Regulatory Impact Statement: Overview of required information

Regulatory Impact Statement

Medicines Amendment Bill

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health (the Ministry).

A medicines amendment bill provides an opportunity to amend some specific provisions of the Medicines Act to streamline the legislation. A more comprehensive overhaul of the Medicines Act will be required in the future to modernise and recast the medicines legislation and to address issues such as the regulation of medical devices and cellular therapies, and controls on advertising.

This assessment considers options to amend the provisions of the Medicines Act to improve the efficiency and flexibility of approval processes for new medicines and related products, streamline the prescribing framework and make it more responsive to innovative practice and a number of other technical or minor amendments to the legislation. The proposed changes are consistent with the Government's commitment to review existing regulation in order to identify and remove requirements that are unnecessary, ineffective or excessively costly.

The Ministry consulted with key stakeholders on specific proposals and their feedback has been incorporated in the final proposals. A number of the options contained in this assessment, including most of the technical or minor amendments, were developed as part of the Therapeutic Product and Medicines (TPM) Bill. These proposals were developed, consulted on and supported in 2007. Due to the previous work undertaken on these issues and the limited timeframes available to develop a medicines amendment bill, the Ministry has not developed multiple options for implementing these proposals. The proposal for delegated prescribing was publicly consulted on in 2007. There was strong support for the general proposal.

In 2003, Australia and New Zealand signed an Agreement to establish a joint agency to regulate therapeutic products. This treaty remains in place today. The TPM Bill proposed the establishment of a joint Australia New Zealand Therapeutic Products Authority but was put on hold in 2007 due to a lack of Parliamentary support. The proposals relating to the prescribing frameworks and the technical or minor amendments would not preclude or be inconsistent with the establishment of a joint Australia New Zealand regulatory scheme. These proposals are ones which would either sit within domestic medicines legislation or are compatible with the expected regulatory approach under a joint regulatory scheme should such a proposal be progressed in the future. The proposals in relation to the approval process for medicines will be of interest to industry and to Australian officials given the New Zealand and Australian Governments' agreement to restart work to progressively implement the Australia New Zealand Therapeutic Products Agency.

None of the proposals outlined in the assessment will impair private property rights, market competition, reduce incentives on health care providers to innovate and invest or override fundamental common law principles. None of the options covered in this assessment impose additional costs on the health sector. The proposals aim to improve efficiency and enhance innovation by reducing regulation where possible and making the legislation more enabling and responsive.

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16/9/11

Status quo and problem definition

In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 and associated regulations, most notably the Medicines Regulations 1984. This legislative framework is in need of updating, to ensure it safeguards consumers while not creating unnecessary barriers to innovation.

A medicines amendment bill provides an opportunity to address some problematic provisions of the Medicines Act to further streamline the legislation. The following issues have been identified as benefiting from review:

- a lack of efficiency and flexibility in the current approval processes for medicines and related products
- the regulatory framework for prescribing is not empowering enough to enable the making of regulations to deal with changes in prescribing practice and innovative models of care, eg, to allow delegated prescribing under an approved supervisory arrangement
- provisions relating to licensing of medicine manufacturers and wholesalers, pharmacies and other medicine retailers are out-dated, lack clarity, and/or do not adequately safeguard consumers
- a lack of regulation-making powers to enable flexibility for new standards and innovations in medicine such as electronic prescribing.

In order to improve the efficiency of these processes and accommodate new approaches, greater flexibility and more streamlined processes are required.

Objectives

The amendments to the Medicines Act considered in this assessment have the objective of reducing barriers to innovation in the health sector, improving the flexibility and efficiency of approval processes for new and changed medicines and related products, reducing unnecessary costs for the Crown, industry, health service providers and consumers and addressing some health and safety risks.

The proposed amendments to the Act provide benefits, if done now, and are achievable within the required timeframe.

Regulatory impact analysis

Definitions

Modernise definitions of 'medicine', 'medical device' and 'therapeutic purpose'

Issue/Status Quo

The definition of medicine currently captures products such as pregnancy test kits, contact lens solutions, eye lubricants and nasal irrigation fluids that would be more appropriately treated as medical devices, as they are in key overseas markets.

Preferred option

Modernise the definitions of *medicine, medical device* and *therapeutic purpose* in order to align the boundary between medicines and medical devices with international norms. This will reduce the level of regulatory oversight of products such as pregnancy test kits, contact lens solutions, eye lubricants and nasal irrigation fluids but the remaining

safeguards are considered adequate. It will reduce compliance and regulatory costs for the industry and may increase consumer choice.

Improving the efficiency and responsiveness of the legislation

Improve the efficiency and timeliness of approval processes for new and changed medicines and related products

Pharmaceuticals have significant health benefits, but can present serious risks, especially if used inappropriately. Medsafe assesses the safety, quality and efficacy of new and changed medicines before they are granted consent for sale or supply in New Zealand to ensure that the benefits of use outweigh the risks if the product is used appropriately, and to identify any appropriate special requirements or restrictions on supply.

Issue/Status Quo

The legislation currently is very prescriptive and does not reflect current international practice for medicines approval processes. It sets out the data that must be provided in support of an application for approval for a medicine and the process that must be followed to assess an application. Processing inefficiencies arise because the legislation does not distinguish between medicines of different risk categories, does not allow poor quality applications to be rejected or require companies to respond to queries in a timely manner. In addition, the small size of Medsafe's evaluation resource leads to difficulty managing volume increases and recruiting experienced evaluators.

The current regulatory approach does not enable the approval process to be flexible and adaptive in response to shifts in international best practice or domestic regulatory capacity issues.

Option 1: Update the approval process in the Act

This proposal would update the approval process set out in the legislation to reflect current international best practice. However, specifying the process in the legislation does not provide flexibility to amend the approval process in response to capacity restraints or changes in best practice.

This proposal would trigger the need for the development of a new fees model and subsequently an amendment to the applicable fees set out in the Medicines Regulations 1984, following consultation with the sector and government agencies. Fees are reflective of the work required by the regulator so if a simpler process occurs, the fee could be expected to be lower.

Option 2: Set out the detail of the approval process in regulation (preferred option)

This proposal would remove most of the detail about the application and process requirements for new and changed medicines and related products from the Act and instead require applications to conform to requirements that are specified in the regulations. The delegate of the Minister/Director-General of Health would, as now, consider all the applicable information and weigh the likely therapeutic benefit of the medicine or related product against the risk (if any). The process to amend and/or update the requirements set out in regulation is much simpler than amending primary legislation. This approach would enable different approval processes to be specified for different product types (e.g. innovative prescription medicines, generic prescription medicines, non-prescription medicines) and would enable these to be updated in a much more timely fashion in response to capacity issues and changes in best practice. This approach would also enable the development of the regulations to be informed by the work programme that is being undertaken following the recent announcement that the New Zealand and Australian Governments have agreed to restart work to progressively implement the Australia New Zealand Therapeutic Products Agency.

As with option 1, this proposal would trigger the need for the development of a new fees model and subsequently an amendment to the applicable fees set out in the Medicines Regulations 1984.

Streamline regulatory oversight of the prescribing framework

Issue/Status Quo

Currently medical practitioners, midwives, dentists, nurse practitioners and optometrists have prescribing rights under the Medicines Act 1981. All these health practitioners are able to prescribe independently (ie, without supervision) within scopes of practice defined by their responsible authorities (eg, the Medical Council and the Nursing Council)[1], under the Health Practitioners Competence Assurance Act 2003.

When nurse practitioners and optometrists were given prescribing rights in 2005 they were categorised as *designated prescribers.* Designated prescribers are required to have separate regulations which define the scope of practice within which prescribing is permitted, provide a schedule of prescription medicines that may be prescribed, and establish minimum competency requirements (the latter are gazetted by the responsible authority by notice in the *New Zealand Gazette*). Including this detail in regulation is administratively burdensome as the regulations and Gazette notices quickly become out of date. This approach does, however, allow a high level of Parliamentary scrutiny.

Option 1: Require nurse practitioner and optometrist designated prescribers' scopes of practice, competencies etc to be Gazetted rather than listed in regulations

Under this proposal the requirement for separate regulations for nurse practitioners and optometrists would be removed. The information currently specified in the designated prescriber regulations would instead be contained in Gazette notices.

The administrative burden on nurse practitioners' and optometrists' responsible authorities would be reduced compared to the status quo as it is easier to update information by Gazette notice than amend regulations. However, the requirements for the designated prescribers' responsible authorities would still be cumbersome compared to those of medical practitioners, dentists and midwives. In addition, the distinction between designated prescribers and others with independent prescribing rights would be maintained.

Option 2: Align the prescribing framework for nurse practitioners and optometrists with medical practitioners, dentists and midwives (preferred option)

This proposal would remove the requirement for separate regulations for nurse practitioner and optometrist designated prescribers. Instead, as is the case for medical practitioners, dentists and midwives, nurse practitioners and optometrists with prescribing rights will be required to prescribe within their scope of practice for patients under their care. Scopes of practice are defined by the responsible authority, under the Health Practitioners Competence Assurance Act.

The Minister has the authority to audit responsible authorities under the Health Practitioners Competence Assurance Act and to require the responsible authorities to respond to any concerns raised by such an audit. This allows the Minister to take action if a responsible authority is acting outside its brief or in an inappropriate or unsafe manner.

This proposal would reduce the administrative burden on nurse practitioners' and optometrists' responsible authorities, recognising the experience and expertise that these organisations have in promoting and monitoring safe practice within their professional groups (consistent with the principles of the Health Practitioners Competence Assurance Act).

[1] Responsible authorities, appointed by the Minister of Health under the Health Practitioners Competence Assurance Act, are responsible for ensuring that health practitioners are competent and fit to practice their professions.

Delegated prescribing

Issue/Status Quo

The Ministry and other health sector stakeholders have identified the need to create a new class of prescriber, a delegated prescriber, who would be allowed to prescribe under authorisation of an authorised prescriber (a 'delegated prescribing order') [2]. For example, a general practitioner could issue a delegated prescribing order for the practice nurse to prescribe specific medicines to a specified group of practice patients. This type of authorised prescribing is not possible under the current legislation

Establish a new class of delegated prescriber (preferred option)

This proposal provides flexibility to allow for new developments in prescribing practice and innovative models of care. Delegated prescribing would allow more timely access to services for patients (especially important in community and rural settings and in meeting the growing demands of chronic disease) which may result in reduced need for specialist attention and/or surgical intervention. It would also allow a more efficient use of the health workforce and foster collaborative practice by health professionals.

It is difficult to quantify the fiscal impact of delegated prescribing. Prescribers will still be restricted to prescribing in their scope of practice (as they always have been). It is likely that any prescribing by delegated prescribers will largely be offset by a decrease in prescribing by authorising prescribers. However, delegated prescribing will provide more flexibility of roles amongst the members of a health care team. This will presumably provide time for other prescribers in the team to see additional patients who are also likely to require prescriptions for other treatments.

Sub-option 1: Responsible authorities develop delegated prescribing order

Under this option, responsible authorities would apply to the Minister of Health for delegated prescriber status for a class of health practitioner (eg, registered nurses). Following approval by the Minister of a new class of delegated prescriber, the relevant responsible authority would be responsible for developing a delegated prescribing order.

This option would allow the responsible authorities to tailor a delegated prescribing order to meet the needs of their particular group of health practitioners. There is however, scope for wide variation in the prescribing orders for different groups of delegated prescribers as there would be no specified generic requirements.

Sub-option 2: Requirements for delegated prescribing order set out in regulation (preferred option)

Under this option the Act would contain a regulation making power to allow regulations to be made which set out generic requirements for applications to the Minister from responsible authorities and for the form of a delegated prescribing order.

This option would ensure a standardised and robust governance framework for all delegated prescribers. This would reduce transaction costs as the process would be set out and responsible authorities would not be required to separately develop delegated prescribing orders.

Demonstration sites prior to extending prescribing rights

Issue/Status Quo

[2] To optimise the utility of this proposal, delegated prescribers would be allowed to prescribe appropriate Class B and C controlled drugs (eg, opioids for pain relief in palliative care).

Under section 105(1)(qa) of the Medicines Act 1981, regulations are required to give effect to any decisions to extend the prescribing framework for designated prescribers. The regulatory requirements include the need to consult, to specify the designated scope of practice and a schedule of prescription medicines, and provide for minimum competency requirements. This allows a high level of stakeholder and Parliamentary scrutiny.

The requirements to enable the establishment of a demonstration site of extended prescribing rights for specified groups of health professionals are as rigorous as those to extend prescribing rights on a permanent basis. This means that although establishment of such a demonstration site is currently possible, it is cumbersome and time-consuming and does not encourage innovation.

Include an enabling provision to allow demonstration sites to trial new ways of prescribing (preferred option)

The proposal is for an enabling provision to allow time-limited demonstration sites of extended prescribing rights[3]. This would provide a timely and responsive mechanism to establish demonstration sites of new models of care that involve the extension of prescribing rights. The planned demonstration site(s) would be announced via Gazette notice by the Minister of Health, detailing who can prescribe and what competencies they would require, the status of the prescribers (what medicines can be prescribed and with what authority), the number of sites, length of demonstration sites, etc. At the completion of the demonstration sites, there would be an evaluation of issues such as safety, cost and professional collegiality impacts of a new group of prescribers. The evaluation would inform the Minister of Health's decision on whether to permanently extend prescribing rights.

This proposal would not make a demonstration site(s) a mandatory requirement in the application for the extension of permanent prescribing rights to a particular group of health professionals. In some instances a proposal to extend prescribing rights will be sufficiently robust and well supported, that the cost of establishing and evaluating a demonstration site would not be justified.

The provision to enable demonstration sites could involve fewer requirements than proposed above, but this would expose both patients and health practitioners to the potential of adverse outcomes if parameters around prescribing were not clear and/or supervisory arrangements are not adequate.

Technical or minor amendments

The majority of the proposals outlined in this section were contained in the New Zealand-specific part of the Therapeutic Product and Medicines (TPM) Bill[4], were consulted on during the development of that Bill (including the Select Committee process) and were supported by the sector.

Factors the licensing authority can take into account when considering a licence application

Issue/Status Quo

Licences to manufacture, to pack and to sell medicines by wholesale and/or retail, and to operate a pharmacy, are granted under the Medicines Act by the Director-General of Health, acting as the licensing authority. Factors that the licensing authority can take into account

[3] Any proposal to undertake a demonstration site would be required to provide a clear rationale that extended prescribing rights for a particular group of health professionals is needed and that a demonstration site is justified. A review of available evidence/research on similar service models/concepts overseas and/or in New Zealand should be included, interested/affected parties consulted and their support for the proposal verified.

[4] The proposal to clarify the extent of practitioner and pharmacist exemptions relating to manufacture and supply of medicines was not included in the TPM Bill.

when considering whether an applicant is a "fit and proper person" to hold the licence applied for include: a sufficient knowledge base; adequate equipment, facilities and systems; and whether an applicant has had any disqualification or cancellation of a licence by a Court following conviction of an offence against the Act or Regulations. The licensing authority is not, however, able to take into consideration any convictions against the applicant under another Act or in another jurisdiction. This means that pertinent information about past behaviour is not able to be included in the licensing authority's assessment of whether the applicant is a "fit and proper person" to hold the licence.

Preferred option

The proposal is to amend the Medicines Act to allow the licensing authority to take account of any conviction against an applicant when considering whether an application is a "fit and proper person" to hold a licence. A conviction would not automatically disqualify a licence applicant. This proposal would however, give the licensing authority the ability to disqualify applicants who have a record of breaching licensing requirements in other jurisdictions or of unsafe /dishonest practices.

Ability to impose conditions on a licence

Issue/Status Quo

The licensing authority may impose conditions on a licence at the time the licence is issued. In addition, the licensing authority may suspend or cancel a licence at any point, if satisfied that the licensee has failed or is failing to comply with the conditions of the licence. It is not clear however, that the licensing authority can impose additional conditions during the life of a licence (in response to concerns raised by an audit report, etc) other than by or pursuant to regulations made under the Medicines Act. Imposing conditions during the term of a licence by regulation is problematic as it does not allow the licensing authority to respond in a timely manner to issues as they arise. Alternatively, the licensing authority can cancel a licence, close the licensee down temporarily and make them pay for a new licence on which the new conditions were imposed. This may cause more disruption and cost to licensees than may be justified.

Preferred option

It is proposed that the Act be amended to make it clear that the licensing authority is able to impose conditions on a licence at the time of issue or at any time while the licence is in effect, without the requirement for regulations to be made or licences to be cancelled and reissued. This proposal would allow the licensing authority to respond to concerns around safety in a timely way that was commensurate with the level of risk posed. In addition, the regulatory process would be streamlined and the cost to the Crown and industry would be reduced.

Expand regulation-making powers to provide for new standards and innovative practice

Issue/Status Quo

The Medicines Act does not allow the adoption of new standards and innovative practices via regulation.

Preferred option

The proposal is to amend the Medicines Act to include new regulation-making powers to provide for new developments in medicines management. This would enable the uptake of new standards and approaches and to allow the use of new technologies, such as electronic prescribing and changes to child resistant packaging.

These changes would support initiatives that are underway in the sector, including electronic prescribing pilots under the Safe Medication Management Programme. For health practitioners, compliance costs would arise from the time taken to understand the new requirements. However these costs are likely to be off-set by improved efficiency. Consumers would benefit from improved safety standards (ie, child resistant packaging), and more timely and accurate services due to the more efficient transfer of information between health practitioners.

Consultation

There has not been a full public consultation on the proposals. However, the following organisations were consulted on specific proposals: the Nursing Council, Medical Council, Optometrists and Dispensing Opticians Board, Pharmacy Guild, Pharmacy Council New Zealand, Pharmaceutical Society, Dental Council, Midwifery Council New Zealand, Medical Technology Association New Zealand, Optometrists and Dispensing Opticians Board, Family Planning Association and the New Zealand Self Medication Industry Association.

The proposals to align prescribing rights, create a class of 'delegated prescriber' and the minor and technical changes were supported. Two comments were received on the demonstration sites proposal, one cautiously supportive while the other did not see a need for demonstration sites once delegated prescribing was permitted. One submitter was concerned about defining contact lens solutions as medical devices, but other stakeholders consulted were supportive of this change.

In addition, many of the proposals covered by an amendment bill were consulted on during the development of the Therapeutic Products and Medicines Bill and the Select Committee's consideration of that Bill, and officials have made use of the consultation and previous work.

The Ministry of Health undertook public consultation on the development of the delegated prescribing proposal in 2007 in parallel with the Government Administration Committee's deliberations on the Therapeutic Products and Medicines Bill. There was strong support for the general proposal.

Conclusions and recommendations

The above regulatory impact analysis summarises the range of benefits and costs associated with options to amend the definition of *medicine*, improve the efficiency of approval processes for new and changed medicines and related products, streamline regulatory oversight of the prescribing framework, and a number of other technical or minor amendments to the legislation. It is recommended that the Medicines Act 1981 be amended to:

- modernise the definitions of *medicine, medical device* and *therapeutic purpose* to align the boundary between medicines and medical devices with international norms
- remove most of the detail about the application and process requirements for new and changed medicines and related products and instead require applications to conform to requirements that are specified in the regulations
- align the prescribing regulatory requirements of nurse practitioners and optometrists with medical practitioners, dentists and midwives

- establish a new category of *delegated prescriber*, who are able to prescribe under the authorisation of an authorised prescriber, and enable regulations to be made seting out requirements for a delegated prescriber application to the Minister and the form of a delegated prescribing order

- include an enabling provision to allow time-limited demonstration sites of extended prescribing rights for specified groups of health practitioners

- clarify the extent of practitioner and pharmacist exemptions from the requirement to hold a manufacturing licence

- allow the licensing authority to take account of any criminal convictions against the licensee when considering an application for a licence

- allow the licensing authority to impose conditions during the life of a licence

- expand the regulation-making powers to provide for new standards and innovative practice.

Implementation

An amendment to the Medicines Regulations 1984 will be required to implement proposals in relation to the medicines approval process, a revised fees schedule and the promulgation of standards. This work will require consultation with the sector and government agencies. Consequential amendments to the Misuse of Drugs Act 1975 would be required to allow delegated prescribers to prescribe appropriate Class B and C controlled drugs (eg, opioids for pain relief in palliative care).

Enabling provisions in the Act to establish a class of delegated prescribers and to establish demonstration sites prior to extending prescribing rights for new groups of health practitioners could come into effect at the time an amendment bill is given the Royal Assent.

Monitoring, evaluation and review

The Ministry will monitor the changes and report to the Minister of Health on any issues that arise.