



26 September 2022

National Medicines Policy Secretariat
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601

Via email: NMP@health.gov.au

Dear National Medicines Policy Secretariat,

The RACGP thanks the Department of Health for the opportunity to provide comment on the Review of the Draft National Medicines Policy (NMP).

General practitioners (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 prescribing and administering medications, they also educate and counsel their patients regarding medication usage, undertake medication reviews, and deprescribe where necessary.

The RACGP has previously provided a [submission](#) to the National Medicines Policy Discussion Paper in October 2021. Whilst there have been amendments in this National Medicines Policy Draft, the RACGP reiterates that the policy could still be improved if:

- 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
- 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.

Appendix A highlights sections in the RACGP's original submission that have not been incorporated into the policy. The RACGP proposes the Committee give further consideration for these recommendations and suggestions to be included, such as that for consumer-centred medication management.

In addition, the RACGP recommends consideration be given to the following:

- structures be put in place to effectively inform health consumers whether the substance they are taking (such as complementary/alternative medicines) has evidence of efficacy. Traditional ingredients, supplements, etc. are given a tick of approval for safety by the Therapeutic Goods Administration (TGA) but the TGA does not comment on the evidence for the effectiveness of the medicines
- a system for funding research and development is implemented that supports funding for high benefit medication for low profit.



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While the RACGP acknowledges the NMP is an overarching framework, it is important to also focus on its implementation, which will translate into use in clinical practice.

Thank you again for the opportunity to comment. If you have any questions, please contact Mr Stephan Groombridge, National Manager, e-Health and Quality Care at stephan.groombridge@racgp.org.au or 03 8699 0544.

Yours sincerely

Adj. Professor Karen Price

President

References

1. Department of Health. Annual Medicare statistics: Financial year 1984–85 to 2019–20. Canberra: DoH, 2020.
2. Australian Institute of Health and Welfare. Medicines in the health system. Canberra: Australian Institute of Health and Welfare, 2020. Available from: <https://www.aihw.gov.au/reports/australias-health/medicines-in-thehealth-system> [accessed 14 September 2022].



Appendix A

The table below details sections from the original RACGP submission that have not been included in the current Draft National Medicines Policy. A copy of the full submission can be found [here](#).

Previous RACGP submission content	
4.2 Objectives of the National Medicines Policy	
4.2.1 Objective 1 - Access to medicines	<ul style="list-style-type: none">• Guarantee of supply of medications• Removal of the Authority Prescription System• 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.• Expansion of the Active Script List program• Efficient and cheaper alternatives to community pharmacy dispensing
4.2.2 Objective 2 - Quality, safety and efficacy of medicines	<ul style="list-style-type: none">• Automated mechanisms for post-marketing surveillance• Invest in practice-based pharmacists
4.2.3 Objective 3 - Quality Use of Medicines	<ul style="list-style-type: none">• Electronic prescribing/ monitoring• Online medical consultations• Non-GP specialists
5. Definition of medicines expanded to include software as a medical device	<ul style="list-style-type: none">• 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).
5.1 Quality and safety of medical devices	<ul style="list-style-type: none">• 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.



<ul style="list-style-type: none">• Reporting any issues with medical devices should be made easier and clearer for both health professionals and patients.
<p>6.1 Clinical trials and medicines access programs</p> <p>6.1.1 Australian populations are underrepresented in drug trials</p> <ul style="list-style-type: none">• The NMP should develop policies to encourage pharmaceutical industry investment in clinical trials in Australia.• Funding should be provided to enhance the enrolment of underrepresented populations in Australian drug trials.
<p>6.2 Health literacy</p> <p>6.2.1 Digital literacy and access</p> <ul style="list-style-type: none">• 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.• 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.
<p>6.3 Real-world evidence</p> <p>6.3.1 Digital health interventions and use of technology should be evidence-based</p> <ul style="list-style-type: none">• 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.
<p>6.4 Proposed additions to the NMP</p> <p>6.4.1 Integrate medication lists & prescribing software with Residential Aged Care Software</p> <ul style="list-style-type: none">• 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.
<p>6.4.2 Complementary and Alternative Medicine (CAMs)</p> <ul style="list-style-type: none">• 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.
<p>6.4.3 Better Clinical Decision Support for medicines</p>



<ul style="list-style-type: none">• 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 standards¹⁸.
<p>6.4.4 Minimum standards for dispensing software</p> <ul style="list-style-type: none">• The RACGP recommends the development and maintenance of technical and clinical standards for prescribing and dispensing software, including hospital electronic drug charts.
<p>7. Terms of Reference 4</p> <p>The RACGP agrees the NMP should be enhanced to more effectively meet consumer needs and expectations.</p> <ul style="list-style-type: none">• Consumer-centred medication management <p>Alternative dispensing arrangements should be in scope for the NMP, to simplify the dispensing of medications for consumers.</p> <p>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.</p>
<p>8. Terms of Reference 5</p> <ul style="list-style-type: none">• The RACGP recommends the development of an ongoing and publicly available conflict of interest register for all NMP committees.• The NMP needs to be communicated across all sectors, including consumers, health professionals, sponsors, organisations involved in medication such as 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.• 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.
<p>9. Terms of Reference 6</p> <ul style="list-style-type: none">• Partnerships should be established between all sectors of the health industry, with partners working to achieve integrated care for the community.• Medical software plays an important role and the RACGP recommends the medical software industry be considered as a partner in this collaboration.• 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



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monetary (including grants for research and development) or non-monetary gifts to the members of all committees.