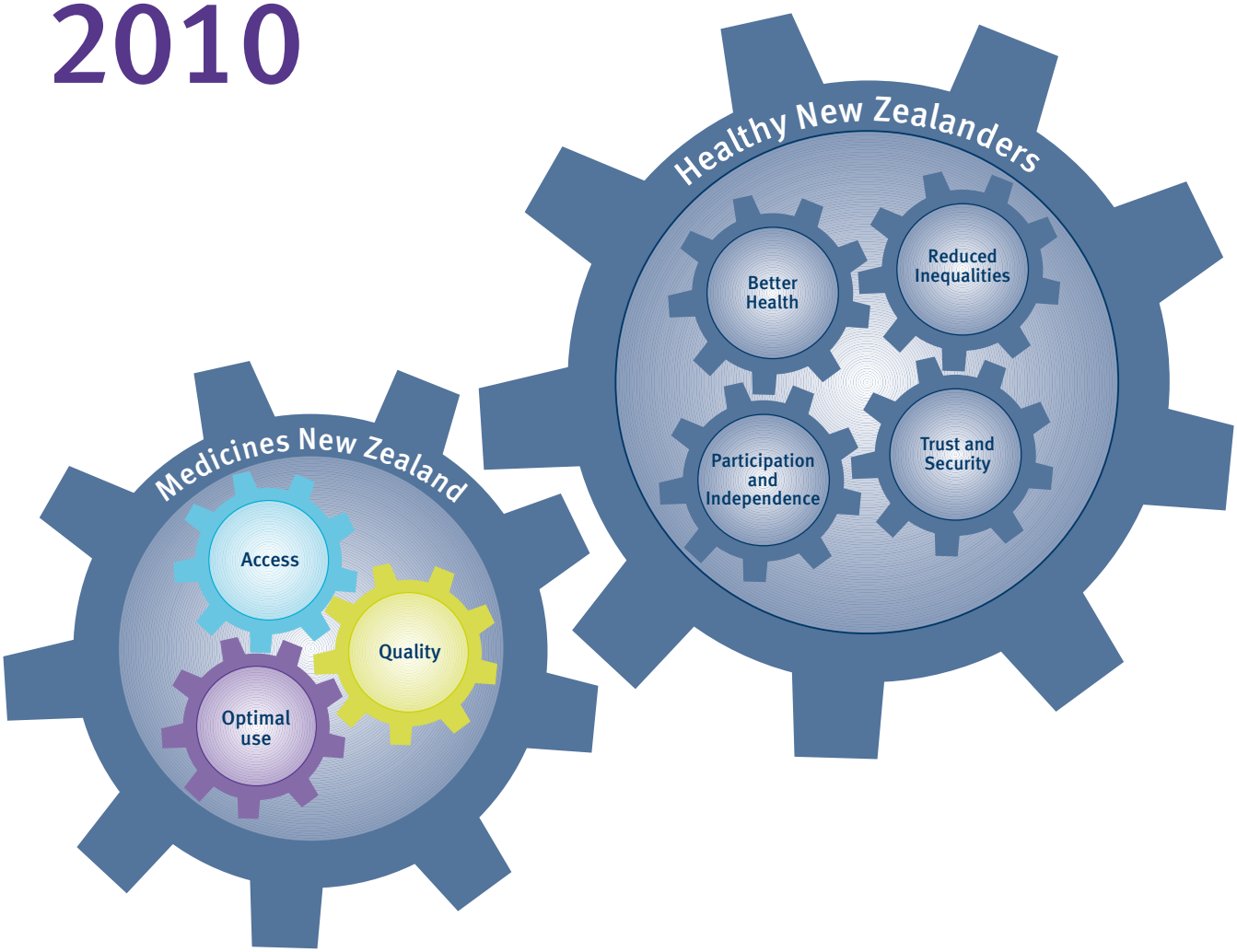
Actioning *Medicines New Zealand* 2010



New Zealand Government

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Actioning Medicines New Zealand

Actioning Medicines New Zealand is the action plan for *Medicines New Zealand* – the medicines strategy for New Zealand. It is not an exhaustive list of actions, but rather shows what can and will be done to deliver *Medicines New Zealand* outcomes.

This is a living document. The initiatives it contains will change over time.

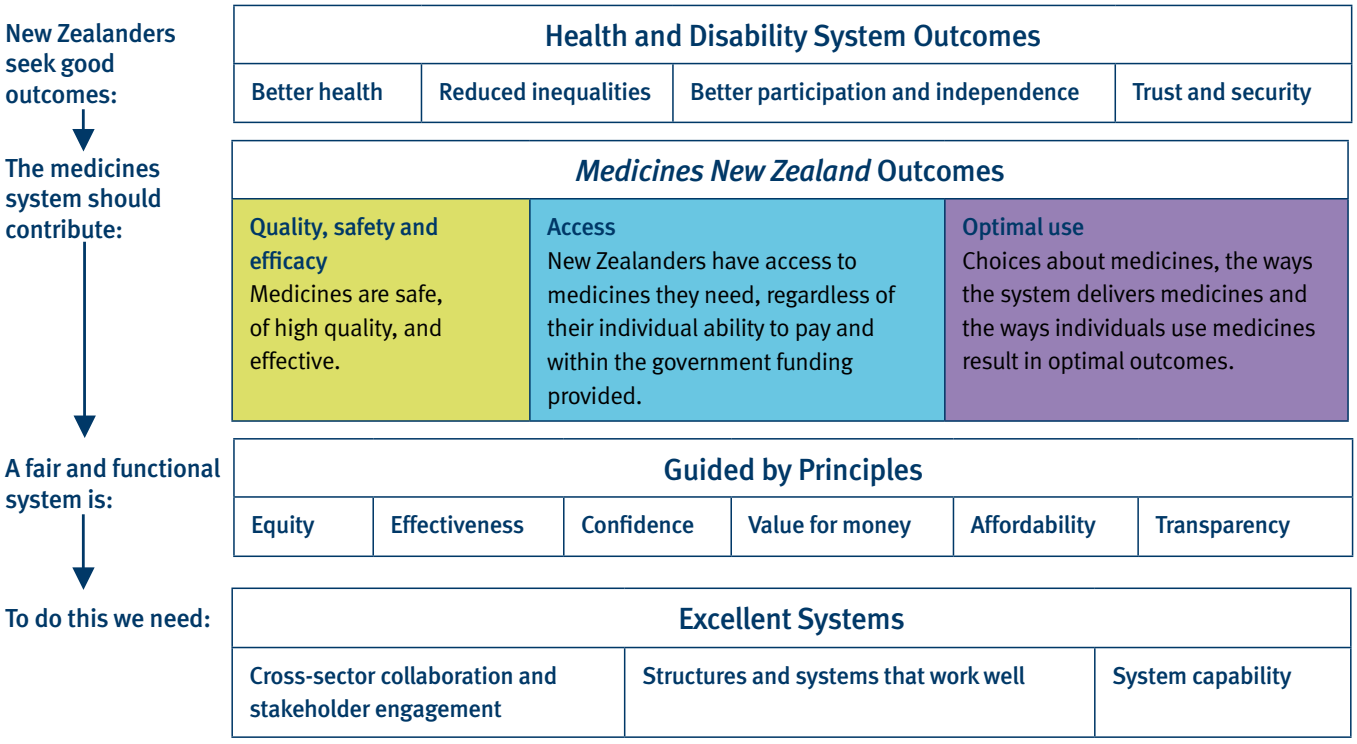
Following on from *Medicines New Zealand, Actioning Medicines New Zealand* seeks to support the medicines system to deliver:

- **Quality, safe and effective** medicines for New Zealanders
- **Access** to the medicines New Zealanders need regardless of their individual ability to pay and within the government funding provided
- **Optimal use** of medicines resulting in optimal health outcomes.

These outcomes will be implemented through:

- cross-sector collaboration and stakeholder engagement
- structures and systems that work well
- a medicines system that has the capability (financial resources, workforce, infrastructure and knowledge and information) it needs.

Medicines New Zealand: strategic framework



Progress since the first action plan

Significant progress has been made in key areas since the first Action Plan was published in December 2007, and the focus will now shift to other priority actions. The major areas of achievement are:

- PHARMAC has made considerable progress on improving the transparency of its processes, and giving stakeholders a greater opportunity to participate.
  - Funding applicants are now formally invited to meet with PHARMAC at the beginning of the funding application process.
  - *Have Your Say in Our Decisions*, a guide for stakeholders on how to get involved in PHARMAC's decision process, was released at the end of 2008.
  - Several PHARMAC documents and PHARMAC's website have been changed, to better outline medicines funding proposals and explain decisions.
  - PHARMAC held its second Stakeholder Forum on 9 October 2009. The Forum was well attended by medicines system stakeholders, and was positively received.
- Changes have been made to the Pharmacology and Therapeutics Advisory Committee's (PTAC's) Terms of Reference to ensure optimal arrangements are in place for PTAC to provide objective advice to the PHARMAC Board. The Ministry of Health and PHARMAC have also reviewed the PTAC appointment protocol to ensure that it supports the independent appointment process required by the New Zealand Public Health and Disability Act 2000.
- The $3 co-payment for prescription charges was extended to prescriptions written by DHB prescribers for people moving from secondary health care services back into the community.
- Medsafe has introduced an abbreviated approval process under section 23 of the Medicines Act 1981 for approving new medicines routinely used in hospital practice that would otherwise be supplied under section 29 of the Medicines Act 1981.
- The Hon Peter Dunne hosted a workshop in August 2009 on realising the potential of the pharmacy workforce to achieve optimal use of medicines. It was well attended by the pharmacy sector, and representatives of other parts of the health sector, including District Health Boards (DHBs), primary health organisations, general practice, and nursing. An ongoing work programme has been developed, which will be jointly overseen by the Ministry of Health and the Pharmaceutical Society.
- In May 2009, the Minister of Health established an independent panel to provide advice on practical ways to improve access to high-cost, highly specialised medicines (incorporating a review of the Exceptional Circumstances Schemes). The panel has consulted extensively with the medicines sector, and is presenting its final recommendations in March 2010.
- In January 2009, the Minister of Health established a Ministerial Review Group (MRG) to provide advice on improving health system performance. One of the MRG's recommendations was to expand PHARMAC's role into prioritisation and procurement of medical devices. In December 2009, Cabinet agreed in principle to expand PHARMAC's role into hospital medicines and a limited range of medical devices, subject to further consultation with clinicians (which is being led by Dr David Sage, Chief Medical Officer, Auckland DHB). Cabinet also directed the Ministry of Health and PHARMAC to continue discussions on arrangements for improving value for money in vaccine prioritisation and procurement.
- The process by which PHARMAC and DHBs develop a proposed budget for Community Pharmaceuticals has become increasingly sophisticated over time, as more information becomes available on the relative costs and benefits of different health interventions. The setting of the budget for 2009/10 was explicitly underpinned by a set of principles (maximising the benefits from investment in community pharmaceuticals; aligning incentives across the sector; improving access to existing and new medicines; ensuring that DHBs remain within overall funding parameters), and spending decisions for individual medicines are consistent with PHARMAC's nine decision criteria. PHARMAC, DHBs and the Ministry of Health are also exploring whether the budget parameters are optimal.

There are some activities that were in the Action Plan that are no longer considered to be priorities.

- It is no longer considered a priority for the Ministry of Health to hold a stakeholder forum every two years. The Ministry is expected to engage regularly with stakeholders as it develops, monitors and evaluates medicines policy. At this stage, an additional forum will not add any value to existing processes and forums.
- As PHARMAC has made several changes to improve transparency, including improvements to its consultation and notification letters, and better explanation of its work generally, it is not considered a priority at this stage for it to publish public summaries of decisions on medicines funding applications.

Between now and the next update of the Action Plan, the priority areas will be:

- making changes to medicines legislation and regulations to ensure that our medicines regulatory framework provides adequate protection to medicines consumers, while facilitating access to new medicines and enabling innovative practice to support optimal use of medicines (eg, collaborative prescribing, reviewing use of standing orders). The Ministry of Health is currently consulting on a series of proposed changes to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002
- progressing the work programme arising from the August 2009 workshop on realising the potential of the pharmacist workforce
- considering improvements to PHARMAC's consumer engagement processes, and finalising a new Terms of Reference for the Consumer Advisory Committee
- better communicating the process for setting the Community Pharmaceuticals budget and exploring whether the budget parameters are optimal
- exploring the possibility of PHARMAC having a greater role in the medicines system, particularly for hospital medicines, vaccines, and some medical devices
- considering and, where appropriate, implementing the recommendations of the high-cost, highly specialised medicines panel on mechanisms to improve access to high-cost, highly specialised medicines
- continuing to move towards a New Zealand Medicines Formulary, by launching the Universal List of Medicines and developing clinical reference information on medicines.

Excellent Systems: Cross-sector collaboration and stakeholder engagement . . .

Stakeholders are engaged in action under a common strategic direction and know, understand and respect the roles of others in the medicines sector.

Actions . . .	Goals . . .
• The Ministry of Health will support other agencies engaged in regulatory and pharmacovigilance-related activities to maintain a coordinated approach to ensure the medicines used by New Zealanders are safe, of good quality and effective.	**Quality, safety, efficacy:** New Zealand has a sustainable, efficient and effective regulatory system that is consistent with international best practice. It ensures that safe, quality and effective medicines are available to New Zealanders in a timely way.
• Evaluate and review Medicines New Zealand. The Ministry of Health will report annually on progress with implementing the Action Plan.	**Access:** The systems within the medicines sector work well and contain appropriate checks and balances and clear accountabilities.

Key: Quality, safety, efficacy | Access | Optimal Use

• PHARMAC will hold a regular forum for interested stakeholders to comment on PHARMAC's operation, including PHARMAC's stakeholder engagement activity. • PHARMAC will complete a review to identify what, if any, improvements it should make to its consumer engagement activities.	**Access**: Stakeholders, including consumers, will have the opportunity to provide information or perspectives that will contribute to PHARMAC's decision-making processes and will be provided with guidance on how to do so.
• The Ministry of Health will support agencies engaged in access-related activities to ensure a collaborative and cohesive approach so New Zealanders have access to the medicines they need.	**Access**: Medicines are affordable for individuals, the community and the health and disability system and meet the needs of New Zealanders.

Excellent Systems: Structures and systems that work well . . .

Structures and systems within the sector work well together and duplication is minimised. The medicines system is sustainable over time, has robust checks and balances, clear accountabilities, evaluation is used to inform change and is understood by, and responsive to, stakeholders.

Actions . . .	Goals . . .
• Extend the audit function provisions in the Health Act 1956 (section 22G) to support robust accountability and monitoring across the medicines system.	**Safety, quality, efficacy**: New Zealand has a sustainable, efficient and effective regulatory system that is consistent with international best practice and ensures that safe, quality and effective medicines are available to New Zealanders in a timely way.
• District Health Boards (DHBs) and PHARMAC will better communicate the principles-based approach to setting the community pharmaceuticals budget, and work with the Ministry of Health to explore whether the budget setting parameters are optimal.	**Access**: New Zealanders understand and can access information about the medicines system including, where appropriate, information about medicines funding decisions and related health and disability system prioritisation criteria.
• Update the DHB/PHARMAC Memorandum of Understanding so there is a clear structure and processes for how the organisations work together.	**Access**: The roles and functions of agencies within the medicines system are aligned to enable them deliver Medicines New Zealand outcomes effectively and efficiently and to minimise duplication.
• PHARMAC will complete its review of the Consumer Advisory Committee's (CAC) Terms of Reference to ensure optimal arrangements for CAC to undertake its legislative role.	**Access**: The systems within the medicines sector work well and contain appropriate checks and balances and clear accountabilities.
• PHARMAC will continue to make careful choices about medicine brand changes and support health practitioners and consumers to ensure that brand changes are implemented as smoothly as possible. • Investigate and, where appropriate, implement mechanisms for improving access to high cost, highly specialised medicines (including changes to the Exceptional Circumstances Schemes, which provide flexibility to handle variation in individual circumstances of medicine consumers). • PHARMAC will continue its review of and, where appropriate, removal of specialist restrictions on subsidised prescribing of specified Pharmaceutical Schedule medicines.	**Access**: Taking account of and balanced against other health priorities, the medicines system is responsive to individual variation, within a population focus.

• Explore an expanded role for PHARMAC in the prioritisation and procurement of hospital medicines, vaccines, and some medical devices.	**Access:** New Zealand will implement a nationally co-ordinated decision-making, funding and procurement programme for hospital medicines and vaccines.
• Consider and implement a mechanism to support a cohesive and co-ordinated approach to Optimal Use of medicines practices (including those that address inequalities). This would aim to build on the existing structures and agencies across all parts of the medicines sector (including the Best Practice Advocacy Centre, the Centre for Adverse Reactions Monitoring, the Safe and Quality Use of Medicines Group and PHARMAC).	**Optimal Use:** The roles and functions of agencies within the medicines system are aligned to enable them to deliver Medicines New Zealand outcomes effectively and efficiently and to minimise duplication.

Excellent Systems: System capability . . .

The medicines system has the resources it needs to work efficiently and effectively. It has the financial resources, infrastructure, knowledge and information it needs.

Actions . . .	Goals . . .
• Address the outdated regulatory framework in the Medicines Act 1981 to: – provide a modern regulatory framework – regulate all medicines in a way appropriate to their risk profile – address sustainability and capacity issues – improve child safety provisions in medicines packaging and labelling – improve timeliness.	**Safety, quality, efficacy:** New Zealand has a sustainable, efficient and effective regulatory system that is consistent with international best practice and ensures that safe, quality and effective medicines are available to New Zealanders in a timely way.
• Continue to progress plans to build enhanced pharmacovigilance practices, in particular: – maintain pharmacovigilance capacity in New Zealand – facilitate growth in research capacity with a focus on projects that benefit public health (eg, by using electronic data to integrate pharmacovigilance information into wider national utilisation and epidemiological data and to detect signals of adverse reactions to medicines and other therapeutic products) – facilitate data collection, specifically adverse patient reactions through the integration of an online reporting tool into GP practice software.	**Safety, quality, efficacy:** Pharmacovigilance activities are supported by input from all stakeholders, including consumers, health practitioners and the medicines industry, to achieve post-market monitoring in-line with international best practice.
• Develop user friendly and linked websites across the medicines system so stakeholders can easily navigate the medicines system and find the information they require.	**Access:** New Zealanders understand and can access information about the medicines system including, where appropriate, information about medicines funding decisions and related health and disability system prioritisation criteria.

• The Ministry of Health will work with regulatory authorities and education providers to ensure cultural competence and knowledge about the drivers of health inequalities is incorporated in training for health practitioners. This will include addressing known issues about the over- and under-use of medicines by particular population groups.	**Access:** Health practitioners will be aware of, and responsive to, the particular needs of Māori, Pacific people, disabled and low-income people and children, including defined processes and mechanisms to achieve improved outcomes for these groups.
• Explore amending the Medicines Act 1981 and the Medicines Regulations 1984 to give nurse practitioners and optometrists the same prescribing rights (within their scope of practice) as currently available to medical practitioners, dentists and midwives. • Amend the Medicines Act 1981 to create a new class of prescriber called a 'collaborative prescriber'. Collaborative prescribing is a mechanism to allow non-prescribing practitioners, such as registered nurses, to prescribe medicines under the direct authorisation of a medical practitioner, dentist or midwife. • Review the Medicines (Standing Orders) Regulations 2002 to ensure patient safety in the current practice environment in which they are being used. • Support initiatives to realise the potential of the pharmacist workforce and address the barriers to the delivery of innovative pharmacy and pharmacist services, including those identified at the health sector workshop in August 2009.	**Optimal Use:** The medicines system has the capability it needs to deliver *Medicines New Zealand* outcomes effectively: financial resources; workforce availability and skill sets; infrastructure; and knowledge and information.
• Develop and implement a national formulary (including an electronic prescription ordering system and New Zealand-specific guidelines) to support best practice prescribing. This would include examining links to a comprehensive medicines reference source and to the Pharmaceutical Schedule, and build upon the work under way to develop the New Zealand Medicines Terminology and Universal List of Medicines. • Continue to progress the Safe Medication Management Programme to reduce the rate of errors in medication management including: – developing systems to effectively and continually reconcile a patient's medication list, particularly when a patient is transferring from one part of the health system to another – introducing standardised inpatient medication charting in all public hospitals – introducing an electronic prescribing system – verifying medication at the bedside through the use of bar-coded point-of-care systems – identifying high-risk medicines and introducing safety mechanisms to support safe administration practices. • Address regulatory barriers that impede the use of electronic technology to support safe prescribing.	**Optimal Use:** Robust and integrated systems support and monitor best-practice prescribing and the optimal use of medicines, including safe medicines use practices.