Regulatory Impact Statement: Product and activity controls for medical devices

Coversheet

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

Problem Definition

Consumers and medical professionals usually cannot establish the safety, quality or performance of a medical device for themselves; and unsafe, low quality and/or poor performing devices can cause death and other serious harm. Some activities with medical devices pose risks to public health if carried out without adequate skill or care.

Some medical devices, especially implanted devices (eg, pacemakers, breast implants and artificial hip joints), remain within a patient for many years. Problems may not arise immediately and, without the ability to trace where a product has ended up, it can be difficult to follow up with patients and identify any harms.

Increasingly, software (eg, a smartphone app or web-service), is being used to perform complex medical tasks, including diagnosing conditions and recommending treatment options. As with traditional medical devices, it can be difficult for consumers to establish that this software – software as a medical device (SaMD) – meets appropriate safety, quality and performance standards.

The Medicines Act 1981 (Medicines Act) does not appropriately manage the risks associated with medical devices and is not capable of appropriately regulating innovative products. Current regulatory settings do not prevent avoidable harms to patients, and the Medicines Act is increasingly out of step with international regulatory norms

Executive Summary

This analysis considers two core elements of medical device regulation:

- Product controls –pre-market authorisation system for medical devices
- Activity controls – regulatory controls for medical devices supply-chain activities.

Medical devices cover a huge range of products with very different risks associated with their use across their lifecycle. Pathways need to provide for the different types of products (general medical devices, in-vitro diagnostics and software as a medical device) as well as provide for the varying risk classes of devices and proportionally apply requirements. We need to ensure innovation is encouraged, but that the risks to safety of devices are managed.

Medical devices are currently largely unregulated and pose a risk to the general public if government does not intervene. The majority of medical devices are imported and likely to have approval in other jurisdictions, so any proposed controls should recognise and leverage off these approvals as much as possible to avoid regulatory duplication and divergence. Medical devices manufactured in New Zealand for local supply and export also need to be considered.

Activities related to the manufacture and supply of medical devices are also largely unregulated. There is very little visibility on the supply chain of devices in New Zealand, which has impacts on identifying devices in cases of adverse events and post-market actions such as recalls. There is also no mechanism to impose requirements on medical device activities, such an internationally recognised standards for Quality Management Systems for manufacture.

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

- Introduce pre-market authorisation for all medical device risk classes (with exemptions enabled): Medical devices are required to be authorised and registered by the regulator prior to supply, based on meeting safety, performance and quality requirements.
- Introduce a requirement for supply chain actors (manufacturers, importers and distributors) to register with the regulator.
- Introduce a requirement for supply-chain actors to notify to the regulator of certain activities relating to medical devices.

This option significantly improves on the status quo for medical devices and introduces more robust assurances for patients and healthcare professionals about the safety, quality and performance of medical devices. It responds to industry requests for a modern and internationally harmonised system which can appropriately regulate medical devices according to the type and risk classification of products. This option also enables the traceability of a medical device through the supply chain, and ensures the regulator has visibility on who is undertaking activities relating to medical devices and allows for those activities to be done to internationally recognised standards. This option also responds to stakeholder concerns about the Therapeutic Products Act 2023 (the TPA) potentially over-regulating medical devices and introducing unnecessary compliance costs.

The option is preferred as it enables a modernised, risk-proportionate, regulatory regime for medical devices that increases confidence in the medical devices patients receive, maximises efficiencies for the New Zealand health system, and minimises duplication of regulatory efforts for industry, the regulator and associated compliance costs. This option incorporates regulatory reliance, emergency-use authorisation, pathways for innovative products and exemption making powers, to operate effectively and efficiently.

Proposals in this analysis should be read alongside other proposals for the regulation of medicines, the establishment of a regulator with post-market surveillance powers, and for a compliance and enforcement framework for regulating medical products.

Limitations and Constraints on Analysis

The Government wishes to have new legislation enacted within this term of parliament. This involves short timeframes for policy development, relative to the number and complexity of decisions needing to be made. This limitation is mitigated by several decades of policy development, including development of the TPA. However there has

been limited time to assess new evidence or test policies which differ significantly from both the status quo and the TPA.

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

Under the Medicines Act and the proposed regulatory system, the funding process and approval process for medical devices are separate and carried out by different entities. This RIS therefore does not address funding issues. Where it refers to access, this does not include funding or affordability.

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

Section 1: Diagnosing the policy problem

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

What are medical devices?

1. Medical devices work primarily through physical and electronic means. They include a wide range of apparatus, instruments and appliances, ranging from tongue depressors and surgical gloves through to implantable heart valves and machinery (such as ventilators and CT scanners).
2. Medical devices play a critical role in healthcare delivery, as they enable accurate diagnosis, effective treatment and continuous monitoring of diseases and conditions, improving patient outcomes.
3. Medical devices are generally separated into two groups, with distinct regulatory treatment, and are referred to as:
    - **General medical devices**: Devices that are used for a medical purpose such as surgical gloves through to MRI machines and implantable defibrillators. Additionally general medical devices include software that is used for a medical purpose (called **Software as a medical Device – SaMD**).
    - ***In-vitro* diagnostic (IVD) medical devices:** Devices that are used for the examination of human specimens to provide information for diagnostic, monitoring or compatibility purposes, such as **point-of-care tests** (POCTs) to test for pregnancy or COVID-19 infection.
4. Some individuals and communities rely heavily on medical devices to maintain life (such as pacemakers, glucose monitors and dialysis machines) and support daily living (such as hearing aids, wheelchairs and walking frames).

Product controls

5. The importance of these devices means it is vital that they meet acceptable standards of safety and quality, and that they performed as expected. Devices which are counterfeit, substandard or ineffective can cost lives, significantly reduce quality of life, and waste health system funding by causing more damage and failing to prevent serious conditions.
6. Market authorisation provides the ability for a regulator to have control over what medical devices are available in their country. The regulator should be able to issue market authorisation for devices that have established safety, performance and quality, and refuse or revoke market authorisation for devices that do not meet those requirements.
7. It is not possible for individuals and healthcare professionals to personally assess the safety, quality and performance of medical devices. Even organisations with suitably qualified and experienced staff will usually not be able to fully assess all the devices they procure without information from the manufacturer, which is usually not publicly available. Regulation of manufacture and the supply chain addresses information asymmetry and provides assurance of acceptable safety, quality and performance.
8. Even when manufactured to appropriate standards, medical devices have risks, including allergic reactions (eg, to latex used in condoms and medical gloves), ionising radiation, rejection by the patient's body, toxicity from leaching components, or the presentation of false positive/negative results. For implantable devices, risks may take weeks, months or years to eventuate and require risky corrective surgery.
9. For higher risk medical devices, clinical expertise is usually needed to work out if a device is appropriate for an individual, to administer or implant the device in the patient, and to provide necessary follow up care. Even low-risk medical devices which are intended for

the consumer to use directly, such as condoms, require clear information to ensure they are used effectively and in the right circumstances.

10. In recent decades the regulation of medical devices has increasingly become internationalised. Various international bodies, including the World Health Organization and harmonisation groups such as the International Medical Device Regulators Forum, have established common regulatory norms, benchmarks and minimum requirements for the manufacture and design of medical devices,[1] and the processes by which devices are evaluated (eg, for quality, safety and performance) and approved. Efficiencies in regulation can be achieved through engagement in harmonisation activities and work-sharing programmes. However, participation in these programmes requires local regulations to meet international norms.

Activity controls

11. Under the Medicines Act, manufacture and other activities with medical devices are essentially unregulated, even for high-risk devices.
12. Regulatory controls on activities related to medical devices are intended to provide assurance to people along a product's supply chain that others involved in the product's development, manufacture, transport and storage are not acting in a way that undermines the safety, quality or performance of the products. Activity controls support other important objectives of medical product regulation, such as post-market surveillance and traceability of products. Finally, activity controls can also serve direct protective purposes as well, such as controls over the conduct of clinical trials.
13. There is currently little visibility on the medical device supply chain in New Zealand, which has impacts on identifying devices involved in cases of adverse events and post-market actions such as recalls. The Global Harmonization Task Force guidance on vigilance reporting states that a regulator should be able to identify manufacturers, sponsors, distributers and users of a medical device to be able to trace and locate particular devices within the supply chain.
14. Better regulating supply-chain activities would enable a regulatory authority to require manufacturers and distributors comply with internationally recognised standards, such as having accredited Quality Management Systems (QMS) in place, ensuring the activity is undertaken appropriately.

Status quo: Regulation of medical devices under the Medicines Act 1981

15. Medical devices are currently regulated under the Medicines Act 1981, the Medicines Regulations 1984 and the Medical Devices (Database of Medical Devices) Regulations 2003. Other relevant legislation includes the Misuse of Drugs Act 1975 (in relation to medical devices that can also be used for medicinal cannabis) and the Contraception, Sterilisation, and Abortion Act 1977.
16. The status quo regulatory model for medical devices is very light touch. The major focus of the legislation is the regulation of medicines, and only covers medical devices to a very limited extent. Unlike medicines, there are far fewer formal requirements for the medical device industry in New Zealand, and no requirement to provide assurance of acceptable safety, quality and performance. Medical devices do not currently require a consent for distribution or any other kind of market authorisation – even if they have never been approved in New Zealand or overseas. Pre-market assessments are not required, and there is no mechanism to require a recall of a dangerous device.

[1] For example, Quality Management Systems (QMS)

17. The asymmetries inherent in the Medicines Act mean that medicines are regulated far more comprehensively than medical devices, even those with comparable risks to prescription medicines. For example, high-dose vitamins are regulated as medicines and are required to have pre-market authorisation that verifies compliance with appropriate standards such as that they are manufactured under Good Manufacturing Practices. In contrast implantable pacemakers are regulated as medical devices, and are able to be supplied through notification, without any assurances of appropriate manufacturing quality systems despite posing higher risks than vitamins.
18. The majority of medical devices in New Zealand are imported from other countries. Most comparable jurisdictions – Australia, the United Kingdom (UK), European Union (EU), United States of America (USA), Canada and Singapore – have robust regulatory regimes for medical devices in place. Products that are supplied in these markets must meet appropriate product standards and there is an assumption that, if these products are also imported into New Zealand, they are of the same quality. However, compliance with international product standards cannot be confirmed with the information required to be submitted to Medsafe about medical devices currently supplied in New Zealand.
19. The current regulatory scope fails to assess the safety, quality and performance of medical devices. Technical information is not publicly available, and where information is available, it is usually complex and not readily understandable by consumer.
20. Likewise, there is little transparency of the manufacturing and risk management process, so some of this information required to accurately make an assessment may not be readily available. Even if this information is available, there may be differences in a specific batch of product to the 'specification' or advertised product.
21. The Healthcare Practitioners Competence Assurance Act 2003 establishes some limited controls on who can undertake surgeries (which impacts who can implant medical devices in patients), but New Zealand lacks a comprehensive regulatory regime to control the use of most medical devices. In contrast, the Medicines Act 1981 has prescribing and supply controls for medicines.

Status quo: The current process for pre-market authorisation

22. The Medicines (Database of Medical Devices) Regulations 2003 establishes basic requirements for medical device sponsors, most of which relate to the requirement for some medical devices to be notified to the Web-Assisted Notification of Devices (WAND) database. Other requirements set out the information required to be submitted to Medsafe, timeframes for notification, information updates, risk-classification of devices, and prohibited statements. There is no approval system for medical devices under the Medicines Act 1981. There is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand.
23. The WAND database collects basic information about medical devices supplied in New Zealand. It is a mandatory requirement for importers, exporters and local manufacturers to notify their medical devices to the database. WAND is not an approval system for medical devices and notification to the WAND database does not mean or imply that a medical device has been assessed by Medsafe in terms of quality, safety, efficacy or performance.
24. There are no user-charges associated with the database.
25. Some types of medical devices are exempt from notification to the WAND database. Exempt devices include all IVD devices, medical devices imported for clinical trials and medical devices that are made or supplied for the intended use in relation to a particular patient.
26. The absence of a market authorisation system for medical devices in New Zealand has led to an inability to address or act upon known safety, quality or performance issues with medical devices. For example, there are known issues in relation to POCTs

available for the diagnosis of sexually transmitted infections (STIs) which have a high risk of producing a false negative result. This has significant public health implications, particularly when users get a false negative result for an infection, and risk transmitting the infection further.

27. Additionally, the lack of a market authorisation system for medical devices has significant impacts for health emergencies. During the COVID-19 pandemic, New Zealand was vulnerable to receiving poor quality and ineffective POCTs intended to diagnose COVID-19 infection. As a result, a bespoke Order was made under the COVID-19 Public Health Response Act 2020 to control the availability of POCTs to diagnose COVID-19. Not every scenario requiring emergency use of a medical device will occur in a public health emergency.

Status quo: Activity controls for medical devices

28. There are multiple controlled activities for medicines under the Medicines Act, however the following require a greater focus for medical device activities, including:
    - manufacturing
    - importing
    - distribution.
29. Additional risks attach to these activities where the importer or distributor is not also the manufacturer of the product or otherwise legally responsible for the safety, quality of performance of the product (ie, a product's 'sponsor').
30. There is very little visibility of the supply chain of devices in New Zealand, and in the case of exempt devices, no visibility at all. This has impacts on identifying devices in cases of adverse events and post-market actions such as recalls.
31. There is no mechanism under the Medicines Act, or associated regulations, to impose controls on medical device activities, such an internationally recognised standards for Quality Management Systems for manufacture.

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

32. The New Zealand public will continue to use and rely on medical devices that have not been through any assurance of safety, performance or quality. There are documented instances of harm from medical devices in New Zealand, which is not limited to high-risk or implantable devices. For example, a low-risk bed lever led to the preventable deaths of three elderly people[2]. Public confidence in the safety of medical devices is likely to continue to erode over time without sufficient regulation of medical devices.
33. The lack of a market authorisation system presents unacceptable public health risks, and during the COVID-19 pandemic, the Government used a temporary ban on importing point of care COVID-19 tests and enacted an Order under the COVID-19 Public Health Response Act 2020 to implement a quasi-approval system to allow the supply of tests which are accurate and reliable. This episode shows how the absence of regulation can create medium-term risks to the public and uncertainty to industry.
34. Further, Medical devices are becoming more complicated. Legislation needs to be **future-focused**. It needs to be flexible to respond to both the emergence of new device types (eg, SaMD and the therapeutic use of AI), combination products (eg, nano-drug delivery systems) and evolving international regulatory practices.

[2] Coroner calls for bed levers to be removed after three deaths | RNZ News

35. Without change, it is likely that the same issues could arise in relation to our inability to control the availability of sub-standard devices that do not perform as intended, risking public health and avoidable harms to New Zealanders.

International approaches to regulation of medical devices

Pre-market authorisation

36. Safety, performance and quality of medical devices is assured internationally through pre-market authorisation. Medical devices are authorised to be marketed when they demonstrate compliance with essential principles of safety and performance, which are assessed by a Conformity Assessment Body or Regulator (for medium- to high-risk devices) or self-assessed and declared by the manufacturer (for low-risk devices). Quality is established through manufacturer compliance with Quality Management Systems which are accredited by an auditing organisation.
37. There is a preference by this Government and the medical device industry for harmonisation with international approaches for several reasons including ensuring patient safety, fostering innovation, facilitating exports and streamlining regulatory processes. Harmonisation involves aligning regulatory requirements and standards across different countries to achieve a consistent approach to evaluating and monitoring medical devices.

Activities

38. Unlike medicines, medical device activities do not tend to be licensed. Instead, international approaches use a combination of registration and notification requirements relating to their activities, and requirements to meet internationally recognised standards for their conduct (for example, Quality Management Systems (QMS) and good distribution practices).
39. An accredited QMS touches on elements beyond quality (such as post-market requirements), which are out of scope of this analysis.

What is the policy problem or opportunity?

Problem A: Pre-market Authorisation for medical devices

40. Numerous problems have been identified with the current system under the Medicines Act. In particular:
    a. The Medicines Act does not allow for the pre-market assessment of medical devices to assess conformity with quality, safety and performance standards. This allows substandard products to be freely marketed, with limited powers by Medsafe to enforce actions. This has led to preventable deaths and other serious harm in New Zealand, and means that consumers and the health system are likely to be wasting money on devices which are poor quality and/or ineffective.
    b. The Medicines Act does not allow for unilateral or mutual recognition of decisions by other regulators in respect to medical device authorisation.
    c. New Zealand is implementing centralised procurement of medical devices under PHARMAC, but the issue of the safety and risks of such products and how they should be managed is unclear.
    d. The lack of pre-market authorisation has impacts for medical devices that may be required in public health emergencies, as there are no mechanisms to control the availability of sub-standard devices that do not perform as intended.

Problem B: Activity controls for medical devices

41. Legislative controls on activities relating to medical devices (**manufacture, Import and distribution**) are necessary to ensure the health and safety of all New Zealanders by ensuring these activities are undertaken by suitably qualified people and under appropriate processes and systems.
42. Manufacture is currently able to be undertaken by anyone and does not need to be done under accredited Quality Management Systems or by people that are suitably qualified.
43. There is no traceability of a medical devices once manufactured and imported, and importantly, implanted.

Stakeholder engagement

44. This RIS has been informed by significant engagement over the past 30 years. Most recently, this included engagement in relation to the Therapeutic Products Bill, which received over 16,000 submissions. As a result, the views of key stakeholders on the Medicines Act and potential replacements are well-known.
45. Consultation will focus on targeted engagement with key stakeholders. Development of new legislation will also draw strongly on submissions on the Therapeutic Products Bill. In combination with targeted engagement, these submissions will be used to ensure that concerns about the TPA are appropriately addressed in new legislation.

Stakeholder views: Consumers

46. Nearly everyone will use a medical device at some point in their lives. Consumers need medical devices to be, safe, good quality, perform as intended, reasonably affordable, and accessible. There are varying opinions amongst New Zealand consumers on how to balance affordability and access on the one hand with safety, quality and performance on the other.
47. Some groups of consumers have particularly strong interests. **Disabled people and people with long-term health conditions** often rely on medical devices (including disability aids) without which they would experience significant decline in quality of life. For this group, it is very important both that devices are accessible and affordable, and that they meet quality, safety and performance standards.
48. **Māori** tend to have higher rates of ill-health and are therefore more reliant on medical devices and more affected if products are unsafe or inaccessible. Māori individuals and organisations who submitted on the TPA tended to focus on regulation of natural health products, which included rongoā (traditional Māori healing) products, including some products which could have met the definition of a medical device.
49. **Women** have elevated concerns regarding medical device harm compared to other groups of consumers. One study found that women experienced around two-thirds of reported harms from medical devices in the United States.[3] Women's health advocates are more involved in medical device issues because of the harms experienced with medical devices, particularly implantable medical devices such as contraceptive devices and surgical mesh. Clinical trials have historically tended to focus on men, which has meant that side effects and other issues are less likely to be discovered if they mostly affect women. Compared to other patient advocacy groups, women's health groups that submitted on the TPA tended to take a more cautious approach to products, and to prioritise safety over access.

[3] https://www.icij.org/investigations/implant-files/we-used-ai-to-identify-the-sex-of-340000-people-harmed-by-medical-devices/

Stakeholder views: Medical device industry

50. The medical device industry includes manufacturers, importers, exporters and distributors, and are represented by industry associations. The majority of medical devices in New Zealand are imported, but there is some local manufacture, including companies that make software that is used for a medical purpose (Software as a Medical Device - SaMD).
51. The medical device industry supports introducing requirements for medical devices entering the New Zealand market to demonstrate they meet international standards for safety, performance, and quality.
52. Industry feedback has strongly emphasised that regulation of medical devices should be **internationally harmonised** for the following reasons:
    - harmonisation facilitates timely access to products, minimised compliance costs and other impediments to the choice of, and equity of access to, medical products.
    - harmonisation reduces the time and cost for manufacturers to bring new devices to multiple markets thereby ensuring patient access and leads to cost savings that can be passed on to healthcare providers and patients.
    - harmonisation enables access to global markets and enhances the commercial viability of new technologies for New Zealand innovators, supporting economic growth and job creation within the medical technology sector.
53. Industry is supportive of **risk-proportionate** regulation that enables:
    - low-risk devices to be subject to simplified regulatory procedures to be commensurate with risk, promote innovation and reduce unnecessary burdens on manufacturers and suppliers.
    - the level of regulatory oversight, the evidence requirements and the elements of a device assessed to be more robust for medium- and high-risk devices.
54. Industry is supportive of a market authorisation that enables **regulatory reliance and recognition pathways** for the following reasons**:**
    - The majority of medical devices in New Zealand are imported. The medical device industry believes New Zealand can leverage the assessments undertaken overseas and offer expedited pathways to market that rely on or recognise the market authorisations granted in other jurisdictions.
    - Regulatory reliance does not impact sovereignty; pursuing a harmonised regulatory reliance model does not prevent New Zealand from making unique decisions to benefit its public.
55. As with the medicines industry, there was concern about how the TPA would work in practice, in particular for innovative or unusual products such as SaMD. There were also concerns about transitioning existing medical devices (possibly numbering more than 100,000 different products) into a new regime in order to ensure continuity of supply.
56. Mandatory export authorisation was a contentious issue in the TPA, and the medical device industry felt that mandatory authorisation was overly burdensome, not in line with international approaches and was not risk-proportionate.
57. Industry is of the opinion that **activities** should not be licensed in the same way as for medicines, or as the TPA would have required for medical devices. Licensing of activities, such as manufacture or distribution, would be a departure from approaches in other jurisdictions.
58. The regulatory focus on activities should be in compliance with internationally recognised standards, such as having accredited Quality Management Systems, which are sufficient for ensuring the activity is undertaken appropriately.

Stakeholder views: Health professionals

59. Health practitioners are health professionals who are regulated under the Health Practitioners Competence Assurance Act 2003.
60. Practitioners have a range of views on medical device regulation, typically depending on the extent to which they are also involved in activities that might be considered 'manufacturing'. For example, many dentists use device production systems in their clinics (or elsewhere) to manufacture patient-matched and custom devices. This group of practitioner/manufacturers generally support light touch regulation of devices and the exemption of the products they produce (eg, dental crowns) from any scheme for pre-market authorisation and registration.
61. In general, health practitioners are concerned about the safety, quality and performance of medical devices, although they also consider access to be important. They are more aware than other groups of the potential risks from unsafe devices. Some also consider that a better regulatory system is needed to manage legal risks to practitioners.
62. Most practitioner groups support a system which continues to enable practitioners to access, supply and administer medical devices, with little regulatory overhead. Practitioners also requested that mechanisms continue to be available to authorise the supply of unapproved devices.

What are the opportunities?

63. To provide assurance to patients and users of medical devices, and healthcare providers, that medical devices are safe to use, perform as intended and are of appropriate quality.
64. To provide efficiencies for medical device procurement by PHARMAC by providing a pathway for regulatory approval, in order to remove this responsibility that the status quo has imposed on them, and which is not their core role.

What objectives are sought in relation to the policy problem?

65. The primary objectives are to provide future-proofed regulation of medical devices that will support all New Zealanders having timely access to safe, quality medical devices, that perform as intended. Additional objectives are to ensure there is visibility over the medical device supply chain to facilitate post-market actions such as recalls, and controls in place for supply-chain activities to ensure they are being done by appropriately qualified individuals.
66. An assurance system for medical devices should enable risk-proportionate regulation, that is internationally harmonised and fosters innovation. This will minimise the trade-offs that need to be made between assurance of safety, quality and performance on the one hand, and access and affordability on the other.

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

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

67. The criteria are:

Criteria	Description
Protection	Extent to which the option will provide assurance that products meet appropriate standards of safety, quality and performance. A high-scoring option would enable robust decisions based on sound evidence, to ensure the benefits associated with medical devices outweigh the risks
Efficient	Extent to which the option will achieve the objective in a way which is cost-effective for all parties – the Crown, the health system, product sponsors, and consumers.
Fit for product	Ensuring that devices are regulated in a way which makes sense for their nature and risk profile. In particular, it will ensure that assessments look at the right things to determine whether a device should receive market authorisation and are not over- or under-regulated. A high-scoring option will also be sufficiently flexible to accommodate innovative devices, including future technologies that cannot be envisaged/predicted at present.
Harmonised	The extent to which the option is harmonised with international approaches.

What scope will options be considered within?

Pre-market authorisation of medical devices

Products that are in scope of pre-market authorisation

68. The scope of products proposed to be regulated as medical devices, and therefore require pre-market authorisation, encompasses products that are generally considered to be medical devices in other countries.
69. This includes **general medical devices**, **in-vitro diagnostic (IVD) medical devices** and software that is used for a therapeutic purpose (**Software as a Medical Device – SaMD**). It should also include **combination products** which have a component of a medical device and incorporate a medicine. Depending on their primary mode of action, combination products tend to be either primarily a medicine with a medical device component (eg, an insulin auto-injector) or primarily a medical device with a medicine component (eg, a coronary stent that is coated with an anti-coagulant).
70. **International approaches:** Definitions should be harmonised (ie, be the same or achieve the same effect) including the scope of products regulated, to avoid confusion amongst suppliers as to what the requirements are to supply their devices.
71. There are some product areas where there is ambiguity as to whether they should be regulated as medical devices and divergent approaches are taken by regulators, such

as devices that are used for cosmetic purposes, but pose the same risks to users. For example, cosmetic dermal fillers and medical grade cosmetic lasers. The inclusion or exclusion of such products will need to be considered further in subsequent advice.

Options that are out of scope of this analysis

72. The option of full pre-market assessment for all medical devices by a New Zealand regulator is out of scope, as this was a requirement of the TPA, which is being repealed by the Government for several reasons, including:
    - Over-regulation or differing requirements compared to other markets, leading to disincentives for manufacturers and suppliers entering the New Zealand market.
    - Potential for patients losing access to medical devices they rely on.
    - Divergence from the international approach of using third-party conformity assessment bodies, which are accredited/recognised by the regulator, to undertake the conformity assessment.
    - Lack of local capacity and expertise to assess devices.
    - Did not allow for self-declaration by manufacturers that their devices meet regulatory requirements, which is an accepted practice for low-risk devices.
73. The option of requiring a pre-market assessment by a New Zealand regulator of medical devices – without regard to whether products have already been approved overseas – has also not been considered. This would likely significantly reduce timely access to devices and is contrary to the Government's priority of improving access. It is also unlikely to be an efficient use of Crown or industry resources, particularly for lower-risk products.
74. Authorisation for export-only medical devices is out of scope of this analysis. Export authorisation and licensing was a contentious issue during the development of the Therapeutic Products Bill, and more targeted consultation will be undertaken prior to an analysis of options in subsequent advice.

Activity controls for medical devices

75. Options considering export controls and obligations on medical device sponsors are out of scope of this analysis and will be covered in a subsequent RIS.
76. Options considering use of medical devices and any restrictions on that use are out of scope of this analysis ad will be covered in a subsequent RIS.

What options are being considered?

77. This options analysis consists of two parts:

    Question 1: What pre-market approval system should be set for medical devices?

    Question 2: What regulatory controls should be set for medical devices supply-chain activities?

78. The first part looks at how consumers and the health system can be assured that medical devices meet acceptable standards of safety, quality and performance and how this assurance can be provided in a cost-effective and risk-proportionate way.
79. The second part addresses commercial and system-level management of medical devices from their manufacture through to supply to health care provider or user.
80. It should be noted that post-market activity (such as pharmacovigilance and recalls) is also a key part of medical device regulation. This RIS only covers pre-market activities – options for post-market activity will be covered in a subsequent RIS.

Problem A: Pre-market Authorisation for medical devices

Question 1: What pre-market authorisation system should be set for medical devices?

81. This section looks at the high-level system of assurance (pre-market approval) that medical devices meet reasonable standards of quality, safety and performance, and how best it can deliver the objectives.
82. The options are:
    - **Option 1.1 Status quo under the Medicines Act:** Notification of some medical devices to Medsafe, when they are imported or manufactured. No evaluation of safety, performance or quality.
    - **Option 1.2 Enhanced status quo:** Expand notification to include in-vitro diagnostic medical devices and software that is used for a medical purpose.
    - **Option 1.3 Pre-market authorisation for medium and high-risk devices:** Medium- and high-risk devices are required to be authorised prior to supply, based on meeting safety, performance and quality requirements.
    - **Option 1.4 Pre-market authorisation for all medical devices:** All medical devices are required to be authorised prior to supply, based on meeting safety, performance and quality requirements.
83. Options 1.1 and 1.2 could also include licenses for activities related to medical devices. This is covered under Question 2. All options assume that legislation will include post-market surveillance and enforcement powers for an appropriately resourced regulator, to ensure product safety throughout their post-market lifecycle.

Option 1.1 – Status quo under the Medicines Act

84. The status quo is described in detail in Section 1.
85. There may be a perception by healthcare professionals, patients and users of medical devices that notification of medical devices to Medsafe ensures that medical devices meet acceptable standards.
86. The status quo does allow for timely and affordable access to medical devices as it is a very simple process and therefore does not impose barriers to market for medical devices manufacturers and sponsors. There is no fee associated with notification, so there are no compliance costs passed down to users and patients.
87. However the current notification process does not involve any assessment by Medsafe, or submission of technical documentation and therefore does not provide any assurance of safety, performance or quality. Other medical devices, such as IVDs are not required to be notified to Medsafe at all because the database does not support IVD risk classification, rather than a risk-based justification.
88. The status quo does not offer different regulatory treatment based on risk posed by a device. Of the medical devices required to be notified to Medsafe, a bandage is treated the same as an implantable pacemaker.
89. The status quo has long been considered outdated and inflexible. This option does not provide sufficient flexibility for the regulator to adapt to emerging technology and apply appropriate controls. Many modern medical device technologies are out of scope of the current legislation (eg, Software and Artificial Intelligence (AI) used for a medical purpose).
90. The status quo is not harmonised with international regulation of medical devices and has long been considered out-of-step with international best practice.

Option 1.2 – Enhanced status quo

91. This option is to continue the current system of notification of medical devices to the regulator, but to require notification for all medical devices, including IVDs and software and artificial intelligence used for a medical purpose. The information required to be submitted to the regulator for notification could be expanded upon, compared to the status quo.
92. As with option 1.1, this option allows for timely and affordable access to medical devices as it is a very simple process and therefore does not impose barriers to market for medical devices manufacturers and sponsors. A small fee for notification could be cost-recovered so there may be very small compliance costs passed down to users and patients. It emphasises reducing regulatory burden and compliance costs, over managing the risks that medical devices pose, particularly for medium- to high-risk devices.
93. As with the status quo, this option does not ensure medical devices meet acceptable standards of quality, safety and performance. There may be a perception by healthcare professionals, patients and users of medical devices that notification of medical devices to Medsafe ensures that medical devices meet acceptable standards.
94. This option does not offer different regulatory treatment based on the risk posed by a device. It may appropriately regulate low-risk devices but not medium or high-risk devices.
95. This option does allow for innovative devices to be supplied with few barriers. While this could be seen as a positive for access to new devices, it is outweighed by insufficient management of risks, especially which can be greater with new technology where the full risks and benefits of using the device may not be fully understood (eg, neural implants or the use of AI in diagnosing cancer through medical image analysis).
96. An enhanced status quo is not harmonised with international regulation of medical devices.

Option 1.3 – Enable pre-market authorisation for medium- to high-risk medical devices

97. This option enables mandatory pre-market authorisation for medium- to high-risk devices to be imported into or supplied in New Zealand. This would include point of care tests for diseases, such as COVID-19, HIV and STIs. Low-risk devices would specifically not require pre-market authorisation or registration with the regulator.
98. Within this option there is scope to provide for an efficient and risk-proportionate system for market authorisation.
99. This option 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 medical devices.
100. This option reduces the work needed to be undertaken by the regulator, compared to option 1.4, by reducing the number of devices that would need to be registered and approved by the regulator (approximately 40% of the devices in notified to Medsafe are low-risk).
101. This option focuses all regulatory effort on higher risk devices. Under this option, medium- and high-risk devices would be able to be approved via multiple regulatory pathways, including expedited reliance pathways based on approvals held in other jurisdictions, emergency use pathways and innovation pathways.
102. This option does not fully enable the safe use of medical devices as it does not provide a mechanism to ensure low-risk devices are meeting requirements of safety, performance and quality. It would be excluding a significant portion of the medical device market from regulation (approximately 40%).

103. Completely exempting low-risk devices from pre-market approval would reduce the regulator's ability to:
    - ensure low-risk devices have appropriate assurances of safety, performance and quality (low-risk devices still have inherent risks and benefits to their use)
    - have visibility of the entire medical device supply-chain
    - respond to safety issues relating to adverse events in low-risk devices.
104. This option provides flexibility for medium- to high- risks devices, as market authorisation could be granted through several pathways.
105. This option would not, however, enable future options for regulating low-risk devices.
106. This option is harmonised with the approaches to medium- and high-risk medical devices in other countries, and IMDRF guidance.
107. It is the approach taken by Singapore where low-risk devices are exempted fully from authorisation and registration. In Singapore this lighter touch for pre-market authorisation is compensated by requiring facility licensing and strong post-market surveillance.

Option 1.4 – Enable Pre-market authorisation for all medical devices

108. This option requires mandatory pre-market authorisation for all device risk classes.
109. Mandatory pre-market authorisation for all devices enables the regulator to ensure that devices are safe to use, perform as intended and are of acceptable quality.
110. Although low-risk devices would be exempt from many 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, undertake post-market activities, have visibility of the supply chain, and have a mechanism by which they can remove a low-risk device from the market in cases where it is justified.
111. Under this option, compliance costs associated with meeting safety, performance and quality requirements are expected to be insignificant for most medical device suppliers, as they are understood to already meet these requirements to supply these devices in other countries. Some suppliers, particularly in New Zealand, may have new compliance costs to meet the appropriate standards.
112. Registration costs would be proportionate to the level of regulatory scrutiny. It would be expected that the cost to notify a low-risk device would be small, and the cost to register a medium- to high-risk devices may increase as the regulator will need to cost-recover the work taken to verify compliance.
113. The regulatory framework should enable the regulator to exempt certain device types and certain classes of devices from some or all requirements of pre-market approval. There are justified exemptions in all medical device regulatory regimes where it is appropriate to exempt requirements, including:
    - Exempting low-risk devices 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.
    - Exempting custom-made devices from some requirements, including the requirement to register the device with the regulator (eg, dental fillings and crowns and 3D-printed prostheses).
    - Exempting human organs which are intended for donation from pre-market authorisation as there are appropriate clinical controls in place, and authorisation prior to supply would fundamentally impact access.
114. This option enables efficiencies as it focuses regulatory effort on higher-risk devices and allows for low-risk devices to be authorised based on self-declaration. Under this option, medium- and high-risk devices would be able to be approved via multiple regulatory

pathways, including expedited reliance pathways based on approvals held in other jurisdictions, and innovation pathways.

115. Flexibility is also enabled by this option, as pathways can be created as needed in the future that are tailored to the needs of new device types.
116. Exemptions can also be utilised during the establishment of medical device regulatory capabilities in New Zealand. As there are a significant amount of current in-market devices in New Zealand, it will be a significant change to the medical device industry and it would be pragmatic to introduce and increase requirements in a phased way, which would be enabled by exemptions and transitional provisions.
117. This option is the most harmonised with approaches in comparable jurisdictions (eg, US, Australia, EU, UK, Canada) and is the recommended approach by the IMDRF.
118. By being harmonised 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 status quo/counterfactual?

	Option 1.1 – [*Status Quo / Counterfactual*]	Option 1.2 – Enhanced Status quo	Option 1.3- Pre-market approval for medium-high risk devices	Option 1.4 – Pre-market approval for all devices (Preferred)
Protection	0	0	+	++
		Does not improve safety, performance or quality	Improves safety, performance and quality for medium and high-risk devices	Improves safety, performance and quality for all medical devices
Efficient	0	0	0	+
		Is less efficient for the regulator and industry, without improving efficiencies in the wider health system	Is less efficient for the regulator and industry, but improves efficiencies for healthcare providers and users	Is much less efficient for the regulator and industry, but significantly improves efficiencies for healthcare providers, users and procurers.
Fit for product	0	+	++	++
			Medical devices that pose the most risk are regulated appropriately and have oversight	All medical devices regulated appropriately and have oversight
Harmonised	0	0	+	++
		Is not in line with international approaches	Is partially in line with international approaches	Is in line with international approaches
Overall assessment	0	+1	+4	+7

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

119. Option 1.4 delivers the most benefits, followed by option 1.3, with both being preferable to the status quo and option 1.2.
120. Option 1.4 offers the most protection, ensuring that the benefits outweigh the risks for all medical devices supplied in New Zealand. It also offers the most efficient overall system as the assurance of safety, performance and quality enables better efficiencies for healthcare providers in making informed decisions on medical devices used in the practice, and PHARMAC and other procurers in undertaking health technology assessments. These system wide benefits compensate for the increased regulatory burden for industry and the regulator. It is also the most internationally harmonised option and pre-market authorisation is able to be applied in a way that is risk-proportionate and fit-for-product (ie, can enable multiple pathways to market based on risk or type of product).
121. Compared to the status quo, option 1.3 also delivers net benefits. This option is not as strong as option 1.4 due to the exclusion of low-risk devices (a significant proportion of the medical device market). The exclusion of low-risk devices would be more efficient for industry and the regulator, but it would not improve efficiency at a systems level, as low-risk devices are used in high quantities in healthcare, and assurances of quality, safety and performance through pre-market authorisation would help inform procurement decisions and healthcare professionals.

What are the marginal costs and benefits of the option?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Medical device industry	Increased compliance costs associated with gaining market authorisation, which are minimised by taking an internationally harmonised approach that utilised regulatory reliance.		
Crown	Regulator costs addressed in Regulator Detailed Business Case development		
Health practitioners	No significant cost impact expected. Some costs may be associated with ensuring devices used are authorised, and ensuring compliance for custom-made devices.		
Health service providers	Efficiency gains from certainty about devices safety, quality and performance.		
Consumers	Potential for increased compliance costs to industry being passed on to the consumer.		
Total monetised costs		Medium	
Non-monetised costs		*Low*	
Additional benefits of the preferred option compared to taking no action			
Regulated groups			
Regulators			
Others (eg, wider govt, consumers, etc.)			
Total monetised benefits			

Non-monetised benefits		*(High, medium or low)*	

Problem B: Activity controls for medical devices

Question 2: What regulatory controls should be set for medical devices supply-chain activities?

122. This section looks at the regulatory controls on domestic activities related to medical devices, which include manufacture, distribution, import and export, a system of ensuring activities are undertaken in an inappropriate manner, and to achieve an appropriate level of traceability of devices.
123. The options are:

> **Option 2.1 Status quo under the Medicines Act:** No requirement on supply chain actors to register with the regulator. Only sponsors notify their devices to the regulator.
>
> **Option 2.2 Licencing/permit system:** that focuses on issuing a licence/permit to companies with accredited quality management systems and compliance with internationally recognised standards (TPA approach).
>
> **Option 2.3 Registration system:** Requirement for supply-chain actors to register with the regulator.
>
> **Option 2.4 Notification system:** Requirement for supply-chain actors to notify to the regulator of activities relating to medical devices.

Option 2.1 – Status Quo / Counterfactual

124. The status quo is described in detail in Section 1.
125. The WAND database collects information about medical devices supplied in New Zealand. It is a mandatory requirement for a medical device sponsor to notify each medical device or group of medical devices that is imported, manufactured and exported to the database.
126. Notification is a one-off requirement and the information collected is basic identifying information of the device and sponsor. Not all medical devices are required to be notified to Medsafe and supply-chain actors (such as manufacturers, importers and distributors) do not have to register their information with the regulator if they are not the product sponsor.
127. The current system does not enable supply chain visibility or traceability, and this has led to significant patient concerns, particularly in cases of recalled devices that have caused harm in New Zealand patients.
128. The status quo is not harmonised with international approaches and under-regulates the supply chain in comparison.

Option 2.2 – Licensing and permit system

129. This option enables manufacturers, distributors, importers and exporters to hold a licence or permit to undertake activities relating to medical devices.
130. This is the approach taken by Singapore where a dealer's licence is required to manufacture, import or wholesale medical devices. This approach appears to compensate for the lack of pre-market authorisation or registration for low-risk devices, and the focus on reliance for market authorisations.
131. This option should be considered alongside **options 1.1 and 1.2** to compensate for light pre-market authorisation.

132. Conditions may be placed on a licence such as having a Quality Management System in place to maintain devices quality throughout the manufacturing and distribution process.
133. This is the approach taken by the TPA, and the medical device industry had objections to licencing medical device activities, particularly for low-risk devices stating it was not proportionate to the risks posed, and not an approach taken internationally. Depending on the decisions taken on pre-market authorisation, this option should still be considered, especially with different regulatory settings compared to the TPA.
134. This option enables regulator visibility of medical devices throughout their lifecycle and ensures that activities are being undertaken by appropriately qualified people under appropriate systems.
135. There is scope to expand the requirements of granting a licence or permit over time to require compliance with internationally recognised standards, however this would be introduced in a phased way, and in consultation with industry.
136. This option could be applied in a tiered way, where activities for low-risk devices are licenced or permitted via a simplified or more automated process, and activities regarding higher-risk devices undergo a more rigorous assessment for a licence or permit to be granted.
137. Exemptions could be utilised to remove the requirement for a licence or permit where appropriate.
138. This option may negatively impact New Zealand manufacturers and suppliers by imposing requirements that are higher than those applied in most comparable countries.
139. Requiring activities to be licensed or permitted prior to undertaking the activity represents the least efficient option. It also introduces uncertainty for applicants as to when or if they may receive a licence or permit, and therefore impact business planning.
140. Requiring a licence for these activities, without exemptions, would be inflexible. If implemented there should be the ability to exempt certain activities from the requirement for a licence, particularly for low-risk devices.
141. This option is not aligned with the approach taken in the majority of international regimes. Canada and Singapore require activity licences, however most other regulatory systems do not take this approach, as systems and personnel are managed through accreditation to internationally recognised standards.

Option 2.3 – Registration system

142. This option would require establishments that manufacture, import and distribute medical devices to register with the regulator and list the devices and the activities performed on those devices at that establishment.
143. This option can be implemented alongside **option 2.4,** and the requirement to register or notify can be used flexibly by the regulator according to the risks that are being managed. For example, a manufacturer of a high-risk implantable device should register with the regulator, and the manufacturer of cotton swabs may simply notify the regulator of their manufacture activity.
144. This option enables visibility over the medical devices supply chain actors and to have information available on who is undertaking activities, which would facilitate faster post-market actions such as recalls.
145. The regulatory burden for establishments to register with the regulator and submit basic identifying information is relatively low. The likely compliance costs associated with this option will also be relatively low, and associated fees associated with cost-recovery for administering the registration system will be minimal.
146. There is scope to expand the requirements of registration over time to require compliance with internationally recognised standards under a risk-proportionate approach. This would be introduced in a phased way, and in consultation with industry.

147. Registration would not require an approval by the regulator per se, so registration would not introduce delays or uncertainty for the regulated party.
148. The regulator would ensure the entered information is in the correct, and over time there could be specific requirements introduced to submit at registration an accredited certificate of compliance with an internationally recognised system that is appropriate for that activity (For example, a Quality Management System – ISO 13485) that the regulator verifies.
149. Where industry holds an accreditation or certification under internationally recognised standards for certain activities (eg, manufacturing), these could be recognised by the regulator.
150. This option enables the regulator to adapt to evolving needs over time to ensure supply chain activities are appropriately controlled.
151. This is the approach taken by the US, UK and EU, where manufacturers, authorised representatives (sponsors) and importers must register with the regulatory authority.

Option 2.4 – Notification system

152. This option would require establishments that manufacture, import and distribute medical devices to notify the regulator that they are undertaking these activities and list the devices they deal with.
153. This option can be implemented alongside **option 2.3,** and the requirement to register or notify can be used flexibly by the regulator according to the risks that are being managed. For example, notification could be used to manage low risk activities, or activities that are otherwise appropriately controlled, so that the regulator has visibility over the supply chain and who is undertaking activities but with very little compliance effort by the regulated party.
154. While this option is similar to Option 2.3, there are differences in that the notification would be immediate upon submission, and the regulator would not verify information contained in a notification, as they may for registration.
155. This option would allow the regulator to adapt to evolving needs over time and provide a risk-proportionate approach to managing supply chain activities.
156. Exemptions should be enabled under this option to maintain flexibility.

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

	Option 2.1 – Status Quo / Counterfactual	Option 2.2 – *Licensing and permit system*	Option 2.3 – Registration system (preferred)	Option 2.4 – Notification system (preferred)
Protection	0	++	++	+
		Ensures activities are undertaken to appropriate standards and enables product traceability	Ensures activities are undertaken to appropriate standards and enables product traceability	Enables product traceability, but does not ensure activities are undertaken to appropriate standards
Efficient	0	- -	0	0
		Is significantly less efficient for the regulator and industry	Is slightly less efficient for the regulator and industry, but enables health system efficiencies in tracing devices	Is no less efficient for the regulator and industry, but enables health system efficiencies in tracing devices
Fit for product	0	-	++	+
		Enables the application of appropriate standards, but would over-regulate many medical device activities	Enables the application of appropriate standards, and can be applied in a risk-proportionate way	Does not enable that application of appropriate standards, but can be applied in a risk-proportionate way
Harmonised	0	+	++	+
		Is partially in line with international approaches	Is in line with international approaches	Is partially in line with international approaches
Overall assessment	0	0	+6	+3

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

157. Option 2.3 delivers the most benefits, followed by option 2.4, with both being preferable to the status quo and option 2.2.
158. Compared to the status quo, option 2.2 offers the same net result. Increased benefits to protection are offset by the decrease in efficiency that this option would have on the medical device industry in meeting and attaining licences or permits, and regulator resources in assessing and issuing licences and permits. This option is less fit for

product/risk proportionate than the status quo, as it would likely over-regulate many device activities, particularly those relating to low-risk goods (eg, a cotton swab distributor).

159. Compared to the status quo, option 2.3 delivers the most benefits; it enables better protection through supply-chain traceability and the ability to require compliance with internationally recognised standards as a condition of registration. It is in line with international regulatory practices and is able to be implemented in a risk proportionate way. This option is as efficient as the current system, with decreased efficiency for the medical device industry and the regulator, offset by the increased efficiency for the consumer. Option 2.3 could be implemented as a stand-alone option.
160. Option 2.4 is similar to option 2.3 but offers fewer overall benefits. These benefits may be better suited to activities relating to low-risk products, as the same level of protection is not justified compared to high-risk products (ie, compliance with internationally recognised standards) but still enables supply-chain traceability. This option is as efficient as the current system, with decreased efficiency for the medical device industry and the regulator, offset by the increased efficiency for the consumer. It is not recommended that option 2.4 be implemented as a stand-alone option, as it would under-regulate high-risk activities.
161. Implementing both options 2.3 and 2.4 would maximise the benefits, by applying both options in a risk-proportionate way to activities.

What are the marginal costs and benefits of the option?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Medical device industry	Marginally increased compliance costs associated with registration and notification		
Crown	Marginally increased costs associated with maintaining a register and processing notifications		
Health practitioners	No significant cost impact expected.		
Health service providers	Efficiencies gained in having enhanced traceability of medical devices		
Consumers	No significant cost impact expected.		
Total monetised costs		Low	
Non-monetised costs		Low	

Additional benefits of the preferred option compared to taking no action			
Regulated groups			
Regulators			
Others (eg, wider govt, consumers, etc.)			
Total monetised benefits			
Non-monetised benefits		*(High, medium or low)*	

Section 3: Delivering an option

How will the new arrangements be implemented?

162. Decisions on who would implement the new regulation will be subject to future government decisions. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.
163. The market authorisation system will be operated and enforced by the Crown. The form of any regulator is discussed in a separate Cabinet Paper.
164. The regulation of medical devices will change significantly. This will require several years to enable a smooth transition period, in addition to the time needed to develop secondary legislation.
165. Education campaigns are likely to be needed for healthcare professionals, industry and the public, where there are significant changes from the status quo.
166. The Ministry of Health will retain a stewardship and oversight role.
167. As with all new systems, there is significant risk of time and cost over-runs. There are lessons New Zealand can learn from its existing regime for medical devices. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for market authorisation, in particular those involving reliance and notification.

Transition

168. There will need to be sufficient transition periods for regulatory requirements to come into force for medical devices.
169. Requirements will likely need to be implemented in phases, where requirements are gradually increased over time.
170. Lessons can be learned from the implementation of the Medical Device Regulation and In-Vitro Diagnostic regulations in the European Union and other jurisdictions, where the introduction of new requirements led to many medical devices being unable to be supplied because of administrative backlogs.
171. Stakeholder feedback on the TPA implementation was that the transition periods (six months, three years and five years) were insufficient, and the regulator would not have the capacity to assess the many thousands of in-market medical devices over the transition period.

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

172. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:
    - time taken to approve medical devices via the various pathways
    - time taken to process registration for controlled activities
    - compliance and enforcement action taken.
173. Potentially there will be a review of the new system within five years of it taking effect.
174. The medical devices industry and the healthcare sector have productive relationships with the Ministry and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.
175. Work will be needed on how to ensure that patient/consumer problems with the new system are heard and responded to.