RACGP

Royal Australian College *of* General Practitioners

# *Submission to Review of the National Medicines Policy*


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# 1. Introduction

The RACGP thanks the Department of Health for the opportunity to provide comment on the Review of the National Medicines Policy Discussion Paper. We welcome the update to Australia's National Medicines Policy.

GPs are the first point of contact for most Australians seeking healthcare, with almost 90% of the population seeing a GP at least once each year.[1] According to Australian Institute of Health and Welfare (AIHW) data, GPs prescribed the most Pharmaceutical Benefit Scheme (PBS) and Repatriation Pharmaceutical Benefit Scheme (RPBS) medicines in Australia, accounting for approximately 89% of all prescriptions dispensed.[2] While GPs play an important role in the prescribing and administering medications, they also educate and counsel their patients regarding medication usage, undertake medication reviews, and deprescribe where necessary.

# 2. About the RACGP

The Royal Australian College of General Practitioners (RACGP) is the voice of general practitioners (GPs) in our growing cities and throughout rural and remote Australia. For more than 60 years, we've supported the backbone of Australia's health system by setting the standards for education and practice and advocating for better health and wellbeing for all Australians.

We cultivate a stronger profession by helping the GPs of today and tomorrow continue their professional development throughout their careers, from medical students and GPs in training to experienced GPs. We develop resources and guidelines to support GPs in providing their patients with world-class healthcare and help with the unique issues that affect their practices. We're a point of connection for GPs serving communities in every corner of the country.

Australia's GPs see more than two million patients each week, and support Australians through every stage of life. The scope of general practice is unmatched among medical professionals, so the RACGP supports members to be involved in all areas of care, including aged care, mental health, preventive care and Aboriginal and Torres Strait Islander health.

Patient-centred care is at the heart of every Australian general practice, and at the heart of everything we do.

# 3. Summary of RACGP key recommendations

While the RACGP acknowledges the National Medicines Policy (NMP) is an overarching framework, it is important to also focus on its implementation, which will translate into use in clinical practice. We provide high level and practical feedback related to the objectives of the policy.

- Mechanisms and/or mandates implemented to ensure a minimum supply of medication is available in Australia
- Efficient and cheaper alternatives to community pharmacy dispensing are considered
- Post-marketing surveillance is improved
- The term 'medical devices', particularly software as a medical device, is clearly defined,
- Standardisation and quality assurance for supporting tools and software for medical devices
- Prescribing software and medication lists be fully integrated with Residential Aged Care Facilities software
- Complementary and Alternative Medicines are included in medicine databases

# 4. 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 RACGP supports the five proposed principles and finds them to be appropriate. Further comment is provided specifically addressing the principles of 'equity' and 'consumer-centred approach'.

## 4.1 Proposed principles of the National Medicines Policy

### 4.1.1 Equity

The RACGP supports equity in access to medicines for the Australian community. Sustained health inequality disproportionately impacts specific Australian populations, including, but not limited to:

- Aboriginal and Torres Strait Islander people[3,4],
- Culturally and linguistically diverse (CALD) and refugee communities,
- Socioeconomically disadvantaged communities[3],
- Rural and remote communities[5,6].

These communities experience a relatively high burden of chronic disease, and greater barriers to accessing medical care and medicines, impacting on their overall health and wellbeing. Targeted and ongoing investment, policy development and systemic changes are required to address the social determinants of health, and to ensure equitable access to medicines and health care in Australia. As such, we would like to see the NMP make specific reference to these groups.

### 4.1.2 Consumer-centred approach

The RACGP supports the importance of having informed and engaged consumers. Consumer-centred approaches should also be evidence-based to ensure the best possible health outcomes for the Australian population. We recommend this is acknowledged in the NMP.

## 4.2 Objectives of the National Medicines Policy

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

The RACGP broadly agrees with the NMP's four objectives and finds them to be relevant. We make some suggestions to enhance the objectives 1, 2 and 3 and also provide some comments more broadly related to these areas for consideration.

### 4.2.1 Objective 1 - Access to medicines

*Guarantee of supply of medications*

Medication shortages, both before and during the COVID-19 pandemic, has impacted on patient care and safety. At the time of this submission, there are 282 current medication shortages, with a further 49 anticipated[7]. Ensuring minimum supply is available is particularly important for critical needs medication, and for medications with no alternatives for the same indication.

The RACGP recommends mechanisms and/or mandates be put into place to ensure a minimum supply of medication is always available in Australia to meet demand more effectively.

Other comments:

- *Removal of the Authority Prescription System*
  Removal of the Authority Prescription System would increase efficiency and productivity without any impact on safety.

- The Pharmaceutical Benefits Scheme (PBS) Restricted Items (medicines that are prescribed only if the patient's condition meets the stated restrictions) process could be expanded as an alternative and implemented with increased auditing, supported by existing prescribing decision support tools. This would be more efficient than obtaining authority from the Authority Prescribing phone line which can take between 3-5 minutes each time. The Provider Digital Access (PRODA) / Health Professional Online Services (HPOS) system does not integrate with general practice prescribing systems and can take just as long.

- *Expansion of the Active Script List program*
  The Active Script List program should be implemented nationally to allow patients with complex medication lists, and those who cannot use digital technologies, to participate in telehealth and access electronic prescriptions.

- *Efficient and cheaper alternatives to community pharmacy dispensing*
  There are alternative models to community pharmacy dispensing that offer efficiencies and reduced costs, to the consumer and the broader health system, that should be considered. For example, a central supplier would take on the role of drug storage and supply of drugs for non-urgent illness medication, rather than pharmacies as is now the case, and medication delivery would utilise IT and transport systems taking the drugs straight to the patient's door. In such models, computer decision support, QUM with practice-based pharmacist support could be effective mechanisms for patient education and safety monitoring.

#### 4.2.2 Objective 2 - Quality, safety and efficacy of medicines

*Automated mechanisms for post-marketing surveillance*

Post-marketing surveillance is an important element in ensuring the quality, safety and efficiency of medicines when they reach market, and this could be improved and benefit from a greater focus in the NMP.

For example, integration of post-marketing surveillance within clinical software could enhance and streamline the process, making reporting easier and efficient. Systems could be enhanced to detect the 'signal' of unknown side effects for new medicines. Mechanisms should be developed using de-identified patient-level primary care data with data linkages to hospitals. Post-marketing surveillance systems have been successfully implemented in the United Kingdom and Canada.[8]

Other comments:

- *Invest in practice-based pharmacists*
  The RACGP recommends investment in general practice-based pharmacists be considered by the NMP. As a key component of a multidisciplinary team, practice-based pharmacists allow general practices to increase their capacity to offer medication management and education services to patients. Increasing capacity for these services will reduce fragmentation of care and increase medication safety[9].

#### 4.2.3 Objective 3 - Quality Use of Medicines

Other comments:

- *Electronic prescribing/ monitoring*
  The use of digital tools has enhanced efficiency and safety. Such tools should be promoted and supported. For example, electronic prescribing has been widely adopted but further education and training for both prescribers and consumers around the transition to online scripts is needed.

  Another tool is Real time prescription monitoring (RTPM). States and territories should continue to fund, roll out and support RTPM programs, and these should be aligned with the Commonwealth authority systems. Implementation should be supported with the development of education and training for prescribers, reinforced with consumer education and support.

- *Online medical consultations*
  The RACGP has serious concerns with the development of new business models offering online medical consultations outside of a patient's regular general practice. These include pharmacy initiated instant consultation services. While this may increase access for a portion of the community, these business models fragment patient care and risk patient safety. The comprehensiveness of medical review in these instances is questionable, given the lack of access to a patient's medical history and notes, and lack of communication back to a patient's regular GP, further impacting on continuity of care and increasing risk to patient safety[10]

- *Non-GP specialists*
  Non-GP specialist prescribing would benefit from similar multi-layered approaches used to support GP prescribing, including auditing and feedback, peer review and significant event analysis, beyond hospital morbidity and mortality meetings.

# 5. 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?***

Medical devices should be included within an expanded definition of medicines. We recommend the term 'medical devices', particularly software as a medical device, is clearly defined to remove any ambiguity, which may lead to some products being unnecessarily regulated (such as general practice clinical information systems and other support tools in general practice).[11]

## 5.1 Quality and safety of medical devices

While medical devices are regulated to specific standards and registered by the Therapeutic Goods Administration (TGA), the supporting tools and software (such as apps) should be included within the scope of the NMP. These require standardisation and quality assurance. This is particularly important as some medical devices inform medication dosing decisions, and would provide both GP and consumer confidence in the software as a medical device.[11]

Reporting any issues with medical devices should be made easier and clearer for both health professionals and patients.

***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?***

The term therapeutics could be added to the title.

# 6. Terms of Reference 3

**Assess the NMP's utility in the context of rapidly evolving treatments 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?***

The health landscape constantly and rapidly changes, as demonstrated by the current COVID-19 pandemic. The NMP needs to be flexible to address future changes, particularly in emergency situations.

***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?***

The RACGP provides recommendations to better address current and future changes in the health landscape. These recommendations address topics as outlined in the discussion paper. We also propose new additions to be added to the policy framework.

## 6.1 Clinical trials and medicines access programs

### 6.1.1 Australian populations are underrepresented in drug trials

The NMP should develop policies to encourage pharmaceutical industry investment in clinical trials in Australia. According to a study by the Australian New Zealand Clinical Trials Registry (ANZCTR), Australia ranks towards the middle of comparable nations in terms of clinical trial activity on a per capita basis[12].

Funding should be provided to enhance the enrolment of underrepresented populations in Australian drug trials. For example, Cancer Australia is funding projects to provide access to drug trials for cancer treatment for Aboriginal and Torres Strait Islander people[13]. The Culturally and Linguistically Diverse (CALD) community in Australia is also underrepresented in drug trials, due to lack of awareness and barriers to access[14].

## 6.2 Health literacy

### 6.2.1 Digital literacy and access

Bridging the digital divide, whether as a result of digital illiteracy or lack of access, is an increasingly important component of health literacy that needs to be addressed.

While almost 91% of Australians have a smartphone and there were 14.7 million internet subscribers as at the end of June 2018[15], consumers still use technology with a varying degree to experience and confidence, with different levels of access.

Consumer use of digital-based health solutions is on the increase. While some social determinants of health may improve through digital interventions, it can also exacerbate existing poor social determinants of health. For example, some remote communities lack adequate infrastructure for quality video calls, and people in lower socioeconomic areas may not be able to afford high speed internet and/or have small data caps. A systematic review in 2020 found the role of digital health literacy in designing eHealth interventions targeted at socially disadvantaged groups is generally overlooked[16].

Any new or emerging digital health solutions, including the use of new technologies, should be adequately implemented, alongside well-funded education and well-constructed information campaigns for both health professionals and consumers.

## 6.3 Real-world evidence

### 6.3.1 Digital health interventions and use of technology should be evidence-based

Digital health interventions can be extremely beneficial (as discussed under 4.2.3) but they should only be supported and implemented if there is clear evidence of benefits. Technology providers often push to increase uptake of their product before any evidence of benefit can be assessed.

## 6.4 Proposed additions to the NMP

### 6.4.1 Integrate medication lists & prescribing software with Residential Aged Care Software

Prescribing software and medication lists need to be integrated with Residential Aged Care Facilities (RACF) software. This is an enormous clinical care gap that should be urgently rectified.

The GRACE-Med Study[17] found that RACF systems were not designed to support GP workflow, including a lack of prescribing medicines functions (such as allergy alerts and interactions), no ability to generate electronic scripts and no interoperability between GP systems and RACFs. Due to the lack of interoperability and integration, it is also difficult to securely send notes, discharge summaries and referrals.

### 6.4.2 Complementary and Alternative Medicine (CAMs)

CAMs should be included in medicine databases to allow doctors to document coded CAMs to assist with adverse reaction monitoring. The NMP should consider the financial and opportunity cost (harms from delaying or avoiding conventional medical care) of CAM treatments and claims, in addition to potential direct harms from such treatments.

### 6.4.3 Better Clinical Decision Support for medicines

The RACGP recommends an overarching body be created to encourage the advancement of electronic clinical decision support (eCDS) and oversee the development and maintenance of technical and clinical standards[18].

### 6.4.4 Minimum standards for dispensing software

The RACGP recommends the development and maintenance of technical and clinical standards for prescribing and dispensing software, including hospital electronic drug charts.

Quality use of medicine is strongly influenced by eCDS. The current unregulated environment creates significant risks for practitioners due to the varying quality and currency of information, as well as the lack of consistency across different software. It is important there is confidence in the development processes that underpin eCDS and in the way that information is delivered[18]. It is important to ensure eCDS systems support clinical workflow[18] and data is standardised across all platforms, to allow future data collection for research and reporting.

# *7. 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 the consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?*

The RACGP agrees the NMP should be enhanced to more effectively meet consumer needs and expectations.

Other comments:

- *Consumer-centred medication management*
  Alternative dispensing arrangements should be in scope for the NMP, to simplify the dispensing of medications for consumers.
  Medication pack sizes for stable long-term drugs are currently inconsistent and should be standardised. Pack size quantity varies between a 28 day, 30 day, and 100 day supply. It should also be in scope to allow a two- or three-month supply of stable, long-term chronic disease drugs to be dispensed to the consumer when they fill their script. Currently, consumers with several medications have multiple repeat script timings, and need to make a number of visits to the pharmacist. Consumers and carers need to carefully monitor the next repeat dates for all the medications. These changes would simplify the process for consumers, particularly those on multiple long-term chronic disease drugs.

# 8. 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?*

The RACGP recommends the development of an ongoing and publicly available conflict of interest register for all NMP committees.

The RACGP develops the *Standards for general practices* which support general practices in identifying and addressing any gaps in their systems and processes. This is implemented via an accreditation process which includes QUM and medication management. We welcome continued engagement with the Department of Health on the NMP and opportunities to advise on strengthening governance arrangements.

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

The NMP needs to communicated across all sectors, including consumers, health professionals, sponsors, organisations involved in medication such professional bodies, and the media. Use of contemporary communication methods such as social media should be incorporated to reach out and connect to a broad audience.

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

Mechanisms should be in place to support communications with key stakeholders. As an example, key stakeholders are invited to be involved in development of communication and dissemination of the policy.

# 9. 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?*

Partnerships should be established between all sectors of the health industry, with partners working to achieve integrated care for the community.

### *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?*

Medical software plays an important role and the RACGP recommends the medical software industry be considered as a partner in this collaboration.

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

The NMP should be reviewed regularly, with ongoing engagement with all relevant partners.

***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?***

Declarations of conflicts of interest should be appropriately applied and managed uniformly for all partners. An ongoing, publicly available conflict of interest register should be provided to declare any monetary (including grants for research and development) or non-monetary gifts to the members of all committees.

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