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**RACP Submission**

**Australian Department of Health and Aged Care's  
Draft National Medicines Policy - Committee's  
Draft**

**October 2022**

## About The Royal Australasian College of Physicians (RACP)

We connect, train and represent 28,000 medical specialists and trainee specialists from 33 different specialties, across Australia and Aotearoa New Zealand. We represent a broad range of medical specialties including addiction medicine, general medicine, paediatrics and child health, infectious diseases, cardiology, respiratory medicine, neurology, oncology, public health medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, and geriatric 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.



*We acknowledge and pay respect to the Traditional Custodians and Elders – past, present and emerging – of the lands and waters on which RACP members and staff live, learn and work. RACP acknowledges Māori as tangata whenua and Te Tiriti o Waitangi partners in Aotearoa New Zealand.*

## Introduction

The Royal Australasian College of Physicians (RACP) welcomes and values the opportunity to provide feedback on the latest draft National Medicines Policy (NMP). This submission has been developed based on input from relevant RACP committees and RACP-affiliated specialty societies.

The RACP has previously made two submissions to inform the review of the NMP:

- On the Discussion Paper in October 2021<sup>1</sup>
- On the NMP Consultation Draft in March 2022<sup>2</sup>

In addition to these written submissions, the RACP representative, Associate Professor Madlen Gazarian FRACP, has attended stakeholder meetings organised by the Australian Department of Health and Aged Care (DoHAC) since the NMP Review was initiated. We thank the NMP Review Committee and DoHAC for providing these valuable opportunities to inform the revised NMP.

Medicines' prescribing is a core aspect of physician training and practice. A nationally integrated approach to optimising all components of the medicines' "pipeline", including medicines research, education, regulation, health technology assessments (HTA), equitable access, quality use of medicines (QUM) and medicines safety is of great importance to the RACP. Specialist physicians and especially those with Clinical Pharmacology and Therapeutics (CPT) training contribute uniquely valuable expertise and provide leadership in each of these domains across all settings and levels of the Australian health care system. CPT specialists also have an important role in providing overall leadership for the development, implementation and evaluation of the NMP within a "whole of government" framework.

As the RACP highlighted in its first submission to the NMP review, to benefit all Australians, the revised 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.

## High-level comments on the draft NMP

We are pleased to see that specific elements of the RACP's previous feedback have been incorporated into the latest draft NMP:

- In particular, we welcome the fact that the **revised version clearly acknowledges the importance of the broader research sector as part of Pillar 4 Responsive, innovative and sustainable medicines industry and research sector with the capability, capacity and expertise to respond to current and future health needs**. As outlined in the first RACP submission to the NMP Review in October 2021, it is essential that research partners are given responsibility alongside industry to ensure the priority health needs of all Australians, including priority populations whose needs are typically underserved, are adequately addressed in future. Not all of Australians' medicines research needs will be able to be met by industry-funded research. Therefore, this is a very important enhancement to the updated NMP and one which will require specific and targeted attention in the implementation phase to ensure that these needs are better met in future.

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<sup>1</sup> Available online: [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-nmp-discussion-paper.pdf?sfvrsn=3846c41a\\_8](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-nmp-discussion-paper.pdf?sfvrsn=3846c41a_8) [last accessed 05/10/22]

<sup>2</sup> Available online: [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a\\_8](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a_8) [last accessed 05/10/22]

- We also **welcome the revised draft’s stronger emphasis on equity and access as a fundamental principle underpinning the NMP and the fact that key priority populations are now specifically delineated.** Clearly identifying priority populations is an essential first step towards meeting their needs. However, this needs to be coupled with rigorously developed data-driven insights informed by appropriate specialised expertise and evidence-based decision-making to accurately identify the needs of such groups as well as to evaluate the impact and outcomes of any proposed solutions. These are listed as enablers in the revised draft and the importance of that approach to effectively meeting the needs of priority populations cannot be underestimated. It is especially important for those groups who are least able to speak up and are often under-represented when priority setting might be driven by strong consumer voices alone. Such groups include children, the elderly, and people living with disabilities or rare and under-recognised diseases. As outlined in our October 2021 submission<sup>3</sup>, relevant specialist physicians (e.g., paediatricians, geriatricians, CPTs) can also speak for the needs of such groups as well as helping to inform concurrent data-driven insights with relevant specialised clinical and scientific expertise.

However, we note a number of ongoing gaps in three important areas that we believe the revised NMP needs to adequately address to be effective:

1. Ensuring the effective implementation of the NMP through governance, accountability, evaluation and resourcing
2. Improving pathways to allow equitable access to needed treatments for all Australians
3. Embedding relevant specialist advice throughout the NMP process.

These gaps and our recommendations to address them in the revised NMP are detailed below.

### **1. Ensuring the effective implementation of the NMP: Governance, accountability, evaluation and resourcing**

Throughout the NMP review process, **stakeholders have advised that the revised NMP should include sufficient detail on overall governance and accountability, evaluation and resourcing to enable its effective implementation.**

The Review Committee’s Summary Consultation Report and Recommendations made available on the DoHAC website clearly acknowledges this point when it states that:

*“There were consistent calls for greater clarity on the Policy’s governance arrangements. This included calls for clear descriptions of policy ownership and the roles and responsibilities of each of the Policy’s partners. The re-introduction of a governance committee, comprised of multi-stakeholder representation, was the most common suggestion to strengthen the Policy’s governance. Consistent feedback was also heard about the need for governance mechanisms to remain relevant and flexible in recognition of the evolving health and policy landscape.*

*Stakeholders viewed the functions of governance mechanisms to be oversight and the monitoring of the Policy’s implementation and progress towards the delivery of its aim; the facilitation of ongoing collaboration and consultation between the Policy’s partners; and the management of the evaluation, monitoring, review and reporting of progress against the Policy’s intended outcomes. Stakeholders consistently emphasised the importance of identifying and managing conflicts of interest and to strengthen transparency.*

<sup>3</sup> Available online: [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-nmp-discussion-paper.pdf?sfvrsn=3846c41a\\_8](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-nmp-discussion-paper.pdf?sfvrsn=3846c41a_8) [last accessed 05/10/22]

*Establishment of a monitoring and evaluation framework, with process and outcome metrics, was also emphasised. This was seen as an important foundation for strengthening accountability, promoting continuous quality improvement, and supporting periodic review of the impact and effectiveness of the NMP. There was general agreement that any measures should be aligned with the Policy’s aim, Central Pillars, intended outcomes and Principles.”<sup>4</sup>*

The Summary Consultation Report also acknowledges that whilst it “supports the creation of a governance structure which we believe will assist in the achievement of the intended outcomes of the Central Pillars”, “the Committee has not made recommendations with respect to the structure and composition of this governance structure within the draft 2022 NMP, as this was considered outside the Terms of Reference”. The Summary Consultation Report recommends that “the Commonwealth Government considers the appropriate mechanisms and processes to ensure the participation of all partners, including diverse consumer partners, and to enhance transparency and accountability in overseeing the implementation, evaluation and communication of the NMP”.

On page 22, the revised draft NMP states that “the role of the Commonwealth is to lead and encourage collaboration between partners towards shared goals, promote transparency in relation to accountability, reporting and communication” and further down that “leadership is required to monitor and report on achievements against the central pillars, how the NMP’s principles have been put into action and the overall impact of the NMP”.

While we welcome and support these statements, they lack necessary details about specific arrangements to deliver on these broad objectives. We remain concerned that the revised draft NMP lacks information on overall governance and accountability mechanisms and specific details on the implementation and evaluation of the Policy. **In our view, it is essential that the revised NMP clearly outlines who will be accountable overall at a national level for its effective delivery and implementation and how these will be achieved in practice.**

With regard to evaluation, **the revised NMP offers a vital opportunity to embed sound evaluation principles and practices into all future medicines-related policies, programs, research and initiatives. The expectations of all partners in relation to monitoring and evaluation should be clearly outlined.** This could include an expectation that all NMP-aligned programs and initiatives build a logic model that includes inputs, activities, outputs and short-and long-term outcomes as a way to build effective evaluation indicators into their program and initiative design. As part of this process, it would also be important to clearly outline that equity considerations should be part of any planned evaluation. The Commonwealth Evaluation Policy<sup>5</sup> which includes an evaluation toolkit could be used as a framework for the evaluation objectives of the NMP. Another suggestion would be to add a framework such as the RE-AIM framework<sup>6</sup> or similar to complement *Figure 3 – Guidance for an evaluation strategy aligned with the NMP* on page 23.

As the RACP suggested in previous submissions, the Governance section of the NMP needs to specifically set out the various governance mechanisms the NMP deals with as these are complex. This could be done through the inclusion of a diagram of the various agencies and how they relate to each other and to Health Ministers, both at Federal and State/Territory levels. This would help

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<sup>4</sup> Review of the National Medicines Policy NMP Review Committee – Summary Consultation Report and Recommendations – 27 May 2022. Available online: [https://consultations.health.gov.au/pbs-subsidy-taskforce/national-medicines-policy-revised-consultation/supporting\\_documents/Summary%20Stakeholder%20Consultation%20Report%20%20NMP%20REVIEW%20COMMITTEE%20May%202022.pdf](https://consultations.health.gov.au/pbs-subsidy-taskforce/national-medicines-policy-revised-consultation/supporting_documents/Summary%20Stakeholder%20Consultation%20Report%20%20NMP%20REVIEW%20COMMITTEE%20May%202022.pdf) [last accessed 25/09/22]

<sup>5</sup> Available online: <https://www.finance.gov.au/government/managing-commonwealth-resources/planning-and-reporting/commonwealth-performance-framework/commonwealth-evaluation-policy> [last accessed 25/09/22]

<sup>6</sup> See for example: Holtrop, Jodi Summers, et al. "Understanding and applying the RE-AIM framework: Clarifications and resources." *Journal of Clinical and Translational Science* 5.1 (2021). Available online: <https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/understanding-and-applying-the-reaim-framework-clarifications-and-resources/6EC2598C1C83F65FE5495A220A8A500E> [last accessed 25/09/22]

provide improved clarity of roles, better position stakeholders/partners and support consumer health literacy.

As part of such an approach, it is **important that the revised NMP sets out a truly “whole of government” strategy, with governments at all levels working in a nationally coordinated way, including allocating adequate resources and funding, to support all partners in delivering the NMP’s objectives now and into the future.**

An example of this would be a **better coordinated approach to the implementation of the QUM pillar of the NMP across all health care settings.** This requires ongoing investment and further development in a number of key areas, including provision of high-quality medicines information and education/training (for consumers and health professionals) to support effective QUM in practice and rigorous processes to monitor medicines use in order to help optimise outcomes.

It is therefore **essential that the revised NMP ensures that valuable existing QUM resources, including NPS MedicineWise’s National Prescribing Curriculum (NPC) are safeguarded to support the objectives of the NMP.** The NPC has held a pivotal role in educating prescribers across the multiple disciplines (medical, dental, nursing, optometrists, podiatrists) for many years and is ranked highly at an international level. With the upcoming cessation of the NPS Medicines Wise programme, the continuation of these important teaching and learning resources is unclear.

The RACP and the RACP-affiliated Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) strongly recommend that a commitment is made within the revised NMP to safeguard these modules and transfer them to another platform or provider as needed to ensure their continuation and ongoing contribution to the objectives of the NMP.

The RACP believes the areas outlined above need to be adequately addressed in the revised NMP and that doing this successfully requires significant further discussions and planning with stakeholders including the RACP.

## **2. Improving pathways to allow equitable access to needed treatments for all Australians**

The RACP’s previous submission stressed the importance of the NMP adequately addressing equity of access to medicines for all Australians and particularly for people living with rare diseases including under-recognised condition. This submission stated the following:

*“It would be beneficial for the revised NMP to acknowledge that although the costs of individual treatments for people living with rare diseases can be high, the broader costs on the health system and society of these conditions can be lessened if these treatments enable them to live productive lives. Given many of these rare diseases are first detected in children and young people, these broader costs on the health system and societies would be further lessened and the health and economic outcomes for these patients would be further improved by the NMP acknowledging the importance of appropriately managing these conditions from the earliest ages.”<sup>7</sup>*

People with rare and under-recognised diseases are mentioned in the revised draft NMP within the *Equity and access principle* (p.6) and in the *Equity section* (p.8). As stated on page 8, “people, including children living with rare and under-recognised diseases, often face inequities due to the scientific and technical complexities of data and its collection, and the absence of evidence for the evaluation and subsidisation of treatments for rare conditions.”

<sup>7</sup> RACP response to the Australian Government’s National Medicines Policy Consultation Draft – March 2022. Available online: [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a\\_8](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a_8) [last accessed 26/09/22]

Despite these mentions, the RACP and its affiliated Australasian Society of Clinical Immunology and Allergy (ASCIA) remain concerned that the revised draft does not adequately recognise the added challenges faced by people with rare and under-recognised diseases in accessing medicines.

The pathways to access new therapies for rare diseases are limited:

- Reimbursement applications for rare disease treatments can take several years, due to clinical trial and health economic data being difficult to obtain, as these rely on large numbers of patients.
- At present, clinical immunology/allergy specialists rely on applications to individual committees within hospitals to allow access to these treatments for patients. This is by no means a guaranteed pathway, and access will vary across states and hospitals.

Such challenges and unacceptable variability in HTA processes and decision-making for medicines access within the hospital system also apply across many conditions and therapeutic areas besides rare diseases.

The revised NMP needs to **include improved pathways to allow equitable access for all Australians to needed treatments through nationally consistent and appropriately resourced processes for HTA and funding decisions, regardless of the health condition or setting in which health care is provided.** For rare conditions, these processes also need to take into consideration the special circumstances of such patients and align with international best practice in this rapidly evolving area. These challenges will also need to be acknowledged and addressed as part of the ongoing HTA Review.<sup>8</sup>

### **3. Embedding relevant specialist advice throughout the NMP process**

The RACP has previously advised the Review Committee that it was critical for relevant specialist advice to be directly and consistently embedded throughout the NMP process and we would like to see this aspect strengthened in the revised NMP.

Specialist physicians and paediatricians can assist in the effective implementation of the NMP in three key areas:

- a) **Contributing to delivering effective governance arrangements and planning for the NMP.** The expertise of CPT specialists in particular should be included as a key component within future governance arrangements and planning for the NMP as was outlined in the RACP's previous submission:

*“Ensuring the currency and sustainability of the specialist clinical pharmacology workforce to enable safe, effective and quality use of medicine. Clinical and Experimental Pharmacologists and Toxicologists play key leadership roles in the design and implementation of national medicines policies. As outlined in the joint Council for International Organisations of Medical Sciences (CIOMS)/World Health Organization (WHO)/International Union of Basic & Clinical Pharmacology's (IUPHAR) 2012 report titled [Clinical Pharmacology in Health Care, Teaching and Research](#), 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. The importance and role of clinical and experimental pharmacologists and toxicologists should be explicitly mentioned and acknowledged in the description of the “health workforce enabler” in the revised NMP and their expertise should be included as a key*

<sup>8</sup> <https://www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/Fact-sheet-3-Health-Technology-Assessment-Review.pdf> [last accessed 05/10/22]

*component within future governance arrangements and planning for the NMP.*<sup>9</sup>

- b) **Advocating for and advising on the needs of priority populations** whose voices may not be as strong as other consumers but who have particular high unmet needs which should be better addressed in future. Relevant specialist physicians (e.g., paediatricians, geriatricians, CPTs) can: (i) advise about priority needs of such groups directly; (ii) advise about meaningful approaches to effective engagement of such groups in the NMP process, e.g., age-appropriate methods for engaging children and young people; and (iii) help inform concurrent data driven insights for priority populations with relevant specialised clinical and scientific expertise.
- c) **Facilitating collaboration and communication across community and hospital settings, national and state boundaries** as specialist physicians and paediatricians routinely work across these settings.

The RACP recommends that the revised draft NMP appropriately acknowledges the important enabling role of specialist physicians and paediatricians in the effective delivery of the NMP.

## Additional specific feedback

In addition to the above high-level feedback, we add the following specific recommendations and comments:

- Indigenous Community Controlled Organisations need to be added as a stand-alone category in *Figure 1 – Centrality of individuals, carers, families and communities, and the relationships between NMP partners*.
- “Culturally safe and responsive” is missing from the third dot point in the Enablers section on page 7: “Workforce – to ensure an adequate workforce that is knowledgeable, competent, accessible, culturally safe and responsive and resourced to provide coordinated, integrated and person-centred care.”
- “Data-sharing and strong data systems” should be added to the fifth dot point on data and information in the Enablers section on page 7.
- On page 18 in the ‘Health practitioners’ section, amend the wording as follows: “Prescribe, supply or administer medicines in line with relevant guidelines, and in consultation with the person taking medicine ~~or~~ and their carers and families” as it is important not to assume lack of capacity for informed consent.
- The revised NMP should outline that Consumer Medicines Information (CMI) needs to be made available in Easy Read format and that improving accessibility of information about medicines for consumers needs to include making these resources easy to find in addition to making the information accessible in terms of the language and format used.
- In the section on *Pillar 3 – Quality use of medicines and medicines safety*, we suggest explicitly referring to the importance of appropriate review of medications
- In the sub-section on patient-centred care under *Pillar 3*, we suggest adding “accessible” and “resources” to the first dot point: “provide culturally appropriate, person-centred services, including accessible health and medicines information and resources and support for both face-to-face and online interactions.”
- The definition of medicines adopted in the revised NMP includes “complimentary medicines”. The Australian Government does not currently assess efficacy<sup>10</sup> nor mandates the publication of supporting information about complimentary medicines’ indications to

<sup>9</sup> RACP response to the Australian Government’s National Medicines Policy Consultation Draft – March 2022. Available online: [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a\\_8](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-feedback-on-the-australian-government-s-national-medicines-policy-consultation-draft.pdf?sfvrsn=7928c81a_8) [last accessed 26/09/22]

<sup>10</sup> Therapeutic Goods Administration (TGA), Listed medicines webpage: <https://www.tga.gov.au/listed-medicines> [last accessed 26/09/22]



consumers.<sup>11</sup> This conflicts with the revised NMP's Pillar 2 *Medicines meet the required standards of quality, safety and efficacy* and its stated outcomes. In order to improve the transparency and accuracy of the revised NMP, we recommend that it explicitly acknowledges that the efficacy of complimentary medicines is not assessed by the Australian Government and that there is currently no mandate for sponsors of such products to provide information to support their products' indications to consumers. We also recommend that the NMP Review Chair advises the Australian Government to make compulsory Recommendation Forty-Three of the 2016 Expert Review of Medicines and Medical Devices Regulation.<sup>12</sup>

Thank you for the opportunity to contribute to the National Medicines Policy Review. It is critical that relevant specialist advice is directly and consistently embedded throughout the NMP process, and we look forward to ongoing engagement with the finalisation and implementation of the NMP.

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<sup>11</sup> Therapeutics Good Administration (TGA), Review of Medicines and Medical Devices Regulation (2016). Online, available: <https://www.tga.gov.au/news/news/australian-government-response-review-medicines-and-medical-devices-regulation> [last accessed 26/09/22]

<sup>12</sup> Therapeutics Good Administration (TGA), Review of Medicines and Medical Devices Regulation (2016). Online, available: <https://www.tga.gov.au/news/news/australian-government-response-review-medicines-and-medical-devices-regulation> [last accessed 26/09/22]