact-of-growing-drugs/

As a comprehensive national policy, this document should also address the environmental impact of medicines through the manufacturing process, human metabolic processes, and the disposal of unused drugs.[5]

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.

Principles

- Equity, as defined here, focuses on access to medicines. Equity of access to expert advice is also essential for effective use of medicines and to secure equity of outcomes. It is important that the words "irrespective of age" be included to read "Equity – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of age, background or personal circumstance." For the NMP to be effective, practices must be specific and relevant to identifiable population groups to minimise harm and enforce best practice. This should be made explicit in the policy.
- For the principle of "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 national framework" we suggest adding "within a transparent, well-resourced and well-coordinated national framework".
- We suggest the addition of a reference to scientific principles and the need for a quality evidenced-based approach to all decisions.
- The principles should reflect a bioethical perspective promoting the use of medicines in ways that best serve the patient's interests, considering in the first place the degree of necessity and the requirement to minimise harm.
- We suggest the inclusion of a principle: "Integrated functioning – all stakeholders and partners function in ways that respond to and enhance the interconnectedness of the objectives with both the components of the NMP and the different parts of the health care system, consistent with the national health strategy."
- To avoid the overuse of the word "transparent" in this section, we suggest other terms such as clearly designed or well-articulated.

In giving effect to the principles of the NMP, we raise two points in relation to Aboriginal and Torres Strait Islander people:

- In relation to the principle of equity, the revised NMP should consider its application to Indigenous Australians, as a group with a unique status that is also not a homogenous population. To achieve equity of safety for Aboriginal and Torres Strait Islander people an active and comprehensive post-market pharmacovigilance strategy is required.
- The principle of accountability needs to encompass the accountability for the safe use of medicines among Australia's Indigenous populations. The Expert Advisory Committee should consider and improve the adequacy of current mechanisms for achieving this goal through, for example, spontaneous reports to the TGA and feeding back TGA findings to relevant organisations and groups.

Objectives

Overall, the Objectives remain relevant. However, it is important that the Expert Advisory Committee is cognisant of and addresses the greater challenges and gaps that lay in the effective implementation of the Objectives in what is currently not a "one health care system". The NMP must be underpinned by a proactive, data-driven mechanism for identifying the needs of different population groups. This would support the implementation of the NMP through targeted resource allocation and effective identification and response to issues relevant to specific sub-populations.

[5] https://dualdiagnosis.org/the-environmental-impact-of-growing-drugs/

NMP implementation must address the risks and needs of various populations to meet quality use of medicines requirements for all Australians.

Absent among the objectives is the purpose and function of medicines which is broadly to cure, halt, or prevent disease; ease symptoms; promote or maintain well-being or help in the diagnosis of illnesses.

We note that "person-centred" does not feature in any of the Objectives and we recommend this value be included.

"Access to medicines"

- The objective of access, and the related principle of equity, are central to this policy. It should also note the importance of access to expert advice to obtain full benefits from medicines.
- The objective should cover timely access to accurate and independent information about obtaining medicines. An example is the experience of patients paying for expensive drugs that are TGA-approved but not PBS-funded, which undermines a justice principle. Consumers (or patients) should be informed of the difference in costs of medicines between a PBS-approved pharmacy and a non-approved pharmacy and of the higher prices for medicines that originally come from a non-PBS approved pharmacy where the next repeat is obtained from a PBS-approved pharmacy.
- The NMP should acknowledge that there are different levels of access and equity disparities experienced by population groups, including culturally and linguistically diverse people, children, Indigenous people, frail older patients and refugees.
- There are also growing divides and life expectancy differentials between healthier metropolitan Australians and rural and other underserviced Australians.[6] In addition to social determinants of health, a contributing factor to such outcomes is poor access to care. This can lead to the variance in use of high-end expensive medications. Access to information is also important in this context since expensive medications that are heavily promoted by industry may not prove as effective in real-life situations as in the trials.[7]
- The NMP should have regard for the inequitable access to expert advice, evaluation, appropriate information about and supply of off-label medicines.
- We also note the long-standing issues related to medicines and children that include paucity of evidence on which to base evaluations, therapeutic decision-making and use of existing and new medicines. Specialised skills and systems are needed to address the gaps in access for this substantial and vulnerable sub-population of Australians.[8] Australian research has also shown that policy makers, prescribers, pharmacists and, most importantly, the children of Australia need a more uniform, streamlined process for hospital-based paediatric drug approval and an establishment of a national infrastructure for paediatric clinical trials. [9]

These practical measures are suggested to improve access:

- A national prescribing support program. Practice programs vary (e.g., Genie, Mediflex) and there is no best practice reliable resource on the internet that covers dosing recommendations and tablet/suspension availability. Although most hospitals have injectable guidelines, a national resource would be beneficial.

[6] Adair T, Lopez A. Widening inequalities in premature mortality in Australia, 2006-16. Australian Population Studies. 2020 May 22;4(1):37-56.

[7] Skovlund E, Leufkens HG, Smyth JF. The use of real-world data in cancer drug development. European Journal of Cancer. 2018 Sep 1;101:69-76.

[8] As stated in Sinha YK, Craig JC, Jo-anne EB. Paediatric drug policy in Australia. Journal of paediatrics and child health. 2015 Mar;51(3):259-62.

[9] As stated in Sinha YK, Craig JC, Jo-anne EB. Paediatric drug policy in Australia. Journal of paediatrics and child health. 2015 Mar;51(3):259-62.

- Making ePrescriptions available to any pharmacist anywhere in Australia via Medicare card, which would assist with lost prescriptions and help older people less competent with technology.

"Quality, safety, and efficacy of medicines"

- We suggest emphasis be placed on the need for medicines to meet *contemporary standards* of quality, safety and effectiveness.
- The first sentence states "The NMP commits all partners to consider that the quality, safety, and efficacy of medicines available in Australia should be equal to that of comparable countries (i.e., economic/health systems/education)." We note the need to recognise in this context the impact of cultural, ethnic or ancestry status, as is the case in work of the Food and Drug Administration in the United States.[10] Aboriginal and Torres Strait Islander people are negatively impacted if there is no requirement for the evaluation or surveillance of medications in this population. We also stress the need to assess for the age-appropriateness of medicines which is especially important for children. [11]

"Quality use of medicines"

- Regarding the following statement: "The publications from Drug Utilisation Sub Committee (DUSC) aim to uphold the NMP in terms of assisting consumers and health professionals in understanding the costs, benefits, and risks of medicines," we note an important omission: Adverse Drug Reactions (ADRs) are not reported through this mechanism.
- In relation to the sentence "The ACSQHC also leads and coordinates a range of national initiatives to reduce medication errors and harm, and to optimise medicines use', it is important to stress that there is a difference between errors and harms: harms can occur without error, so a focus on errors alone will not prevent harms, and a failure to investigate harms whenever they occur is a lost opportunity for risk mitigation.
- We also note in this section the conflation of alternative and complementary therapies with medicines. In light of the definition of medicines and the commitment to evidence-based medicine, calling alternative and complementary therapies "medicines" elevates them to a therapeutic level that is not supported by evidence. Notwithstanding, regulation of these products to ensure the contents are as claimed is important.

"Maintaining a responsible and viable medicines industry"

- The objective should acknowledge the requirement to ensure that the cost of medicines to the community supports the long-term sustainability of the health system.
- Considering the importance of securing Australia's medicines supply, promotion and support of a local industry and support and funding for relevant research institutes should be prioritised.
- The Review might consider prioritising the manufacture of vaccines in Australia.
- Greater transparency is needed about how new, sometimes expensive drugs receive PBS funding.
- The objective should note the imperative to respond to the changing health needs of Australians in accordance with the safety & quality recommendations of the Australian Technical Advisory Group on Immunisation (ATAGI), the National Safety and Quality Health Service (NSQHS) and emerging research evidence.
- Public health and population health must be a priority for regulatory decisions related to medicines.

Additional Objectives

[10] Maliepaard M, Taams AC, Sung C, Poh J, Yu Y. Ethnicity-Specific Drug Safety Data in European Medicines Agency Registration Dossiers, European Public Assessment Reports, and European and Singapore Drug Labels: Lost in Translation?. Pharmaceutical medicine. 2019 Oct;33(5):407-16.

[11] WHO 2007 Promoting safety of medicines for children

- Another objective should be to sustain a highly skilled workforce of health professionals and partners who contribute to the quality use of medicines; the NMP must support quality education for professionals to support this goal.
- The Committee might consider an objective to foster health literate consumers who understand how standards of quality, safety and efficacy are developed and met.

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

The rationale behind the Committee's consideration of the expansion of the definition of medicine stems from the emergence of new drugs and novel medical technologies blurring the boundaries between medicines and medical devices (such as diagnostic tests). A key consideration is the degree of convergence of functional objectives between medicines and other therapeutic devices, and the policy and regulatory implications where they differ (for example, where the stakeholders may be different). Any policies and regulations in this respect must be appropriately designed, aligned and supported in practice.

- Our members expressed varying views on this question and the RACP does not have a position on this matter. Members support the recognition of digital health and associated devices and technology and acknowledge the need to make provision for adequate and effective regulation. One potential solution for an expanded definition of medicines might be to develop a high level "national medical treatment policy".

- Policy has an impact on funding and the accessibility and availability of medicines and health technologies. In Australia, the processes for public reimbursement of high-cost pharmaceuticals and medical devices differ.[12] Because of the differing funding mechanisms there is a potential for inequitable reimbursement decisions for medical devices and pharmaceuticals.[13] For example, high-cost pharmaceuticals may be funded by a single source (federal government) while securing funding for high-cost devices is more complex, with funding typically sourced from a combination of federal, state and private health insurance.

- The Expert Advisory Committee might consider the best policy approaches for funding and providing access to non-pharmacological interventions. These may be more effective and safer than some medicines but without pharmaceutical company sponsorship to back them up are less well known and accessible. The high levels of antidepressant prescriptions for mild depression reflect a combination of sponsorship power and lack of access to psychological treatments.[14] Likewise, higher levels of opiate prescriptions in rural areas reflect limited access to physiotherapy.[15]

- There is a rapidly growing market of diabetes monitoring and insulin delivery devices that need regulation. Improved and equitable access to these new devices must be a priority. If certain devices (insulin delivery devices, pumps, and blood glucose monitoring systems) were considered medicine, they would be more available to patients.

[12] Saing S, van der Linden N, Hayward C, Goodall S. Why is there discordance between the reimbursement of high-cost 'life-extending 'pharmaceuticals and medical devices? The funding of ventricular assist devices in Australia. Applied health economics and health policy. 2019 Aug;17(4):421-31.

[13] Saing S, van der Linden N, Hayward C, Goodall S. Why is there discordance between the reimbursement of high-cost 'life-extending 'pharmaceuticals and medical devices? The funding of ventricular assist devices in Australia. Applied health economics and health policy. 2019 Aug;17(4):421-31.

[14] Alduhishy M. The overprescription of antidepressants and its impact on the elderly in Australia. Trends in psychiatry and psychotherapy. 2018 Sep;40(3):241-3.

[15] Adair T, Lopez AD. An egalitarian society? Widening inequalities in premature mortality from non-communicable diseases in Australia, 2006–16. International Journal of Epidemiology. 2021 Jun;50(3):783-96.

- The NMP should consider ways to increase oversight of a variety of “natural supplements”, “vitamins” and biosimilars available in the marketplace. Considering the increasing patient use of these products and potential interaction with other medicines, some members ask that the NMP address preventable harms from complementary or alternative medicines.

- There are many potential regulatory implications of the final definition. One relevant example is the alteration of the Prosthesis definition to only include implantable devices. Devices (consumables or those left in the body for short periods) are recognised as appropriate treatment and should be funded accordingly. These include insulin pumps, pillcams, and consumables for atrial ablation. There are others that do not fit well into the existing policy areas, such as external monitoring devices for glucose, oxygen levels and cardiac monitoring. These also require different specialists to evaluate their effectiveness, safety and cost benefits.

- In the interests of health literacy and supporting consumer rights, any definition of medicines should be clearly and accessibly explained to consumers, including any implications for out-of-pocket costs. Use of devices should be accompanied by an evidence base and use information that is easily accessible to consumers.

- The Committee will be aware that the Medicines and Medical Devices Act 2021 was passed this year in the United Kingdom and that new medical devices legislation will be introduced within the UK in July 2023, post Brexit.[16] It is expected that regulating software as a medical device may become more challenging for healthcare providers and device manufacturers alike and will necessitate the involvement of a range of stakeholders to ensure these developments do not become a barrier to innovation. The Act relates to human medicines, veterinary medicines and medical devices and makes provisions about the enforcement of regulations and the protection of health and safety in relation to medical devices.

Some arguments for not expanding the definition to include medical devices, vaccines and health technologies include:

- Medicines should have a specific focus in the national policy. Expanding to include health technologies would result in a broad policy that dilutes the focus on medicines.
- Other therapeutic products require specific policies which can be informed by the NMP, since many therapeutic products are fundamentally different. Factors related to accessibility, regulation, quality, safety and efficacy of software, prostheses, syringe pumps and masks as well as their use by patients and health professionals vary considerably.
- Two new policy areas that do not fit well into the existing structures and may require different policies are genomics and the emergent evolving therapies and health technologies which can be used for assessment, diagnosis, monitoring and treatments.
- While the safety and efficacy of pharmaceuticals are evaluated separately to other interventions, this may not be possible for medical devices.[17] Clinical trials are commonly used to assess the efficacy and effectiveness of drugs whereas other study designs are often used to examine procedures and devices.

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.

[16] Kwong MT, Stell D, Akinluyi E. Medical Device Regulation from a Health Service Provider’s Perspective. Prosthesis. 2021 Sep;3(3):261-6.
[17] Productivity Commission 2005, Impacts of Advances in Medical Technology in Australia, Research Report, Melbourne.

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

The level of awareness of the NMP could be improved among the stakeholders involved in or responsible for leading on its many components. While the NMP is relevant to many of the domains and programs outlined in the document, limited awareness and lack of linkages between different initiatives, sectors and the NMP reduce the alignment of practice and implementation with the NMP's objectives.

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?

Several features might enable the framework to better address the present and emerging health care needs:

- Regular and more structured review of the NMP.
- Significantly improved integration and co-ordination of the various components it is intended to influence, including all relevant stakeholders and partners. This will help support a more relevant, agile, flexible and responsive policy framework.
- Recognising the need for dedicated clinical pharmacologist roles at both state and Commonwealth level to support implementation and monitoring of the revised NMP. Specialist Physicians in general and Clinical Pharmacologists need to be an integral part of the NMP refreshment, development and evaluation processes.
- Introducing systematic wide-scale strategies to promote quality use of medicines and the rational use of medicines. Increasing a focus on QUM (including the elimination of inappropriate off-label/unlicensed medicines use) may help stimulate adherence to and oversight of regulatory measures.
- Addressing the need for relevant data and information and their importance for health care: the right information, at the right place, at the right time for medicines. The accelerated adoption of digital health initiatives will help to improve system efficiencies and connectivity. Data repositories from these technologies can help inform health policies and outcomes.
- Fostering care of individuals as a partnership based on the goals of the individual using all information available. Clinical medicine incorporates a full range of information about individuals, their genetics, their biochemistry, their physiology, their anatomy, their culture, their beliefs, their diseases, their other medicines, their capacities.
- Explicitly framing the framework to respond to a health care landscape in which multi-disciplinary health care approaches are part of the infrastructure and where several practitioners may be prescribing treatments.
- In view of the widening span of prescribing rights (for example, optometrists, nurse practitioners, podiatrists), promotion of embedding clinical pharmacists in aged care facilities and rural/remote primary care practices to promote quality use of medicines.
- Revalidating prescribing competencies in niche areas (such as biologics and immunotherapies) to promote safe prescribing and/or disincentivise inappropriate or dangerous prescribing. This is especially important for some populations, for example, children and older people, now there is a wider range of non-medical prescribers.

- Ensuring there is adequate policy around the handling of supply chain issues and the need for rapid approval of alternative medicines in certain circumstances. For example, many endocrine medications had critical shortages during the past twelve months of the pandemic. Some of these shortages were communicated through patients without clinicians being informed about the issues. There was poor communication between industry partners through to TGA and then clinicians through professional bodies. The solution was to form a medicines shortage taskforce, and this should be continued beyond the pandemic.

- Stipulating that treatment centres and health care services have an obligation to maintain supply of medicines and therapeutic supplies, as exampled by COVID-19, such as where palliative care-related medicines are necessary.

- A nationally coordinated research strategy for paediatric medicines research.[18] Public policy is needed to direct funds to support study of high-priority paediatric medicines not prioritised by the industry. This population has special health needs and considerations for optimising medicines research, regulation, access and use, which need focused and coordinated attention. A fundamental problem is the lack of or insufficient evidence (about efficacy/effectiveness; safety, especially longer term; comparative effectiveness/safety and cost-effectiveness) to inform optimal evaluations (including by medicines regulators and Health Technology Assessment bodies), therapeutic decision-making and use of many existing (e.g., off-label) or new medicines that are likely to be used in the paediatric population.

- Improving regulation of access to drugs that are under investigation. Similar to very expensive drugs that are not PBS funded, a transparent approach to patient access needs articulating. This includes use in trials, reporting outcomes, and ensuring the trials are not compromised by out-of-trial access.

- Re-examining current processes for the reporting of adverse events and identifying ways to simplify these processes to encourage greater rates of reporting amongst consumers and health professionals. This will be even more important if the Australian system begins to rely upon the decisions of overseas regulators.

- Augmenting pharmacovigilance activities and future-proofing the NMP from regulatory failures (one example being the regulatory failure to warn Australians of COX-2 [cyclooxygenase] inhibitor and related cardiovascular risks).

- Acknowledging and addressing the challenges of anti-microbial stewardship. This key issue needs to be tackled across all healthcare settings in a coordinated and targeted way, noting that any solution to this problem will need to extend beyond the NMP and the health systems to other sectors, such as agriculture.

- Providing meaningful information to medicine users. There is confusion when it comes to brand names as medicines names are confusing and largely meaningless to the public. Plain language information may assist with lessening the potential for error. This is also important when it comes to information about efficacy. Improving the level of information and health literacy among a population can also reduce the demands on consumers when it comes to the health care system and lessen the complexity of how the policy operates to affect its objectives.

- Clarifying the section “this includes weighing up the risks and benefits when medicines are provided and recognising that medicines and vaccines, even the best of them, can have side effects for some individuals*”,* by adding that this can also apply to some populations.

[18] Gazarian M. Delivering better medicines to children. Pediatric Drugs. 2009 Jan;11(1):41-4.

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

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

Several members welcome the NMP's stronger efforts to improve the health literacy of consumers with a diversity of issues and needs. The NMP must be written in a way that allows it to serve as a guidance and directional document, but also to be translated into practice across diverse regions and health care sectors so that people receiving health care services and those that provide them have a consistent experience. Members stress the need to acknowledge the disparate and specific requirements regarding access to high-quality medicines for some populations. Examples of groups with such needs include people from Aboriginal and Torres Strait Islander or CALD backgrounds, children and young people, older people, pregnant women, people with disability, and people living in rural or regional or remote communities.

Targeted strategies to achieve the NMP's objectives and principles are required to ensure it is effective, remembering that these population/consumer groups often do not have strong voices. Relevant specialists can speak to these issues, such as geriatricians, paediatricians and clinical pharmacologists. Improving the availability of data about the medicines use and outcomes (including safety) in these groups is an imperative basis for evaluating and reviewing the NMP and for proactively monitoring and addressing problems in a nationally coordinated way.

Clinical medicine incorporates a full range of information about individuals, their genetics, their biochemistry, their physiology, their anatomy, their culture, their beliefs, their diseases, their other medicines, their capacities. The NMP should foster care of individuals as a partnership based on the goals of the individual using all information available.

Consumer demand can be influenced by the many potential sources of misinformation. The curation of available information relating to medicines can be problematic and poses health and safety risks when not based on accepted and high standard evidence. Here social and anthropological research is needed to bring conflicting perspectives together. Media reporting also plays an important role.[19]

Two key aspects of this NMP should be to include and specifically make provision for the strengthening of partnerships across health care sector medicines administrations arenas that involve seats at the table for consumers and Clinical pharmacologists. Working collectively with the National Prescribing Service MedicineWise, Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, clinical pharmacology can help build and implement consumer health education platforms and programs. The policy framework of the NMP should support and strengthen these collaborations.

On page 17 where representation on key health technology assessment committees is discussed we recommend a mention of Australia's Indigenous populations. On the same page, in the reference to "promoting equity of access to timely and affordable treatment, when, where and how it is needed" we suggest acknowledging the need to promote continuity of care for patients.

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

[19] Roberts DM, Bennett A. COVID-19 and the quality use of medicines: evidence, risks and fads. Australian Prescriber. 2020 Jun;43(3):78.

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

Partnerships and partnering with industry are crucial to a viable and responsible industry. The Australian market is relatively small and there are emerging global challenges such as supply shortages, pandemic, climate change and others that must be responded to. Research funding is another key factor.

Skilled clinical pharmacologist involvement would strengthen governance arrangements for the NMP. Clinical pharmacologists contribute to a fit-for-purpose regulatory system, supporting clinicians, scientists and the pharmaceutical industry.

The National Prescribing Service, Council of Australian Therapeutic Advisory Group and individual state and territory Therapeutic Advisory Groups are pillars of the NMP. Maintaining and supporting the roles of these expert bodies will advance governance and health literacy.

Promotion of the NMP via avenues that reach consumers could be improved. Effective mechanisms would involve partnering with health consumer organisations, Consumer Health Forum, state peak bodies, Carers Australia, Consumer Support Groups including those for disability, and others.

As the governance mechanisms the NMP deals with are complicated, a diagram of the various agencies and how they relate and report to the Minister would give some clarity, position stakeholders and support consumer health literacy.

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

Many of the challenges to building greater accountability require investing in working as one health care system. National policies such as this, if directive and clear, can go a long way to supporting improved practice that reinforces the quality and safe use of medicines and therapeutic instruments. However, a framework must explicitly speak to this need for higher levels of consistent practice and reinforce the need for coordination.

A “whole of government”, nationally coordinated & appropriately resourced strategy is needed, one that is informed by high quality data and appropriately specialised expertise at the highest levels of decision-making. A better informed and integrated approach for optimising all components of the medicines’ “pipeline”, that is, research, regulation, access and QUM, is needed to deliver on achieving the objectives of the NMP for all Australians.

Within a “whole-of-government” framework, State government funded health systems should become key partners committed to the effective implementation of the NMP within those systems (such as hospitals) and in the transitions of care between hospital and community. There is currently a mismatch between the level of resourcing and coordination provided for the implementation of the NMP’s objectives at the Commonwealth compared to the state level, with consequences for health and economic outcomes for individuals and the wider health system.

Research funding bodies (e.g., NHMRC, MRFF) should become key partners of the NMP, to drive and support relevant medicines research. Not all of Australians’ medicines research needs will be able to be met by pharmaceutical industry funded research. This could also include strategic public-private partnerships to deliver on these objectives, which we have seen in the response to the COVID pandemic internationally.

In addition, a much closer, more direct and more agile two-way link is needed between partners responsible for medicines use and medicines research in line with the overall objectives of the NMP.

This issue has also been highlighted in the context of our COVID response, when less well evaluated and off-label medicines are proposed for use to treat COVID.

Members broadly support the improvements in the development and use of Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMS) to better inform health assessments. We also support the close monitoring of QUM indicators, health outcomes and the measurement of errors.

Conclusion

The RACP believes that the multi-step review process of the NMP will lead to the identification of key actions for improvement and innovation of the existing system of medicines and medical devices regulation.

The RACP reiterates that it is critical that relevant specialist advice is directly and consistently embedded throughout the review process, especially as it is the first such a revision in two decades.

We look forward to ongoing engagement with the review through the upcoming consultative meetings and to the opportunity to comment on the forthcoming draft of the NMP.