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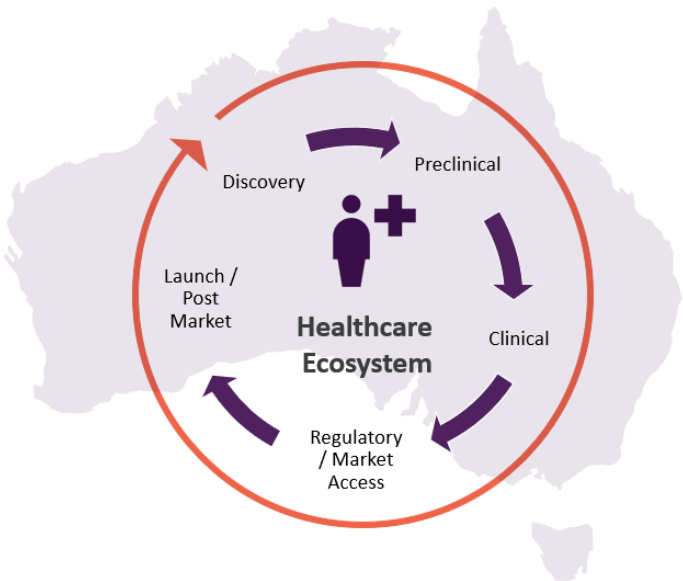
TOR 1: Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.

- *Question: Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?*
- *Question: Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?*

Principles

The proposed principles are generally considered to be an appropriate foundation of the NMP. Further weight, however, should be given to the *consumer centred approach.*

Patients and healthcare consumers are fundamental to Australia's broader healthcare ecosystem, at all stages for the medicines value chain. Medicines are developed, prescribed and dispensed in order to improve health outcomes at the individual patient level. As such, the perspectives, rights and experiences of consumers should be taken into account in all aspects of the provision and utilisation of medicines.



Therefore, a *consumer centred approach* to medicines should be considered a fundamental, underlying principle of the NMP and underpin all other principles and pillars. This will help facilitate a truly consumer centric approach to the utilisation of medicines in Australia. For example, in terms of access, the new Medicines Australia Strategic Agreement has a specific workstream to further improve consumer engagement in access processes and decisions.

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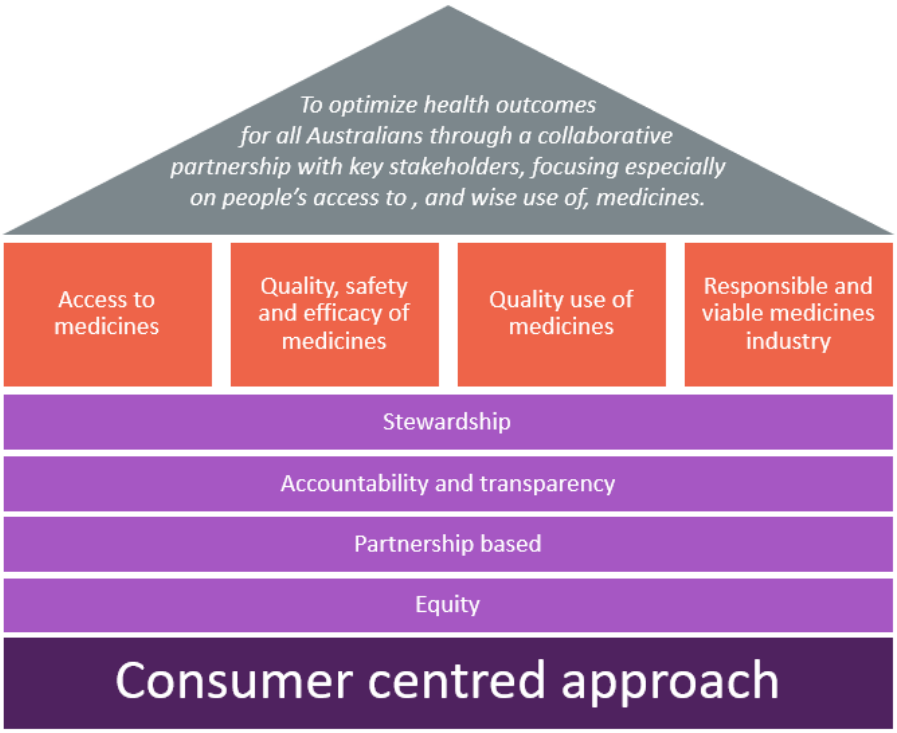


Objectives

Access to Medicines

Innovative medicines should be made available for patients as soon as practicable. *Access to medicines* is therefore considered an appropriate and important objective of the NMP and could be facilitated by the following:

- The path to market for new medicines in Australia is long – frequently exceeding that of other comparable markets. On top of this, Australia is often not a launch priority for new medicines and therefore Australian patients stand to wait much longer for access to new medicines. As such, it should be a priority to drive efficiencies throughout the path to market with a view to streamline and expediting access to new medicines.
- Improving access to clinical trials, acknowledging that clinical trials can be an important access and treatment option for patients. This will require ensuring Australia is an attractive destination for clinical trials and improving the ability of all patients to access trials – particularly those outside of metropolitan areas and or of culturally and linguistically diverse backgrounds.
- Designating an appropriate timeframe within which medicines should be listed on the PBS post regulatory approval (for example, 90 days). This could be supported by appropriate metrics and accountability processes, as outlined below in response to TOR 6.
- Similarly, existing HTA and reimbursement processes for new medicines should be further revised to expedite patient access to innovative therapies. This could include the early identification of major and minor gaps identified during regulatory review and the establishment of early reimbursement pathways for innovative medicines which may not fit within existing processes (subject to further collection and review of additional evidence).

- Improving guidance and transparency around the use of real-world evidence (RWE) and real-world data (RWD). Here, the use of RWE to support the evaluation of new medicines has the potential to drive improvements in patient access, particularly where the utility of randomised controlled trials may be limited (for example in the instance of rare diseases). As such, the NMP should align with the latest Strategic Agreement and subsequent HTA policy and methods review, in acknowledging the importance of RWE to support access to and quality use of medicines and the need to progress specific guidance.

Quality, safety and efficacy of medicines

BMS Australia support the ongoing prioritisation of quality, safety and efficacy of medicines as a key objective of the NMP.

Quality Use of Medicines

Quality Use of Medicines (QUM) is an important component of the ongoing utilisation of medicines. It seeks to facilitate the appropriate use of medicines in a manner that is responsible, safe and effective for each individual patient and the broader population. As such, QUM should remain a core objective of the NMP moving forward. Where assessed to be clinically and cost-effective, efforts should be made to optimise the uptake of a medicine to achieve maximum gains in health outcomes.

At present, post-market reviews (PMRs) are largely utilised as a mechanism to drive price reductions, which does little to facilitate the QUM. A component of QUM should include ensuring optimal use of medicines where shown to be clinically and cost-effective – that is, volumes should be maximised if a medicine is proven to be best practice.

Consequently, the role of PMRs in driving the QUM should be strengthened. Alignment on how best to apply these should be considered within the context of the latest strategic agreement between Medicines Australia and the Commonwealth government, including the planned HTA review.

Additionally, there is an ongoing role for HCP education to ensure QUM which would require a continuing commitment from stakeholders within the NMP.

Maintaining a responsible and viable medicines industry

A responsible, sustainable and viable medicines industry is crucial to the health of Australians. Meeting this objective requires a focus beyond that of sustainability of supply alone. Though important, this is but one aspect of a viable medicines industry.

Australia's healthcare ecosystem is diverse and consists of a broad range of stakeholders throughout the value chain – from the early stages of drug development, throughout the medicine life cycle (as outlined in response to TOR 3). In order to cultivate a thriving medicines industry, it is important to consider the broader healthcare ecosystem – including how the perspectives and expertise of relevant stakeholders throughout the landscape can be leveraged to facilitate innovation both at a local and international level.

An ecosystem wide approach also appropriately captures the important role that clinical trials play both from a research perspective and as a treatment option for patients. Clinical trials provide patients with access to cutting edge therapies, often where they have limited other treatment options. As such, a viable medicines industry should revolve around all treatment options for patients, rather than focusing solely on those therapies which have reached the post-marketing phase.

This ecosystem wide approach to the industry should be reflected within the objectives of the NMP.

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

- *Question: 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?*
- *Question: 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?*

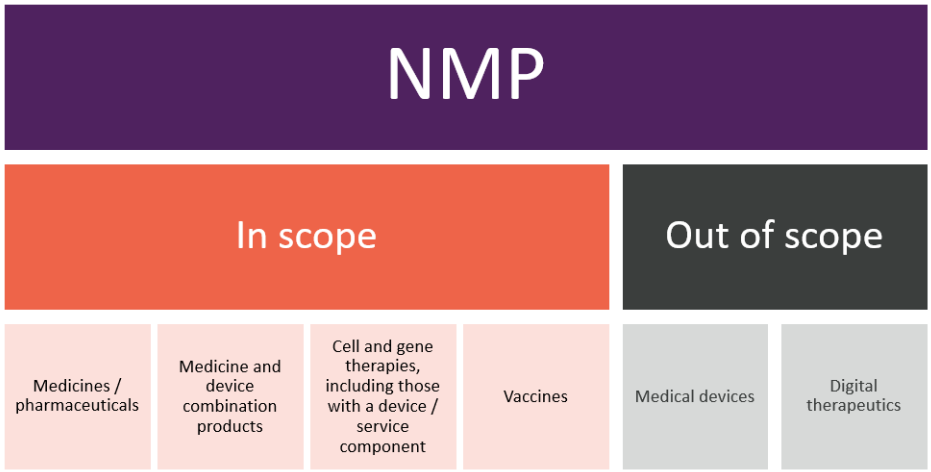
The definition of medicines should be expanded to reflect the arrival of innovative therapeutic products (such as CAR-T cell therapies and gene therapies) which do not fit within the traditional definition of a medicine – for example, those which consist of a service or device component yet provide their therapeutic effect via a physiological mechanism.

Consideration could be given, for example, to the definition of *Advanced Therapy Medicinal Products (ATMPs)* and *combined ATMPs,* as utilised by the EMA and NICE. This effectively captures those therapies which are based on genes, tissues or cells – including where there is a device component: https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview

Vaccines should also be included in the scope of the NMP. The current pandemic has highlighted the range and scale of issues associated with preventative vaccines, with many of the issues relating directly to the pillars of the NMP. In addition, vaccine technology is rapidly expanding to include a pipeline for therapeutic and oncology vaccines.

Devices and medical technology which do not fit the above criteria are not considered to be appropriate or relevant for inclusion in the NMP.

Overall, a definition in line with the below scope is considered appropriate for the NMP:

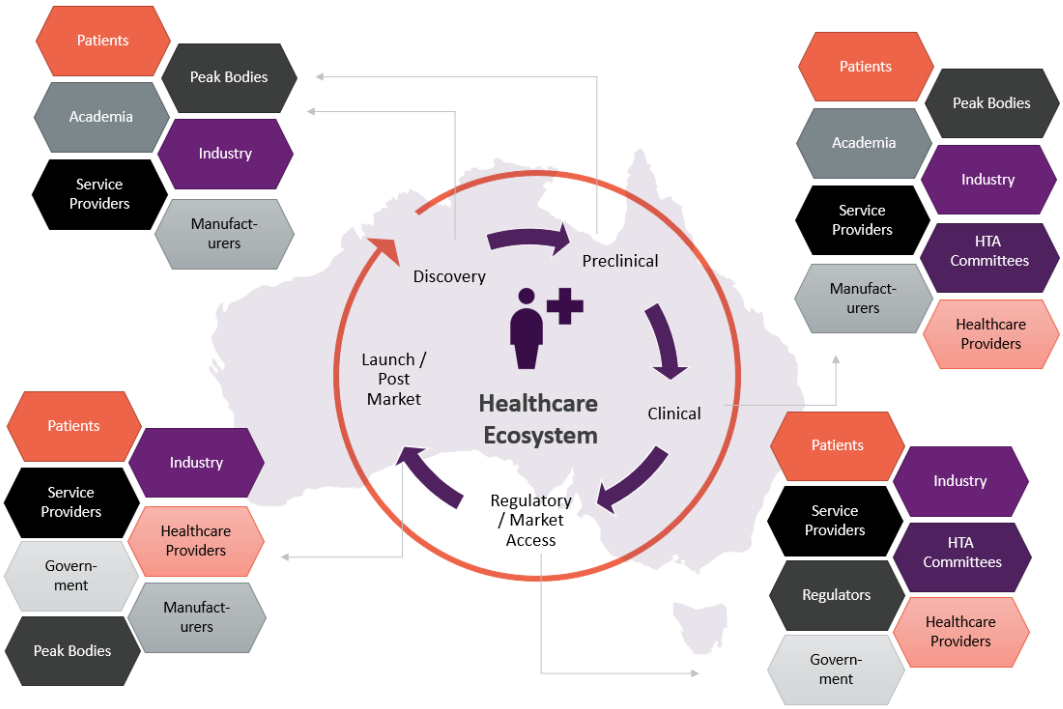


TOR 3: Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

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

There are several areas where a revised NMP would be more adaptable to ongoing developments in the health landscape, including a broader definition of medicines and the industry, elevation of consumer centricity (as outlined in TOR 1 and 2) and clear recognition of the whole medicines ecosystem within the scope of the NMP.

Here, Australia's healthcare landscape is better described as an ecosystem. This consists of a broad and diverse range of stakeholders throughout– from research and discovery through to the post market phase.



There is an increasing need for collaboration, consultation and engagement amongst stakeholders throughout the ecosystem to deliver a truly patient-centric approach to healthcare and the use of medicines – particularly within the context of emerging innovations such as digital technologies, precision medicines and the increasing utility of RWE and RWD. Here such innovations have the potential to reshape healthcare throughout the value chain – with the potential to both increase collaboration among stakeholders as well as providing positive health outcomes for patients. This has been illustrated by the arrival of CAR-T therapies – the commercialisation of which as required intense collaboration amongst a broad range of stakeholders including federal and local government, treatment centres, clinicians, and patient advocacy organisations.

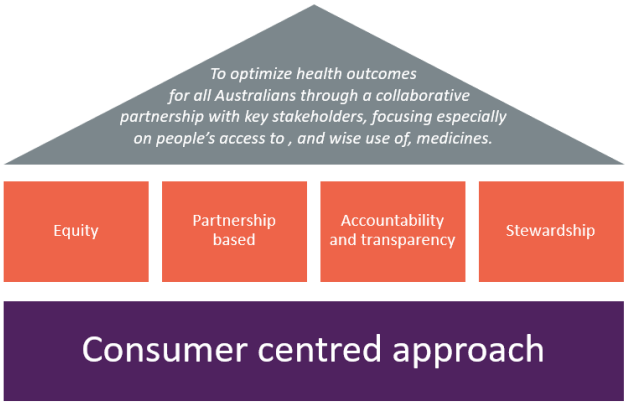
As a result, the NMP should reflect the importance of an ecosystem wide approach to medicines and healthcare.

As outlined above, an ecosystem wide approach to medicines policy would also appropriately capture the importance of clinical trials as a treatment option for patients. Many of the barriers within Australia's current clinical trial landscape stem from a lack of harmonization in clinical trial requirements across jurisdictions. Acknowledging the importance of clinical trials within the broader ecosystem and appropriately capturing this within the NMP is seen as an opportunity support broader goals for clinical trial harmonization across the country, for example the Australian Government's "one stop shop" initiative.

TOR 4: Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

- *Question: How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?*

As outlined above in response to TOR 1, consumer centricity is fundamental to the provision of healthcare and medicines. As such, the role of the consumer should be strengthened, with the *consumer centred approach* underpinning all aspects of the NMP.



Australia's population is highly diverse, and there is a need to better reflect this diversity in all aspects of the NMP and its implementation. A good example is clinical trial participation. This includes considerations like diversity of location (regional/rural versus metropolitan), the representation of Aboriginal and Torres Strait Islander populations and those of varying socioeconomic and ethnic backgrounds.

In order to achieve broader consumer engagement and participation in all aspects of the NMP, an increase in consumer health literacy will be essential. This needs to be recognised as an important contributor to outcomes of the NMP and efforts should be made via associated governance processes to ensure resources are available and applied to increase national medicines literacy. As with QUM in TOR 1, there is a significant and ongoing role to provide education to consumers and HCOs to improve health literacy.

Ultimately there is a need for greater consumer representation throughout the healthcare ecosystem and this should be reflected in medicines policy. The role of consumers should align with the revised strategic agreement and the processes implemented to elevate the patient and consumer voice in medicines access.

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

- *Question: What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?*
- *Question: How can communication about the NMP be enhanced or improved?*
- *Question: What would be effective mechanisms to support communication about the policy?*

An appropriate governance framework should be included in the NMP to help progress the objectives of the policy and improve accountability (as discussed in response to TOR 6). This should include reinstating a multi-stakeholder committee(s) to oversee the implementation of the policy and track performance on agreed metrics (as outlined in response to TOR 6). Much like the past governance model of the APAC, such a stakeholder committee gives an opportunity to align responsibilities with the pillars and objectives of the NMP. However, given the increased diversity and complexity of the medicines ecosystem described above, consideration should be given to representation on these governance committees of a broader range of stakeholders than was the case in the past.

Similarly, the roles and responsibilities of all NMP stakeholders should be clearly defined. This should take a broad, ecosystem wide approach, to capture all relevant stakeholders, and should also consider each of the objectives of the NMP. The NMP should therefore also outline which stakeholders are responsible for driving progress towards each objective.

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

- *Question: How should the NMP's 'partnership-based' approach be defined?*
- *Question: 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?*
- *Question: How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?*
- *Question: How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?*

As outlined in TOR 1 and 3, there is a need for an ecosystem wide approach to medicines policy. This ecosystem wide view should be captured within the context of the NMP's approach to partnerships to help ensure that all relevant partners are captured within the NMP, and that an appropriate framework is established to facilitate collaboration between and accountability of these stakeholders. As outlined in TOR 5, representation on the appropriate governance committee/s should be broader than was the case historically, given the increased complexity and diversity of the medicines ecosystem.

In terms of accountability, there is a need for a system that reviews and reports on performance of the NMP to ensure visibility of progress for all stakeholders. Performance metrics are therefore necessary to help drive accountability and ensure the objectives of the NMP are realised. They should be developed with a view to targeting each objective of the NMP. For example, a timeframe of 90 days for reimbursement post TGA approval could instated to measure progress in improving access to medicines.

The latest Medicines Australia – government Strategic Agreement and subsequent HTA review (in the case of access metrics) create an opportunity to operationalise the above and therefore objectives should be developed in line with this.

Metrics should be developed by an appropriate governance committee (as outlined in response to TOR 5), tracked annually and ideally communicated in an annual report (e.g. both publicly and to parliament). In developing these metrics, consideration should be given to assigning responsibility to the appropriate NMP partners. This approach should also acknowledge the co-dependency across multiple NMP stakeholders for at least some of the appropriate metrics.

Conflicts of interest should be declared and managed at the governance committee level and a charter for the committee/s should clearly emphasise the collective and collaborative nature of the NMP in its objectives and implementation.