Regulatory Impact Statement: Innovative medical products and regulatory pathways to market

Decision sought	Seeking initial Cabinet decisions on the regulatory settings under the Medical Products Bill for: • regulatory pathways for innovative medical products (medicines and medical devices) and; • the regulation of software and artificial intelligence intended for a therapeutic purpose.
Agency responsible	Ministry of Health
Proposing Ministers	Hon Casey Costello, Associate Minister of Health
Date finalised	23 June 2025

As part of the development of the Medical Products Bill (the Bill), these proposals will provide clear, risk-proportionate, efficient and internationally harmonised regulatory pathways for:

- innovative medical products (through regulatory and financial incentives to encourage product development and access for patients in New Zealand), and
- software and artificial intelligence intended for a therapeutic purpose (software-as-a-medical device).

Summary: Problem definition and options

What is the policy problem?

Delivering better health outcomes requires access to innovative medical products, including software-as-a-medical device (SaMD). Without a suitable regulatory framework and flexible regulatory approaches that keep pace with innovation, access to innovative products will be difficult; patients, healthcare providers and purchasers will struggle to make informed decisions; and industry will face unnecessary barriers.

The Bill needs a regulatory framework designed for SaMD -which includes clinical decision support tools and AI-based diagnostics. SaMD is an emerging technology and is an increasingly important component of health care delivery, being used to screen for conditions, support diagnosis and guide treatment selection or deliver therapy. New Zealand does not currently require adverse event reporting for SaMD, meaning there is limited domestic data on harm. However, a growing body of international evidence shows that SaMD can cause patient harm due to algorithmic error, bias, poor clinical validation and inappropriate clinical use, for example in Australia over 20% of all medical device recalls from 2015 – 2020 were due to software faults. Without clear and internationally aligned

regulation for SaMD, these products will be able to enter the NZ market and be used in health care without any requirement to demonstrate safety or clinical performance. There will also be no mechanism to monitor or respond to safety issues, software failures or biases – even where these products directly influence clinical decisions.

What is the policy objective?

The core objective for regulation of innovative products is to support New Zealanders to have timely access to innovative medical products which meet acceptable standards of safety, quality and efficacy/performance.

The intended outcomes of this change are to:

- improve approval times for innovative medical products, particularly those addressing gaps in available treatments, in a way which still protects patients.
- align with international standards and approaches to innovative medical products that provide appropriate protection for patients, enabling faster approvals of products approved overseas and more efficient access to global markets for local manufacturers.
- have flexible and adaptable regulation that keeps pace with new technologies.
- support and incentivise manufacturers of innovative products to develop and market those products in New Zealand.

What policy options have been considered, including any alternatives to regulation?

Cabinet has already agreed to regulate the products covered in this RIS, so the option of no regulation has not been considered [SOU-24-MIN-0115].

<u>Problem A: Regulatory pathways for innovative medical products</u>

The options in this section have two parts.

A1 addresses regulatory settings and pathways for innovative medical products, particularly those that address gaps in available treatments. The options considered are:

- A1.1 The counterfactual – no flexible assessment provisions or financial incentives.
- A1.2 Enabling pathways and incentives for eligible innovative medical products (**preferred**) – flexibility in the assessment and market authorisation process (including enabling priority reviews, rolling reviews and conditional approvals) and financial incentives in the form of fee waivers and reductions.

A2 addresses regulatory approaches that accommodate emerging technologies. The options considered are:

- A2.1 The counterfactual – no regulatory support programmes, pilot programmes for approval pathways or joint working groups.
- A2.2 Enabling regulatory approaches that accommodate emerging technologies (**preferred**) – structured regulatory support programmes, pilot programmes ('regulatory sandboxes') and joint working groups.

<u>Problem B: Regulatory settings for Software-as-a-Medical Device (SaMD)</u>

B1 looks at options for the high-level settings for regulating SaMD:

- B1.1 The counterfactual – SaMD will be regulated as a medical device but with no internationally harmonised definitions or product-specific pathways.
- B1.2 Exclude low-risk SaMD from pre-market authorisation requirements; regulate medium–high-risk SaMD in line with international definitions and approval pathways.
- B1.3 Pre-market authorisation required for all SaMD; enabling risk-based approval pathways such as self-declaration pathways for low-risk SaMD, as with other medical devices (**preferred**).

What consultation has been undertaken?

This analysis has been informed by significant engagement over the past 30 years, including as part of Parliament's consideration of the Therapeutic Products Bill which received

submissions on the matters covered in this RIS. Recent consultation has focused on targeted engagement with key stakeholders in the medical product industry and government. As a result, the views of stakeholders are well known and have been taken into consideration for this analysis.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?
Yes.

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

The costs outlined below are based on time and effort incurred by organisations. It is not possible to provide monetised costs as they are completely dependent on the number of applications for products that will be made under the new regime, and whether time and effort savings or costs will affect product pricing.

Regulatory pathways for innovative medical products

- **Patients:** No increased costs expected.
- **Regulator:** Increased costs associated administering regulatory support programmes, pilot programmes and assessment of eligibility for innovation pathways. Increased work associated with enhanced post-market monitoring.
- **Crown:** Increased costs from fee reductions and waivers for eligible products. Increased costs to cover the regulators costs of administering regulatory support programmes.
- **Industry:** No additional cost impacts expected through implementing this policy.
- **Healthcare providers:** No cost impact expected.

Software-as-a-medical device

- **Patients:** Some costs of compliance expected to be passed on to consumers.
- **Regulator:** Higher costs associated with regulation and compliance activities to be recovered through industry fees.
  Crown: No cost impacted expected.
- **Industry:** Cost of assessment. Manufacturers not complying with current standards will have higher costs from compliance.
- **Healthcare providers:** No cost impact expected.

Benefits (Core information)

Regulatory pathways for innovative medical products

- **Patients:** direct benefits of improved access to innovative medical products, particularly for people lacking available treatments and with rare disorders. Remote monitoring through digital health technologies to reduce travel and cost burdens, particularly for rural communities.
- **The regulator:** improved efficiencies, adaptability and learning in evaluating innovative medical products.
- **Healthcare providers:** improved information on the risks and benefits of innovative medical products. Time and effort saved by providing robust regulatory assurance of safety and efficacy of innovative products.
- **Crown:** Increased access to innovative medical products may increase procurement costs through having more products available. However, the use of innovative medical products may overall reduce the overall burden of cost on the health system for managing long-term and serious health conditions, through better diagnosis, management and treatments.

- **Industry**: Time and money saved through greater clarity and information on the pathways to approval, and regulatory support to meet requirements. Possibility of financial incentives for eligible developers and small and medium sized companies, lower barriers to commercialisation. Alignment with international requirements improves exports.

Software-as-a-medical device

These benefits are relative to the counterfactual of SaMD being regulated in the same way as other medical devices.

- **Patients:** improved access to high-quality therapeutic software. Reduced harm from unsafe (including privacy and security harms) or ineffective therapeutic software.
- **The regulator:** improved efficiencies in the approval process through alignment with international definitions and standards and recognising international approvals.
- **Crown:** greater clarity on safety and efficacy of therapeutic software, may allow better prioritisation of health funding.
- **Healthcare providers:** improved information on the availability, and risks and benefits, of digital therapeutics. Efficiencies gained from enabled remote monitoring of patients, allowing better allocation of time and efforts.
- **Industry**: greater clarity through improved alignment with international requirements, reduced duplication of efforts due to reliance pathways, and decreased cost for applications via notification or reliance pathways. Improved access to global markets for local innovators through alignment with international requirements.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

Yes

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

Implementing this proposal will require several years to enable a smooth transition period, in addition to the time needed to develop secondary legislation. The Medical Products Bill is anticipated to be introduced in 2026, with a go-live date of late 2030, with further time to allow for transition to the new regime. The Ministry of Health will implement the new regulatory regime. Options on the form of the medical products regulator is yet to be considered by Cabinet.

As with all new regulatory systems, there is a risk of time and cost over-runs. To minimise these risks, there are lessons that can be applied from its existing system for authorising innovative medicines like gene therapies, including gaps and challenges in the existing system. We can also learn from the implementation of SaMD regulation and similar innovation programmes in other countries.

Limitations and Constraints on Analysis

There are no significant limitations or constraints on this analysis, other than previous Cabinet decisions. There has been extensive prior policy development and stakeholder engagement on how to best foster innovation in New Zealand, including through the development of the Therapeutic Products Act 2023 (TPA). While there has been limited time to assess new evidence or test policies which differ significantly from both the status quo and the TPA, proposals considered in this analysis have been circulated to relevant government agencies and Crown Research Institutes.

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Responsible Manager(s) signature:
Tim Vines
Manager, Therapeutics
23 June 2025

Quality Assurance Statement	
Reviewing Agency: Ministry of Health QA panel	**QA rating:** Meets
Panel Comment: The Impact Statement is clear, concise, consulted, complete 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. In September 2024, Cabinet agreed to replace the Medicines Act 1981 with modern regulation of medicines and medical devices under a Medical Products Bill (the Bill) [SOU-24-MIN-0115]. It also agreed that the overarching principles of the Bill should express the ideas that the regulatory system should support innovation, competition, economic growth, and exports in a way that maintains New Zealand's reputation as a producer of high-quality products.
2. This analysis focuses on two key approaches to supporting innovation under the Medical Products Bill:
    a. Regulatory pathways for innovative medical products (**Problem A**) and,
    b. Regulatory settings for Software-as a-medical-device (**Problem B**).

Problem A: Regulatory pathways for innovative products

What are innovative medical products?

3. Innovative medicines and medical devices are new medical products that use novel technologies or active ingredients, show significant advancements over existing treatments, or offer improved outcomes, precision or personalisation.
4. Innovative medical products can enable earlier detection and treatment of illness, improved outcomes, fewer side effects, and more personalised and efficient medical products and healthcare delivery.
5. However, these products may not fit neatly within existing regulatory systems due to their unique nature, complexity, or novel mechanisms.

What do regulatory pathways for innovative medical products achieve?

6. The goal of pathways to market for innovative medical products ('innovation pathways') is to reduce barriers that innovators face when addressing complex medical problems or conditions requiring advanced therapeutic solutions, by aligning commercial and regulatory incentives with health priorities.
7. The ability to make new pathways to market that are tailored to particular products is an important element of appropriate regulation of emerging technologies. Cabinet has made decisions that enable the creation of new pathways to market [SOU-24-MIN-0115]. Cabinet has also agreed to the Bill including reliance pathways for medicines and medical devices, which would accelerate local approval of new and innovative medical products approved by trusted jurisdictions.
8. For medical products that are locally manufactured and cannot demonstrate safety, efficacy and quality through reliance pathways, further settings are required to encourage and support their development.
9. From a regulatory perspective, there is a distinction between regulatory pathways for innovative medical products that:

    a. address gaps in available treatments, and

    b. accommodate emerging technologies.

10. While both categories of innovation require regulatory flexibility, their pathways differ in purpose and execution. Pathways and incentives for products that address gaps in available treatments should prioritise efficient access for patients through flexible assessment criteria, whereas pathways that accommodate emerging technologies prioritise adaptability in assessment and product standards.
11. Accelerating access to innovative medical products can help address unmet needs for populations without currently available treatments and drive advancements in medical practice, contributing to overall public health improvements.
12. The Medical Products Bill must anticipate new types of medical products which have not yet been conceived, just as Artificial Intelligence (AI) only existed in science fiction in 1981 when the Medicines Act came into force.
13. Legislation that can be flexibly applied by the regulator, ensures that regulatory decisions keep pace with scientific advancements and emerging technologies without requiring constant legislative changes, which can be slow. This helps reduce inefficiencies and bottlenecks in the approval process. Furthermore, adaptable legislation – such as provisions enabling regulators to alter assessment criteria, pilot new approval pathways, establish new approval pathways and expedite review - ensures that frameworks remain relevant over time. Therefore, legislative flexibility is crucial for supporting patient access to breakthrough treatments while maintaining appropriate safety, quality and efficacy/performance standards.

Why are conventional regulatory pathways not appropriate for innovative medical products?

14. Conventional regulatory pathways for medical products are structured processes designed to ensure the safety, quality and efficacy/performance of medical products before they reach the market. These pathways rely on comprehensive and specific pre-market evidence, often requiring extensive clinical trials for medicines and clinical investigations for medical devices. These pathways are not appropriate for some innovative products because the requirements may not be appropriate for a particular

technology, or do not allow for exemptions to certain requirements that are otherwise clinically or scientifically justified.

15. A rigid regulatory framework like the Medicines Act, creates barriers to market, delays patient access to beneficial technologies, and stifles innovation.
16. Products which address **rare conditions** or a small population are less likely to deliver a return on investment, due to the small market for the product. Expensive and time-consuming regulatory processes can increase the disincentives to develop treatments for rare conditions and introduce them to small markets such as New Zealand.
17. Medical technology is constantly evolving and offering new ways to diagnose, treat and manage diseases. However, rapid evolution of **emerging technologies** presents regulatory challenges, as conventional frameworks are designed for more static products with predictable development processes. To keep pace with innovation while maintaining safety, quality and efficacy of medical products, regulators are increasingly using adaptive and forward-looking approaches that support technological progress without compromising public health (see below).
18. One of the key challenges is ensuring regulations are adaptable in an environment where products may evolve continuously, integrating new data, functionalities or methodologies over time. In order for the Bill to future-proof itself, it must anticipate these changes and embed flexibility that allows assessment processes to adapt to the changing environment, including enabling most of the detail of the regulatory regime to be set out in secondary legislation.

What are international approaches to encouraging innovation?

19. To encourage the development and approval of innovative medical products, international regulators have 'innovation pathways' which are designed to expedite and encourage the development and approval of medical products that meet certain criteria, such as addressing unmet clinical needs (eg, cancer treatments) and rare disorders (eg, cystic fibrosis). Innovation pathways aim to bridge the gap between public health needs and market-driven research, encouraging investment in transformative technologies that might otherwise remain undeveloped.
20. Overseas regulators offer a variety of approval pathways for eligible innovative products. Examples of overseas approval pathways are provided in 'Box 1: Examples of innovation pathways established by overseas regulators' below. These pathways use one or a combination of the below approaches:
    a. **Prioritised review** – The regulator prioritises the review of products addressing life-threatening conditions or unmet clinical needs, with significant benefit over existing therapies.
    b. **Altered assessment structure** – Approvals based on exemptions to some evidence requirements, surrogate endpoints[1] for clinical evidence, rolling reviews[2] or accepting preliminary evidence followed by confirmatory trials.
    c. **Conditional market authorisation** - Temporary approval based on limited data for unmet clinical needs, with post-market obligations to provide more data.
    d. **Financial incentives** – reducing the financial burden for companies applying for market authorisation, particularly small and medium sized enterprises. For example, fee waivers or reductions.

[1] **Surrogate endpoints** - measurable marker or indicator used in clinical trials as a substitute for a clinical endpoint eg, reduction in blood pressure (surrogate) to predict effect of reducing heart attack or stroke (clinical endpoint).

[2] **Rolling review -** where the evidence is evaluated by the regulator as it is generated by the applicant

21. Overseas regulators are increasingly turning to new assessment approaches that accommodate emerging technologies:
    a. **Regulatory support** – Programmes where eligible companies receive guidance and assistance from the regulator during product development. Enhanced communication between the company and regulator ensures that regulatory requirements are understood early on in development. This helps companies avoid delays, improve the quality of their applications, and bring safe, effective products to the market faster.
    b. **Regulatory sandboxes** – A regulatory sandbox is a tool allowing companies to explore new and innovative products in real world conditions under a regulator's supervision. They can be seen as a pilot programme for new regulatory pathways. Regulatory sandboxes provide innovators with incentives to test their products in a controlled environment and allows regulators to better understand the technology. They allow companies to work closely with regulators to test their products in real-world settings while ensuring safety and compliance. They can speed up innovation by identifying potential issues early and adjusting regulations as needed.
22. Not all innovative medical products are appropriate for 'innovation pathways', when considering the benefits and risks of any given product. Some approaches inherently involve accepting some uncertainty due to limited long-term data. For severe medical conditions with no other treatment options, such as cancers and rare disorders, this risk may be justified. For existing conditions with alternative therapies available, the risk-benefit ratio may be more suited to a conventional regulatory pathway.
23. For this reason, innovation pathways will be limited to medical products that meet eligibility criteria that will be considered in the development of secondary legislation. Eligibility criteria may include limiting innovation pathways to medical products that address unmet clinical needs or rare disorders.

Box 1: Examples of innovation pathways established by overseas regulators

Accelerated Approval pathway (USA, FDA) – Allows faster approval of medicines that treat serious conditions, and fill an unmet medical need, based on surrogate endpoints. If the confirmatory trial shows that the medicine actually provides a clinical benefit, then the FDA grants conventional approval for the medicine.

Conditional Marketing Authorisation (EU, EMA) - conditional marketing authorisation may be granted for medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data is still required. Medicines for human use are eligible if they are intended for treating, preventing or diagnosing seriously debilitating or life-threatening diseases. This includes treatments for rare disorders. Conditional marketing authorisation is for a one-year period and the sponsor musty fulfil certain obligations within specified timelines.

Fast track designation (USA, FDA) - A medicine that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure appropriate data is collected.
- More frequent written communication from FDA about clinical trial design
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.

- Rolling Review, which means that a medicine company can submit completed sections of its for review by FDA, rather than waiting until every section of the application is completed.

Humanitarian Device Exemption (USA, FDA) - a regulatory pathway for medical devices intended for diseases or conditions that affect small (rare) populations. An HDE is exempt from the effectiveness requirements and is subject to certain profit and use restrictions.

Innovative Device Access Pathway (UK - MHRA) - A pilot programme designed to offer regulatory support to accelerate the development of innovative medical devices that meet an unmet clinical need. The aim of IDAP is to enable and improve patient access to innovative and transformative medical devices by providing an integrated and enhanced regulatory and access pathway to developers.

AI Airlock: the regulatory sandbox for AI as a Medical Device (UK - MHRA) - a regulator-monitored virtual area for developers to generate robust evidence for their AI digital therapeutics. It is a partnership between government, regulators and industry which allows advanced AI technology used in healthcare settings, with strict safety controls, ahead of navigating regulatory approval. It is intended to support innovators to work within the current regulatory system, identify where their products need to build more evidence needed for a safety and efficacy assessment and help resolve these issues.

Previous Government decisions

24. Cabinet decided in September 2024 that the Bill should enable approval pathways for medical devices and provide appropriate pathways innovative devices and locally manufactured devices [SOU-24-MIN-0115].
25. Further decisions are required to enable specific approaches to 'supporting innovation competition, economic growth, and exports in a way that maintains New Zealand's reputation as a producer of high-quality products.'

Status quo

26. The Medicines Act's approval pathways were designed for conventional pharmaceutical medicines. Some innovative medicines which do not fit those pathways are unable to be approved. They are either not supplied in New Zealand, or supplied as unapproved medicines with effectively no quality, safety or efficacy requirements.
27. Some innovative medicines do have a pathway to approval, but it is not fit-for-product. For example, personalised medicines such as CAR-T cell therapies for cancer must be approved for individual patients, as each finished product is unique.
28. The Medicines Act therefore both under-regulates and over-regulates innovative medicines.
29. Medical devices have no market authorisation requirement under the Medicines Act. Devices can be supplied in New Zealand via a simple notification to the Web-Assisted Notification of Devices Database, which does not involve any assessment of safety, quality or efficacy/performance.
30. There are essentially no barriers to market for medical devices. While this enables access to innovative medical devices, the status quo poses significant risks as there are no controls over their safety, quality and performance.
31. It is not feasible for consumers and health professionals to establish the safety, quality or efficacy/performance of innovative medical products such as gene therapies and AI for themselves; and unsafe, low quality and/or ineffective medical products can cause death and other serious harm. Ensuring the correct and effective use of innovative medical

products that meet quality and safety standards involves complex considerations that are difficult for consumers and practitioners to identify and resolve.

32. The regulatory framework for medicines and medical devices is not the only barrier for manufacturers to supply innovative medical products in New Zealand. The relatively small size of the New Zealand market makes it a less attractive place for innovators to market their products because the return on investment may not justify the costs of product development, securing Pharmac funding, and establishing local distribution.
33. This also applies to New Zealand based innovators (such as Toku, a medical device company that has developed an AI-powered cardiovascular health assessment tool based on retinal images) who prioritise larger, well-regulated markets such as the United States of America and European Union, where regulatory approvals unlock access to broader patient populations, global markets and larger revenue streams. Without strong regulatory and other financial incentives, a small market like New Zealand is often overlooked in favour of other jurisdictions.
34. *A Decade of Modern Medicines: An International Comparison*[3] produced in 2021, shows New Zealand ranks last out of 20 comparable OECD countries for publicly funded access to modern medicines to treat a range of diseases between 2011 and 2020.

How is the status quo expected to develop? (Counterfactual)

35. Cabinet have agreed that the Bill will provide appropriate pathways for innovative devices and locally manufactured devices. This decision does not enable exemptions to evidence requirements and application fees, in line with international approaches, so further decisions are being sought. Cabinet has not specifically agreed to appropriate pathways for innovative medicines; this analysis assumes that this is Cabinet's intent, and that this will be confirmed.
36. The status quo under the Medicines Act would be replaced through the introduction of the Medical Products Bill. Without specific provisions in the Bill enabling regulatory mechanisms to support timely access to innovative medical products, the regulatory regime would maintain a more conventional approach to regulation, without incentives and adapted requirements.
37. With rigid evaluation processes the regulator will not be able to adapt evidence requirements for medical products in cases where it is justified and still meets an appropriate benefit to risk ratio. For instance, a new treatment for a cancer that doesn't have alternative treatments available - the new treatment may show promising early results but does not yet have the full suite of clinical data available for approval would not be able to be approved until all of the data have been generated.
38. Innovation may be stifled, delaying patient access to breakthrough medical products. Without flexible regulatory pathways, innovators will face unnecessary barriers, reducing competition, slowing commercialisation and limiting export potential.
39. The Bill would not have adaptive regulatory approaches used in other countries (such as altered assessment structures, conditional approvals and pilot programmes for regulatory pathways ('regulatory sandboxes') or financial incentives. Without these features the Bill cannot support fast market entry for innovative medical products when otherwise justified, especially those made in New Zealand that do not have overseas approvals. Patients therefore miss out on access to products and reliable information. Local manufacturers and innovators will miss out on commercialisation incentives to

[3] IQVIA_Report_-_A_Decade_of_Modern_Medicines_An_International_Comparison_2011-2020__FINAL_.pdf

develop treatment for unmet needs, and the opportunity to strengthen New Zealand's position in medical innovation.

Problem B: Regulatory settings for Software-as-a-Medical Device

What is Software-as-a-Medical Device?

40. Internationally, some software is regulated as a medical device when that software performs a medical function – such as diagnosis, treatment, prevention, monitoring or alleviating a disease – without being part of a physical medical device. it is called **Software-as-a-Medical Device (SaMD)**.
41. SaMD includes uses of Artificial Intelligence (AI) when used for a therapeutic purpose. SaMD also includes phone apps that analyse patient data to support diagnoses (eg, melanoma detection apps), AI software that detect anomalies in medical imaging that are not detectable to the human eye, and software that monitors chronic conditions in real-time.
42. International definitions of SaMD do not capture all uses of software and AI in healthcare (eg, it does not include general software used in clinical practice such as AI note taking software). SaMD also does not include software that helps to run a physical medical device (termed software-in-a-medical device – SiMD) which is assessed as part of a physical medical device during regulatory evaluation.
43. SaMD is transforming clinical practice by enabling precision healthcare, personalisation and improved outcomes. However, software products differ significantly from conventional medical devices and pose unique regulatory challenges.
44. Unlike conventional physical medical devices, SaMD products can be continuously updated or modified and may rely on data from various sources, including wearable devices and electronic health records. Key considerations for SaMD compared to other medical devices include data security, transparency of development processes, validation of clinical efficacy and the management of updates or changes that could impact performance. The nature of SaMD allows it to be highly adaptable and responsive to patient needs, but also introduces risks such as cybersecurity vulnerabilities and issues with data integrity.

What are the benefits to regulating Software-as-a-Medical Device?

45. SaMD is becoming an increasingly important part of healthcare delivery and are being used to screen for conditions, support diagnosis, guide treatment decisions or even delivery therapy (eg, a digital cognitive behaviour therapy software).
46. Appropriate regulation of SaMD helps protect patients from potential risks such as incorrect diagnoses, data security vulnerabilities, and errors in treatment recommendations.
47. SaMD is still an emerging technology and New Zealand does not currently require adverse event reporting for SaMD, meaning there is limited domestic data on harm. However, a growing body of international evidence shows that SaMD can cause patient harm due to algorithmic error, bias, poor clinical validation and inappropriate clinical use.
48. An analysis of medical device recalls by the TGA in the five years to April 2020 showed that software defects were one of the most common reasons for hospital or retail level medical device recalls. Over 20 % of all device recalls in that period were due to software

faults – for example, this equated to 50 recalls in the six month period from 1 October 2019 to 1 April 2020[4].

49. Regulation of SaMD enables the prevention and detection of these risks through pre-market authorisation and post-market monitoring and reporting, enhancing patient safety and trust in digital therapeutics.
50. Beyond safety, regulating SaMD also supports health system efficiencies by establishing standards that enable integration of software into clinical workflows, reducing errors and improving the consistency of care.
51. SaMD has significant potential for enabling remote monitoring and access to healthcare, particularly for rural populations through real-time data collection and analysis. These capabilities support telemedicine, early diagnosis, and continuous patient management. For example, wearable devices that incorporate SaMD to monitor heart arrhythmias.
52. Regulatory oversight helps build trust in these new tools, allowing healthcare systems to fully leverage SaMD's potential for cost effective, data-driven and personalised healthcare delivery.

How is SaMD regulated internationally?

53. Due to the novelty and rapid evolution of SaMD, the way other countries regulate SaMD varies, which has created uncertainty for developers, healthcare professionals and patients. Some countries have risk-based classification systems for SaMD, while others are adapting conventional medical device rules to software.
54. There are international efforts to align regulation and establish best practices, ensuring that SaMD is safe, effective and accessible while reducing unnecessary barriers to innovation. The International Medical Device Regulators Forum (IMDRF) has developed high-level principles for SaMD regulation. Implementation of these principles is currently varied, but it is expected that approaches will harmonise over time as the technology becomes better understood and international working groups and forums, such as the IMDRF, refine their guidance.
55. SaMD is regulated under medical device frameworks according to risk level, which allows for low-risk device to self-certify compliance with applicable standards, or in some cases are exempt from certain requirements or regulation altogether.
56. Risk classifications for SaMD are based on the intended use of the information provided by the SaMD (whether it informs immediate, near-term or long-term clinical actions), and the healthcare situation or condition (critical, serious or non-serious).
57. To address the management of updates or changes that could impact performance of SaMD, some jurisdictions offer pre-certification schemes which allow for specified changes and updates to the software to be pre-approved, avoiding the need to frequent updates to be approved as they occur.
58. Some jurisdictions also offer regulatory sandbox initiatives which offer controlled regulatory environments to test products under real-world conditions and close regulator supervision (such as the UK AI-Airlock initiative).

Status quo

59. Under the Medicines Act, software that is used for a therapeutic purpose is classified as a medical device, and therefore not meaningfully regulated. Some companies have notified their SaMD products to the Web Assisted Notification of Devices database, but this does

[4] https://www.tga.gov.au/resources/publication/publications/actual-and-potential-harm-caused-medical-software

not provide any assurance of safety, quality or performance. It is highly likely that other SaMD products are being supplied to the New Zealand public without notification eg, smartphone apps that claim to diagnose melanomas.

How is the status quo expected to develop if no action is taken (counterfactual)?

60. Cabinet have agreed that the Bill will regulate medical devices. SaMD products meet the definition of medical device and would be required to comply with general medical device requirements unless a decision is made to treat them differently.
61. Regulations for general medical devices are designed for physical products, and focus on materials, manufacturing quality and fixed functionality. However, SaMD is digital, can evolve through regular updates and can rely on AI, making static pre-market approvals inappropriate. Manufacturing controls for physical devices emphasise material safety, whereas SaMD requires cybersecurity, software validation, and real-time monitoring. Applying conventional medical device regulations and product standards to SaMD could create unnecessary compliance burdens while failing to ensure patient safety.
62. In the medium term, exemptions from certain requirements or from market authorisation altogether may be necessary if legislation is not workable, to enable access to SaMD products. In this case, SaMD may continue to enter the New Zealand market without oversight, potentially resulting in the availability of unsafe, ineffective or substandard devices. This could lead to serious health risks for patients and undermine the credibility of digital health tools, as there would be no mechanism to ensure that products meet safety and performance standards. Healthcare professionals and patients would likely struggle to trust the performance and safety of SaMD, and be reluctant to adopt innovative technologies.
63. In the long term, the regulatory gaps would likely result in public health risks and a reactive approach to regulation. Reactive interventions could be more disruptive and costly than proactively setting a clear, risk-based regulatory framework. Additionally, as the market remains essentially unregulated in New Zealand, we will continue to fall further behind international standards, leading to regulatory isolation and potential exclusion from international working groups, which we would otherwise benefit from participation in and development of local expertise.

Previous government decisions

64. In September 2024, Cabinet agreed that the Bill should enable approval pathways for medical devices, similar to those for medicines, but suited to the nature and risk profile of each type of medical device, and providing:
    a. a self-declaration pathway for low-risk devices
    b. verification pathways for products already approved by trusted overseas regulators
    c. appropriate pathways for innovative devices and locally manufactured devices.
65. Decisions on the regulation for SaMD were deferred in the September decisions as they need specific consideration and are being sought now.

What is the policy problem or opportunity?

66. Cabinet has agreed to a Medical Products Bill to regulate medicines and medical devices and has made various decisions about regulating those products. Additional decisions are needed to ensure regulatory setting and pathways can effectively achieve the

objectives of supporting innovation and appropriate safety, quality and efficacy of innovative medical products.

Problem A: Regulatory pathways for innovative medical products

67. This policy problem consists of three main aspects:
    a. information problems,
    b. regulatory design, and
    c. market factors.

Information problems

68. Patients and healthcare professionals do not have the information, ability or time to adequately assess the risks and benefits of every innovative medical product. The assessments of medical products, particularly those using new technologies or manufacturing processes, are complex and require access to large amounts of data that is not publicly available. Without centralised regulatory approval processes, patients, healthcare professionals and purchasers are unable to make informed decisions on the use of innovative medical products or ensure they meet appropriate safety, quality and efficacy standards.
69. Furthermore, the medical products are constantly evolving and the number of products is increasing rapidly, so it is unrealistic to expect health professionals to maintain up to date knowledge of every innovative medical product available on the market.

Regulatory design

70. The design of legislation plays a crucial role in fostering innovation and ensuring timely access to innovative medical products. When legislation does not enable flexible and adaptable features such as altered assessments structures, conditional approvals, and regulatory support programmes, it risks creating rigid frameworks that are poorly suited to novel technologies.
71. Traditional regulatory frameworks, often designed for conventional pharmaceuticals and devices, can struggle to accommodate emerging innovations such as AI-driven diagnostics, gene therapies and digital health solutions. Without tailored mechanisms to assess and support these products, regulatory processes can become unnecessarily lengthy and burdensome. It would in turn delay patient access to potentially life-saving treatments and discourage investment in cutting-edge healthcare products.
72. A legislative framework that lacks flexibility can contribute to regulatory failure by misaligning outcomes with policy intent. The goal is to support innovation while ensuring patient safety and efficacy, but rigid legislation can stifle innovation by applying broad requirements to novel products. For example, requiring full traditional clinical data for AI-driven diagnostics, rather than allowing iterative validation using real-world evidence, could slow adoption and limit patient benefits.
73. Similarly, the absence of regulatory sandboxes, regulatory support programmes or joint working group may prevent collaboration between regulators, industry and healthcare providers. This could lead to inefficiencies and missed opportunities to refine regulatory approaches.
74. To truly support innovation and access, legislation must be designed to accommodate emerging technologies and provide structured but adaptable pathways that align with both public health needs and technological advancements.

Supporting local industry

75. Legislation that does not provide for the approaches mentioned above can create barriers to innovators, limiting competition, economic growth and export potential for local innovators. Without structured engagement programmes, smaller companies and

startups may struggle to navigate complex regulatory requirements, reducing opportunities for market entry and innovation.

76. Rigid or overly burdensome approval processes can also discourage investment and delay the commercialisation of innovative medical products, putting domestic industries at a competitive disadvantage globally.
77. By embedding flexible regulatory pathways, regulatory support programmes and regulatory approaches, legislation can foster a dynamic research and development sector. Enabling clarity of requirements and collaboration through approaches like regulatory sandboxes, uncertainty and development costs can be reduced. Regulatory support and financial incentives could support small- and-medium sized enterprises, enabling them to compete alongside larger industry players.
78. Additionally, alignment with international regulatory frameworks through joint initiatives can streamline global market access, boosting exports and strengthening New Zealand's position as a leader in medical innovation.

Problem B: Regulatory settings for Software-as-a-Medical Device

79. This policy problem consists of two main aspects:
    a. Information problems, and
    b. Regulatory design.

Information problems

80. A lack of a clear regulatory framework for SaMD creates significant information gaps for patients, healthcare providers and purchasers. , making it difficult to assess the accuracy, performance and risks of these products. It would also hinder New Zealand's ability to detect and respond to harm, safety issues and biases, particularly in Māori and Pasifika populations who are more likely to be under-represented in datasets used to train SaMD.
81. Unlike traditional medical devices, SaMD often evolves rapidly through software updates and machine learning, meaning static approvals may not reflect ongoing changes to functionality and risk.
82. Additionally, healthcare providers may be unaware of the complexities of evaluating SaMD, including factors like data bias, interoperability with other systems and cybersecurity vulnerabilities.
83. This uncertainty could delay adoption, limit the effectiveness of the tools, and increase risks related to patient safety and data security. As the use of SaMD (such as AI-driven diagnostics, clinical decision support software, and remote monitoring tools) grows, a lack of clarity will continue to hinder safe and effective implementation.

Regulatory design

84. Without intervention, SaMD will be regulated as a medical device. Conventional medical device regulations are designed for physical products with fixed designs, making them unsuitable for SaMD which is dynamic and continuously evolving.
85. Without an internationally aligned framework for SaMD in the Bill, regulatory misalignment with global markets could create unnecessary barriers to market entry, discouraging investment and innovation in digital health. The absence of clear regulatory pathways may result in inconsistent oversight, leading to delays in access for patients.
86. Establishing a fit-for-purpose framework that accounts for SaMD's unique lifecycle, risk profile and need for ongoing regulatory engagement would ensure both patient safety and innovation are supported.

What objectives are sought in relation to the policy problem?

87. The main objective is that regulation of innovative products will support New Zealanders having timely access to innovative medical products which meet acceptable standards of safety, quality and efficacy.
88. Innovative medical products include products that address gaps in available treatments and rare disorders, as well as innovative products types such as SaMD and gene and cell therapies like CAR-T cells and gene editing.
89. A secondary objective is to support innovators and local manufacturers of innovative medical products from product development through to regulatory approval.
90. Incentives such as altered assessment structures may compete with the primary objective, whereby some product standards may be exempted. This will be mitigated by careful consideration of the benefits and risks in the assessment of individual innovative medical products, particularly in cases where there are no or limited alternative therapies available for a particular patient group.

What consultation has been undertaken?

91. This analysis has been informed by significant engagement over the past 30 years, including in the development of the Therapeutic Products Act 2023. 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. We have subsequently received further submissions on the TPA repeal Bill from stakeholders such as the New Zealand Blood Service.
92. Recent consultation has focused 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 under the Medical Products Bill.

Regulatory pathways for innovative products

93. In their submission on the TPB, Medicines New Zealand discussed the development of treatments for rare disorders and challenges to commercial feasibility when there are regulatory delays and the impact of application fees. They recommended that legislation should allow for the future inclusion of additional flexible accelerated market authorisation pathways consistent with other global regulators. They state that such pathways have the potential to meet an unmet clinical need for very serious or life-threatening conditions.
94. Fisher and Paykel Healthcare, a large New Zealand medical device manufacturer and innovator, expressed support through targeted engagement for regulatory support programmes, multiple pathways to market for innovative medical devices and regulation that is adaptable to new technologies.
95. The Mallaghan Institute of Medical Research, who are currently developing a CAR-T cell therapy for cancer, have expressed support for regulatory and reimbursement pathways, similar to the innovation pathways offered by the US Food and Drug Agency. They also support provisions enabling regulatory support programmes, rolling reviews of applications and accelerated and priority review of applications.
96. Medical Technology Association of New Zealand (MTANZ) and MedTechiQ identified during a Medical Technology Innovators event in 2024 that enabling regulatory support programmes under the Bill as the single most effective approach that can be taken for supporting innovation in New Zealand.

97. Relevant Government agencies were consulted in the development of the proposal in this analysis. They are generally supportive of the setting proposed for innovative medical products. The Ministry for Business Innovation and Employment (MBIE) and Callaghan Innovation are supportive of the approaches proposed to streamline access to innovative medical product, while ensuring appropriate safety and management of risks.

Software as a Medical Device

98. The Digital Health Association (DHA) supports greater regulatory oversight of software that is used on patients for therapeutic purposes (such as diagnosing, treating, preventing, or alleviating medical conditions). In their view, potential risks relating to that software should be able to be monitored and controlled via enhanced regulation. The DHA emphasise the importance of ensuring the definition of 'Software-as-a-Medical Device' is internationally harmonised and does not inadvertently capture software that does not undertake a therapeutic purpose.
99. In submissions on the TPB, MTANZ and several medical device companies also supported aligning the definition of 'Software-as-a-Medical Device' with international entities such as the World Health Organization and the International Medical Device Regulators Forum. They also recommended that the definition is placed in secondary legislation to enable greater flexibility and alignment with international organisations.
100. Consulted Government agencies support risk-proportionate regulation of software that undertakes a therapeutic function. The Office of the Privacy Commissioner strongly support the regulation of SaMD and a requirement for pre-market authorisation of SaMD medical devices. They see issues relating to privacy of New Zealand patients as a critical area of risk for medical products and SaMD in particular.
101. Pharmac and Te Whatu Ora support risk-proportionate regulation of SaMD. For SaMD and medical products in generally, Pharmac support clear regulatory oversight and approval processes that give confidence, as a public funder, that aspects such as quality and safety (in particular) have been assessed by the medical products regulator and are found to be of acceptable standards for the public.

Section 2: Assessing options to address the policy problem

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

102. The criteria are:

- **Protective**: will the option provide adequate assurance of safety, quality, and efficacy, and ensure that benefits associated with medicines and medical devices outweigh risks?
- **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 innovative medical products.
- **Fit for product**: will the option enable appropriate regulation of innovative and novel medical products?
- **Flexible**: Will the option enable legislation to keep pace with technological change, and offer options to adapt regulatory approvals while ensuring an appropriate risk-benefit ratio?

103. 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.

104. 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 innovative products in a way which does not take any more time or money than is necessary to achieve the objective.
105. 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 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.
106. The ‘flexible’ criterion is about the extent to which the option can adapt to different circumstances and future developments in best practice.
107. All four criteria will assess whether options will regulate innovative products 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 scope will options be considered within?

Problem A: Regulatory pathways for innovative medical products

108. Additional financial incentives such as research grants and tax credits which are offered in other jurisdictions, are out of scope as they are more appropriately addressed separately from regulation.
109. The option of not regulating innovative medical products is out of scope, as previous government decisions for the Medical Products Bill to cover medicines and medical devices exclude this option.

Problem B: Software-as-a-Medical Device

110. The option of not regulating SaMD is out of scope, for several reasons:
    a. Previous Government decisions for the Bill to cover medical devices, exclude this option.
    b. Exempting SaMD from medical device regulations would mean that software undertaking medical functions could evolve in New Zealand with little accountability. As these technologies often learn and adapt, they could develop in ways that result in incorrect diagnoses or treatments causing patient harm. It would also introduce unacceptable risks for patient data protection and privacy.
    c. There would be no mechanism to remove SaMD from the market in response to safety concerns.

111. The digital nature of these tools means they would be developed and supplied from overseas with ease, and without physical distribution networks or a New Zealand based legal representative. Recourse for harms may be complicated, and the responsible manufacturer may be outside of New Zealand’s legal jurisdiction. Regulating SaMD would enable a New Zealand based legal representative to be required.

112. The option of a regulatory system that focuses on post-market monitoring of SaMD with no pre-market requirements, has also been considered out of scope for the following reasons:
    a. This option would rely on industry self-regulation.
    b. The same issues as above in regard to recourse and jurisdiction.
    c. Issues with data protection and privacy will not be proactively managed.
    d. Does not meet the protective criterion.

What options are being considered?

113. This options analysis consists of three parts:
    - **Problem A**: How can the Medical Products Bill support innovation and access to innovative products?
    - **Problem B**: What regulatory controls should be set for Software that is used for a therapeutic purpose?

Problem A: Regulatory pathways for innovative products

114. This problem has two parts:
    - A1 addresses regulatory settings and pathways for innovative medical products, particularly those that address gaps in available treatments.
    - A2 addresses regulatory approaches that accommodate emerging technologies.

A1: What regulatory settings will support and incentivise innovative medical product developers to supply products in New Zealand?

115. This part analyses the high-level settings for pathways to market for innovative medicines and medical devices. The options are designed to facilitate efficient access to innovative medical products that show promise in addressing gaps in available treatments.
116. The options are:
    - Option A1.1 – Counterfactual
    - Option A1.2 - Enabling pathways and incentives for innovative medical products manufacturers to supply products in New Zealand.

Option A1.1 – Counterfactual

117. The counterfactual is described in detail in Section 1 Problem A: 'How is the status quo expected to develop? (Counterfactual)'. Under this option the status quo would be replaced under the Medical Products Bill. Without specific decisions on the inclusion of regulatory mechanisms to support timely access to innovative medical products, the regulatory regime would maintain a more conventional approach to regulation, without incentives and adapted requirements.
118. Under this option, pathways for innovative medical products would be enabled by previous Cabinet decisions but their effectiveness will be limited by an inability to use flexible assessment criteria (such as issue conditional approvals, accept iterative evidence (rolling reviews) or exempt certain requirements in a risk appropriate way).
119. The inflexibility of this option could delay access to new treatments, as applicants will be required to provide complete safety, efficacy and quality data which can take several years to produce. For patients that have life-threatening conditions with no available treatments, exemptions to data requirements that would otherwise be justified, would not be enabled under this option. Delays to approval can lead to patients seeking

treatment overseas or through clinical trials (if eligible), but many do not have the means or opportunities to seek other options.

Option A1.2 – Enabling flexible and adaptable assessment and financial incentives for innovative medical products

120. Under this option, innovative medical products will be eligible for more flexible assessments, regulatory support programmes and financial incentives.
121. Such pathways will be designed to encourage and incentivise manufacturers to apply for market authorisation in New Zealand, enhancing access to medical products for high-need populations.
122. The Bill would embed flexibility in the assessment and market authorisation process, including enabling priority reviews, rolling reviews and conditional approvals:
    a. **priority reviews**, the regulator may prioritise the review of applications for eligible medical products.
    b. **conditional approvals**, products may be granted early access through exemptions to certain evidence requirements, with enhanced post-market monitoring.
    c. **rolling reviews** allow the manufacturer to submit data to the regulator for review as it becomes available, rather than waiting for a complete data package, enabling faster assessment. Together, flexible assessment criteria facilitate a more dynamic evaluation of medical products in a manner that maintains an appropriate benefit-risk ratio of the medical product.
123. This option is particularly relevant for companies that may have promising early clinical results that show a significant improvement on existing treatments but may not yet have the full suite of data that would typically be expected for approval of a medical product.
124. This option also enables **financial incentives** such as fee waivers and fee reductions, with a focus on small- and medium-sized enterprises, in order to encourage applications for market authorisation.
125. Under this option, fees for applications for product evaluation, clinical trial assessment and regulatory support may be reduced or waived in their entirety. The cost of undertaking assessments by the regulator would need to be covered by crown funding.
126. All of the regulatory mechanisms enabled by this option may be offered in various combinations as pathways to market for innovative products, with differing objectives. They can be implemented to be similar to innovation pathways offered by overseas regulators. Examples are provided in **Box 1: Examples of innovation pathways established by** overseas regulators**.**
127. Under this option, conditional approvals and exemptions to certain data requirements may meet the protective criteria, by ensuring ongoing safety monitoring, while allowing early access for innovative products. However, enhanced safety monitoring compensates for the less comprehensive data being available at the time of approval, which could raise safety concerns. For severe conditions with no other therapeutic options, this risk can be justified.
128. This option meets the efficiency criteria, by offering rolling and priority reviews, time to market for innovative products may be substantially reduced, meaning innovative medical products are available to New Zealand patients faster. This option also meets the criteria for efficiency for industry stakeholders, as it would make it easier for them to navigate the regulatory process, thus increasing market efficiency. It would potentially be less efficient for the regulator as they would be investing time and resource into evaluations, which may not necessarily lead to direct or immediate improvements in access to innovative medical products.

129. By setting specific eligibility criteria for flexible approval pathways, such as limiting the pathways to medical products that address unmet clinical needs and rare disorders, this option meets the 'fit-for-product' criteria.
130. This option is also fit-for-product for eligible innovative medical products that face high development costs or lengthy approval processes, particularly in emerging fields. It also meets the flexible criteria in how incentives are applied as the settings for eligibility could be adjusted to target specific sectors or type of innovation.
131. Finally, this option is, by design, highly flexible and enables adjustments to assessment processes based on clinical need and the overall context of use when determining the overall benefit-risk ratio of a product.

How do the options compare to the counterfactual?

	Option A1.1 – Counterfactual	Option A1.2 – Enabling pathways and incentives for innovative medical products
Protective	0	0 There may be less comprehensive data being available at the time of approval which would reduce protection, but this would be compensated through enhanced safety monitoring and follow up trials.
Efficient	0	+ Time to market may be significantly reduced through efficient regulatory pathways, and easier navigation of regulatory requirements by industry. This option would be less efficient for the regulator through increased time and resource required to administer pathways and incentives.
Fit-for-product	0	+ Appropriate for products that use new technologies, and address gaps in available treatments and rare disorders. Eligibility criteria, set in secondary legislation, will ensure eligibility criteria is fit-for-product.
Flexible	0	++ This option is highly flexible, allowing adaptation of regulatory requirements according to clinical need and unique benefit-risk ratio of a particular product or technology.
Overall assessment	0	**+ 4**

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

132. Option A1.2 – 'Enabling pathways and incentives for innovative medical products' best addresses the problem compared to the counterfactual.
133. This option is more efficient, fit-for-product and flexible than option A1.1. They both offer the same level of protection.

Is the Minister's preferred option in the Cabinet paper the same as the agency's preferred option in the RIS?

134. Yes.

A2: What regulatory approaches can appropriately accommodate emerging technologies?

135. This part looks at the high-level settings for pathways to market for medical products that incorporate new or emerging technologies. The options are designed to be agile and forward thinking to adapt to emerging technologies, while maintaining appropriate safety and efficacy standards.
136. The options are:
    - **Option A2.1** - Counterfactual
    - **Option A2.2** – Enabling collaborative regulatory approaches.

Option A2.1 - Counterfactual

137. Under this option the status quo would be replaced under the Medical Products Bill. Without specific decisions on the inclusion of regulatory approaches to accommodate emerging technologies, the regulatory regime would maintain a more conventional approach to regulation, without adaptable and flexible requirements.
138. Regulatory sandboxes, which allow controlled real-world testing of innovative digital products, would be absent and regulatory issues with emerging digital technologies would need to be resolved through the conventional assessment process, which could create delays to approvals. There is also a lost opportunity to identify patient safety risks early within the regulatory sandbox.
139. Regulatory support programmes would also not be available to product developers to help them navigate regulatory requirements, which would create inefficiencies for industry and could delay approval processes. Without such support programmes, New Zealand based innovators will continue to seek regulatory support from overseas regulators (such as the Australian Therapeutic Goods Agency and the US Food and Drug Administration) or seek other advice on how to meet regulatory requirements.
140. This option is not flexible enough to achieve the objectives. While the medical products regulator may create new pathways to market under the Bill, there would be a missed opportunity to test and refine potential pathways through regulatory sandboxes, before amending secondary legislation.
141. This option is not fit-for-product as new technologies may arise that do not fit into existing regulatory pathways. There would be uncertainty for both the developers, as to what requirements should be met, and the medical products regulator as to how to ensure appropriate quality, safety and efficacy of a new technology. New pathways could be created by the regulator but this would delay time to approval and there would be little direct experience the regulator could draw on to ensure the new pathways are appropriately designed.

Option A2.2 - Enabling regulatory collaborative regulatory approaches

142. As medical products become more complicated and the state-of-the-art continues to progress rapidly, medical products regulators are turning to new regulatory approaches that enhance efficiencies in the assessment process and optimise the resources available to them.
143. Under this option, the following approaches will be enabled:
    - **'Regulatory sandboxes'** – A controlled regulatory environment which allows innovative products to be tested in a real-world setting under close regulatory oversight. They can be viewed as pilot programmes to evaluate new regulatory approval pathways. Regulatory sandboxes provide both industry and the regulator

real-time learning opportunities to assess a products performance, adapt regulatory processes and identify issues and challenges.

- **Tailored regulatory support** – Structured programmes with eligibility criteria that offer early and ongoing guidance to innovators, helping them navigate regulatory requirements and ensuring compliance through the development process.
- **Establishment of joint working groups** – Groups may be set up with other regulators in New Zealand (such as the new Gene Technology Regulator) to speed up consideration of application for new technologies that might require dual approval or regulators overseas (such as the International Medical Device Regulator Forum) to establish agreement to approaches internationally and problem solve regulatory issues related to emerging technologies.

144. This option meets the efficiency criteria, as regulatory sandboxes and support programmes provide both the regulator and developers opportunities for regulatory learning in a way that is mutually beneficial. It could speed up the development of digital products, while enhancing the regulators' ability to rapidly develop fit-for-product pathways for emerging technologies. Establishing joint working groups could also enhance efficiencies of the regulatory system through shared learning and coordination of efforts.
145. This option is significantly more flexible, as it enables the regulator to quickly adapt to new technologies by establishing a regulatory sandbox without amending legislation. It can then establish legislated pathways to market that are fit-for-product on the basis of the learnings from a regulatory sandbox.
146. This option is also more protective compared to the counterfactual as it enables closer regulatory oversight of new technologies. It also enables the regulator to better communicate best practice with product developers through regulatory support programmes, from clinical trials through to product approval. This would lead to better designed studies and adherence to appropriate standards of safety, quality and efficacy.

How do the options compare to the counterfactual?

	Option A2.1 –Counterfactual	Option A2.2 – Enabling regulatory approaches that accommodate emerging technologies
Protective	0	+ This enables closer regulatory oversight of new technologies. It also enables the regulator to better communicate best practice with product developers through regulatory support programmes. This would lead to better designed studies and adherence to appropriate standards of safety, quality and efficacy.
Efficient	0	+ Regulatory sandboxes and support programmes provide both the regulator and developers opportunities for regulatory learning in a way that is mutually beneficial.
Fit-for-product	0	++ It could speed up the development of digital products, while enhancing the regulators' ability to rapidly develop fit-for-product pathways for emerging technologies. It can then establish legislated pathways to market that are fit-for-product on the basis of the learnings from a regulatory sandbox.
Flexible	0	++ This option is significantly more flexible, as it enables the regulator to quickly adapt to new technologies by establishing a regulatory sandbox without amending legislation.
Overall assessment	0	**+ 6**

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

147. Option A2.2 – 'Enabling regulatory approaches that accommodate emerging technologies' best addresses the problem compared to the counterfactual.
148. This option is more efficient, fit-for-product, protective and flexible than option A2.1.

Is the Minister's preferred option in the Cabinet paper the same as the agency's preferred option in the RIS?

149. Yes.

What are the marginal costs and benefits of the preferred options to problems A1 and A2 in the Cabinet paper?

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			
Patients	No cost impact expected.	Low	Medium
Regulator	Increased costs associated with more work to administer regulatory support programmes, regulatory sandboxes and assessment of eligibility for applicants to innovation pathways. Increased work associated with enhanced post-market monitoring. This will be slightly offset by more efficient processes and altered assessment structures.	High	High
Crown	Increased costs through funding financial incentives for eligible innovators targeting unmet needs. Increased costs to support the	Medium	High

	regulator providing targeted regulatory support programmes. Costs to the Crown may be capped.		
Industry	Reduced costs through theransfer of regulatory costs in some instances from industry to the Crown.		High
Healthcare providers	No cost impact expected.		Medium
Total monetised costs		Medium	Medium
Non-monetised costs		Low	Medium
Additional benefits of the preferred option compared to taking no action			
Patients		High	High
Regulator	Learning, efficient updates and adaptability etc	High	Medium
Crown	Increasing access to innovative medical products reduces the overall burden of cost on the health system for managing long-term and serious health conditions.	Medium	High
Industry	Greater regulatory clarity and support to meet requirements. Financial incentives for eligible developers and small and medium sized companies should lower barriers to commercialisation. Improved access to global markets.	High	Medium
Healthcare providers	Regulatory approval improves available information on innovative medical products, saving time and effort.	Low	Low
Total monetised benefits		Low	Low
Non-monetised benefits		High	Medium

Problem B: Software-as-a-Medical Device

B1: What regulatory controls should be set for Software that is used for a therapeutic purpose?

150. This part looks at options for regulatory controls of Software-as-a-Medical Device (SaMD), and how best they can deliver the objectives.
151. The options are:
    a. **Option B1.1** - Counterfactual
    b. **Option B1.2** - Exempt low-risk SaMD from pre-market authorisation requirements
    c. **Option B1.3** - Pre-market authorisation for all SaMD

Option B1.1 - Counterfactual

152. This option is discussed in detail in Section 1. Without specific decisions on how SaMD is regulated, the status quo would be replaced under the Medical Products Bill. The Bill will likely capture many SaMD products by default, meaning they will be regulated as a medical device, but with no clear definitions or pathways to market that are appropriate for the products.
153. Applying conventional medical device regulations and product standards to SaMD could create unnecessary compliance burdens while failing to ensure patient safety. Over time the counterfactual could develop through exempting SaMD from product requirements or making reactive changes to legislation.
154. This option therefore does not meet the protective, fit-for-product, efficient or flexibility criteria.

Option B1.2 - Exclude low-risk SaMD from pre-market authorisation requirements

155. This option enables mandatory pre-market authorisation for medium- to high-risk SaMD imported into or supplied in New Zealand. High-risk SaMD would include software that performs diagnostic image analysis for making treatment decisions in patients with acute stroke.
156. Low-risk SaMD would specifically be excluded from regulatory requirements and pre-market authorisation. Low-risk SaMD could include a software that stores a patient's heart rate from a wearable device for a health care provider's later review.
157. This option focuses all regulatory effort on higher risk SaMD. Under this option, medium- and high-risk SaMD would be able to be approved via multiple regulatory pathways, including expedited reliance pathways based on approvals held in other jurisdictions, product-specific pathways for SaMD, and innovation pathways. This option provides flexibility for medium- to high- risks SaMD.
158. Completely excluding low-risk SaMD from regulation would reduce the regulator's ability to:
    a. ensure low-risk SaMD have appropriate assurances of safety, quality and efficacy (low-risk SaMD still have inherent risks and benefits to their use)
    b. have visibility of the entire medical device supply-chain, and
    c. respond to safety issues relating to adverse events in low-risk devices.
159. This option partially meets the fit-for-product criteria as regulation would be risk-proportionate and ensure that devices that pose more risks to patients and users are appropriately regulated and reduces the regulatory burden on suppliers of low-risk SaMD.
160. This option partially meets the efficient criteria by reducing the work needed to be undertaken by the regulator, compared to option B1.3. This is because it reduces the overall number of devices that would need to be registered by the regulator, however the

work to authorise low-risk devices is not intensive; under B1.3, low-risk medical devices can be authorised on the basis of self-declaration of compliance by the manufacturer.

161. The moderate efficiencies are countered by the potential effect of health system inefficiencies – healthcare providers and patients will not be able to determine whether a low-risk software that is claiming a therapeutic purpose, actually performs as it claims with any accuracy. This could lead to purchasing decisions that are not effective.
162. This option does not fully enable the safe use of SaMD as it does not provide a mechanism to ensure low-risk SaMD are meeting requirements of safety, efficacy/performance and quality. It would be excluding a portion of the SaMD market from regulatory controls. There is also a risk of suppliers incorrectly claiming their SaMd is low-risk when it isn't, to avoid regulatory compliance. This option therefore would partially meet the protection criteria, as medium and high-risk SaMD would be appropriately regulated. Low-risk SaMD which may be ineffective or unsafe, may be supplied in New Zealand with few barriers to market, and difficulties in removing.

Option B1.3 – Pre-market authorisation for all SaMD

163. This option requires mandatory pre-market authorisation for all device risk classes of SaMD. Regulation will be risk proportionate, and internationally harmonised risk classifications would apply to SaMD. As with other medical devices, low risk devices may self-certify compliance with relevant product standards in order to supply in New Zealand.
164. Mandatory pre-market authorisation for all devices enables the regulator to ensure that all SaMD are safe to use, perform as intended and are of acceptable quality. Although low-risk SaMD would be exempt from many regulatory requirements under this option, pre-market authorisation should still be undertaken to ensure the regulator is able to require self-declaration of compliance with safety, performance and quality requirements, ensure appropriate labelling, undertake post-market activities, have visibility of the supply chain, and have a mechanism by which they can remove a low-risk SaMD from the market in cases where it is justified.
165. The regulatory framework would enable the regulator to exempt certain SaMD types and certain classes of devices from some or all requirements of pre-market authorisation, including:
    a. Exempting low-risk SaMD from the requirement to conform to certain requirements so that regulation is risk-proportionate. The most important aspect is to exempt low-risk devices from mandatory third-party or regulator assessment, to allow manufacturers to self-declare conformity with safety, performance and quality.
    b. During the period of transition into the new medical device regime. Exemptions can be utilised to phase in requirements for SaMD according to risk-level ie, focus regulatory efforts on ensuring high-risk SaMD is compliant before requiring compliance for lower-risk SaMD.
    c. Exempting software that technically meets the definition of SaMD but is inappropriate or disproportionate to regulate as a medical device.
166. Enabling exemption making powers for some product types or classes of products (eg, low-risk SaMD), would mean option B1.2 could be enacted if appropriate. This would not require future legislative change, meeting the flexibility criteria.
167. This option enables efficiencies as it focuses regulatory effort on higher-risk SaMD and allows for low-risk SaMD to be authorised based on self-declaration. Under this option, medium- and high-risk SaMD would be able to be authorised via multiple regulatory pathways, including expedited reliance pathways based on approvals held in other

jurisdictions, product-specific pathways for SaMD, and innovation pathways. It also contributes to health system efficiencies by enabling healthcare providers, patients and purchasers to make informed decisions on low-risk SaMD.

168. Registration costs would be proportionate to the level of regulatory scrutiny. It would be expected that the cost to notify a low-risk SaMD would be small, and the cost to register a medium- to high-risk SaMD would increase as the regulator will need to cost-recover the work taken to verify compliance.
169. This option is fit-for-product as it is the most harmonised with approaches in comparable jurisdictions (eg, USA, Australia, EU, UK, Canada) and is the recommended approach by the IMDRF. By harmonising with most comparable jurisdictions, it reduces the barriers to market and compliance costs for international medical device suppliers as they will already be meeting the harmonised standards and will be familiar with the requirements for market authorisation, that this option proposes.

How do the options compare to the counterfactual?

	Option B1.1 – Counterfactual	Option B1.2 – Exclude low-risk SaMD from pre-market authorisation requirements	Option B1.3 - Pre-market authorisation for all SaMD
Protective	0	+ This option improves protection through regulating medium and high -risk SaMD. It does not fully enable the safe use of SaMD as it does not provide a mechanism to ensure low-risk SaMD are meeting requirements of safety, efficacy/performance and quality.	++ This option contributes to health system efficiencies by enabling healthcare providers, patients and purchasers to make informed decisions on low-risk SaMD.
Efficient	0	+ This option reduces the work needed by the regulator by reducing the overall number of devices to be registered. The efficiencies are countered by the potential effect of health system inefficiencies – healthcare providers and patients will not have the ability to determine safety or accuracy of a low-risk software.	++ This option enables efficiencies as it focuses regulatory effort on higher-risk SaMD and allows for low-risk SaMD to be authorised based on self-declaration, which is not a significant increase in workload for the regulator.
Fit-for-product	0	+ This option partially meets the fit-for-product criteria as regulation would be risk-proportionate and ensure that devices that pose more risks to patients and users are appropriately regulated and reduces the regulatory burden on suppliers of low-risk SaMD.	++ This option is fit-for-product as it is the most harmonised with approaches in comparable jurisdictions and is the recommended approach by the IMDRF.
Flexible	0	+ This option is more flexible than the status quo through enabling appropriate regulation of medium and high-risk SaMD. Low-risk SaMD which may be ineffective or unsafe, may be supplied in New Zealand with few barriers to market, and difficulties in removing from the market.	++ Enabling exemption making powers for some product types or classes of products (eg, low-risk SaMD), would mean option B1.2 could be enacted if appropriate. This would not require future legislative change, meeting the flexibility criteria.
Overall assessment	0	**+4**	**+8**

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

170. Option B1.3 ‘ Pre-market authorisation for all SaMD’ best addresses the problem compared to the other options.
171. It is the most efficient, fit-for-purpose, protective and flexible option.

Is the Minister’s preferred option in the Cabinet paper the same as the agency’s preferred option in the RIS?

172. Yes.

What are the marginal costs and benefits of the preferred option in the Cabinet paper?

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			
Patients	Some costs of compliance expected to be passed on to consumers. These will be minimised through reliance pathways (approvals granted overseas).	Low	High
Regulator	Higher costs associated with enhanced regulation and verifying compliance.	Medium	High
Industry	Higher costs associated with complying with enhanced regulations, however many manufacturers will already be compliant. Costs of regulator assessment to be incurred through industry fees.	Medium	Medium
Healthcare providers	No cost impact expected.	Low	Medium
Crown	No cost impact expected.	Low	Medium
Total monetised costs		Low	Medium
Non-monetised costs		Low	Medium

Additional benefits of the preferred option compared to taking no action			
Patients	Assurance of safety, quality and efficacy to enhance informed user choice. Reduced risk of harm to patients. Reduced costs of travel and healthcare visits through remote monitoring enabled by therapeutic software.	High	High
Regulator	Efficiencies through alignment with international standards and membership to joint-working groups.	Medium	High
Industry	Efficiencies through alignment with international standards and clear pathways to market.	Medium	High
Healthcare providers	Efficiencies through assurance of safety, quality and efficacy, to enhance informed choice of therapeutic software. Overall service efficiency through remote and electronic monitoring of patients and reduced burden of in-person visits.	High	High
Crown	Increased certainty that therapeutic software is safe and effective may allow better prioritisation of health funding.	Medium	Medium
Total monetised benefits		Medium	High
Non-monetised benefits		High	High

Section 3: Delivering an option

How will the proposal be implemented?

173. These issues will be advanced through the forthcoming Medical Products Bill. The form of the medical products regulator - who would implement the new regulations – and how they will be funded 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.
174. As with all new regulatory systems, there is significant risk of time and cost over-runs. There are lessons New Zealand can learn from its existing system for innovative medical products. In addition, comparable jurisdictions have already undergone similar regulator reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for innovative medical products, in particular those involving reliance and notification.

How will the proposal be monitored, evaluated, and reviewed?

175. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. Based on current reporting by Medsafe, the metrics are likely to include:
    a. The number of applications received and competed in each application category, including innovative medical product pathways.
    b. The number of applications received for targeted programmes to support innovators.
    c. The outcome of evaluations (approved, declined, refused).
    d. Target timeframes and actual time taken for evaluations in each application category.
176. There is open communication between the health sector and the Ministry of Health, we expect them to be proactive in raising any problems or concerns with the new system.
177. Patients and consumers will be consulted during Select Committee consideration of the Medical Products Bill and in the development of secondary legislation, to ensure their perspectives are understood and accommodated.