

RACP response on the Australian Government’s National Medicines Policy Consultation Draft

Note regarding the format of the response to the NMP Consultation Draft: The Australian Department of Health has advised that all feedback on the Draft needed to be submitted through its [online survey](#). The format of the survey presents many constraints including the use of numerous multiple-choice questions which are compulsory, so we have (1) selected the “neither agree nor disagree” option in answer to all multiple-choice questions and (2) included a note in the first free text section of the survey outlining that this has been done given it is not practical for the College as a large member organisation to provide specific ratings.

The introductory note:

The Royal Australasian College of Physicians (RACP) welcomes and values the opportunity to provide feedback on the National Medicines Policy Consultation Draft.

As a large member organisation, it is not feasible for the RACP to respond to multiple choice questions given our feedback is compiled through consultation with multiple committees and affiliated specialty societies. Therefore, we have selected the “neither agree nor disagree” option in answer to all multiple-choice questions and our feedback has been provided in the relevant free text sections of the survey.

Feedback on Governance, Implementation and Evaluation sections (pages 7-8, 21-22 and 23, respectively, of the [NMP Consultation Draft](#))

The feedback below relates to the Governance, Implementation and Evaluation sections of the Consultation Draft.

The revised NMP’s focus on co-ordination, shared problem solving and accountability amongst all partners is welcome and we acknowledge the importance of each partner being responsible and accountable for achieving the aims and outcomes of the NMP.

However, we are concerned that the Consultation Draft lacks information on overall governance and accountability mechanisms and specific details on the implementation and evaluation of the NMP. The current document is not clear on who will be accountable overall at a national level for the effective delivery and implementation of the NMP.

The lack of clear governance frameworks with ambitious goals, clear objectives, outcomes and commitments to regular review of the NMP along with no apparent provision for their urgent development is disappointing at this stage of the review process. The need for these components in the revised NMP has been repeatedly stressed by the RACP and numerous other stakeholders. As [raised recently by Medicines Australia](#), these components are also markers of international best practice for developing national medicines policies as outlined in the World Health Organization’s [How to Develop and Implement a National Drug Policy – 2nd ed.](#) It is essential that the revised NMP clearly outlines who will determine if/when agreed outcomes are not being achieved and articulates how this will be determined and how appropriate changes will be made to the NMP implementation strategies in a timely way to address arising issues.

The relationships between the partners delivering the NMP are critical to its effective implementation and success. On page 7 of the Governance section of the Consultation Draft, it is stated that Figure 2 “illustrates the relationships between the NMP partners”; however, the figure merely presents key partners and does not illustrate the complex relationships between partners which need to be clearly articulated in the revised NMP. As we suggested in our previous submission to the Review Committee, the Governance section of the NMP also 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 and report to the Minister for Health to provide clarity, position stakeholders/partners and support consumer health literacy.

Further, as was outlined in [the RACP’s previous submission to the NMP Review](#), the following should be included in the revised NMP as an essential component to its successful implementation:

“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.”

These are important areas that need to be adequately addressed in the revised NMP. Doing this successfully requires significant further discussions and planning with stakeholders including the RACP.

General comment on the [NMP Consultation Draft](#)

We are pleased to see some of the issues outlined in the [RACP’s October 2021 submission](#) addressed in the Consultation Draft including a strengthened focus on the judicious use of medicine, medicine safety, and patient-centredness throughout as well as recognition of the importance of the research sector, sustainability and securing supply chains. In addition, we broadly agree with the aim, scope, central pillars, principles and enablers outlined in the Consultation Draft.

However, we are concerned that the Consultation Draft does not adequately address several key issues that we and other stakeholders have previously raised, and we urge the Review’s Expert Advisory Committee to address the following in the next iteration of the NMP:

- As outlined in our feedback on the Governance, Implementation and Evaluation sections of the Consultation Draft, we are concerned that the Draft lacks information on overall governance and accountability mechanisms and specific details on the implementation and evaluation of the NMP. These are important areas that need to be addressed in the

revised NMP and this requires significant further discussions and planning with stakeholders including the RACP.

- **Recognition of the specific needs of children and young people.** The omission of the specific mention of the special needs of children and young people from Australia's NMP to date is a significant gap that needs to be rectified in the revised NMP. This population has special health needs and considerations for optimising medicines research, regulation, access and use, which need focused and coordinated attention. The importance of recognising the specific needs of children and young people is outlined in the [2016 World Health Assembly Resolution on Promoting innovation and access to quality, safe, efficacious and affordable medicines for children](#). Australia is a signatory to this important resolution which urges Member States *"to take all necessary measures, including legislation, as appropriate for the establishment of national plans and organizational structures and capacity to enhance such measures in the framework of national pharmaceutical policies, as appropriate, to improve children health"* and *"to ensure the national health policies and plans incorporate consideration of the needs of children based on the national situation, with clear objectives for increasing access to children's medicines."* Children and young people should be explicitly acknowledged in the description of the "Equity principle" and the revised NMP should outline the need for a nationally coordinated research strategy for paediatric medicines research which is necessary to direct funds to support study of high-priority paediatric medicines not prioritised by the industry.
- **Strengthening the NMP's commitment to equity of access to medicines for all who are disproportionately impacted by health inequities** by explicitly acknowledging the need for: (1) establishing proactive data-informed mechanisms for identifying the needs of different population groups to assist in the operationalisation of the NMP by directing resources and meeting requirements in an efficient and targeted way, (2) including requirements for the evaluation or surveillance of medication for Aboriginal and Torres Strait Islander people and other populations such as children and young people, people living in rural and remote areas, and people living with disability who are negatively impacted if these are not present and (3) assessing the age-appropriateness of medicines, especially for children. This is essential, as outlined in the [2016 World Health Assembly Resolution on Promoting innovation and access to quality, safe, efficacious and affordable medicines for children](#) and in the [WHO's publication titled Promoting safety of medicines for children](#).

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 such as geriatricians, paediatricians and clinical pharmacologists can speak to these issues. Improving the availability of data about the medicines use and outcomes (including safety) in these groups is imperative for evaluating and reviewing the NMP and for proactively monitoring and addressing problems in a nationally coordinated way.

- **Addressing equity of access to medicines for people living with rare diseases including under-recognised conditions.** 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.

- **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 component within future governance arrangements and planning for the NMP.
- **Recognition of the importance of the National Prescribing Service, the Council of Australian Therapeutic Advisory Group and individual state and territory Therapeutic Advisory Groups** to the successful implementation of the NMP. The revised NMP should also acknowledge that maintaining and supporting the roles of these expert bodies will advance governance and health literacy.
- In addition, as highlighted in the [initial submission made by the Australian and New Zealand Society of Nephrology to the NMP Review](#), it would be valuable for the revised NMP to stress the importance of regulatory authorities consulting with relevant specialty societies and medical colleges when medicines are being considered for listing on the Pharmaceutical Benefits Scheme (PBS) or when they are withdrawn.

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.