

NATIONAL MEDICINES POLICY

Response to the 2021 Review

October 2021

ABOUT RESEARCH AUSTRALIA

We are the national peak body representing the whole of the health and medical research pipeline.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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Summary of Recommendations

Terms of Reference 2	The National Medicines Policy (NMP) should be expanded to include health technologies.
Terms of Reference 3	The role of research in supporting the objectives of the NMP should be explicitly recognised.
	The NMP should explicitly recognise the need to link surveillance of AMR, development of new treatments and reducing the overuse of antibiotics as elements of an integrated national response to antimicrobial resistance.
Terms of Reference 4	Data on medicines use can be better utilised to make the NMP more consumer centric.
	The NMP should enable the active use of medicines data to investigate consumer behaviour, and support research with consumers and prescribers to understand what is driving the behaviours.
Terms of Reference 5	The NMP should be included in the curricula of diverse health professional undergraduate and postgraduate courses.
	The NMP needs to be promoted among the peak health care bodies relating to the key discipline groups involved with medicines, namely nursing, medicine and pharmacy.
Terms of Reference 6	The Australian health and medical research community should be explicitly identified as partners in the NMP.

NATIONAL MEDICINES POLICY

RESPONSE TO THE 2021 REVIEW

Introduction

Research Australia welcomes the opportunity to make this submission to the review.

We are the national peak body for Australian health and medical research (HMR), representing the entire pipeline from the laboratory to patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

As the national peak body for the entire health and medical research pipeline we have a strong interest in medicines. Our members include researchers who investigate diseases and help discover and develop new medicines. They include researchers who seek to understand how medicines currently in use can be better used and can complement other therapeutic interventions. They also seek to determine the dangers of medicines as well as the factors that limit access to medicines in an effort to ensure medicines provide the best possible health outcomes for us all.

Research Australia's submission draws for this broad spectrum of research in responding to each of the Terms of Reference.

TOR 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.

Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?

The Proposed Principles are appropriate

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

The four Objectives are still relevant.

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

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?

Since development of the initial NMP in 2020, there has been enormous growth in the utilisation of therapeutic entities such as medical devices and vaccines. It is appropriate to include vaccines as medicines within the NMP. The Therapeutic Goods Administration classifies vaccines as medicines as does the Australian Medicines Handbook.¹

Medical devices can be very different to medicines in their physical makeup, intended purpose, and how they are utilised. There is also an extremely broad diversity of medical devices.

Nonetheless the Objectives and proposed principles are equally applicable to medicines and medical devices. How these apply in practice to medical devices can be different but that is a question of how the NMP's principles and objectives are implemented, and involves a range of guidelines, programs and regulation that sit beneath the policy itself.

There are also new products which blur the lines between medicines and medical devices or where the medicine is integral to the device. In these instances, having the products covered by one overarching policy may help reduce ambiguity about policy coverage.

Research Australia recommends the NMP be expanded to include health technologies.

Does the Policy's title, National Medicines Policy, reflect the breadth of technological developments within the Policy's scope? If not, how best can these and future developments be appropriately represented in the policy's title?

If the NMP is expanded to cover vaccines, it may be sufficient to clearly define vaccines as medicines without a need to change the title. If the policy is to be extended to medical devices, it is likely the title will need to be changed to reflect this broader application.

¹ <https://www.tga.gov.au/vaccines-overview>

TOR 3 Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

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

The general nature of the NMP, with a focus on some key high-level objectives, has enabled the Policy to remain relevant.

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 role of research in supporting the objectives of the NMP should be explicitly recognised.

Research has a particular role to play in creating an evidence base for change and improvement; and helping the system remain relevant, take advantage of technological and other advances, and respond to demographic change and disease burden.

Relevant disciplines include health services and systems researchers, demographers, pharmacologists, pharmacoepidemiologists and other epidemiologists, informatics and big data researchers. Researchers can help the policy framework with responding to chronic conditions, comorbidity, polypharmacy, and understanding interactions with the socioeconomic determinants of health. Research can also help guide the design, implementation and evaluation of new programs and policy.

How do consumers make decisions about different prescription and non-prescription medicines, and how could information be better presented to them to support their decision making? The COVID-19 epidemic has highlighted the different sources of information that influence decisions about whether to be vaccinated and about treatments for COVID-19.

While there has been some research undertaken in Australian and internationally into how consumers make decisions about medicines, more research is needed to understand how to support better decision making by consumers about the medicines they use and how they use them.²³ By paying particular attention to disadvantaged and minority groups, the involvement of researchers can support the NMP in relation to the principle of Equity.

The role of research in informing activities to support Quality Use of Medicine should be explicitly recognised in the NMP. Much more could be done in partnership between the Department, researchers, health practitioners and consumers to refine policy and guidelines for the use of medicines and support interventions at the patient-practitioner interface as well as at the population level.

A case study is provided on the following page.

² <https://www.safetyandquality.gov.au/our-work/partnering-consumers/shared-decision-making/decision-support-tools-consumers>

³ Lisa M. Schwartz, Steven Woloshin and H. Gilbert Welch, The Drug Facts Box: Providing Consumers with Simple Tabular Data on Drug Benefit and Harm, *Med Decis Making* 2007 27: 655 originally published online 14 September 2007, available at <http://mdm.sagepub.com/content/27/5/655>

Case Study:**Veterans' Medicines Advice and Therapeutics Education Services (Veterans' MATES)**

In partnership with the Quality Use of Medicines and Pharmacy Research Centre at the University of South Australia, the Department of Veterans' Affairs (DVA) delivers the Veterans' MATES program with the aim of improving the use of medicines and related health services in the veteran community.

Administrative claims data are used to identify DVA clients who are at risk of medicine related problems and the health providers who treat them. Veterans' MATES uses this information to provide educational material that is tailored to DVA client's specific health care needs. Veterans' MATES also provide direct patient-based feedback to treating doctors regarding medicines and health services that have been provided to their DVA client patients. This information is tailored to an individual doctor's practice.

Supporting educational material is also sent to community pharmacies, accredited pharmacists and other health professionals providing care for DVA clients. A team of clinical experts contribute to the development of the health and medicine information.

Each year Veterans' MATES focuses on four topics and utilises DVA's administrative claims data to pinpoint members of the veteran community who would benefit. The program has focused on increasing use of under-used medicines, reducing adverse medicine events, reducing use of unnecessary medicines and improving the utilisation of health services. A range of health conditions and medicines have been covered including pain, diabetes, insomnia, depression, falls, osteoporosis and wound care.

The national program is evaluated using surveys provided at the time materials are distributed, as well as observational studies using administrative claims data to measure the impact of the interventions. Over the past two years, 70% of DVA clients and 80% of general practitioners who have provided feedback through the surveys have reported the educational materials beneficial.

Since its inception:

- Veterans' MATES has reached more than 300,000 DVA clients, 33,000 general practitioners and 8,500 pharmacists.
- Each year approximately 77,000 DVA clients receive educational material from Veterans' MATES specific to their health care needs.
- Collectively there have been over 500,000 mailings sent to doctors, with 1.5 million targeted messages individually tailored for each DVA client's health care needs.
- The program has delivered 1.5 million mailings to identified DVA clients providing health education and self-management advice.

The Quality Use of Medicines and Pharmacy Research Centre (QUMPRC) specialises in improving the use of medicines. Research within the Centre ranges from large-scale data analysis, to the translation of evidence into policy and practice.

It works with consumers, health professionals and organisations, ensuring the advanced technologies and methods developed within the centre find their way into policy and practice to improve patient lives. It's research focuses on 6 key areas: medicines safety, optimising medicine use, digital health, pharmacy practice, Aboriginal traditional medicines, and evidence translation and policy.⁴

⁴ <https://www.unisa.edu.au/research/qumprc/>

Research can also be undertaken using medicines data to understand variations in the use of medicines across Australia and across different demographic groups. Are there unwarranted variations in use due to information asymmetry between groups of consumers and health practitioners, and/or different levels of access to other treatment alternatives?

Research using medicines data can also help better understand the role of medicines within the broader health system. For example, could higher level of prescribing of antidepressants in some communities point to inequitable access to non-pharmaceutical treatment alternatives, and support the planning and delivery of mental health services?

Antimicrobial resistance

Antimicrobial resistance is a growing global problem and one which has significant implications for the NMP. The policy response to AMR encompasses the whole of our health system and is broader than medicines use but the NMP has a critical role to play in our response.

Medicines data is already being used to identify the overuse of antibiotics in Australia.⁵ **The NMP should explicitly recognise the need to link surveillance of AMR, development of new treatments and reducing the overuse of antibiotics as elements of an integrated national response to AMR.**

TOR 4 Consider the centrality 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 centrality and engagement be strengthened? Is anything missing, and what needs to change?

What is currently missing is a consumer centric focus on the use of medicines data. **Data on medicines use can be better utilised to make the NMP more consumer centric.** We also need to leverage other data (MBS, hospital, health insurance) to better understand medicines use in a more consumer centric way.

A consumer centric approach will allow us to better understand equity of access, variations in use, preferences across all types of medicines prescription and non-prescription, subsidised versus non-subsidised and conventional versus complementary and alternative.

The NMP should recommend that education and decision support tools for practitioners and consumers are developed and used to support shared decision-making, patient-centred practice, and to boost health literacy about medicines and health technologies.

Although safety nets and PBS subsidies might prevent substantial economic hardship, many patients still face financial barriers substantial enough to affect adherence to treatment – resulting in presentable complications and hospitalisations. Medicines data can help understand these barriers, the consequences, and what can be done to address them.

⁵ <https://www.amr.gov.au/about-amr/what-current-amr-situation/amr-internationally>

Using data to understand consumer preferences

Consumer preference for particular medicines, particularly prescription medicines that are not listed on the PBS, can provide important insights into consumer behaviour and the reasons for the demand for particular medicines.

For medicines with a high cost to the consumer and/or large volumes, the reasons for use of the medicine should be investigated. Is it because there is no PBS listed medicine for the indication?

Alternatively, are non-PBS listed medicines being purchased where there are PBS listed medicines for this indication? If this is the case, why are consumers prepared to spend so much if there are PBS listed alternatives? Is it a case of information asymmetry about the PBS listed medicines or are there unique features of the unlisted medicines that mean they are particularly suited to consumers in particular circumstances?

Case Study

Anticholinergic medicines are prescribed for a range of different conditions but are also associated with an increased risk of cognitive impairment. They can also reduce the effectiveness of medications used to treat the symptoms of dementia (which are often cholinergic medicines), meaning the use of anticholinergic medicines by people already experiencing cognitive decline can be particularly problematic.⁶

Overactive bladder and urinary incontinence are serious health conditions with higher incidence in the older population, which is also the group with the greatest incidence of dementia. Most pharmaceutical interventions for the treatment of overactive bladder are anticholinergic medicines. Research Australia understands that while there are some TGA approved incontinence medicines for this condition that are not anticholinergic, they are not listed on the PBS. These medicines are, however, being prescribed by doctors and purchased by Australian consumers at significant cost.

The NMP should enable the active use of medicines data to investigate consumer behaviour, and support research with consumers and prescribers to understand what is driving the behaviours. Where decision making is not optimal, it can support the creation of decision making tools and the distribution of information to support better decisions.

The policy could also support the creation of a mechanism for using this information to bring forward drug candidates for consideration for subsidy where there is a demonstrated need for a particular consumer group and the purchase of these non-subsidised drugs is:

- a barrier to appropriate treatment; and/or
- places a significant economic burden on the consumers, their carers and families.

⁶ https://www.dementia.org.au/sites/default/files/helpsheets/Helpsheet-DementiaQandA24_AnticholinergicDrugs_english.pdf

Non-drug alternatives

Similarly, medicines data could be used to explore opportunities for the greater use of non-drug alternatives. Continuing with the topic of incontinence, referral to a physiotherapist for assistance in strengthening the pelvic floor can be an appropriate alternative to drug treatment.⁷ Are consumers in some areas being provided with a greater range of treatment options? What other non-drug alternatives are underutilised and could be promoted to consumers and health professionals?

Understanding the use of medicines data in this way furthers not only the proposed principle of a Consumer Centred Approach but also the principle of Equity. It helps provides a better understanding of the role of medicines and medicines policy within the broader Australian health system. In doing so, it promotes a consumer centric rather than a medicines centric approach.

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

How can communication about the NMP be enhanced or improved?

There has been uptake of the Policy within universities in the teaching of pharmacology and medication safety to health professional students, particularly those relating to medicine, nursing and pharmacy. Professional organisations such as the Society of Hospital Pharmacists and the Pharmaceutical Society of Australia have utilised the NMP in their teaching and professional activities in association with members.

The NMP should be included in the curricula of diverse health professional undergraduate and postgraduate courses. The NMP needs to be promoted among the peak health care bodies relating to the key discipline groups involved with medicines, namely nursing, medicine and pharmacy.

⁷ <https://www.racgp.org.au/clinical-resources/clinical-guidelines/handi/conditions/musculoskeletal/pelvic-floor-muscle-training-urinary-incontinence>

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

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?

The Australian health and medical research community should be explicitly identified as partners in the NMP. Researchers have an important role to play in supporting the objectives of the Policy in:

- timely and affordable access
- appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Researchers also have an important role in evaluating innovative programs delivered under the NMP, including in terms of effectiveness, cost, implementation outcomes and program sustainability.

Research Australia's response to TOR 3 and 4 above provide several examples of the role researchers can play as partners in the NMP.

Conclusion

Australia undertakes world class health and medical research to deliver health social and economic benefits to the Australian community. One of the ways this benefit is realised is through the development of new medicines and other therapeutic interventions, including medical devices.

The NMP has a critical role to play in ensuring that the efforts of researchers lead to better health outcomes for Australians. Australian researchers also have a role to play in ensuring that the National Medicines Policy delivers on its promise.

While this Review is welcome, it is also well overdue, and **we encourage the Review to recommend to the Government that the NMP is reviewed more regularly and frequently in the future to ensure it remains current and relevant.**

Research Australia is pleased to have had this opportunity to make this submission and is willing to provide further information that would assist the Review in its deliberations.

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