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"Devicive": Medical Device Regulation and the New Zealand Therapeutic Products Act 2023

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Abstract

This paper analyses aspects of the Therapeutic Products Act 2023 ("Act"). The Act creates a regulatory regime that oversees medical devices, medicines, natural health products and active pharmaceutical ingredients. This paper focuses on the regulation of medical devices, asking whether the drafting of the Act reflects the guiding principle that regulation should be proportionate to benefits and risks, and whether the Act aligns New Zealand with international standards. The paper begins by considering the concept of risk and outlining the provisions that are key to the analysis of the Act. It is concluded that the Act does not sufficiently facilitate risk proportionate regulation of medical devices. The paper continues, comparing the regime created by the Act to regimes in comparable jurisdictions, which influenced and informed the recommendations made. It is found that the Act does not necessarily reflect international best practice. The paper then considers the issues and unintended consequences that the Act may create, which were highlighted in the submissions to the Select Committee. There is a danger that the importers New Zealand relies on for its medical devices skip the market entirely and a concern that the Regulator will quickly become overwhelmed. Finally, recommendations are made to address these issues, align New Zealand with international best practice and ensure that the regulation of medical devices is risk proportionate. Firstly, it is recommended that a risk-based classification system be implemented in the Act and that devices are evaluated differently based on their classification. Secondly, the role of overseas approvals in the evaluation process should be clarified, allowing sponsors of devices to use them to expedite the evaluation process. Included are draft amendment options for each recommendation. The paper finishes by considering the delegation of power under the Act and recommending that more guidance be provided in primary legislation.

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Subjects and Topics

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I Introduction

The Therapeutic Products Bill was introduced to the New Zealand Parliament on 30th November 2022 and became the Therapeutic Products Act ("Act") on 26th July 2023. It replaces the Medicines Act 1981 and the Dietary Supplements Regulations 1985. It is an omnibus Act that creates a regulatory environment which will regulate medicines, medical devices, natural health products, and active pharmaceutical ingredients. These products are grouped under the broad definition of "therapeutic products". The Act covers when therapeutic products can and cannot be imported into, exported from, or supplied in New Zealand. It also regulates numerous "controlled activities" which relate to these products, for example manufacturing, exporting, and conducting clinical trials.[1] The Act will establish a Regulator that will oversee the regulation of these products and will be granted a range of compliance and enforcement powers.[2]

Following its introduction, the Act was read a first time on 14th December 2022 and was referred to the Health Select Committee. All parties except for Te Pāti Māori supported the Bill at its first reading. The Act has been the subject of much controversy and debate. There were 16,500 submissions to the Health Select Committee, 16,000 of which were in opposition.[3] The Select Committee's final report was presented on 13th June 2023. Included in that report was opposition from the ACT Party and the National Party. The ACT Party supports the modernisation of regulation of therapeutic products but states that "the bill only offers a tangle of red tape and crippling compliance costs".[4] The National Party supports the guiding principles of quality, safety, effectiveness, and performance for therapeutic products, but considers the Bill is overreaching and is not fit for purpose.[5] The Bill was read a second time on 28th June 2023 and the amendments recommended by the Health Committee were agreed to on the same day. The Bill was opposed by the National Party, the ACT Party and Dr Elizabeth Kerekere at its second reading. They remained opposed at the third reading. Te Pāti Māori changed their position and supported the Bill at the second and third readings. The Committee of the Whole House and third reading occurred on 18th July 2023. The Act received royal assent on 26th July 2023 and if not brought into force prior, will come into force on the 1st of September 2026.

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[1] Therapeutic Products Act 2023, s 10 (2).

[2] Therapeutic Products Bill 2022 (204-1) (explanatory note) at 2.

[3] (28 June 2023) (Therapeutic Products Bill – Second Reading, Dr Shane Reti).

[4] Therapeutic Products Bill 2022 (204-2) (select committee report) at 26.

[5] At 26.

This paper evaluates the Act in relation to medical devices. Medical devices come under the Act if they are "therapeutic products". According to s 16(1) of the Act, a therapeutic product is:

> (a) a product that is intended for use in, on, or in relation to humans for a therapeutic purpose:
> (b) a product that regulations referred to in section 19 (1) say is a therapeutic product:
> (c) a product that is intended for use as an active ingredient of a medicine.

Pertaining to s 16(1)(a), the following are therapeutic purposes:[6]

> (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:
> (b) influencing, inhibiting, or modifying a human physiological process:
> (c) testing the susceptibility of humans to a disease or an ailment:
> (d) influencing, controlling, or preventing human conception:
> (e) testing for human pregnancy:
> (f) investigating, replacing, modifying, or supporting part of a human's anatomy:
> (g) investigating a human physiological process:
> (h) supporting or sustaining human life:
> (i) providing vitamin, mineral, or other human nutritional supplementation:
> (j) maintaining or promoting human health:
> (k) disinfecting medical devices:
> (l) a purpose connected with a purpose referred to in paragraphs (a) to (k).

A therapeutic product is a medical device if it:[7]

> (a) is a therapeutic product under section 16(1)(a) or (b); and
> (b) achieves, or is likely to achieve, its principal intended action by means other than pharmacological, immunological, metabolic, or genetic means (although its function may be assisted by pharmacological, immunological, metabolic, or genetic processes).

Medical device regulation in New Zealand is currently poor. Suppliers merely need to inform Medsafe of basic information regarding their products. They do not need to receive approval prior to entering the market.[8] The current regulatory system provides

[6] Therapeutic Products Act, s 15.

[7] Therapeutic Products Act, s 24(1).

[8] Laura Hardcastle "Submission to the Health Committee on the Therapeutic Products Bill 2022" at 82.

requirements for certain groups of devices, but no attempt is made to verify premarket compliance.[9]

In researching for this paper, I considered the theory behind "risk" which informed my recommendations as to how risk is used in the Act. The Select Committee submissions on the Act were vital to my research. They highlighted issues with the Act and the potential consequences that its drafting could cause. I compared the Act and the regulatory regime it will create with medical device regulatory regimes in comparative jurisdictions. This comparison allowed me to identify flaws in the Act and influenced my recommendations. I have concluded that changes should be made to the Act to facilitate risk-based regulation and avoid unintended consequences which could be caused by the current drafting.

I began this paper when the Act was still a Bill. The recommendations I have made could potentially still be effective if included in secondary legislation, but as I explain, I believe more detail should be included within the Act. With the backstop commencement date being 1st September 2026, there is still scope for the adjustments I suggest to be implemented in the principal Act.

II Risk

The Therapeutic Products Act states that any person "exercising a power under this Act must be guided by the purpose of the Act and the following principles". The first of those principles being "the likely benefits of therapeutic products should outweigh the likely risks associated with them, and their regulation should be proportionate to those benefits and risks".[10] In this paper I explore whether the way in which the Act proposes to regulate medical devices is risk proportionate, whether the drafting of the Act reflects this guiding principle, and if changes can be made which allow risk to be better addressed to avoid unintended consequences.

Risk is the subject of much debate and discussion. Many theorists see risk and how it intersects with the law differently. In her book "*Risks and Legal Theory*" Jenny Steele explores the relationship of risk and legal theory. She highlights the debate and tensions between theorists and outlines different perspectives on risk.[11] Risk is hard to define. Steele tried to lay down a universal meaning of risk: "we are faced with a situation of 'risk' when

[9] At 82.

[10] Therapeutic Products Act, s 4 (a).

[11] Jenny Steele *Risks and Legal Theory* (Hart Publishing, Oxford and Portland, Oregon, 2004).

circumstances may (or importantly, may not) turn out in a way that we do not wish for".[12] She admits that this does not constitute a definition, stating that it would lose its "universality" and would not fit within the many perspectives of risk if it were more specific.[13] Glyn Holton defined risk as "exposure to a proposition of which one is uncertain", but even he acknowledged that this definition is flawed.[14] One of the most significant subjects of debate in relation to risk is whether it identifies problems to be solved or provides a tool to structure decision-making and respond to threats and uncertainties.[15] Steele argued that legal theory adopts risk in a way that enables decision-making.[16]

Medical devices can pose significant risks to end users through the occurrence of adverse events. An adverse event is defined as an unintended consequence associated with the use of a medical device or with an implanted medical device.[17] Regulation is needed to ensure that devices on the market are safe and to reduce the likelihood of adverse events. In the context of medical devices, a balance must be struck between strict regulation, which acts to minimise the risks that devices pose to users, and relaxed regulation, which would facilitate access to devices, market efficiency and reduce costs. As stated, New Zealand currently lacks regulation for medical devices. It is important that stricter regulation be implemented to ensure that devices used by New Zealanders are safe and effective. The Act needs to find an appropriate balance between strict and relaxed regulation that ensures the safety of devices while facilitating a functioning market and Regulator.

Any changes made to the Act should be considered using risk as a decision-making tool. By this I mean that the changes should be evaluated to determine the benefits they create and the risks they bring. In line with s 4(a), the benefits of any changes should outweigh the increased risk they may create, especially in the context of medical devices. In this paper I make recommendations to address issues with the Act. Using risk as a decision-making tool, the best changes will maximise benefits while only marginally increasing the risks. The most convincing recommendations in the context of this Act would be those that address the issues highlighted below, without compromising the safety, quality, and

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[12] At 6.

[13] At 6.

[14] Glyn A Holton "Defining Risk" (2004) 60 Financial Anal J 19 at 22.

[15] Steele, above n 11, at 3.

[16] At 4.

[17] "Medical Device Adverse Event Reporting" (19 March 2020) Medsafe <https://www.medsafe.govt.nz/regulatory/devicesnew/9adverseevent.asp>.

performance of medical devices and without increasing the risk of adverse events. I believe that the recommendations made in this paper achieve this and therefore facilitate better risk-based regulation.

I argue that, due to the wide debate and multitude of perspectives on risk, in order for regulation to truly be risk-based and consistent, further guidance should be written into the Act. The Minister of Health has stated that "the bill provides a risk proportionate approach to regulation".[18] In contrast, Steele wrote that we should be wary "[w]henever it is argued that a problem may be resolved by adoption of 'a risk perspective'" because it is probable whoever is suggesting this resolution is "(at best) drawing a veil over the full range of possibilities that such a perspective might imply".[19] The inclusion of risk-based regulation as a guiding principle is not adequate to ensure that regulation is risk-based in practice. The term is too fluid. More specific guidance should be included to ensure that regulation is risk-based.

III Key Provisions

The lack of risk-based pathways to regulation within the Act could cause many problems, including the inefficient regulation of devices. As it stands, without the bulk of the secondary legislation, most medical devices will be regulated through the same single pathway.

According to s 68, a device cannot be imported, supplied, or exported without market authorisation. Section 68 (1)(a) and (b) provides exceptions to this rule: these activities can be conducted if a provision of sub-pt 3 of pt 3 allows it or if a licence or permit that provides for it has been obtained. The exceptions in sub-pt 3 of pt 3 are limited and would not apply to most sponsors of devices. This means that most devices will be regulated through one pathway, by receiving market authorisation after evaluation by the Regulator.

The Regulator must evaluate a device before it can issue market authorisation.[20] Section 122 provides guidance to the Regulator on how to evaluate a medical device. It allows for a not insignificant degree of discretion. The Regulator must evaluate a device to determine whether it can establish its safety, quality, and performance for its intended authorised

[18] (28 June 2023) (Therapeutic Products Bill – Second Reading, Hon Dr Ayesha Verrall).

[19] Steele, above n 11, at 6.

[20] Therapeutic Products Act, s 121.

indications and whether the likely benefits of the product outweigh the likely risks associated with it.[21] Subsection (2) states that:

> The nature and extent of the Regulator's evaluation of the product must be appropriate and proportionate to---
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> (a) the likely benefits of, and risks associated with, the product; and
> (b) the extent of any previous evaluation of the product or a related product; and
> (c) any matters set out in the regulations; and
> (d) all of the circumstances of the case.

Subsection (3) follows by outlining factors that the Regulator may (without limitation) have regard to in its evaluation, which includes a list of factors that finish with "(i) any other matters that the Regulator thinks are relevant". It is not required to have regard to any of the listed factors, nor is it required to give them any weight. This provides the Regulator with a significant degree of discretion, which in turn deprives readers of clarity as to how the Act will operate practically.

The guidance provided in the Act is vague and offers very little insight as to how devices will be evaluated in practice, just that they will be evaluated. This lack of guidance is concerning as it means that the Act does not provide sufficient certainty and transparency to the industry and end users of devices.[22]

Included in sch 1 of the Act are the transitional provisions. Medical devices that were, immediately before commencement, a medicine under the 1981 Act and had an existing standard consent or provisional consent will receive a temporary market authorisation.[23] Temporary market authorisation expires 5 years after commencement, meaning that these devices will need to be evaluated within five years.[24] The Act does allow for the transitional periods to be to be adjusted.[25]

Section 354 deals with the Regulator's power to rely on decisions, etc., of designated entities. Under subs (2) the Regulator has the power to designate overseas regulators, overseas organisations or any other person body that the Regulator is satisfied on

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[21] Therapeutic Products Act, s 122.

[22] Hardcastle, above n 8, at 8.

[23] Therapeutic Products Act, sch 1 cl 5.

[24] Therapeutic Products Act, sch 1 cl 5(4)(c).

[25] Therapeutic Products Act, sch 1 cl 45.

reasonable grounds has knowledge of, and expertise in, a relevant subject matter. Subsection (1) states that:

> In evaluating a therapeutic product or making a decision under this Act, the Regulator may rely on reports, assessments, or decisions made by, or information received from, an entity designated under subsection (2).

This again, is vague, and provides no substantive direction to the Regulator on when and how to use reports, assessments, decisions made by, or information received from designated entities. Just that it can.

One of my recommendations is that further guidance should be provided in the form of a risk classification system. Under such a system, medical devices would be regulated differently based on their level of risk. For example, a low-risk device such as a band-aid may not need to be evaluated at all, whereas a higher risk device would need to go through a far more thorough evaluation. Such a system would better align the Act with the guiding principle that regulation of therapeutic products should support the timely availability of those products.[26] By evaluating lower risk devices through less onerous processes, regulatory resources are freed up to which can be diverted to evaluate high-risk devices in a more timely and thorough manner. While s 122 (2)(a) states that the nature and extent of the evaluation will be appropriate and proportionate to the risks and benefits associated with the product, no detail is provided as to how the evaluation will be risk proportionate in practice. As explained above, simply stating that the evaluation must be risk proportionate is not adequate to ensure that it is. Implementation of a risk classification system would align New Zealand with comparative jurisdictions and would ensure that regulation is risk-based in practice.

IV Comparative:

By not regulating devices differently based on their risk class, the New Zealand Regulator will be out of line with regulators in comparable jurisdictions. I will compare the medical device regulatory regimes in Singapore, Australia, the USA and Japan. This comparison will inform whether the Act can be adjusted to reflect international best practice and if there are systems used in those jurisdictions that could be adopted to solve some of the problems with the Act.

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[26] Therapeutic Products Act, s 4(b)(i).

A Singapore

The Singaporean Health Sciences Authority (HSA) regulates devices differently based on risk. It also allows for devices to be evaluated under different processes by recognising approvals from comparable jurisdictions.

In Singapore, medical devices are separated through a risk classification system. Classification of a device is the initial task for someone looking to register a device in Singapore.[27] Rules are used to help classify products into one of four categories. These categories are A (Low risk), B (Low-moderate risk), C (Moderate-high risk) and D (High risk). The risk categorisation of a device is a factor in determining which evaluation route the device goes through.

Medical devices that fall within class A are not required to be registered with the HSA.[28] These are the lowest risk devices. Examples given by the HSA are wheelchairs and tongue depressors.[29]

Clause 26(1) of the Health Products (Medical Devices) Regulations 2010 allows for devices to be evaluated under different processes if certain criteria are met. A medical device may be evaluated under an abridged evaluation process; an expedited abridged evaluation process; a full evaluation process; or a priority full evaluation process; or, the Authority may immediately register the medical device.[30] The availability of evaluation under a process other than a full evaluation depends on the device's risk class and/or whether the device has been granted approval for supply in a foreign jurisdiction. This is subject to two conditions, that the HSA recognises that approval and that the device must comply with all other conditions specified on the Authority's website.[31]

Regardless of classification, overseas approvals can be used to qualify for evaluation under an abridged process. According to the HSA:[32]

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[27] "Classification of Medical Devices in Singapore" Emergo by UL <https://www.emergobyul.com/services/classification-medical-devices-singapore>.

[28] Emergo by UL, above n 27.

[29] Health Sciences Authority (Singapore) "Medical Device Guidance. GN-13: Guidance on the Risk Classification of General Medical Devices" (September 2018) Revision 2.1 at 13.

[30] Health Products (Medical Devices) Regulations 2010 (SG), cl 26(1).

[31] Clause 26.

[32] Clause 26(2).

> a medical device may qualify for evaluation under an abridged evaluation process if it has been approved by a competent regulatory agency in a foreign jurisdiction; if that approval is of a type accepted by the HSA and is identified on the HSA's website at the time of the registration of the device; and if the device complies with all other conditions specified on the HSA website.

The detail of the classification system is included within regulations, pursuant to s 29 (2)(a) of the Health Products Act 2007 which gives the Authority the power to "subdivide any category of health products into any number of classes as it thinks fit".[33] The different evaluative processes which can be applied for based on a product's risk class and overseas approvals are also set out in regulations, for the purposes of s 33 of the Health Products Act 2007.[34]

B Australia

Australia classifies devices based on risk. Devices are classed I, Is, IM, IIa, IIb, III and AIMD. Class I is lowest risk class and III/AIMD is the highest.[35] Devices must have undergone "an appropriate conformity assessment" before being included in the Australian Register of Therapeutic Goods (ARTG).[36] They cannot be supplied in Australia if they are not included on this register.[37] In general, the level of assessment increases with the device's risk level.[38] As in Singapore, devices in the lowest risk class do not need to be evaluated by the Authority before they are included on the register.[39]

The Australian regulator, the Therapeutic Goods Administration (TGA), like the Singaporean HSA, recognises other comparable regulatory agency's market

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[33] Schedule 3.

[34] Clause 26.

[35] Dr Mandvi Bharadwaj, "An introduction to regulation of medical devices in Australia" (2021) Therapeutic Goods Administration at 17.

[36] "Australian regulatory guidelines for medical devices (ARGMD)" (19 August 2022) Therapeutic Goods Administration <https://www.tga.gov.au/resources/resource/guidance/australian-regulatory-guidelines-medical-devices-argmd>.

[37] Bharadwaj, above n 35, at 22.

[38] At 23.

[39] "The future regulation of low risk products" (13 April 2023) Therapeutic Goods Administration <https://www.tga.gov.au/future-regulation-low-risk-products#:~:text=Class%20I%20medical%20devices,risk%20posed%20by%20the%20device>.

authorisations.[40] Manufacturers can demonstrate that their device has undergone conformity assessment by providing evidence that the device has been approved by a comparable overseas regulator, the TGA or an Australian conformity assessment body.[41] Evidence of overseas compliance can also be used in an application for an abridged assessment of the device for a TGA conformity assessment certificate.[42] The TGA allows product approvals from European Notified Bodies, Japan, Canada, USA, MDSAP auditing organisations and Singapore to support applications.[43]

The TGA has not always recognised all of these other assessment bodies. It changed its practices based on recommendations by the Expert Review of Medicines and Medical Devices Regulation "in order to improve access by Australian consumers to new medical devices".[44] With timely access to medical devices being a guiding principle of the Act, New Zealand may want to implement a similar practice to achieve the same outcome and avoid limiting New Zealander's access to medical devices.

The Australian regulatory regime for medical devices is created by both primary and secondary legislation. The regime is primarily contained in the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.[45] Australian primary legislation states that regulations may set out conformity assessment procedures

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[40] "Medical Device Registration with the Australian TGA" Emergo by UL <https://www.emergobyul.com/services/medical-device-registration-australian-tga#:~:text=Medical%20device%20classification%20in%20Australia,increases%20with%20increasing%20risk%20level>.

[41] "Overview of medical devices and IVD regulation" (1 October 2020) Therapeutic Goods Administration <https://www.tga.gov.au/overview-medical-devices-and-ivd-regulation>.

[42] "Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)" (23 June 2023) Therapeutic Goods Administration <https://www.tga.gov.au/resources/publication/publications/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds>.

[43] "Using Overseas Approvals for Medical Devices to Enter the Australian Market" Commercial Eyes <https://commercialeyes.com.au/using-overseas-approvals-for-medical-devices-to-enter-the-australian-market/>.

[44] "Comparable overseas regulators for medical device applications" (7 October 2022) Therapeutic Goods Administration <https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications>.

[45] Hardcastle, above n 8, at 137.

and specify medical device classifications.[46] These evaluative processes and classification frameworks are included within secondary legislation.[47]

C Japan

Similarly in Japan, medical devices are categorised based on their potential risk. There are four risk categories in Japan: Class I, Class II, Class III and Class IV. Class I devices are the lowest risk and Class IV are the highest.[48] The process a device goes through to be registered differs based on which risk class it falls within. The higher the devices risk, the more thorough the registration process.

The process that Class I devices, which pose the lowest potential risk to a patient's health, go through is notification.[49] To obtain registration, the owner of a Class I device only needs to notify the Pharmaceuticals and Medical Devices Agency (PMDA). The device itself does not need to be reviewed and assessed.[50] Class II and III devices for which a relevant certification standard exists go through a certification process. This involves an evaluation by a registered third-party certification body.[51] All Class IV devices and any Class II and III devices that do not have a relevant certification standard must receive pre-market approval. This involves the device being evaluated and approved by the Ministry of Health, Labour and Welfare of Japan.[52]

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[46] Therapeutic Goods Act 1989 (Cth)(AUS), ss 41DB and 41DA.

[47] Therapeutic Goods (Medical Devices) Regulations 2002 (AUS), sch 2. Therapeutic Goods (Medical Devices) Regulations 2002 (AUS), div 3.2.

[48] "An Overview of Medical Device Regulations in Japan" RedDesk (20 Jan 2019) <https://www.regdesk.co/an-overview-of-medical-device-regulations-in-japan/>.

[49] RegDesk, above n 48.

[50] "Medical Device Registration and Approval in Japan" Emergo by UL <https://www.emergobyul.com/services/medical-device-registration-and-approval-japan#:~:text=Registration%20procedures%20for%20medical%20devices%20sold%20in%20Japan&text=Emergo%20can%20assist%20you%20with,of%20classification%20or%20JMDN%20code.&text=To%20register%20General%20Medical%20Devices,the%20PMDA%20will%20be%20conducted.>.

[51] Atsushi Tamura "Understanding Japanese Medical Device Requirements" (July 2011) PMDA <https://www.pmda.go.jp/files/000164006.pdf> at 9 and 10.

[52] At 9.

D USA

Medical Devices in the United States are also classified based on risk. There are three classes of devices in the USA: Class I, Class II and Class III.[53] According to the US Food and Drug Administration, the level of regulatory control they have over a device increases with each class.[54] Most Class I devices do not need Premarket Notification 510(k). But this is a requirement for most Class II devices.[55] Most Class III devices, the highest risk class, need to receive Premarket Approval.[56] Under Premarket Approval devices undergo scientific and regulatory review to determine their safety and effectiveness.[57]

1 Comparative Conclusion

The regulatory regime that the Act will create does not reflect international best practice. As shown above, all the comparable jurisdictions considered regulate medical devices based on their risk class. They use this classification to determine how rigorously the device is evaluated, or if it is evaluated at all. This ensures that the evaluation and regulation of devices is risk proportionate.

The Act was supposedly developed by "picking and choosing the best elements of legislation and regulations from other jurisdictions internationally".[58] This is not the correct approach to creating a regulatory system in New Zealand. The legislation should be developed considering why New Zealand differs from other countries. Because the Act does not include a risk classification system or expedited evaluative pathways based on overseas approvals, the New Zealand Regulator could potentially have a similar workload to all of the countries considered above. Even though each countries' GDP is significantly

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[53] "Regulatory Controls" (27 March 2018) FDA <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls>.

[54] "Overview of Device Regulation" (4 September 2020) FDA <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>.

[55] FDA, above n 54.

[56] FDA, above n 54.

[57] "Premarket Approval (PMA)" (7 August 2023) FDA <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm>.

[58] Fisher & Paykel Healthcare "Submission to the Health Committee on the Therapeutic Products Bill 2022" at 11.

larger than New Zealand's.[59] The New Zealand Parliament, with the size of the country in mind, should be attempting to reduce the administrative workload on the Regulator and leverage the work done by overseas regulatory bodies who will be better resourced than the New Zealand Regulator is likely to be.

While all the regulatory regimes looked at in this section have a risk classification system, only Australia and Singapore allow an expedited path to market based on a device's approval overseas. Japan and the USA are far larger nations than Australia, Singapore, and New Zealand in terms of both population and GDP.[60] As a smaller nation, with fewer resources, New Zealand's regime should be modelled on other small nations. In not evaluating devices based on their risk class, the New Zealand regime may harness risk more poorly than the USA. North America is the largest market for medical devices. [61] Therefore, the USA can afford to implement a more onerous regulatory regime without the fear that manufacturers will not enter the market. New Zealand does not have the same liberty, with the New Zealand market being only 0.25% of the global market.[62] New Zealand should instead be adopting the practices followed in smaller nations such as Australia and Singapore.

In not following international best practice, New Zealand will be at a disadvantage and could potentially face unintended consequences. New Zealand should be looking to comparable jurisdictions to adopt risk proportionate policies and leverage the work already done by those with more resources, instead of attempting to create a unique regime that may not harness risk adequately.

V Issues

The Act has the potential to cause unintended consequences that could frustrate the New Zealand health system. It could also potentially frustrate the purpose of the Act, to protect, promote, and improve the health of all New Zealanders.[63] As stated above, there were over

[59] "GDP by Country" Wordometer <https://www.worldometers.info/gdp/gdp-by-country/>.

[60] Wordometer, above n 59.

[61] "Medical Devices Market 2021" (2021) The Business Research Company <https://www.thebusinessresearchcompany.com/report/medical-devices-market#:~:text=North%20America%20was%20the%20largest,and%20then%20the%20other%20regions.>.

[62] "Medical Technology: A Guide to Market Access in New Zealand" (2010) Medical Technology Association of New Zealand <https://mtanz.org.nz/filescust/CMS/NZMarket/Guide_Market_Access.pdf > at 8.

[63] Therapeutic Products Act, s 3.

16,500 submissions to the Select Committee and 16,000 of these opposed the Act. I explore some of the issues highlighted by the submitters. There is a concern that the Act will create a regime with "an unnecessary level of complexity" and that this, along with the cost of compliance, could cause unintended consequences which may ultimately result in worse outcomes for members of the public who rely on medical devices.[64]

A Danger of Importers Skipping the New Zealand Market

A potential consequence of the Act is that it may cause international manufacturers to exit the New Zealand market. Of the medical devices currently available in New Zealand, 95% are imported.[65] This means the New Zealand health system is heavily reliant on international manufacturers and importers. There is a concern that, in creating a regulatory regime that does not align with or is potentially more onerous than those in comparable jurisdictions, the Act will disincentivise importers from dealing in New Zealand.[66] According to Fisher & Paykel Healthcare in its submission to the Select Committee and evidenced in my comparison with other jurisdictions above, the Act "includes an unnecessary level of complexity" which could cause importers to completely bypass the New Zealand market.[67]

This is not an uncommon sentiment held among those who submitted on the Act. According to Johnson & Johnson, the system the Act introduces is "cost prohibitive and includes unnecessary regulatory burden which will limit the introduction of new technology in the New Zealand market and reduce access to existing technology".[68] This is echoed by the Medical Technology Association of Australia, which submitted that the Act lacks harmony with other global regulators and that importers may stop supplying devices in New Zealand "rather than undertaking the work required to meet a set of requirements that apply only to this country".[69] It is not only companies that have highlighted this issue. In its opposition to the Act, the ACT Party stated that "[a] needless barrier to accessing therapeutic products is created by imposing New Zealand-specific

[64] Fisher & Paykel Healthcare, above n 58, at 8.

[65] Medical Technology Association of New Zealand "Submission to the Health Committee on the Therapeutic Products Bill 2022" at 3.

[66] Fisher & Paykel Healthcare, above n 58, at 10.

[67] At 10.

[68] Johnson & Johnson "Submission to the Health Committee on the Therapeutic Products Bill 2022" at 11.

[69] Medical Technology Association of Australia "Submission to the Health Committee on the Therapeutic Products Bill 2022" at 1.

approval requirements for products which have already met international standards".[70] Based on my assessment of the submissions, I am of the opinion that these concerns are genuine and are not a ploy to advocate against regulation. All the aforementioned submitters support a regulatory regime, just not the one that will be created by the Act.

As stated above, New Zealand's share of the global market for medical technology is approximately 0.25%.[71] It is a small market. If the cost of complying with an inefficient and unnecessarily onerous regime outweighs the small opportunity in the market, there is a real chance that importers will bypass the New Zealand market. If the Act is not adjusted to properly harness risk and align with comparable jurisdictions, there is a danger that New Zealanders will lose access to the medical devices they rely on. Therefore, the Act may indirectly obstruct its purpose, to protect, promote, and improve the health of all New Zealanders.[72].

B The Regulator

Another unintended consequence of the current drafting of the Act is the unnecessary burden that will be placed on the Regulator. If importers do decide to enter the New Zealand market, the Regulator may not be able to deal with its large regulatory workload. The main concerns under this umbrella are the evaluation of products already available in New Zealand, the staffing of the regulator and its ability to keep up with its workload in the future.

1 Evaluation of Existing Devices

Submitters were concerned that the Regulator would struggle to evaluate the backlog of products already on the market in the time frame that Parliament has given.

There is a risk that the Regulator will be overwhelmed before it receives any applications for the market authorisation of new devices. The Medical Technology Association of New Zealand estimates that there are approximately 250,000 different medical device products

[70] Therapeutic Products Bill 2022 (204-2) (select committee report) at 26.

[71] Medical Technology Association of New Zealand, above n 62, at 8.

[72] Therapeutic Products Act, s 3.

available in New Zealand.[73] As explained in Part III, unless the transitional period is adjusted, devices that already have standard or provisional consent will receive temporary market authorisation and will need to be evaluated within five years. Fisher & Paykel Healthcare is of the opinion that the task of evaluating this number of devices would overwhelm an experienced regulator and would be "all but impossible" for a regulator that is establishing itself.[74]

Considering that the Regulator may struggle to deal with this large backlog of devices, changes should be made which allow for more efficient regulation and leverage the work done by other competent regulators. This would alleviate the burden on the Regulator and prevent it from becoming overwhelmed.

If the Regulator became overwhelmed, the transitional periods might need to be extended. This would mean that some devices would remain on the market without having been evaluated for a longer period of time. It is undesirable to have devices on the market which have not received a pre-market evaluation as this could increase the likelihood of adverse events. Therefore, if it can be helped, the transitional period should not be extended.

2 Workload and Staffing

As stated above, New Zealand is much smaller in comparison to all the countries considered in Part IV, with the exception of Singapore. New Zealand and Singapore's population sizes are similar, but Singapore's GDP per capita is 50% larger than New Zealand's.[75] As explained, the Act provides one pathway to market for most devices. It also does not include a requirement to recognise overseas approvals or a risk classification system. This could see the New Zealand Regulator take on a similar, if not greater, burden than other regulators that provide multiple risk-based pathways to market. The evaluative process does not consider how many devices will be sold in New Zealand. Whether it is one or one hundred thousand, the device will still need to be evaluated in the same way in order to receive market authorisation. As a smaller country New Zealand should be leveraging the work done by its counterparts, in line with Australia and Singapore's

[73] Fisher & Paykel Healthcare, above n 58, at 11.

[74] At 11.

[75] Paul Adams "NZ has fallen behind its peer nations. Here's why" (5 December 2022) EverEdge <https://www.everedgeglobal.com/nz-has-fallen-behind-its-peer-nations-heres-why/#:~:text=Singapore's%20GDP%20per%20capita%20is,%25%20(NZ's%20is%2039%25).>.

approach. This becomes particularly important when considering that the Regulator's workload will not only consist of the regulation of medical devices, but also natural health products, medicines, and active pharmaceutical ingredients.

The Regulator may also face staffing issues. The Australian Therapeutic Goods Administration employs approximately one thousand staff.[76] Its staff includes trained professionals such as medical practitioners, scientists, pharmacists, laboratory technicians and compliance inspectors and investigators.[77] As I have explained, the workload of the New Zealand Regulator is likely to be similar if not greater than that of the TGA. This means that the Regulator will likely need to employ a similar number of staff.[78] Fisher & Paykel Healthcare, in its submission, stated that hiring people with the requisite experience is "not an easy task" and that it has had to significantly invest in finding or training up regulatory staff.[79] This is an issue that the Regulator too will face. If the Regulator struggles to find appropriate staff, this could increase its costs and hinder an efficient regulatory process. An understaffed Regulator would be far more likely to be overwhelmed.

If the Regulator is overwhelmed in any capacity, it is the New Zealand public that will ultimately be impacted. Either through the use of unevaluated devices or by being deprived of access to devices because of the increased length of time it will take to receive market authorisation. With these concerns in mind, it is important to implement changes which reduce the Regulator's workload while ensuring that the devices available in New Zealand are safe. Risk-based regulation that recognises overseas approvals will help to do this.

VI Recommendations

The Act should be adjusted to prevent these unintended consequences. Changes should be made to clarify the vague guidance provided in relation to the evaluation of medical devices and the use of risk in the Act. Changes also need to be made to mitigate the concerns that the regulatory regime may cause New Zealanders to lose access to medical devices and to prevent the Regulator from being overwhelmed. These adjustments should better align the

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[76] "Work at the TGA" Therapeutic Goods Administration <https://www.tga.gov.au/about-tga/corporate-information/work-tga#:~:text=Our%20vision%20is%20for%20better,about%201%2C000%20staff%20around%20Australia.>.

[77] Therapeutic Goods Administration, above n 76.

[78] Fisher & Paykel Healthcare, above n 58, at 12.

[79] At 12.

New Zealand regulatory environment with those in comparable jurisdictions. Based on the analysis in this paper, I propose two recommendations: That medical devices be classified based on their risk level and regulated differently on that basis; and that New Zealand recognise overseas approvals to fast track the evaluation process.

A Risk Based Classification System

The first recommendation is the inclusion of a risk-based classification system. Devices would be regulated differently based on the risk class they fall into. Such a framework already exists in New Zealand. Medsafe classifies devices into either Class I, Class II, Class III or AIMD, with the class ascending based on the device's risk level.[80] Considering that a risk-based classification system already exists in New Zealand, it would not be complex to include it in the Act. I do not make recommendations as to the technicalities of the risk classification of medical devices. My recommendation is that a schedule with a similar structure to the Schedule 2 of the Medicines (Database of Medical Devices) Regulations 2003, which outlines the rules for medical device risk classification, be included in the Act or within secondary legislation. If it is to be included within secondary legislation, an indication to this effect should be included in the Act. These rules will allow device sponsors to deduce which class their device falls into.

The inclusion of risk classification rules allows for the classifications to be used to create different evaluative pathways. This recommendation could be included in the Act as a fourth subsection of s 122.

Implementation of a risk classification framework would ensure that the regulatory process devices are evaluated under is risk-based. A devices classification would determine how thoroughly it would need to be evaluated before receiving market authorisation. Regulatory oversight and the level of evaluation would increase with the level of risk. Inclusion of such a framework would also better reflect risk as a principle in the Act.

Below are examples of how this recommendation could be implemented in the Act. For both recommendations, options as to how the changes could be made have been provided. I have no particular preference. These options are examples and show that there is

[80] "Risk Classification of Medical Devices" (10 May 2011) MedSafe <https://www.medsafe.govt.nz/regulatory/devicesnew/3-7RiskClassification.asp>.

flexibility in how these changes could be included. Provided the essence is the same, it would not matter how the amendments were structured or worded.

1 Amendment Examples:

Option one: Amendment to s 122.

> (4) The Regulator must evaluate products differently based on their risk class (See Schedule [rules for risk classification] …).
>
> (a) Low risk devices must be evaluated through [ ] process.
>
> (b) Medium-low risk devices must be evaluated through [ ] process.
>
> (c)…

Option two: Amendment to s 122 based on Australian legislation – s 41DB of the Therapeutic Goods Act 1989.

> (4) The Regulations must specify:
>
> (a) classifications, to be known as *medical device classifications,* applying to medical devices or kinds of medical devices based on the risk they pose to human health; and
>
> (b) matters in relation to the classification of medical devices or kinds of medical devices.

As in Singapore, Australia, the USA and Japan, I recommend that the lowest risk devices not be evaluated at all and that device sponsors simply notify the Regulator in order to receive market authorisation. This would significantly cut down the regulatory workload and would facilitate timely availability of these devices, upholding one of the guiding principles of the Act.[81] The regulation of these devices would occur post market. To prevent fraudulent classifications by device sponsors, audits could be carried out on a random basis. Strict penalties could be put in place for fraudulent or negligent classification of devices to incentivise correct and thorough classification.

B The Role of Overseas Approvals

[81] Therapeutic Products Act, s 4(b)(i).

The ability of the Regulator to rely on overseas assessments, decisions, reports and information is already touched on in the Act. As stated above, under s 354 the Regulator may rely on reports, assessments, or decisions made by, or information received from a designated entity. While inclusion of this section is welcome, it does not provide the Regulator with clear enough guidelines on how overseas regulatory decisions can and should be used. The guidance provided in the Act with regards to the decisions, etc., of designated entities is too vague. This could lead to inefficient decision-making that does not properly leverage the work done by better resourced regulators and to potentially inconsistent regulatory decisions.

Therefore, my second recommendation is that the Act be amended to allow for overseas regulatory decisions, etc., to expedite the market authorisation process. It should continue to be the decision of the Regulator as to what bodies it designates. The Act should clearly indicate that reports, assessments, or decisions made by, or information received from designated bodies must, instead of may, be considered when evaluating a device for market authorisation and clearly outline how these are to be used. These decisions, etc., are not binding on the Regulator, but significant weight should be given to them in the evaluation process. The Act should direct the Regulator to consider them, and secondary legislation should provide more guidance on how they are to be used.

The system should look something like the Singaporean or Australian systems, where the number of overseas approvals and the risk class of the device determine whether it goes through an abridged or expedited process, or where the approvals can be used as evidence that the device has already undergone the requisite conformity assessment for market authorisation. As explained above, Australia has recently changed its approach to overseas approvals "to improve access by Australian consumers to new medical devices".[82] New Zealand should learn from Australia and implement a similar approach in order to achieve the same result.

A subsection could be added to s 122 which states that product approvals from certain designated bodies can be used to demonstrate that a device's safety, quality, and performance for its intended authorised indications have been satisfactorily established and therefore, that market authorisation should be granted. The New Zealand Regulator should still retain the discretionary power to not recognise these approvals for legitimate reasons.

[82] Therapeutic Goods Administration, above n 44.

Below are examples of how this change could be made. As explained above, I have no preference as to how it is implemented. Provided the essence is the same, there is flexibility as to how it could be included.

1 Amendment Examples:

Option One: Amendment to s 122

> (5) In evaluating a device the Regulator must have regard to reports, assessments, or decisions made by, or information received from bodies designated under s 354 (2).[83]
>
> (6) Product approvals granted by designated bodies, following an evaluation of the device, may be used as evidence that a device's safety, quality, and performance for its intended authorised indications have been satisfactorily established.
>
> (7) The Regulator has the power to refuse to recognise product approvals granted by designated bodies for legitimate reasons.
>
> (8) The Regulator may, without having conducted a full evaluation itself, grant market authorisation if a device has received a certain number of product approvals following an evaluation by a designated body.
>
> (9) The number of approvals needed to satisfy subsection (8) must be specified within the regulations.

Or

> (8) The regulations must specify when overseas product approvals can be used by the Regulator as sufficient evidence of a device's safety, quality, and efficacy for its intended authorised indications to warrant granting market authorisation.

Option Two: Amendment to s 122

Primary Legislation

[83] Section 354(2) of the Therapeutic Products Act 2023 gives the Regulator the power to designate entities.

(5) In evaluating a device the Regulator must have regard to reports, assessments, or decisions made by, or information received from received from bodies designated under s 354 (2).

(6) Expedited, abridged and priority evaluative processes for medical devices must be developed in the rules and regulations.

(7) Qualification for an expedited abridged or priority evaluation process depends on -

(a) a device's risk class; and
(b) approvals the product has received from designated bodies; and
(c) any other matter that the Regulator deems relevant.

Regulations [Based on the Singaporean Health Products (Medical Devices) Regulations 2010]

(1) For the purposes of s 122 of the Therapeutic Products Act, the Regulator may, upon application for market authorisation –

(a) evaluate the medical device under –
(i) an abridged evaluation process;
(ii) an expedited abridged evaluation process;
(iii) a full evaluation process; or
(iv) a priority full evaluation process; or
(b) immediately register the medical device.

(2) [Outlines the technical requirements that must be met to qualify for each evaluation process. In Singapore this is determined by a product's risk class and the number of recognised approvals that it has been granted].

This change would have many benefits and would mitigate the issues and concerns outlined above in Part V. The Regulator would be able to utilise the work done by regulatory bodies that are far better resourced than the New Zealand Regulator is likely to be. This would reduce its workload and would address the concerns around it being overwhelmed. Another benefit would be that it would encourage importers to enter the New Zealand market. If they can easily enter the market on the basis that their devices have been approved elsewhere, they will be more likely to do so. Therefore, New Zealanders will be able to continue to access the medical devices that they rely on. If it were included in primary

legislation, this system would also help provide greater transparency and clarity within the Act as to how devices will be regulated in practice.

The rewards of this system greatly outweigh the risks associated with it. Devices would still be going to market having been evaluated and approved, either by the Regulator or by a body that it recognises as competent enough to do the same work.

C Recommendations Conclusion

These recommendations provide benefit by addressing the issues with the Act. Using risk as a decision-making tool, these changes are appropriate. They only marginally increase the risks devices pose because all devices on market will still have gone through some evaluative process, whether that be overseas or domestically, proportionate to the risks they pose. The recommendations made are specific to medical devices but if appropriate they could potentially apply to other therapeutic products.

VII Primary or Secondary Legislation?

There is a question as to whether these recommendations should be implemented in primary or secondary legislation. It is important that the changes outlined above be included as guidance within primary legislation. At the very least an indication that such systems will be developed within secondary legislation should be added. As discussed, the Act is currently too vague in its outline of how devices will be evaluated. More detail is needed within primary legislation. According to Johnson & Johnson, under the current drafting the secondary rules and regulations "will materially control the practical implementation of the regulatory regime".[84]

As explained in Part IV, in Australia and Singapore the risk classification system and evaluative processes are created by both primary and secondary legislation. In the Australian Therapeutic Goods Act 1989, ss 41DA and 41DB state that the regulations may specify medical device classifications and set out conformity assessment procedures. It is my recommendation that New Zealand follows suit and provides further guidance within the Act. The New Zealand Parliament, however, should go further by requiring that the regulations set out a risk classification system and different evaluative procedures.

[84] Johnson & Johnson, above n 68, at 14.

A Legislative Design and Advisory Committee Considerations

The Legislative Design and Advisory Committee (LDAC) outlined four competing considerations that need balancing in determining what Parliament can appropriately delegate under an Act.[85] In my view, these factors weigh in favour of including more detail within the Act and potentially suggest that Parliament has inappropriately delegated too much power.[86]

The first is the legitimacy of the law. The committee states that "too much delegation, or having delegated powers that are too broad or uncontrolled, undermines the transparency and legitimacy of the law".[87] Laura Hardcastle, in her submission on the Bill, highlighted that the drafting of the Bill will involve the delegation of important powers to unelected officials and that these officials will be developing New Zealand's regulatory regime "from scratch", with only the broad principles included in the Bill as a guideline.[88] Because unelected officials will determine how the regulatory regime will operate, it can be argued that the Act involves far too much delegation, and far too little detail. This undermines the legitimacy and transparency of the Act.

The second factor to be weighed is the durability and flexibility of the law. It is important that some powers are delegated to ensure that the Act is durable and flexible, especially considering the innovation that occurs within the medical sector.[89] This, however, is something that can be facilitated or achieved by delegating fewer powers than are currently being given to the Regulator and those who are drafting the secondary legislation, or by defining the powers more narrowly.

The third factor to be considered is certainty or predictability of the law. The committee states that clarity about what the law requires can be undermined if too much policy content

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[85] *Legislation Guidelines: 2021 Edition* (Legislation Design and Advisory Committee, September 2021) at 67.

[86] This paper considered only the competing considerations laid out in the introduction of Chapter 14 of the Legislation Guidelines. The chapter outlines further questions to ask when considering the delegation of Parliament's power. There is more detail than I can go into in this paper.

[87] Legislation Design and Advisory Committee, above n 85, at 67.

[88] Hardcastle, above n 8, at 13.

[89] Legislation Design and Advisory Committee, above n 85, at 67.

is delegated.[90] The explanatory note of the Bill states that "a very large amount of secondary legislation will need to be made before" it comes into force and uses the equivalent Australian legislation as an indication, which included around 2,500 pages of secondary legislation.[91] Hardcastle noted that the Australian legislation relies more on primary legislation than the Act currently does.[92] Therefore, it may be expected that the Act will need a greater volume of secondary legislation before it can come into force. With the regime being built "from scratch" through secondary legislation, it is fair to argue that too much policy content will be delegated and that this will undermine the clarity or predictability of the law.[93]

The fourth factor is the transparency of the law. Two points are balanced here. The first is that layers of secondary legislation can make it hard for readers to navigate and understand the law. The second is that the inclusion of a large amount of technical detail can make the Act hard to understand. In the case of the Act, it is important that technical detail be included in secondary legislation and that this be decided by experts. However, considering that the secondary legislation will currently "materially control the practical implementation of the regulatory regime", there is more than just technical detail being included in secondary legislation.[94] This will impact the transparency of the law and may make it hard for readers to navigate.

The balancing of these factors suggests that Parliament may be inappropriately delegating its power. Therefore, more guidance should be included in the Act, at least in the form of the recommendations made in Part VI. Generally, more detail may need to be included within primary legislation to balance the LDAC factors. Change may also be necessary in the interests of democracy, given that unelected officials will determine how the regulatory regime will operate in practice.

VIII Conclusion

[90] At 67.

[91] Therapeutic Products Bill 2022 (204-1) (explanatory note) at 5.

[92] Hardcastle, above n 8, at 13.

[93] At 13.

[94] Johnson & Johnson, above n 68, at 14.

Based on my analysis, I conclude that the Act does not practically facilitate risk-based regulation beyond simply stating that it will. Nor does it completely align with international standards as Manatū Hauora Ministry of Health claims.[95] The Act needs to be adjusted. New Zealanders who depend on medical devices could be negatively impacted if importers, which New Zealand relies on for 95% of its medical devices, decided to skip the market.[96] An overburdened and understaffed regulator would also detrimentally impact the New Zealand public. It could mean delayed access to devices or a lower standard of evaluation. The purpose of the Act is to protect, promote, and improve the health of all New Zealanders. As it stands, it could endanger, interfere with, and impair the health of New Zealanders who depend on medical devices.

[95] "Therapeutic products regulatory regime" (19 July 2023) Manatū Hauora Ministry of Health <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime>.

[96] Medical Technology Association of New Zealand, above n 65, at 3.

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