Regulatory Impact Statement: Proposed verification pathway for medicines approvals

Coversheet

Purpose of Document	
Decision sought:	*Policy decisions to draft amendments to the Medicines Act 1981 to enable an additional medicines approval reliance pathway.*
Advising agencies:	*Ministry of Health*
Proposing Ministers:	*Hon David Seymour, Associate Minister of Health*
Date finalised:	*30 July 2024*

Problem Definition

The proposal is an opportunity to reduce timeframes for new medicines approvals, speeding up the public's access to approved medicines.

Executive Summary

This analysis has been limited by the direction set by the Government. The National-ACT and National-New Zealand First Coalition Agreements contain a commitment to progressing a proposal to introduce a 30-day verification system based on the approval of medicines by two recognised overseas regulators.

Medicines regulation is an important part of all modern health systems. In New Zealand, Medsafe (a business unit of the Ministry of Health) is responsible for the regulation of medicines and other therapeutic products under the Medicines Act 1981 and associated regulations.

The approval process for new medicines (that is, "new" as in not previously marketed in New Zealand) begins with a company (or 'sponsor') making a New Medicine Application to Medsafe to distribute the medicine in New Zealand. Medsafe assesses whether the medicine meets acceptable standards for quality, and that the benefits (efficacy) outweigh the risks (safety) when used properly. The initial evaluation is typically followed by one to three rounds of requests for information from Medsafe.

There are three current pathways for applying for approval (or 'consent') for a new medicine:

- The standard pathway, which involves a thorough assessment.
- The abbreviated pathway, also called a 'reliance pathway' because it relies on an assessment report by another recognised regulatory authority overseas. About half of Medsafe's approvals go through this pathway.

- The provisional consent pathway, which is a way for Medsafe to expedite approval of new medicines where there is an urgent clinical need but incomplete data.

Concerns have been raised by some within industry and other commentators that aspects of Medsafe's approvals process are too slow or may be hindered by outdated systems. Currently, New Zealand's timeframes to approve medicines are slower than Australia's in most pathway categories (when measured using working days).

There is an opportunity to streamline approval processes and reduce timeframes. Medsafe has a work programme to streamline medicines approvals, through operational changes and a range of short- and long-term actions.

We compared this option of non-legislative changes (Option One) with the proposed legislative option (Option Two).

Option Two involves amending the Medicines Act 1981 to introduce a new, alternative reliance process which utilises other countries' decisions with minimal Medsafe assessment. New secondary legislation will be needed to set out the pathway rules (such as the eligibility criteria).

The new verification process will require applicants to have received approval from two recognised regulators, and meet the requirements set out in the pathway rules. Medsafe will make a decision within 30 working days of acceptance of the application. The decision may be to approve, refuse, or transfer the application to another pathway under the Act. The 30-day timeframe excludes time spent awaiting a response from the applicant to a request for information, and following a proposed new approach to measurement which counts in working days (instead of calendar days).

The objective of this initiative is to reduce the timeframe for decisions, while maintaining appropriate safety measures, and maintaining Medsafe's international credibility as an effective regulator.

The Ministry's analysis concluded that both options will meet the policy objectives, with the legislative option being better but with more uncertainties. One risk is that few companies find it an attractive option, due to the preparation required in the screening phase, or inability to meet the eligibility criteria.

Option Two builds on the operational enhancements in Option One. It provides companies another option for approval of medicines, reduces barriers to applying and provides New Zealand with an additional reliance pathway, that more heavily relies on overseas approvals compared to the current abbreviated pathway. So long as the finalised pathway aligns with international best practice it will provide a credible reliance pathway that provides reassurance to New Zealanders about the efficacy, quality and safety of medicines approved in this pathway.

Post-implementation, the new arrangements will be monitored by Medsafe, including monitoring for any problems or quality issues that may arise. The results will be reported in its routine annual performance reporting. The Ministry intends to review the pathway rules a year after it is established to fine-tune it.

Limitations and Constraints on Analysis

This analysis has been limited by the direction set by the Government. The National-ACT and National-New Zealand First Coalition Agreements contain a commitment to progressing a proposal to require Medsafe to approve new pharmaceuticals within 30 days of them being approved by at least two overseas regulatory agencies recognised by New Zealand.

The Government included streamlining Medsafe medicine approval processes as a Quarter 2 priority, with Cabinet to take decisions by 30 June 2024.

Because of the narrow scope and time constraints, the Ministry's work on this proposal has been focussed primarily on designing workable policy.

In June 2024, Cabinet agreed to endorse Medsafe's work programme to streamline medicines approvals processes, which includes a range of short-, medium-, and long-term actions [SOU-24-MIN-0055]. Cabinet also invited the Associate Minister of Health (Hon David Seymour) to report back to Cabinet by the end of August with policy details for the proposed new 30-day verification system and to seek approval to issue drafting instructions for necessary legislative changes.

Responsible Manager(s) (completed by relevant manager)

Suzanne Townsend
Manager, Regulatory Policy
Strategy, Policy and Legislation
Ministry of Health
Date signed out:

Quality Assurance (completed by QA panel)

Reviewing Agency:

Panel Assessment & Comment:	The Ministry of Health quality assurance panel has reviewed the Regulatory Impact Statement titled "Proposed verification pathway for medicines approvals", produced by the Ministry of Health and dated July 2024. The panel considers that the Statement partially meets the quality assurance criteria. The Statement is clear, concise, complete, and consulted. The analysis is balanced in its presentation of the information and impacts are identified and assessed. The panel does not consider the analysis meets the criteria to be convincing due to the limited options available.

Section 1: Diagnosing the policy problem

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

The role of medicines regulation

1. Medicines regulation is an important part of all modern health systems. The public reasonably expect medicines to be of high quality and be acceptably safe and effective. All medicines have the potential to cause significant harm, whether through toxicity, side effects, or defects in manufacture. Because consumers are not in a position to judge the quality, safety, or efficacy of medicinal products themselves, we need good regulation that provides confidence to the public and health practitioners, without imposing an unreasonable regulatory burden.
2. Effective and transparent regulation benefits the pharmaceutical industry by providing a level playing field, eliminating the risk of market share being eroded by products of low quality and questionable effectiveness. It provides evidence for companies that their products are of high quality and that the risks are being appropriately managed, thus protecting the company's reputation.
3. Medsafe (a business unit of the Ministry of Health) is responsible for the regulation of medicines and other therapeutic products for New Zealand under the Medicines Act 1981 and associated regulations. Its functions include the approval (or consenting) of new and changed medicines for distributing in New Zealand, as well as monitoring the ongoing safety of medicines and undertaking enforcement activities to protect the public.

The current approval process

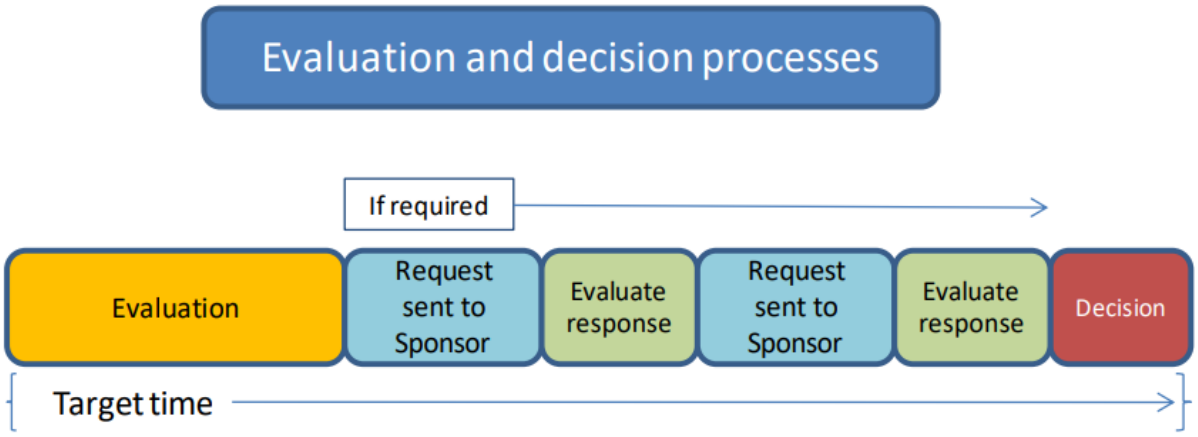
4. The approval process for new medicines (that is, not previously marketed in New Zealand) begins with a company (or 'sponsor') making a New Medicine Application to Medsafe to distribute the medicine in New Zealand. Medsafe assesses whether the medicine meets acceptable standards for quality, and that the benefits (efficacy) outweigh the risks (safety) when used properly. The initial evaluation is typically followed by one to three rounds of requests for information from Medsafe.
5. An approval only applies to specific products made or distributed by specific entities (for example a 10 pack of Sudafed Sinus 12 Hour Relief (Pseudoephedrine hydrochloride 120mg) tablets). This is because evaluation includes assessment of the quality of starting materials, manufacturing, testing, quality assurances processes, and New Zealand-specific criteria such as labelling. The supporting data provided is extensive, often running into thousands of pages, and is provided in line with internationally aligned formats.
6. Companies often do not supply an identical version of a medicine to every country. Medsafe's work ensures New Zealand does not receive batches that have been rejected by bigger markets because they did not meet their specifications or acceptable quality assurance.
7. The information obtained is needed not only to evaluate and approve a new medicine but also to enable Medsafe to monitor the medicine once marketed and respond to any issues that may arise once it is on the market (e.g., adverse reactions).
8. There are three current pathways for applying for approval for a new medicine:
    - The standard pathway. This is a full evaluation of data submitted for approval of a medicine, usually consisting of thousands of pages. Medsafe undertakes a thorough assessment of the data. Medsafe can give priority to medicines where

there is significant clinical need, or significant potential cost savings to the taxpayer, or for medicines manufactured in New Zealand for export.

- The abbreviated pathway is called a 'reliance pathway' because it relies on an assessment report by another recognised regulatory authority overseas. Medsafe's assessment work focuses on key data. The abbreviated pathway comes with reduced timeframes and fees. About half of Medsafe's approvals go through this pathway.
- The provisional consent pathway, which is a way for Medsafe to expedite approval of new medicines where there is an urgent clinical need but incomplete data. Provisional approval lasts for a maximum period of two years; however, this can be renewed if needed. This pathway was used, for example, to approve COVID-19 vaccines while clinical and manufacturing data was still being generated. It is also used to assist Pharmac in managing stock shortages, as it can be used for a short-term approval based on limited data.

9. These pathways involve communication and exchanges of information between the sponsor and Medsafe. **Figure 1** outlines the basic evaluation and decision process. Often the process is more iterative than this.

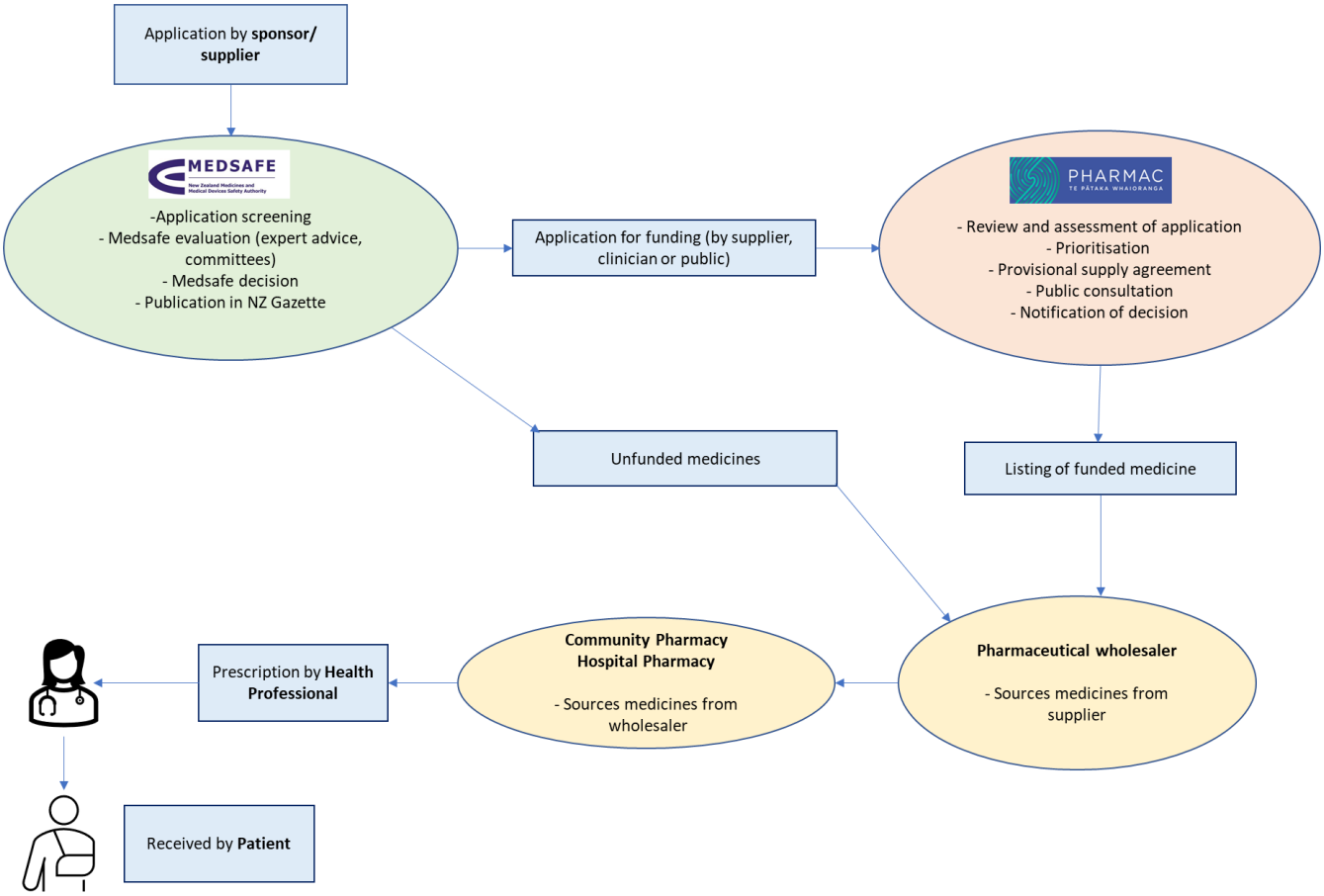
Figure 1: Evaluation and decision processes



10. Medsafe approval is just one element of a pathway for bringing new medicines to market and getting them to patients (see **Figure 2** below). Other elements include funding and procurement decisions (by, for example, Pharmac, Health New Zealand, and public and private health care providers); decisions by manufacturers and sponsors to apply for a New Zealand approval and to supply the market; and decisions by prescribers and pharmacists, who supply the product to patients. Each of these actors play a role in determining how fast a medicine can reach patients.

11. Unapproved medicines are able to be imported and supplied, and are sometimes publicly funded. In these cases it is the responsibility of the prescriber to discuss with the consumer the evidence to support the use of the medicine and any potential associated safety concerns.

Figure 2: Overview of Medicine Approval and Supply in New Zealand of Prescription Medicines



Timeframes

12. Medsafe sets target timeframes for evaluating new and changed medicines. These timeframes vary based on the risk level of the medicine and the approval pathway that is taken (including where information is accepted from recognised international regulators). Timeframes are discussed in more detail in the next section.

What is the policy problem or opportunity?

13. There is an opportunity to further streamline approval processes and reduce timeframes for new medicines approvals.

14. There is also an opportunity to harmonise Medsafe's performance measures with other countries, which will improve transparency and accountability.

15. The proposal came about in the context of concerns about New Zealander's access to medicines generally, which involves wider factors than the approvals process.

16. In research commissioned by the New Zealand medicines industry, comparing registration (approval) of medicines across 20 OECD countries, New Zealand ranked last for the registration of modern medicines between 2011 and 2020, with only 131 medicines registered of the 441 modern medicines registered and launched

internationally. Only 26% of the medicines which were registered in New Zealand were then publicly funded. [1]

17. The reasons why New Zealand ranks low on access to medicines are multiple and include factors common to all trading such as profitability and the size of the market, which affect its importance to pharmaceutical suppliers, shipping costs, and regulatory requirements.

18. Feedback from the pharmaceutical industry is that one reason why pharmaceutical companies are slow to launch medicines in New Zealand is the long length of time anticipated for the medicines to become publicly funded. Industry has advised that until a medicine is funded by Pharmac, the size of our market is very small, so New Zealand is not generally a high priority for pharmaceutical suppliers.

19. Compared to these wider market and funding issues, Medsafe's approval process timeframes have a relatively minor impact on the New Zealand public's overall level of access to medicines. Nevertheless, concerns have been raised by some within industry and other commentators that aspects of Medsafe's approvals process are too slow or may be hindered by outdated systems.

20. Reducing time to approve medicines may reduce transaction costs and contribute to faster access to medicines.

Comparing our approval timeframes with Australia's timeframes

21. Directly comparing approval timeframes between medicines regulators in other countries is complicated because of different processes and reporting measures. Medsafe's reported timeframes include all calendar days and the time the applicant takes to respond to requests for information. However, regulators in other countries may report their timeframes discounting weekends and holidays and the time the application is with the applicant.

22. **Table 1** compares New Zealand timeframes against the Australian Therapeutic Goods Administration (TGA; Medsafe equivalent) legislated timeframes, using the Australian reporting method, which discounts the time the application is with the applicant and uses working days. The Australian regulator generally meets Australian legislated timeframes. Note that this is not a strict comparison as the medicines and quality of the dossier applications will be different. The table shows decisions in New Zealand are slower in some categories.

[1] New Zealand was the second-slowest country for public funding. In New Zealand, for all modern medicines funded from 2011-2020, the average time from in-country registration to public funding was more than 2 years (822 days), ranking 19th of 20 countries. In comparison, the OECD average was 427 days. IQVIA_Report_-_A_Decade_of_Modern_Medicines_An_International_Comparison_2011-2020__FINAL_.pdf (medicinesnz.co.nz)

Table 1: Performance statistics Medsafe against TGA legislative timeframes

Description	Medsafe Actual approval 2023/2024 YTD	TGA target approval Time 2022/2023 (last publication)	Difference
New Chemical Entities (NCEs) – full assessment *NCEs are medicines with novel active ingredients that have not previously been approved in NZ*	244 days	255 days	NZ 11 days shorter
New Chemical Entities – current 'abbreviated' reliance pathway *Comparative Overseas Regulator B (TGA)* *Abbreviated Pathway (NZ)*	198 days	175 days	NZ 23 days longer
Generic Medicines – full assessment *Generic medicines are (generally cheaper) versions of brand name medicines*	284 days	255 days	NZ 29 days longer
Generic Medicines – current 'abbreviated' reliance pathway *Comparative Overseas Regulator B (TGA)* *Abbreviated Pathway (NZ)*	218 days	175 days	NZ 43 days longer

What objectives are sought in relation to the policy problem?

23. The objective is to reduce the timeframe for decisions, while maintaining appropriate safety measures, and maintaining Medsafe's international credibility as a regulator.

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

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

24. The primary evaluative criterion is whether the option is effective in reducing timeframes for new medicines approvals.

25. The other criteria are:

    - Maintains safety measures.
    - Maintains Medsafe's credibility as an international regulator.
    - Strengthens transparency, accountability, and harmonisation.
    - Maintains Medsafe's ability to prioritise work and respond to urgent issues.

Maintains safety measures

26. Maintaining safety measures is critical because if public safety is compromised, serious harm can result. The World Health Organization reports that a key driver to increasing risk of substandard or counterfeit medicines entering the distribution chain is a lack of effective regulation. Many examples demonstrate this risk, most recently in 2022 when over 200 children died from taking contaminated cough medicine in countries that did not effective controls in place (such as Indonesia and The Gambia).

27. Other examples include counterfeit medicines entering the mainstream distribution chain and adulterated or substandard medicines ordered by members of the public via the internet, leading to deaths. Medsafe has a number of examples of attempts to supply New Zealand with poor quality batches of products in recent years, including ones from otherwise reputable pharmaceutical companies.

Maintains Medsafe's credibility as an international regulator

28. Medsafe's credibility as a regulator is an important criterion because in order to share data and work with other regulators, New Zealand needs some data and work to share back with them. International cooperation is voluntary, and likely to cease if New Zealand is seen as a free rider by only receiving data and not contributing to regulatory oversight of medicines globally.

29. Medsafe participates in international collaborative groups that have work sharing arrangements that reduce the volume of work required for each country for a shared single decision on medicines regulation. New Zealand is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S – an international association of medicines manufacturing regulators) which provides assurance that members meet high standards of inspection of manufacturing sites. As most New Zealand medicines are manufactured overseas, we recognise various regulators to competently inspect those manufacturing sites.

Strengthens transparency, accountability, and harmonisation

30. The proposed changes will harmonise New Zealand's performance measures with those of other countries, i.e., counting by working days instead of calendar days.

Maintains Medsafe's ability to prioritise work and respond to urgent issues

31. A legislated target timeframe would mean Medsafe has less flexibility with the use of its resources. This may affect its ability to work on higher priority applications or respond to urgent issues that may arise such as stock shortages, adverse reactions, or enforcement actions.

What scope will options be considered within?

32. The scope of options has been limited by the coalition Government's commitment to a 30-day policy.

What options are being considered?

33. The options discussed in this section are:

    - Option One – non-legislative enhancements
    - Option Two – introduce 30-day pathway (legislative change)

Option One – non-legislative enhancements

34. This option does not create a new pathway nor make any legislative change. It assumes some non-legislative changes as part of implementing Medsafe's work programme to streamline medicines approvals. These actions include operational changes that Medsafe can implement within existing resources. Short-term actions include:

    - Increasing the types of applications that can be considered under Medsafe's existing abbreviated assessment pathway. This will provide companies with increased access to this faster and lower-cost assessment route.
    - Adopting a change in the way the approval timelines are measured to enable more direct comparison with other countries such as Australia. Changes including measuring medicines assessment in working days and excluding the time an application is with the company following requests for additional information.
    - Tightening the application process by enforcing a maximum number of requests Medsafe can make for additional information, the time taken by applicants to respond to such requests and decision time.
    - Ensuring timely recruitment to Medsafe vacancies and imbedding retention strategies for technical staff.

35. These changes are expected to provide improvements and extensions to current practice, with the effect of reducing average approval time for medicines by a small number of weeks, with the expectation that this reduction could be greater in individual cases.

Option Two – Legislative change proposal – 30 day pathway

36. Option Two is to amend the Medicines Act 1981 to add a new verification pathway to approve new pharmaceuticals within 30 days of an application being accepted, if the product has already been approved by at least two overseas regulatory agencies recognised by New Zealand. New secondary legislation will be needed to set out the pathway rules (such as the eligibility criteria). This actions the coalition Government's agreement and subsequent Cabinet decisions.

37. The new pathway will be a new reliance process which utilises other countries' decisions with minimal Medsafe assessment. This will provide another option for companies considering bringing new medicines to New Zealand.

38. The new verification process will require applicants to provide approval from two recognised regulators and meet agreed eligibility criteria. Medsafe will make a decision within 30 working days of acceptance of the application. The decision may be to approve, refuse, or transfer the application to another pathway under the Act. The 30 days excludes time spent awaiting a response from the applicant to a request for

information, and follows a proposed new approach to measurement which counts in working days (instead of calendar days).

39. As with other pathways, the new pathway will be funded through fees, on a cost-recovery basis.

40. In order to implement this pathway safely and effectively, the following eligibility criteria are under development:

    - The application is initiated by the company. The decision to supply the medicine needs to sit with the company due to their global safety requirements and being responsible for wherever their medicine is being used. Companies also need to set up distribution channels in each country.
    - The quality and manufacturing of the medicine must be identical (or close to) that approved in those two countries. This ensures New Zealand receives the same quality product as approved in those markets.
    - The approval by the reference authorities must have been within the last two years. There should be minimal changes made to the product.
    - The clinical use (indication) should be essentially similar to that initially approved in the two countries.
    - Medsafe will require unredacted assessment reports from both countries and a full copy of the raw data submitted. This information will not be assessed using this process but enables post-market monitoring by Medsafe.

41. A pre-vetting ('validation') system will decide if the medicine meets the above criteria before being accepted for the verification pathway.

42. Exclusion criteria are also proposed for medicines that would not be able to use this pathway, for example:

    - Medicines with specific considerations for the New Zealand population, such as genetic specific diseases or safety risks.
    - Medicines where the benefit/risk balance depends on country specific factors e.g., the approval of vaccines depends on country-specific communicable diseases.
    - Products approved where the reference regulator has used a recognition pathway for their own approval or where the approval is an emergency use authorisation (i.e., where a full approval has not been undertaken by a recognised regulator).

43. We propose that the initial list of countries Medsafe trusts for this pathway would match the current abbreviated process and would be consistent with other international recognised regulators. The list should be regularly reviewed with more countries added as appropriate. Medsafe will develop an assessment process for how new countries are added.

Consultation and analysis

44. Medsafe has met with industry representatives to help inform policy development. There is wide support for faster reliance pathways generally and feedback on particular aspects of the proposal that are still in development.

45. As part of our analysis, the Ministry investigated regulatory systems in other countries. Reliance pathways are commonly used in other developed countries. **Appendix One** compares the timing approaches of the regulatory systems of New Zealand, Australia, Europe, Singapore, the United Kingdom (UK), and the United States. These countries have similar evaluation approaches, but with different ways of measuring the time

taken. Most countries ‘stop the clock’ when awaiting further information from an applicant.

46. These countries all use reliance pathways or mutual recognition. The shortest timeframe is in the UK. The Medicines and Healthcare Products Regulatory Agency (MHRA) has a timeframe for screening of 50 business days for the abridged or verification pathway, with a 30 working day timeframe for the completed evaluation (with the ability to extend the timeframe if responses to queries are incomplete). The MHRA has a second abridged pathway with a 110 working day timetable. In addition the MHRA only accepts applications once per month.[2]

47. Singapore has a pathway that is the most similar to the proposed verification pathway, but with a longer timeframe. The Singapore pathway has a timeframe for screening of 50 business days for the abridged or verification pathway, with a 180-day timeframe for the completed evaluation (with the ability to extend the timeframe if responses to queries are incomplete).

Risks

48. There are risks with introducing this new pathway. The risks are that:

- Few companies find it an attractive option, due to the preparation required in the screening phase, or inability to meet the eligibility criteria.
- If and when applications are made to the new pathway, it could impact on the timelines for other applications, making them longer.
- Products make it through the pathway that Medsafe would not otherwise have approved (less likely).
- Companies don’t fulfil their obligation. The pathway places a lot of trust in them to provide all data and simply declare it is complete and consistent with the data provided in the other countries (there is very limited up-front assessment of the quality of data).
- Medsafe fails to meet the 30-day timeframe. There is no explicit consequence for this planned for legislation. However, there would be a reputational consequence on Medsafe, as it would be reported in its annual performance results. Medsafe will manage this risk, although it is likely that this will divert time from other application pathways, resulting in longer timeframes for those.
- Public confidence in these approvals is eroded (this is related to misinformation, mistrust of other regulators such as the US Food and Drug Administration).

49. The risks will be mitigated by setting clear procedures and eligibility criteria for acceptance onto the pathway in secondary legislation (the ‘pathway rules’). The Ministry will review these rules post-implementation so that any necessary refinements can be made.

Other options

50. Other options have not been fully considered as alternatives at this time due to the narrow scope and time constraints of this project. They are discussed here briefly for completeness. We note that in the longer term these options may be considered and consulted on as part of longer-term medicines legislation reform.

Longer pathway (e.g. 60 days)

51. As noted above, a 30-day timeframe is an extremely tight timeframe and comes with a risk that few applications take this pathway. If this proves to be true, an alternative

[2] International Recognition Procedure - GOV.UK (www.gov.uk)

option is to set longer target timeframes. For instance, 60 days, which is similar to comparable pathways used by Singapore's Health Sciences Authority and the UK's Medicines and Healthcare products Regulatory Agency. This option could provide the same benefits as the 30-day pathway, while strengthening international harmonisation as well as maintaining Medsafe's flexibility to respond to other priorities.

Increased resourcing

52. This non-legislative option could be adopted in addition to or instead of Options One or Two. An increase of 3-4 staff to process applications would significantly reduce approvals timeframes. Funding for this would need to be found. Currently, 95% of Medsafe's work is funded through fees charged to applicants.

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

	Option One – non-legislative enhancements	Option Two – 30-day verification pathway
Reduces timeframes	**+** Projected average approval time for medicines to reduce by a small number of weeks.	**+** Projected average approval time to reduce further than Option One, through a small number of applications going through the new pathway. It is uncertain how many applications would take this path.
Safety	**0** No change.	**0** No change, as the pathway will align with best international best practice.
International credibility	**0** No change.	**0** No change.
Transparency and international harmonisation	**+** Increased transparency due to harmonisation of performance reporting.	**+** Increased transparency due to harmonisation of performance reporting combined with changes to legislation to not only create the new pathway but also potentially consequential amendments to make counting days consistent across pathways (i.e. counting working days only and enabling 'stop clocks').
Ability to prioritise work	**0** No change.	**-** Medsafe staff will be less able to respond to new priority issues, due to capacity being focussed on the imperative to meet the 30-day statutory deadline as a priority.
Overall assessment	This option will provide benefits in the form of shorter average approval times and increased transparency.	The benefits of this option are in the same areas as Option One. However, there are minor risks and uncertainties with regard to the size of the benefits and Medsafe's ability to balance applications through the reliance pathway against other evaluation work (full and abbreviated applications).

++: much better than doing nothing; **+**: better than doing nothing; **0**: about the same as doing nothing; **-**: worse than doing nothing; **- -**: much worse than doing nothing. Note: plus/minus ratings are for the purpose of reading the table at a glance, and are not meant to be added up with a conclusion reached based on a numerical calculation

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

53. The Ministry's analysis compares the non-legislative and legislative option and concludes that both options will meet the policy objectives, with the legislative option having more uncertainties.

54. Option Two builds on the operational enhancements in Option One. It provides companies another option for approval of medicines, reduces barriers to applying and provides New Zealand with a complete reliance pathway (rather than the current partial one). So long as the finalised pathway aligns with international best practice, it will provide a credible reliance pathway that provides reassurance to New Zealanders about the efficacy, quality, and safety of medicines approved in this pathway.

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 Government's preferred option compared to Option One			
Regulated groups	No new costs	Low	Medium. The fee cost is yet to be determined but it will be less than other pathways.
Regulators	Set up cost – officials to work on amendment bill and new policies.	Low	High
Consumers	No new costs	NA	High
Additional benefits of the Government's preferred option compared to Option One			
Regulated groups	Reduced cost of fee (amount yet to be determined)	Low	High
Regulators	No benefits	NA	High
Consumers	Consumers benefit by getting access to some medicines sooner	Low	Medium. Uncertain how many products will take the pathway.

Section 3: Delivering an option

How will the new arrangements be implemented?

55. Implementation will be the responsibility of Medsafe. Medsafe will design a comprehensive process for applications entering this pathway, including guidance for data requirements and pre-vetting required. Stakeholders will be informed through Medsafe's established channels of communication. Medsafe will publish guidelines to explain the new pathway.

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

56. Post-implementation, the new arrangements will be monitored by Medsafe, including monitoring for any problems or quality issues that may arise. The results will be reported in its routine annual performance reporting. This will provide an accountability mechanism to show that the 30-day timeframe is being met. Progress and outcomes will also be reported to the Associate Minister of Health periodically as part of work on the longer-term programme to streamline medicines approvals processes.

57. The Ministry intends to review the pathway rules a year after it is established and then review it periodically to fine-tune it.