Regulatory Impact Statement: Medicines regulation

Coversheet

Purpose of Document	
Decision sought:	Analysis produced for the purpose of informing initial Cabinet decisions on the design of new legislation for the regulation of medicines.
Advising agencies:	Ministry of Health | Manatū Hauora
Proposing Ministers:	Hon Casey Costello, Associate Minister of Health
Date finalised:	29 August 2024

Problem Definition

Consumers and medical professionals usually cannot establish the safety, quality or efficacy of a medicine for themselves; and unsafe, low quality and/or ineffective medicines can cause death and other serious harm. The correct and effective use of medicines that do meet quality and safety standards involves complex considerations that are difficult for consumers and practitioners to identify and resolve. Finally, the incorrect use of otherwise safe and effective medicines can cause death, addiction and other serious harms – including intergenerational harms.

While the Medicines Act 1981 appropriately manages some risks from medicines, it is outdated and inflexible. It is not capable of appropriately regulating some innovative medicine types, and does not recognise the capabilities of some health practitioners.

Executive Summary

Medicines are regulated under the Medicines Act. This Act is outdated, inflexible, and no longer fit for purpose, particularly in relation to innovative treatments such as gene therapies. It also fails to recognise the expertise of many health practitioners, or to provide meaningful safeguards around the supply of unapproved medicines.

The Ministry of Health's preferred option has two parts:

- Introducing flexibility and future proofing to the current system of medicines approval, enabling innovative products to be assessed in a way which makes sense for those products. This option would maintain the current system of licensing for manufacturers and most wholesale suppliers.
- Managing higher risk medicines (prescription medicines and unapproved medicines) in a more flexible and risk-proportionate way. This option would create a clear pathway for professions to gain or expand powers in relation to medicines, with an appropriate level of oversight. This option also adds a licence requirement for supply of unapproved medicines.

This option would retain the elements of the status quo[1] which are working well, such as the approval process for conventional medicines and post-market obligations on medicine sponsors. It responds to industry requests for a modern system which can appropriately regulate all innovative medicine types, and to practitioners who want a system which better recognises their expertise. This option also responds to stakeholder concerns about the Therapeutic Products Act 2023 (the TPA).

This option is also expected to contribute to improving access to medicines by providing a clearer path to approval for innovative medicines, and by enabling the prescribing and supply powers of some health professions to be expanded, where appropriate. To mitigate risks associated with any increase in the supply of unapproved medicines, this option includes a requirement for businesses to obtain a licence to supply unapproved medicines. As most suppliers will already be licensed manufacturers, wholesalers or pharmacies, we expect the impact of the new requirement to be minimal.

Limitations and Constraints on Analysis

The Government wishes to have new legislation enacted within this term of Parliament. This involves short timeframes for policy development, relative to the number and complexity of decisions needing to be made. There has been extensive prior policy development and stakeholder engagement, including on development of the TPA. However there has been limited time to assess new evidence or test policies which differ significantly from both the status quo and the TPA.

Improving access to medicines is a Government priority, as is reducing regulation and government spending. This has limited the scope of potential policies, as we have assumed that options involving more regulation will not be considered unless there is a compelling rationale.

Personal importation of prescription medicines was debated extensively during passage of the Therapeutic Products Bill, and there is broad support for enabling personal import if the importer (the patient or their carer) has a New Zealand prescription. We therefore intend to carry over this approach.

We have treated policies agreed by Cabinet but not yet implemented, such as the verification pathway for medicines approval, as part of the status quo.

Responsible Manager(s) (completed by relevant manager)

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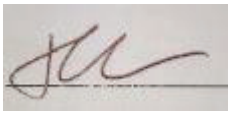

22 August 2024

[1] The status quo includes planned changes, such as the introduction of a verification pathway for medicines approval.

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled "*Medicines regulation*", produced by the Ministry of Health and dated August 2024. The panel considers that the Impact Statement Meets the quality assurance criteria. The Impact Statement is clear, concise, complete, consulted and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

1. Most people will need to use medicines at some point in their lives. Medicines can be life-saving and are often needed to achieve or maintain an acceptable quality of life. They are a crucial part of modern healthcare.
2. Because medicines are so important, it is vital that they meet reasonable standards of safety, quality and efficacy. Medicines which are contaminated, counterfeit or ineffective can cost lives, significantly reduce quality of life, and waste health system funding by causing more damage and failing to prevent or treat serious conditions.
3. It is usually not possible for individuals to personally assess the safety, quality and efficacy of medicines. Even organisations with suitably qualified and experienced staff will usually not be able to fully assess medicines without information from the manufacturer, which is usually not publicly available. Regulation of manufacture and the supply chain of medicines addresses information asymmetry and provides assurance of acceptable safety, quality and efficacy.
4. Even when manufactured to appropriate standards, most medicines have risks, including side effects, allergic reactions, fetal harm, dependence and accidental overdose. These risks can have broader impact, for example through antibiotic resistance or societal harm from drug dependence. For higher risk medicines, clinical expertise is usually needed to work out if a medicine is appropriate for an individual, and how any risks can be managed.
5. In recent decades the regulation of medicines has increasingly become internationalised. Various international bodies, including the World Health Organization and harmonisation groups, have established common regulatory norms, benchmarks and minimum requirements for the manufacture of medicines,[2] and the processes by which medicines are evaluated (eg, for quality, safety and efficacy) and approved. Efficiencies in regulation can be achieved through engagement in joint assessments and work-sharing programmes. However participation in these programmes requires local regulation to meet international norms.

Status quo: regulation of medicines under the Medicines Act 1981

6. Medicines are currently regulated under the Medicines Act 1981 and the Medicines Regulations 1984, which control how medicines can be manufactured, prescribed and supplied in New Zealand.
7. The Medicines Act imposes some post-market obligations on product sponsors and grants the Crown limited post-market powers. Post-market regulatory activity will be covered in a subsequent RIS; this RIS focuses on pre-market activity and whether certain activities involving medicines should be controlled.

Licensed activities

8. All medicines manufacturing in New Zealand must be carried out under a manufacturing licence. This includes manufacture of active pharmaceutical ingredients, material for clinical trials, biologic cells and production of blood products. Licence holders must operate under Good Manufacturing (GMP) standards for pharmaceuticals. Maintaining GMP is a condition of a manufacturing licence.

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[2] For example, Good Manufacturing Process (GMP).

9. A licence is not required to import medicines. Wholesale supply of medicines (other than general sale medicines) requires a wholesaling licence. Licensed wholesalers are required to comply with GMP for storage and transport. Repacking of medicines (whether or not for further supply) also requires a licence.

Medicines approvals

10. The standard approach to supply of medicines is that they are approved ('consented for distribution') by Medsafe, as the delegate of the Minister of Health, before being supplied. How Medsafe assesses a medicine for approval is set out in sections 21 and 22 of the Medicines Act. There is a coalition agreement to amend the Medicines Act to enable Medsafe to approve a medicine based on approvals by two trusted overseas regulators (the verification pathway). This verification pathway for new medicines has been treated as part of the status quo, as it is expected to be in effect before the proposals in this RIS take effect.
11. Medsafe's approval includes the condition(s) which the medicine has been shown to treat effectively, sometimes in relation to a specific age group. This is the authorised indication for the medicine. For restricted or prescription medicines there will also be a data sheet setting out the indication, the recommended dosage, and other information. Use of the medicine outside the data sheet indications is known as 'off label' use (or sometimes unapproved use) and is usually permitted, although there are sometimes restrictions on who can administer or supply a medicine off-label.
12. The Medicines Act was drafted when most medicines were 'small-molecule' medicines. These medicines (eg, aspirin) are usually chemically synthesised under processes that a relatively straightforward and easier to measure for quality. Since the passage of the Medicines Act, however, there has been an increase in the number of biologic ('large-molecule') medicines, made from biological materials. Examples of these medicines include insulin, monoclonal antibodies, and newer gene and cell therapies. These products have different challenges and risks in their manufacture and evaluation, and the product may have higher variability across batches.
13. The Medicines Act is highly prescriptive about what evidence must be provided in support of an approval application. This makes it challenging to appropriately assess and consent innovative medicines such as biologics and gene therapies.

Medicines classification

14. Medicines are classified as prescription, restricted (pharmacist), pharmacy-only, or general sale.[3] A key step in the process is consideration by the Medicines Classification Committee, which makes recommendation as to the classification. The Minister or delegate may then consider this recommendation and make a decision as to the classification.
15. The Medicines Act does not specify what should be considered in making a classification decision. A key consideration of classification is who should make decisions when selecting a medicine. For example, prescription medicines are not suitable for self-selection, but should only be selected as part of a clinical consultation. At the other end of the scale, low risk medicines for some self-limiting ailments may be suitable for the consumer to select at a supermarket.

[3] There is technically no 'general sale' classification under the Medicines Act – a medicine is general sale if it has been approved but not been classified as prescription, restricted, or pharmacy.

Prescribing

16. Prescription medicines can generally only be supplied on the orders of a practitioner with the authority to prescribe that medicine. Medical practitioners (doctors), dentists, midwives, optometrists and nurse practitioners can prescribe any approved medicine, as long as it is within their scope of practice. Designated prescribers (pharmacist prescribers, nurse prescribers and dietitian prescribers) can prescribe medicines from lists set out in *Gazette* notices for each profession.
17. Scopes of practice are set by the Responsible Authority for each profession under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act). Scopes of practice set out broad areas of practice within professions – for example neurosurgery, paediatric dentistry, or nuclear medicine technology. Scopes of practice do not specify named medicines or types of medicine. Prescribing within a scope of practice means that practitioners may only prescribe medicines that they have the training and expertise to prescribe, but exactly which medicines these are can vary from practitioner to practitioner.
18. There are two ways for a profession to be granted prescribing rights:
    1) Regulations made under the Medicines Act giving the profession designated prescriber status: this enables practitioners with special prescriber training to prescribe medicines from a list published in the *Gazette* by the Director-General of Health.
    2) Amending the Medicines Act so that its definition of 'authorised prescriber' includes the new profession. This would give the profession that same prescribing powers as dentists, midwives, optometrists and nurse practitioners.

Administering prescription medicines

19. In relation to medicines, 'administer' means to apply or introduce a medicine to the body, for example orally or via injection. It can also encompass situations when a person gives a medicine to a person who then consumes it. For example, if a nurse gives a hospital in-patient a pill which the patient then swallows, this is usually administration rather than supply, even if the nurse does not help the patient consume the pill.
20. Under s19 of the Medicines Act, prescription medicines can be administered by anyone if the medicine has been prescribed to the specific patient. If there is no prescription, then administration has to be enabled through a standing order, or regulations. For example, a person being vaccinated at a community pharmacy or community vaccination centre has usually not been prescribed the vaccine; instead administration of the vaccine is authorised via regulations or standing orders. Where a medicine has not been prescribed to a specific patient, administration is sometimes not allowed for off-label use.

Supply of unapproved medicines

21. Medical practitioners can also prescribe medicines which do not have Medsafe approval, if the medicine is within their scope of practice. Unapproved medicines are usually supplied in one of three circumstances:
    1) an approved medicine becomes unavailable and there is no approved substitute
    2) a medicine has been recently developed and has not yet gone through the approval process, but early evidence suggests it will be beneficial for some patients
    3) for a patient who initially received the product as a participant in a clinical trial.
22. In addition, industry have reported that they may not seek approval for their medicine in New Zealand due to the perceived time and cost of a Medsafe application, or because they see little value in seeking approval if their product is not eligible for

Pharmac funding. These commercial decisions are influenced by the small size of the New Zealand market, especially for treatments for rare conditions.

23. Practitioners are expected to seek ethical approval before authorising supply of recently developed medicines, but this is not a formal legal requirement.

Further context on the need for reform

24. The Medicines Act has been considered out of date since the 1990s. This view has been shared by successive governments, practitioners, industry and the public. The Therapeutic Products Act (the TPA) was enacted in 2023, and was intended to replace the Medicines Act with modern legislation which could appropriately regulate medical devices and innovative medicines such as biologics. It would also have regulated natural health products.
25. There were concerns from industry and other stakeholders that the TPA would have made product approvals too difficult, expensive and/or time-consuming to obtain, particularly for natural health products and lower-risk medical devices. As a result, a bill to repeal the TPA is currently before the Health Select Committee.
26. Repeal of the TPA means status quo regulation under the Medicines Act will continue.

What is the policy problem or opportunity?

27. There are numerous problems with the Medicines Act.[4] In particular:
    1) Some innovative medical products, such as biologics (eg, gene therapies and tissues grown from a patient's stem-cells), are difficult to appropriately assess under the current system.
    2) Prescribing provisions are inconsistent and do not reflect the expertise of some professions. Changing which professions can prescribe which kinds of medicine is often slow and complicated. This issue relates to approved and unapproved medicines. There are similar issues around who can administer prescription medicines, especially off-label.
    3) The Medicines Act is overly prescriptive, with detail such as the content of application forms included in primary legislation. Combined with overly rigid decision-making requirements, this makes it difficult to implement timely approval pathways and for New Zealand to participate in, and benefit from, international work-sharing programmes and joint assessments.
    4) Its compliance and enforcement framework (including penalties) are not sufficient to provide assurances that the Act, and its safety regime, can be meaningfully enforced. (Compliance and enforcement will be considered in a separate RIS.)

Stakeholder engagement

28. This RIS has been informed by significant engagement over the past 30 years, including in the development of the TPA. When it was considered by Parliament in 2023, the Therapeutic Products Bill (the TPB) received over 16,000 submissions. As a result, the views of stakeholders on the Medicines Act and potential replacements are well known.
29. Ongoing consultation will focus on targeted engagement with key stakeholders. This engagement, and analysis of TPB submissions, will ensure that concerns about the TPA are appropriately addressed in new legislation.

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[4] This RIS does not explore issues which are expected to be addressed through planned amendments to the Medicines Act, such as introduction of a verification pathway.

Stakeholder views: consumers

30. Nearly everyone will use medicines at some point in their lives. Consumers need medicines to be safe, of good quality, effective, and available to them in a timely way. There are varying opinions amongst New Zealand consumers on how to balance access on the one hand with safety, quality and efficacy on the other. Access also relates to the cost of medicines, which is largely determined through public funding. This RIS does not consider funding arrangements for medicines, as this is outside the scope of the proposed reforms.
31. Some groups of consumers have particularly strong interests in regulation of medicines. **Disabled people and people with long-term health conditions** often rely on medicines, without which they would experience significant decline in quality of life and/or increased risk of death. For this group, it is very important both that medicines are accessible and that they meet quality, safety and efficacy standards.
32. **People with rare and/or severe health conditions** (and their representative organisations) tend to place more importance on access, particularly in relation to innovative medicines. Where a condition is life-threatening or there is no approved treatment, this group tends to accept a higher level of clinical risk or chance that a product will not be effective for them. For this reason, they generally support clear and broad pathways for access to unapproved medicines, although they can also be more vulnerable to inaccurate marketing and product claims.
33. **Māori** tend to have higher rates of ill-health and are therefore more affected if medicines are unsafe or inaccessible. Māori individuals and organisations who submitted on the TPB tended to focus on regulation of natural health products, especially rongoā (traditional Māori healing) products. Further engagement with Māori is needed on regulation of conventional medicines. Initial work suggests that Māori health providers would get particular benefit from a regulatory system which enables innovative models of care, such as nurse-led services.
34. **Women** have the same concerns as other groups of consumers, and some gender-specific issues. Clinical trials have tended to focus on men, which has meant that side effects and other issues are less likely to be discovered if they mostly affect women. Compared to other patient advocacy groups, women's health groups that submitted on the TPB tended to take a more cautious approach to products, and to prioritise safety over access.

Stakeholder views: medicines industry

35. The medicines industry includes manufacturers, exporters, importers, wholesalers, and retailers (including pharmacies). Most medicines in New Zealand are imported, but there is some local manufacture. The medicines industry has consistently said that the Medicines Act is no longer fit for purpose, and should be replaced.
36. Medicines industry stakeholders opposed elements of the TPA. They were concerned that the TPA did not address some perceived problems with the current approval process, particularly the time taken to approve medicines. For example, some stakeholders felt the TPA should include statutory timeframes for decision-making.
37. Industry stakeholders were also concerned about how elements of the TPA system would work in practice, and felt that innovative or unusual medicines might not be regulated appropriately.
38. Requiring product approval for medicines is an international regulatory norm and features in all comparable jurisdictions. As a global industry, the medicines sector is aware of this accepted practice and are sophisticated actors, usually employing their own Regulatory Affairs teams.
39. Industry emphasises the need for timely and transparent decision making, with administrative processes reduced as far as possible and harmonised with international

standards as far as possible. For this reason, they support policies which will reduce time and money costs for industry, such as reliance on approvals by trusted overseas regulators. Industry opposes 'bespoke' approval processes or domestic product standards for specific medicines that differ from those required in other – usually larger – markets. This includes labelling requirements.

40. They also support a pathway for supply of unapproved medicines, especially medicines with small New Zealand markets (eg, medicines for rare disorders).

Stakeholder views: Health practitioners

41. Health practitioners are health professionals who are regulated under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act).
42. Practitioners have a range of views. They tend to be more concerned than other stakeholder groups about the safety, quality and efficacy of medicines, although they also consider access to be important. They are more aware than other groups of the potential risks from unsafe medicines. They also consider that a robust regulatory system is needed so that practitioners can prescribe and supply medicines in confidence that they are not counterfeit or contaminated, and will do what they are purported to do.
43. Most practitioner groups support a system which more flexibly enables practitioners to prescribe and supply medicines. Practitioners also requested that mechanisms continue to be available to authorise the supply of unapproved medicines, with some arguing that these mechanisms should be available to practitioners other than doctors.

What objectives are sought in relation to the policy problem?

44. The main objective is that regulation of medicines will support New Zealanders having timely access to medicines which meet acceptable standards of safety, quality and efficacy, in a way which is cost-effective.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

45. The criteria are:
    1) **Protective**: will the option provide adequate assurance of safety, quality, and efficacy, and ensure that benefits associated with medicines outweigh risks?
    2) **Efficient**: will the option achieve the objective without unnecessary time and resource cost for the Crown or industry? A high-scoring option will support timely access to medicines, including innovative medicine types.
    3) **Fit for product**: will it enable appropriate regulation of all medicines, including innovative and unusual medicine types?
46. The 'protective' criterion is about the extent to which the option will provide assurance that medicines meet appropriate standards of safety, quality and efficacy. A high-scoring option would enable robust decisions based on good evidence, and reduce the risk of substandard medicines being approved.
47. The 'efficient' criterion is about achieving the objective in a way which is cost-effective (time and money) for the Crown and industry. A high-scoring option will regulate medicines in a way which does not take any more time or money than is necessary to achieve the objective.
48. The ''fit for product' criterion is about ensuring medicines are regulated in a way which makes sense for their nature. For example, a fit for product regime would assess a gene therapy medicine in a way which makes sense for products of that kind, rather than using a process designed for small molecule medicines. Fit for product also ensures that other non-standard products, such as donated blood for transfusion, and nuclear medicines, are regulated appropriately. A high-scoring option will be sufficiently flexible to accommodate medicines that differ from the norm, innovative medicines, and novel medicine types which may be invented in the future.
49. All three criteria will assess whether options will regulate medicines in a risk-proportionate way. The protective criterion is about preventing under-regulation, while the efficient criteria is about preventing over-regulation. The fit-for-product criterion includes preventing under or over regulation as a result of product types being assessed inappropriately.

What options are being considered?

50. This options analysis consists of two parts:
    1) What is the best way to ensure that medicines in the supply chain meet acceptable standards?
    2) How can access to higher risk medicines best be managed?
51. The first part addresses commercial and system-level management of medicines from their manufacture through to supply to a pharmacy or the consumer.[5] It explores how consumers and the health system can be assured that medicines meet acceptable standards of safety, quality and efficacy, and how this assurance can be provided in a cost-effective and risk-proportionate way.
52. The second part looks at medicines which have additional risks: prescription medicines, and medicines which have not been approved by a regulator. This part explores how

[5] Pharmacy regulation will be addressed separately.

patients can appropriately get timely access to medicines that they need, without creating unacceptable risks from potentially dangerous medicines.

53. It should be noted that post-market activity (such as pharmacovigilance and recalls) is also a key part of medicines regulation. This RIS only covers pre-market activities – options for post-market activity will be covered in a subsequent RIS.

Question 1: What is the best way to ensure that medicines in the supply chain meet reasonable standards?

54. This section looks at the high-level system of assurance, and how best it can deliver the objective of supporting New Zealanders having timely access to medical products which meet reasonable standards of safety, quality and efficacy, in a way which is cost-effective.

55. The options are:
    - **Option 1.1: Status quo under the Medicines Act:** All medicines require pre-market assessment and authorisation. Licences are required for manufacturing of medicines and wholesale supply of all medicines except general sale medicines, but not for importing.
    - **Option 1.2: More flexible status quo:** Similar to the status quo except legislation enables more pathways to approval, especially for medicines approved elsewhere and innovative medicines. As with the status quo, licences would be required for manufacturing and most wholesaling, but not for importing.
    - **Option 1.3: More flexible approval process plus import licensing:** This would be the same as option 1.2, except that licences would be required for all commercial and bulk medicine importing, in addition to manufacturing and most wholesaling.
    - **Option 1.4: Licensing-only system:** This option would not have a New Zealand approval process, but instead rely on manufacturing, wholesaling and import licences, and on recognising overseas approvals.

56. All options assume that legislation will include post-market surveillance and enforcement powers for an appropriately resourced regulator, to ensure product safety throughout their post-market lifecycle.

What scope will options be considered within?

57. The option of not regulating medicines is out of scope, for several reasons:
    1) No comparable country adopts a no-regulation approach to medicines. Adopting such an approach would mean that New Zealand would be acting contrary to the advice and recommendations of the World Health Organization. New Zealand would also be ineligible to maintain or obtain membership of international standard setting bodies, which require (as a condition of membership) that a jurisdiction regulate medicines to a certain standard.
    2) It would expose the public to significant risk of death and other harm due to unsafe, poor quality, and/or ineffective medicines. This is a major problem in countries which do not have an effective regulatory system for medicines.
    3) Public and private health providers would need to spend time and money on assessing the safety, quality and efficacy of medicines. This is likely to be less efficient than an official regulatory system. Providers would be less able to take effective action than a Crown entity with enforcement powers.
    4) New Zealand exporters would have difficulty demonstrating that their medicines meet acceptable standards. Some importing countries require certificates issued by the originating country's regulator, so the lack of an official regulator in New Zealand would make exports to those countries very difficult.

58. Systems requiring a full pre-market assessment by a New Zealand regulator of all medicines – whether or not they have already been approved overseas – have also not been considered. This would be likely to significantly reduce timely access to some medicines, especially when there is supply disruption of an approved medicine. It is also unlikely to be an efficient use of Crown or industry resources, particularly for products that have an established history of use and/or which are intended to be used by only a very small population. Finally, it would be contrary to the policy direction of the Government, which is seeking to streamline the existing approval pathways for medicines in New Zealand by placing greater reliance on the decisions and approvals of trusted, overseas regulators.
59. The option of not having licenses for manufacturing, and instead relying on the approval system, was considered but has not been put forward as an option in this RIS, as it would not have been significantly different from the options considered. Approvals depend partly on the manufacturer complying with GMP, so GMP certification would essentially be licensing by another name. Depending on the design of the approval system, relying solely on GMP could increase the regulatory burden for manufacturers, if they need to demonstrate GMP compliance for each approval rather than just for their manufacturing licence.

Option 1.1: Status quo under the Medicines Act

60. Under this option, all medicines are required to undergo some degree of assessment by Medsafe before they can be supplied (except in limited circumstances – see question 2). All medicines manufacturing requires a licence, including manufacture of unapproved medicines, as does wholesale supply of all medicines other than general sale medicines.
61. This option provides good assurance of the safety, quality and efficacy of most small molecule medicines, particularly those which are manufactured in New Zealand. There are some regulatory gaps, particularly around wholesaling. For example, general sale medicines may be imported and supplied by wholesale without anyone in this supply chain needing a licence. There is evidence that this regulatory gap is contributing to the retail sale of unapproved and sometimes highly dangerous medicines.
62. It is challenging to appropriately assess innovative medicines such as biologics under this option, due to the very prescriptive drafting of the Medicines Act. The lack of appropriate assessment provisions for innovative medicines may mean that the process is inefficient and/or unable to provide adequate assurance.
63. There are industry concerns about the amount of time the approval process currently takes. For small molecule medicines, these concerns should be at least partly addressed through the planned verification pathway amendment to the Medicines Act which (subject to parliamentary process) will enable Medsafe to grant approval based solely on approvals by two trusted overseas regulators. As noted above, this change has been treated as part of the status quo.
64. The status quo provides some oversight of supply of unapproved medicines, as manufacture and wholesaling of unapproved medicines requires a licence. However import and non-wholesale supply of unapproved medicines is essentially unregulated. This is addressed further under Question 2.

Option 1.2: More flexible status quo

65. At a high level, this option is the same as the status quo except that it will enable more flexible and future-proofed approaches to innovative and non-standard medicine types. Some adjustments would also be made to improve regulatory clarity and consistency, such as streamlining wholesale licensing requirements and extending them to general sale medicines.

66. In addition to the status quo approval pathways (including the planned verification pathway), this option would enable development of new approval pathways, without primary legislation needing to be amended. This will enable new medicine types, including types not yet invented, to be appropriately assessed. The legislation would also specify some pathways, including those currently included in the Medicines Act, and the planned verification pathway.
67. This option would also include mechanisms to exempt some medicine types from the requirement to be approved if another regulatory mechanism is more appropriate. For example, genetic medicines tailored to a specific patient are not well suited to approval processes designed for mass production. Similar considerations apply to blood and blood products. Under this option, the process and/or the organisation could be licensed. The exemption and details of the licensing system would be enabled via regulations; this would ensure a reasonable level of oversight without requiring primary legislation to be amended.
68. This option does not address the regulatory gap for importing identified under option 1.1, but does address the regulatory gap for general sale medicines. This will help prevent unsafe medicines from being sold in dairies and supermarkets. Wholesalers that carry general sale medicines, but not other medicines, would have some additional responsibilities.

Option 1.3: More flexible approval process plus import licensing

69. This option builds on the future-proofed status quo option (option 1.2) and addresses the regulatory gap for importers.
70. Under this option, all imports of medicines, other than personal imports, would require an importer's licence. Licensed importers would be required to demonstrate due diligence in medicines sourcing, and to have processes for tracking and recalling imported medicines. Importers that are also wholesalers could operate under one licence which covers both wholesaling and importing; they would not have significant extra responsibilities under this option compared to option 1.3.
71. Importers that are not wholesalers would be regulated under this option, but not the status quo or option 1.2.
72. Consumers and the healthcare system would have more assurance that imported medicines have been sourced from manufacturers which follow GMP, and that importers will be able to track and recall imported products should serious safety concerns arise.

Option 1.4: Licensing-only system

73. Under this option, the New Zealand regulator would not issue approvals for medicines. Manufacturers and importers would be licenced (as under option 1.3) but would rely on approvals made by trusted overseas regulators to determine the safety, quality and efficacy of their medicines. This would differ from the planned verification pathway, which involves the New Zealand regulator verifying that the medicine, for which New Zealand approval is being sought, is actually the version that has been approved abroad.
74. As with option 1.3, licensed importers would need to demonstrate due diligence in sourcing, and to have tracking and recall processes. As with the status quo, wholesalers would need to comply with GMP for storage and transport.
75. Total reliance on overseas regulators would mean the New Zealand regulator would lack the capability to assess medicines manufactured in New Zealand. New Zealand manufacturers would need to seek an approval in Australia or another trusted jurisdiction before supplying the New Zealand market (except via any unapproved

medicines pathway). It would also prevent New Zealand engaging into international collaboration on product assessments and standards development.

76. This option would provide only limited assurance of safety, quality and efficacy. As medicines would not undergo any assessment in New Zealand, the only way to prevent the supply of substandard batches of approved medicines is if they are identified and rejected by the importer. This may create unintended consequences for industry if they have to certify to other countries that the medicines they supply in New Zealand (and other third party countries) are regulated appropriately.

77. This option would also create significant problems for New Zealand-based manufacturers wanting primarily to supply to the domestic market, and potentially also for exporters, depending on the requirements of the importing country. The need to have medicines approved overseas would make New Zealand an unappealing location for medicines manufacturing.

How do the options compare to the status quo/counterfactual?

	Option 1.1 – Status quo under the Medicines Act	Option 1.2 – Future-proofed status quo	Option 1.3 – Future-proofed status quo + import licensing	Option 1.4: Licensing only
Protective	0	++ Some increased protection due to innovative medicines being appropriately assessed and wholesaling being licensed for general sale medicines	++ Regulatory gaps for imports closed, plus benefits from option 1.2	-- Limited protection from substandard batches. Regulation of importers will provide some protection
Efficient	0	+ More efficient processes for innovative medicines	0 More regulation for some importers, but has the benefits from option 1.2	0 No requirement to get NZ product approval, but more regulation for some importers. NZ manufacturers would need overseas approval
Fit for product	0	++ All medicines will be regulated appropriately, including some new innovative treatments (eg, CAR-T treatments)	++ All medicines regulated appropriately and have oversight	- Some appropriate regulation for overseas approved medicines
Overall assessment	0	+	+	--

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

78. Options 1.2 and 1.3 deliver around the same level of net benefits, with both being preferable to the status quo and option 1.4. Compared to the status quo, option 1.2 would have better 'fit for product' regulation of innovative medicines such as biologics; this is expected to better protect consumers and be more efficient for industry. Option 1.3 includes all the benefits of option 1.2 but provides more protection due to licensing of importers. However this would make the system less efficient for importers that are not wholesalers. Option 1.2 and 1.3 are both fit for purpose. The preferred option is option 1.2, as it aligns more closely with the Government's focus on lighter touch regulation.

79. Option 1.4 scores less favourably than the status quo on the protection and appropriate criteria, and the same as the status quo on efficient, and is therefore not recommended. It would fail to protect New Zealanders from unsafe and substandard medicines, and create problems for New Zealand manufacturers. However this option is likely to be more efficient than the status quo for importers.

Example key for qualitative judgements:	
++	much better than doing nothing/the status quo/counterfactual
+	better than doing nothing/the status quo/counterfactual
0	about the same as doing nothing/the status quo/counterfactual
-	worse than doing nothing/the status quo/counterfactual
- -	much worse than doing nothing/the status quo/counterfactual

Question 2: How can access to higher risk medicines best be managed?

80. Some medicines have higher levels of risk than others, either due to the nature of the medicine (eg, how it works or potential side effects), or because it has not been through an approval system. This section looks at how higher risk (prescription) medicines and unapproved medicines can be managed.
81. The options are:
    - Option 2.1: Status quo
    - Option 2.2: Flexible pathways via scopes of practice
    - Option 2.3: Expanded prescribing and other powers in primary legislation.
82. The HPCA Act is currently being reviewed and may be amended before the Medical Products Bill comes into effect. This is likely to affect all options in this section, but at this stage no decisions have been made on any changes which would affect the options.

What scope will options be considered within?

83. This section assumes that the prescribing system will remain in place. Elements of prescribing could be clearer, more consistent, and in some cases less restrictive. However, the overall system works well, and is understood and supported by the public and practitioners. It also reduces risk for the medicines industry – if higher risk medicines were more easily accessible, there would be deaths and other harm from inappropriate use, with potential legal consequences for manufacturers and commercial suppliers.
84. In regard to unapproved medicines, enabling unrestricted supply by everyone has not been considered. This would effectively make the assurance system voluntary and remove meaningful regulation from medicines and medical devices. The reasons why this is not desirable are covered under question 1.
85. Conversely, all options are based on the assumption that some supply of unapproved products is necessary. Preventing any supply of unauthorised products is likely to prevent access to important and in some cases lifesaving products. It is also contrary to the Government's priority of improving access to medicines.
86. Some submitters on the TPB believed that supplying unauthorised products would require a separate licence for each product. This option is not considered here, as it would be highly inefficient and likely to significantly reduce access.
87. An option of requiring some degree of pre-approval for unauthorised products has been identified but not developed or considered further. Pre- and post-approval systems for accessing unapproved medicines operate in Australia, but implementing a similar model in New Zealand would require significant resourcing and delay commencement of a new regime. It would also represent a significant departure from s29 of the Medicines Act for medical practitioners and, in the short term, could reduce access.
88. The status quo and the TPA both allow individuals to import medicines for their own use (or for a person they are the carer for). If the medicine is a prescription medicine, the importer must have a prescription. Personal importation of medicines was the subject of extensive debate during the progress of the Therapeutic Products Bill, and the solution is accepted by most stakeholders. The option of changing this has not been considered.

Option 2.1: Status quo under the Medicines Act

89. The status quo is described in detail in section 1.
90. As noted above, the prescribing mechanism generally works well, and is supported and understood by practitioners and the public. It provides good protection from the risks and harms associated with higher risk approved medicines.

91. However the Medicines Act is overly restrictive on which practitioners can prescribe which medicines. It reflects outdated models of care, in which teams were always led by a medical practitioner; and does not reflect the capabilities of other practitioners. It is also very time consuming to grant or expand prescribing powers, as this involves amending primary or secondary legislation. Granting designated prescribing power via regulations also limits the profession to medicines on a list, which can be challenging to keep up to date.
92. The current prescribing system can make access to medicines difficult, particularly for people who cannot easily access general practitioner services. Workload pressures for general practitioners have exacerbated this problem in recent years.
93. Administration of prescription medicines by a non-prescriber is enabled through standing orders and regulations. Some of the regulations were developed as ad hoc fixes to problems, resulting in complex and confusing systems. In particular, who can administer vaccines can depend on clinically irrelevant factors such as the vaccine's funding status.
94. Standing orders are a useful tool to enable innovative services tailored to specific communities. However there are limited safeguards in the Medicines Act and regulations. For example, there is no requirement for standing orders to have an expiry date and there is no external oversight of standing orders, for example from the relevant Responsible Authorities (RA) or the Ministry of Health. Standing orders cannot enable the supply of unapproved medicines.

Unapproved medicines

95. The status quo provides very little protection from dangerous unapproved medicines. It creates risks to practitioners as well as patients. There is no clear responsibility if a consumer suffers death or serious harm from an unconsented medicine, and no legislative requirement for either the practitioner or the supplier to undertake due diligence or quality control.
96. The status quo supports almost unrestricted access to unapproved medicines via a medical practitioner, but not any kind of access via other health practitioners, regardless of the practitioner's capability or expertise. This creates difficulties for non-medical practitioners (such as nurse practitioners) and their patients.
97. The status quo is very efficient in most respects, in that there is almost no oversight or regulation and therefore little regulatory burden. It is possible, however, that some medical practitioners are spending significant time conducting due diligence on unconsented medicines (although this may still fail to protect patients). Some practitioners may also be declining to prescribe unapproved medicines due to legal risk.
98. The status quo is very inefficient for some consumers, as they need to see a medical practitioner when they could appropriately be prescribed the medicine by another practitioner.

Option 2.2: Flexible pathways via scopes of practice

99. Under this option, prescribing of approved and unapproved medicines would primarily be managed via scopes of practice issued by RAs under the HPCA Act. Issuing standing orders, and some administration of prescription medicines, would also be managed via scopes of practice. This option recognises that practitioners know their own professions best and are best able to evolve good practice and models of care. To mitigate risk, this option provides for Ministerial oversight of significant expansions of a scope of practice.

Prescribing and standing orders

100. Under the status quo, medical practitioners can prescribe or issue a standing order for any medicine as long as it is within their scope of practice. This option would apply that model to all professions regulated under the HPCA Act, but with the option of a profession having a list of specific medicines rather than a general prescribing power. Scopes of practice could also refer to a type of medicine, such as vaccines or local anaesthetics.
101. This option could involve some professions gaining significant new powers, and a safeguard would be required in those situations. The TPA also managed prescribing rights via scopes of practice, with the safeguard of the Minister of Health needing to approve any change to a scope of practice that involved prescribing. Several of the RAs strongly opposed this approval requirement, considering that it failed to respect professional independence. However there was broad support for a clearer and faster pathway for professions gaining prescribing rights.
102. A safeguard is only required when a change involves significant expansion of a profession's powers, such as gaining prescribing rights, gaining the power to prescribe unapproved medicines, or moving from a 'list of medicines' approach to being able to prescribe any medicine within a scope of practice. Therefore this option limits the approval requirement to changes which currently require legislative amendment; it is not required for other changes to scope of practice.

Administering prescription medicines

103. The scope of practice approach could also be used to enable regulated health professions to administer prescription medicines. For example, nurses could be enabled via scopes of practice to administer any approved vaccine.
104. This pathway would sit alongside other mechanisms, such as regulations, licences and general provisions enabling (for example) anyone to administer a medicine in the instructions of the person who prescribed it.

Unapproved medicines

105. Under this option, RAs could add prescription of unapproved medical products to their scopes of practice. If this is a new power for the profession, the Minister of Health's approval would be needed (see above).
106. Some safeguards will be needed to prevent inappropriate prescribing. These safeguards will be determined following engagement with practitioner organisations and other key stakeholders. The intent is to encourage practitioners to choose approved medicines where these are available and suitable, while still enabling use of an unapproved medicine where the practitioner considers this appropriate according to their professional judgement. Health practitioners have raised concerns about their liability when supplying unapproved medicines under s29. Many requests for greater flexibility are in the context of brand substitutions where it is assumed – often incorrectly – that someone (eg, Pharmac or the importer or wholesaler) has undertaken some kind of due diligence.
107. This option for unapproved medicines would include supply to people who had participated in a clinical trial who would benefit from continued access to the trial medicine after the trial ends, and as part of routine clinical care. This pathway would likely only be relevant for participants in Phase III or IV trials, where the product has established its safety and presumptive efficacy. Continued supply could be authorised by a practitioner associated with the trial, the participant's usual practitioner, or another practitioner (such as a specialist). Supply following a trial would not need any special provisions in the Bill.

108. Under option 3.2, supply could only occur if the supplier has a licence to supply unapproved medicines. This licence would cover all unapproved medicines, rather than a licence being required for each medicine. Licensing (and licence conditions) will help ensure that supplied medicines are appropriately sourced or manufactured, as licence-holders would be required to take reasonable steps to ensure that the product is genuine and of reasonable quality, rather than this responsibility sitting with the practitioner. It is intended that a licence to import or manufacture medicines would usually cover supply of unapproved products.
109. This option provides more protection to consumers than the status quo, primarily by requiring a licence to supply unapproved medicines. This will impose standards on suppliers, and should help prevent supply of counterfeit or otherwise dangerous or ineffective medicines.
110. This option is likely to improve access to unauthorised medicines, by enabling a wider range of practitioners to prescribe and supply them. There may be some short-term reduction of access as a result of greater responsibilities placed on suppliers, but it is anticipated that market dynamics will see businesses move into this space over time.
111. This option will impose regulatory costs on suppliers of unauthorised medicines, and will therefore be less efficient than the status quo. It may reduce due diligence costs for medical practitioners and healthcare providers, who will be better able to trust suppliers.
112. This option recognises that health professionals and their regulatory bodies are best equipped to make decisions about what their members can do with medicines.

Option 2.3: Expanded prescribing and other powers in primary legislation

113. Under this option, primary legislation would enable (including via secondary legislation) an expanded range of health practitioners to prescribe and carry out other activities with medicines, including unapproved medicines. As with option 2.2, this option includes a requirement for a licence to supply unapproved medicines.
114. Which practitioners would be enabled to do what would be determined in consultation with practitioner organisations and other key stakeholders. However changes are likely to include:
    1) nurse practitioners enabled to prescribe unapproved medicines – nurse practitioners and their employers have been asking for this for some time;
    2) pharmacist prescribers moved from a ‘list of medicines’ approach to a general ‘scope of practice’ approach and potentially enabled to prescribe unapproved medicines;
    3) podiatrists enabled to prescribe from a list of medicines – Cabinet has agreed to this, but it has not yet been implemented.
115. This option would enable affected professions to exercise their expanded powers as soon as the legislation comes into effect, and is likely to reflect current capabilities of health practitioners. However it would not be future-proofed. It is likely that new models of care will emerge, and that more professions will become capable of carrying out an expanded range of activities with medicines. This option would require a further change to primary legislation to reflect those changes. Experience with the Medicines Act suggests that these changes will take many years, even if they are uncontroversial.
116. This option is likely to improve access to medicines in the short to medium term by promptly enabling a wider range of practitioners to prescribe a wider range of medicines. However in the long term (10+ years) this option is likely to make access more restrictive than necessary, as it does not include a pathway to enable new professions to expand their roles.
117. Option 2.3 would provide the same level of protection as option 2.2, due to the licensing requirement for supply of unapproved medicines. It will be more efficient and fit-for-product than the status quo and option 2.2 in the short term, but over the long term will

be less efficient and fit-for-product than option 2.2 (but still better than the status quo), as it will be difficult to keep up to date. It also leaves decisions about which practitioners can do what with medicines to Parliament, rather than professional regulation bodies. This goes against the idea that professions are best qualified to make these decisions.

How do the options compare to the status quo/counterfactual?

	Option 2.1 – Status quo under s29 of the Medicines Act	Option 2.2 – Flexible pathways via scopes of practice	Option 2.3: Expanded rights in primary legislation
Protection	0	+	+
Efficiency	0	+	+
Fit for product	0	++	++
Overall assessment	0	++	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option 2.2 is the preferred option, as it will provide more protection against substandard products, mostly through increased regulation of supply of unapproved medicines. It is likely to be more efficient, as prescribing powers of specific professions are updated to reflect the competence of those professions and modern models of care. However it will be less efficient for suppliers of unapproved medicines, who would have to be licensed. It provides a much better fit for product, as medicines will be able to be supplied by any practitioner who has the expertise and qualifications to do so. It will also provide some regulation of unapproved medicines, which appropriately reflects their risk profile. Option 2.3 has the same rating to option 2.2. Initially it will be more efficient than option 2.2, as changes to prescribing and other rights will take effect as soon as the legislation comes into force. However as time goes on, option 2.3 becomes less favourable relative to option 2.2. Option 2.2 best recognises the expertise of professions in determining what their members can do with medicines.

Example key for qualitative judgements:

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- -	much worse than doing nothing/the status quo/counterfactual

What are the marginal costs and benefits of the option?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Medicines industry	Costs from licensing of unapproved medicine supply Efficiency gains from better approval processes		
Crown	Regulator costs addressed in regulator RIS		
Health practitioners	No significant cost impact expected		
Health service providers	Efficiency gains due to practitioners working to top of scope, and more certainty about quality of medicines		
Consumers	No significant cost impact expected		
Total monetised costs		Low	
Non-monetised costs		Low	
Additional benefits of the preferred option compared to taking no action			
Medicines industry			
Crown	Reduced harm from unsafe medicines		
Health practitioners			
Health service providers	More efficient service delivery through modernised prescribing provisions		
Consumers	Improved access and protection		
Total monetised benefits			
Non-monetised benefits			

Section 3: Delivering an option

How will the new arrangements be implemented?

118. Decisions on who would implement the new regulation will be subject to future government decisions. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.
119. The approval system will be operated and enforced by the Crown. The form of any regulator is discussed in a separate Cabinet paper.
120. Education campaigns may likely to be needed for industry and the public, if there are significant changes from the status quo.
121. Consistent with the Pae Ora (Healthy Futures) Act 2021, the Ministry of Health will retain a stewardship and oversight role.
122. As with all new systems, there is significant risk of time and cost over-runs. There are lessons New Zealand can learn from its existing regime for medicines and medical devices. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for product approval, in particular those involving reliance and notification.
123. Most of the risk comes from other elements not covered in this RIS, such as increased regulation of medical devices and the establishment or redesign of a regulator.

How will the new arrangements be monitored, evaluated, and reviewed?

124. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:
    1) time taken to approve medicines via the various pathways
    2) time taken to issue licences for controlled activities
    3) compliance and enforcement action taken.
125. Currently it is unclear who is responsible for detecting inappropriate prescribing. Decisions are needed on this as part of this work programme and/or the review of health workforce regulation.
126. There may be a review of the new system within five years of it taking effect.
127. The medicines industry and the healthcare sector have productive relationships with the Ministry and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.
128. Work will be needed on how to ensure that patient/consumer problems with the new system are heard and responded to.