Briefing for decision

Statutory timeframes under the Medical Products Bill

Date due to MO:	3 June 2025	**Action required by:**	13 June 2025
Security level:	IN CONFIDENCE	**Reference:**	H2025060718
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon David Seymour, Associate Minister of Health; Hon Simeon Brown, Minister of Health		
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Contact for telephone discussion

Name	Position	Telephone
John McGrath	Director, Priority Projects Strategy, Policy and Legislation	section 9(2)(a)
Tim Vines	Manager, Therapeutics Strategy, Policy and Legislation	section 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Overtaken by events
☐ Needs change	☐ Seen	
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Briefing for decision

Statutory timeframes under the Medical Products Bill

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To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing seeks your feedback on the inclusion of statutory timeframes in the Medical Products Bill (the Bill) and how they could be implemented.

Summary

2. In September 2024, Cabinet invited you to report back on policy matters for the Bill, including statutory timeframes, by the end of the third quarter 2025 [SOU-24-MIN-0132 refers].

3. Industry and researchers advocated for 'performance measures' and statutory timeframes in the Therapeutic Products Act 2023 and were disappointed by their absence. Medicines New Zealand and its members have stressed the importance of statutory timeframes for decision making, including in their recent submissions on the Medicines Amendment Bill.

4. Based on the available evidence of their effectiveness – and risks – we do not recommend including statutory timeframes in primary legislation, with two exceptions. Those relate to clinical trial decision making, which already has a statutory timeframe in the Medicines Act; and any final position agreed by Parliament as to the inclusion (or not) of a statutory timeframe for the new medicines verification pathway – proposed in the Medicines Amendment Bill.

5. Other than those cases, we recommend that, should Ministers wish to establish decision making timeframes, the Bill enable them via secondary legislation. This briefing outlines options for implementation.

6. Any regulations necessary to set out the detail of performance benchmarks and statutory timeframes would be made in consultation with industry, approved by the Government, and subject to periodic review.

7. We recommend you discuss these proposals with officials and provide feedback to the Ministry. Final Cabinet decisions on these matters will be sought in July 2025.

Recommendations

We recommend you:

a)	**Note** that Cabinet has invited you to report back by the end of Q1 2025 on statutory timeframes under the Medical Products Bill [SOU-24-MIN-0115]	**Noted**
b)	**Agree** to include and retain statutory timeframes in the Medical Products Bill and a 45 day approval timeframe for clinical trial applications	**Yes/No**
c)	**Note** that the inclusion of statutory timeframes for the new verification pathway – proposed in the Medicines Amendment Bill – is currently being considered by Health Committee, with industry submissions strongly in favour of including a timeframe in primary legislation	**Noted**
d)	**Agree** that the position ultimately adopted by Parliament on a statutory timeframe for the verification pathway (ie, on enactment of the Medicines Amendment Bill) be carried over to the Medical Products Bill	**Yes/No**
e)	**Agree** to enable regulations to be made under the Bill specifying performance expectations (including timeframes) for decisions involving product approvals, and decisions over licenses and permits	**Yes/No**
f)	**Agree** to include provisions in the Bill setting timeframes for the provision of information to decision makers (eg, Medsafe) by applicants, with a power to lapse applications if information is not provided within time	**Yes/No**
g)	**Agree** that decision makers (eg, Medsafe) should be required to report annually on their performance against the statutory timeframes and performance measures	**Yes,/No**
h)	**Agree** that the Bill enable (where appropriate) a partial refund of fees paid by an applicant, where a decision maker did not meet the statutory timeframe for a decision specified in the regulations	**Yes/No**
i)	**Agree** to the Ministry drafting a Cabinet paper seeking confirmation of the above policy decisions	**Yes/No**
j)	**Note** that implementing statutory timeframes for the regulation of medical products, including partial refunds, will require sufficient resourcing for decision makers (eg, Medsafe) and an appropriate investment in an IT platform	**Noted**

John McGrath

Directory, Priority Projects

Strategy, Policy and Legislation

Date: 30 May 2025

Hon Casey Costello

Associate Minister of Health

Date:

Statutory timeframes under the Medical Products Bill

Background

1. Cabinet has invited you to report back to the Cabinet Social Outcomes Committee (SOU) on matters including statutory timeframes under the Medical Products Bill [H2025066030].

Statutory timeframes under the Medicines Act 1981

2. The Medicines Act 1981 does not currently include statutory timeframes for the approval of medical products. However, Medsafe aims to complete initial review of new medicines within their targeted timeframes[1]. The only statutory timeframe in the Medicines Act is for the approval of clinical trials. The Medicines Act provides that a decision on clinical trial approval must be made within 45 days from the date of application[2].

3. Medsafe also has systems in place to streamline the assessment process. For example, Medsafe offers an abbreviated pathway for product approval which places reliance on overseas evaluation reports as well as an independent evaluation to determine the approval decision. The abbreviated process is intended to be simpler and quicker than the standard evaluation process.

4. On 24 June 2024, Cabinet agreed to establish a verification approval pathway for medicines that utilises a statutory timeframe [CAB-24-MIN-0216]. This pathway requires Medsafe to approve new medicines that have been approved by at least two recognised, overseas regulatory authorities within 30 working days of the application by the company. A Bill to implement the verification pathway was introduced to Parliament on 31 March 2025. Submissions on a Medicines Amendment Bill are currently being considered by Health Committee.

5. Given that submissions are at present under consideration, we propose that the position ultimately adopted by Parliament on a statutory timeframe for the verification pathway (ie, on enactment of the Medicines Amendment Bill) be carried over to the Medical Products Bill.

Views from stakeholders

6. We understand there is concern from industry and the Government that medicines approval in New Zealand is too slow compared to other jurisdictions, ultimately affecting access. We note that several factors could contribute to barriers to access. While approval timeframes may be one factor, it is more likely that market forces (including medicines funding decisions) are more relevant. We also note that industry often

[1] https://www.medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp

[2] All timeframes are in working days, as defined in the Legislation Act 2019, unless otherwise specified.

compares timeframes with different counting methods overseas, such as working days and including or excluding the time applications are with the company.

7. Medicines New Zealand has repeatedly called for the inclusion of statutory timeframes in medicines regulation, including in their engagement with the Ministry on the Medical Products Bill. They also raised this issue with Health Committee in their submission on the Therapeutic Products Act Repeal Bill and Medicines Amendment Bill. They argue this is an important part of ensuring regulator accountability.

8. As the Medicines Act 1981 does not require pre-market approval of medical devices, approval timeframes are not a central issue of concern to the medical device sector. However, timeframes will need to be considered for the Medical Products Bill, even if only a small percentage of devices will undergo a pre-market review or documentation verification.

9. The New Zealand Association of Clinical Researchers supports the use of statutory timeframes in regulatory decisions on clinical trials. Their view is that rapid regulatory review is currently one of the key advantages of conducting clinical trials in New Zealand and that the statutory timeframe for approval is a key factor in this. They want to retain the current statutory timeframe in any future bill.

10. Industry has also suggested that statutory timeframes can assist regulators. This is because a legal deadline to provide information to a regulator helps give incentive/urgency to get information to the regulator from large international companies. However, in practice, some industry stakeholders say this can lead to partial responses or repeated request for information rounds.

11. With regards to proposed changes to the Medicines Amendment Bill, a small number of submissions from practitioner and public health groups have expressed concerns about curtailing Medsafe's ability to undertake its own assessment; and pointed to the risks of statutory timeframes. Industry submissions, however, are strongly in favour of including statutory timeframes in the Medicines Amendment Bill.

Including statutory timeframes in the Medical Products Bill has implications

12. There are benefits and risks to including statutory timeframes in the Medical Products Bill.

13. The Ministry of Health has previously recommended against statutory timeframes and they were not included in the Therapeutic Products Act.[3] This was due to concerns that statutory timeframes could lead to gaming from applicants and that the common use of 'stop-clocks' in overseas jurisdictions undermined their value.

14. We re-examined the literature and international experience around statutory timeframes and found that statutory timeframes may improve approval times for certain products. Although we have not been able to independently verify this claim, Medicines New Zealand has also advised the Ministry and Health Committee via submissions that

[3] **Ministry of Health, Departmental Report, 'Appendix 2 clause-by-clause analysis', p 135-136:**

https://www.parliament.nz/resource/en-NZ/53SCHE_ADV_130084_HE45252/382fc8c1370e14ef7652406cf71e0e41f5edf99a

timeframes can help them secure information from overseas parent companies in a timelier manner. This would be beneficial in a New Zealand context.

15. However, there are risks associated with the use of statutory timeframes. Streamlining or reducing approval timeframes can compromise the regulator's ability to effectively evaluate the safety, efficacy and quality of medical products.

16. The impact of timeframes on safety is a common topic in the literature on the effectiveness of statutory timeframes. Studies show that following the implementation of statutory timeframes, medicines approvals made close to the deadlines were linked with higher rates of post-marketing adverse events[4]. This suggests that prioritising speed to meet statutory timeframes may rush assessment and have negative consequences for the regulation of medical products.

17. Another unintended consequence of statutory timeframes is that the regulator may reprioritise resources and shift focus to meet these timeframes at the expense of other activities that do not have timeframes, but might be considered more important (eg, post market activities). Likewise, if a company doesn't resolve any outstanding issues by the set timeframe, the application will be rejected. In other countries this leads to withdrawal prior to decision to avoid the obligation to inform global markets that they have received a decision of rejection. This is an inefficient process.

18. These risks can be mitigated if timeframes are set within reference to international practices, resourcing and behaviour by applicants (see below). Likewise, timeframes may be able to decrease over time as processes become familiar, additional efficiencies are realised, and applicants and the regulator understand their respective responsibilities. Ensuring these factors can be accommodated strongly supports putting detail in secondary legislation rather than primary legislation.

Potential 'gaming' of timeframes and stop-clocks by industry/applicants or the regulator

19. There is potential for industry to game timeframes by lodging defective or incomplete applications and then complaining that the deadline was not met. To prevent this, decision makers need to have the ability to 'stop-the-clock' while they request more information from applicants. If coupled with a power to lapse applications if requested information is not received in time, stop-clocks can provide a further incentive to applicants to obtain and provide the requested information expeditiously.

20. However, there are risks in adopting stop-clock mechanisms, if they incentivise a decision-maker to avoid missing a deadline by asking for information late in the process or asking for information that is not genuinely required to reach a decision.

21. A New Zealand report in 2022[5] showed that the building sector had concerns that the consenting authority were managing their workloads to meet the statutory timeframes by issuing 'Requests For Information' late in the process (just before the timeframe is due) to stop the clock. On the other hand, the consenting authority felt that applicants

[4] **Cherla A, Davis C, Mossialos E, Naci H. Faster UK drug approvals by relying on other countries *BMJ* 2023; 381 :p 739 doi:10.1136/bmj.p739.**

[5] **https://www.mbie.govt.nz/building-and-energy/building/building-system-insights-programme/evaluation-of-the-building-consent-system**

were submitting poor quality or incomplete applications and then blaming the regulator for delays when reporting back to their clients.

22. Setting out statutory timeframe provisions in secondary legislation allows operational detail to be clearly outlined. It also enables engagement with the sector to ensure appropriate timeframes and tools for implementation such as stop-clocks.

Statutory timeframes can be useful when employed appropriately

23. Overall, the literature has found that, while statutory timeframes are successful at reducing the time spent making a decision (ie, approving a medical product application), they can increase the variance of decision making and increase the error rate in decision making[6].

24. Nonetheless, when used appropriately, statutory timeframes can be useful to focus applicants on submitting complete applications for approval of their product as eligibility for a time-limited evaluation process may be conditional on the completeness of the initial application. On balance, and with the safeguards suggested above, we recommend that, in general, the Bill enable statutory timeframes to be set in secondary legislation. This would be consistent with the Government's focus on ensuring timely access to medicines.

25. Likewise, practical realities support the inclusion of a stop-clock mechanism, and we recommend that they apply to all statutory timeframes. Risks arising from decision-maker behaviour can be addressed through performance reporting, where more nuanced detail can be obtained (eg, showing how many times the clock was stopped and how frequently decision-makers went back to applicants for further information).

Aside from new statutory timeframes, the Medical Products Bill will promote efficiency and timely decision making

26. Many components of the Medical Products Bill will significantly improve the efficiency of medical product approval, contributing to timely access. For example, under the Medical Products Bill, Medsafe will rely on international decisions and information where appropriate to reduce approval times.

27. Moreover, the vast majority of medical devices will still have a fast pathway to market. Under the Medical Products Bill, low-risk medical devices will have automatic approval pathways, requiring only a declaration of conformance by applicants. This pathway will improve efficiency of product approval as there would be no assessment of applications. Instead they would be 'approved' upon receipt of a complete submission.

28. Administratively, many of Medsafe's existing programmes to streamline decision making will carry across to the new regime. Because the Bill will enable approval pathways to be developed via secondary legislation, it will be possible to retain the existing abbreviated approval pathway for new medicines.

[6] **The Downside of Deadlines, Daniel Carpenter and Justin Grimmer, February 7, 2009-**

https://dcarpenter.scholar.harvard.edu/files/dcarpenter/files/downside.pdf

Use of primary or secondary legislation to progress options for statutory timeframes

29. While statutory timeframes could be established in primary or secondary legislation, if Ministers sought to include statutory timeframes or legislative performance measures, we recommend these are included in secondary legislation. Having the timeframes established in regulations will enable flexibility. For example, the government could reduce timeframes if resources for the regulator are increased. It will also allow time for engagement with industry to establish appropriate timeframes and allow more operational detail – providing clarity to industry.

30. Approval processes that could have a statutory timeframe under the Medical Products Bill include approval of a new medicine/medical device or an application to undertake a controlled activity (eg, clinical trial application).

31. To be effective, statutory timeframes will need to be adhered to by industry, as well as decision makers. The Ministry will engage early with industry when developing statutory timeframes. We recommend starting to draft these regulations early so that stakeholders are aware of what is being proposed.

We recommend retaining one existing timeframe in primary legislation and deferring consideration of another

32. Under the Medicines Act 1981, a decision for a clinical trial application must be made within 45 days from date of application. Evidence from industry and Medsafe is that the existing process operate effectively, and that decisions are usually made in less than 45 days, without compromising the quality of decisions.

33. We have also considered how the proposed 30-day verification pathway for new medicines should be reflected in the Medical Products Bill. Under the Medicines Amendment Bill, a verification pathway for products approved by two or more overseas regulators will be established where a decision must be made within a timeframe specified in secondary legislation. Statements from Government indicate that this timeframe is likely to be 30 working days from date of application.

34. For eligible applications, the safety, quality and efficacy has been evaluated by a trusted, overseas regulator. Hence, enabling a 30 working day statutory timeframe for medicines considered under a verification pathway in the Medical Products Bill would provide certainty to industry and would not compromise an adequate evaluation of the product.

35. A Medicines Amendment Bill is under active consideration, so we are unable to make a recommendation at this stage with regards to the Medical Products Bill. When that process is concluded we will ensure that what is in the Medical Products Bill is consistent with that.

Approval of new medicines or medical devices

36. Under the Medical Products Bill, most low-risk medical devices will be authorised via a notification pathway, where the application would be automatically 'approved' following receipt of a complete submission. Approval times for this pathway would already be minimal. Hence, statutory timeframes for this approval process would provide no additional certainty or efficiency.

37. For applications for new medicines that are not eligible for the verification pathway, and higher-risk medical devices that are authorised through verification pathways and approval pathways, it is essential that assessment is at a measured pace and is not pressured, so as to not compromise the evaluation of safety, quality and efficacy. Introducing statutory timeframes for these types of approvals without the safeguards discussed above could risk adequate evaluation of medical products and potentially risk patient safety.

Consequences of not meeting statutory timeframes

38. There are multiple ways that statutory timeframes are implemented in the regulation of medical products internationally:

    a. A decision must be made within a specified number of days, or an application is deemed to be approved or refused. We do not recommend this option because:

        i. despite providing certainty for industry, this option could impede on the regulator's ability to adequately complete the assessment.

        ii. deemed approval, where the regulator had not made a decision within the specified timeframe, could result in gaming from industry and the submission of poor-quality applications and result in unsafe products entering the market.

        iii. deemed refusal would create an unintended barrier to industry seeking to bringing new medicines to New Zealand. This is because the cost and effort of submitting an application would be 'wasted' if the application was deemed to be refused. It is not guaranteed that a sponsor would apply again, meaning a medicine may remain unapproved and unavailable for routine clinical use.[7]

    b. A decision must be made within a specified number of days, or a fee/cost associated with the application is waived or reduced (adopted by the Australian TGA and New Zealand's Resource Consent Application process)

        i. by compensating fees for industry, this option still allows the regulator to complete the assessment if the timeframe is exceeded.

        ii. there are financial implications of this option for the regulator and, potentially, the Crown if it is required to cover any shortfall in operating costs. As such, refunds should be limited to certain applications only and take into account the actions and inactions of both applicant and the regulator.

    c. A regulatory agency must report frequently and publicly on how many applications are approved within specific periods of time (ie, performance reporting)

        i. This option could be adopted alongside (a) and (b), rather than alone, as it is unclear what happens if a deadline is missed.

39. We recommend that any statutory timeframes under the Medical Products Bill should follow that of 38 (b) and (c) above, the same approach that the Australian TGA adopts.

[7] **Automatic deemed refusal is different from allowing the regulator to 'lapse' an application where an applicant has not taken any further or necessary steps to progress their application. In this case, the regulator would attempt to engage with the sponsor and the refusal would not be automatic.**

This option has the clearest consequence of not meeting the timeframe and to keep decision makers accountable, compared to the other options.

40. To encourage applicants/industry to submit complete applications, we also recommend using stop-clocks. As to mitigate the risks associated with stop-clocks, the requirements that allow the clock to be stopped should be clearly set out in secondary legislation and be established in a way that prevents gaming of the system.

Financial implications

41. It is expected that there will be no new financial implications of retaining the 30-working day verification timeframe and the 45 days clinical trial decision timeframe.

42. If statutory timeframes are implemented for other processes, this would require additional resources to ensure timeframes are practical. Resourcing for the Medical Products Bill and future regulatory regime will be considered by Cabinet later in 2025, and the specific implications of timeframes would be part of setting regulations under the Bill, including cost recovery regulations.

Equity

43. We do not expect the policy in this briefing to have any significant equity impacts within New Zealand.

Next steps

44. As noted above, you are due to report back to SOU on matters including statutory timeframes under the Medical Products Bill. We recommend that you present a combined paper on statutory timeframes and other matters.

45. If we are informed of your preferred policy direction by 13 June 2025, agency and Ministerial consultation can be carried out in time for the paper to be considered by Cabinet by the end of July 2025.

ENDS.