MANATŪ HAUORA
MINISTRY OF HEALTH

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7 November 2024

Steven

By email: fyi-request-28706-40233748@requests.fyi.org.nz
Ref: H2024053438

Tēnā koe Steven

**Response to your request for official information**

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 9 October 2024 for:

> *"Can you please provide a copy of all submissions made by MTANZ towards the upcoming Medical device and products legislation"*

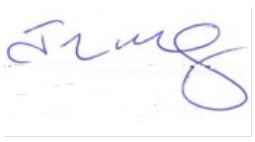
Six documents have been identified within scope of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed. In determining the release of the information within these documents, the Ministry of Health consulted with MTANZ. The documents are being released with no redactions.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā



John McGrath
**Director Priority Projects**
**Strategy Policy and Legislation | Te Pou Rautaki**

**Appendix 1: List of documents for release**

| # | Date | Document details | Decision on release |
|---|---|---|---|
| 1 | 1 March 2023 | MTANZ Therapeutic Products Bill Submission | Refused under section 18(d) of the Act as the information is publicly available here: www.parliament.nz/resource/en-NZ/53SCHE_EVI_130084_HE40065/d0d9623843397b270f7f9e1a9383d964f95426f2. |
| 2 | 1 March 2023 | MTANZ Therapeutic Products Bill Submission Supplementary | Refused under section 18(d) of the Act as the information is publicly available here: www.parliament.nz/resource/en-NZ/53SCHE_EVI_130084_HE44900/5ca8102ff4a56e9b9d4f031dcbb44c20b6561291. |
| 3 | June 2024 | MTANZ Medical Device Regulatory Framework Recommendations - Ministerial Consultation 2June 2024 | Released in full. |
| 4 | 26 July 2024 | Letter to Health Select Committee – MTANZ Submission – Therapeutic Products Act Repeal Bill | Refused under section 18(d) of the Act as the information is publicly available here: www.parliament.nz/resource/en-NZ/54SCHEA_EVI_8847fc37-a580-4680-d10f-08dc93dd1b2f_HEA1563/b8db27c7d2d3b38778efc45b6b1ee087fddf9e93. |
| 5 | 26 August 2024 | MTANZ Recommendations to Ministry of Health - New Legislation to Replace the Medicines Act 1981 | Released in full. |
| 6 | October 2024 | Transition Period for Introducing Medical Device Regulations | |

Document 3

2024

# MTANZ Proposed Regulatory Framework for Medical Devices



**MINISTERIAL CONSULTATION JUNE 2024**

CUSHLA SMYTH

medical technology
ASSOCIATION OF NEW ZEALAND

Document 3

## EXECUTIVE SUMMARY

This report outlines a preferred regulatory framework for medical devices in New Zealand providing three key recommendations:

1. The need for global harmonisation of medical device legislation and regulations
2. A distinct carve-out provision in the new legislation for medical devices, including IVDs
3. A regulatory recognition model

This proposal aims to ensure a robust regulatory framework for medical devices ensuring patient safety, fostering innovation, facilitating exports, and streamlining regulatory processes. Adopting these recommendations will ensure the availability of safe and effective medical devices and provide high-quality healthcare solutions to the population.

## RECOMMENDATION ONE

**'Ensure the Global Harmonisation of Medical Device Regulations in NZ'**

Global harmonisation of regulations for medical devices is critical 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.

**Key Reasons for Global Harmonisation:**

1. **Patient Safety and Public Health:**
    - **Consistency in Standards:** Harmonisation ensures that medical devices meet consistent safety and performance standards worldwide, reducing the risk of harmful or substandard products entering the market.
    - **Improved Surveillance:** Coordinated post-market surveillance allows for more effective monitoring of adverse events and rapid response to safety concerns, protecting public health.
2. **Facilitation of Innovation and Market Access:**
    - **Reduced Duplication:** Harmonised regulations minimise redundant testing and documentation requirements, reducing the time and cost for manufacturers to bring new devices to multiple markets thereby ensuring patient access.
    - **Accelerated Innovation:** A streamlined regulatory process encourages innovation by allowing companies to focus resources on research and development rather than navigating complex regulatory landscapes in different countries.
3. **Economic Benefits:**
    - **Lower Costs:** Harmonisation reduces the financial burden on manufacturers associated with complying with multiple regulatory systems, leading to cost savings that can be passed on to healthcare providers and patients.
    - **Market Expansion:** Enabling access to global markets enhances the commercial viability of new technologies for NZ innovators, supporting economic growth and job creation within the medical technology sector.

4. **Improved Regulatory Efficiency:**
    - **Resource Optimisation:** Regulatory bodies can allocate resources more effectively by relying on assessments and approvals conducted by trusted international counterparts, enhancing overall efficiency.
    - **Knowledge Sharing:** Harmonisation promotes collaboration and knowledge exchange among regulators, fostering the adoption of best practices and improving regulatory capacity.

**Jurisdictions Embracing Global Harmonisation:**

1. **European Union (EU) - Medical Device Regulation (MDR) and Invitro Diagnostics (IVDR):**
    - The EU MDR and IVDR aligns with international standards, including those set by the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Task Force (GHTF). This ensures that devices approved under the MDR and IVDR meet globally recognised safety and performance criteria.
2. **United States - Food and Drug Administration (FDA):**
    - The FDA participates in international harmonisation initiatives, such as the IMDRF, and adopts guidelines that align with international standards. This helps streamline the approval process for devices intended for both domestic and international markets.
3. **Australia - Therapeutic Goods Administration (TGA):**
    - The TGA aligns its regulations with international standards and participates in global harmonisation efforts through organizations like the IMDRF. This facilitates the recognition of approvals from other jurisdictions, simplifying the regulatory process for manufacturers.
4. **Singapore - Health Sciences Authority (HSA):**
    - Singapore's HSA adopts a regulatory recognition model that acknowledges approvals from established international regulators. This approach leverages global expertise and ensures that medical devices meet high standards of safety and efficacy.
5. **Canada - Health Canada:**
    - Health Canada is an active participant in international harmonisation efforts and aligns its regulations with global standards. This collaboration helps ensure that medical devices approved in Canada are consistent with those available in other major markets.

**Why Harmonisation is Effective:**

- **International Collaboration:** Harmonisation efforts, such as those led by the IMDRF, facilitate collaboration among regulatory authorities, promoting the adoption of best practices and consistent regulatory frameworks.
- **Regulatory Reliance:** Countries like Singapore and Australia use regulatory reliance models, recognising approvals from trusted international bodies. This approach reduces duplication of efforts and accelerates market and patient access.

- **Standardisation Initiatives:** The adoption of international standards, such as ISO 13485 for quality management systems and ISO 14971 for risk management, ensures a uniform approach to device safety and performance.
- **Harmonisation and Regulatory Reliance do not impact sovereignty:** Pursuing a Harmonised regulatory reliance model does not prevent New Zealand from making unique decisions to benefit its public. The Australian TGA has made various decisions tailored to the needs of the Australian population. Examples include the up classification of surgical mesh devices and the introduction of Patient Implant Cards (PICs) and Patient Information Leaflets (PILs) for implantable devices, reflecting early adoption of EU MDR requirements. However, some regulations, like the reclassification of software-based medical devices, remain specific to Australia.

**'Key aspects of the Therapeutic Products Act and the 2019 exposure draft were not harmonised with relevant jurisdictions or IMDRF'**

There are many examples of the TPA and the 2018/19 exposure draft not being harmonised, the most significant being the definition of a medical device itself. Global harmonisation of medical device regulations is essential for enhancing patient safety, promoting innovation, facilitating international trade and exports, and improving regulatory efficiency. Jurisdictions like the EU, USA, Australia, Singapore, and Canada exemplify successful implementation of harmonised regulatory frameworks, demonstrating the benefits of coordinated global efforts. By aligning regulations with international standards and collaborating through organisations like the IMDRF, countries can ensure the availability of safe, effective, and innovative medical devices worldwide.

## RECOMMENDATION TWO

**'Implement a Carve-Out Provision for Medical Devices in the Therapeutic Product Legislation'**

1. **Objective:**
    - To establish a distinct regulatory framework for medical devices that ensures their safety, performance, and efficacy while fostering innovation and timely market access.
2. **Scope:**
    - The carve out section applies exclusively to medical devices, which include IVDs, instruments, apparatus, appliances, software, implants, reagents, materials, or other articles intended for medical purposes.
3. **Regulatory Requirements:**
    - **Classification:**
        - Medical devices shall be classified according to their intended use and inherent risks, following a risk-based classification system similar to the one used by the TGA and the European MDR/IVDR.
    - **Clinical Evaluation and Assessment:**
        - Devices must undergo appropriate clinical evaluations and conformity assessments appropriate to their classification to demonstrate safety and performance.
    - **Post-Market Surveillance:**
        - Manufacturers must implement post-market surveillance systems to monitor device performance and manage any risks that arise after market entry.

4. **Licensing and Facility Requirements:**
    - Unlike medicines, medical devices shall not require licenses for manufacturing facilities and wholesaling activities. The regulatory focus will be on the accredited quality management systems in place and compliance with internationally recognised standards.
5. **Harmonisation with International Standards:**
    - The regulatory framework for medical devices will align with global standards, such as ISO 13485 for quality management systems, to facilitate international trade and ensure global best practices are followed.
6. **Exemptions and Simplified Procedures:**
    - Low-risk devices may be subject to simplified regulatory procedures to promote innovation and reduce unnecessary burdens on manufacturers and suppliers.

By implementing this carve-out, New Zealand can ensure that its regulation of medical devices is on par with internationally respected models like those of the TGA and European MDR/IVDR, avoiding unnecessary regulatory burdens and ensuring NZ remains an attractive market for medical device manufacturers.

**'The Medical Devices frameworks proposed over the years for have been implemented as an extension of the medicine legislation.'**

This co-mingling of legislation leads to incongruencies and complexities for medical Devices and IVDs that do not align with global medical device regulation frameworks.

The international trend to separate regulatory legislation for medical devices and medicines has emerged due to the fundamental differences in their development, risk profiles, and mechanisms of action. This differentiation of legislative provisions is crucial for ensuring that each category receives appropriate oversight tailored to its specific requirements, thereby enhancing safety, efficacy, and innovation.

**Importance of Separate Legislation:**

1. **Tailored Evaluation Processes:**
    - **Medicines:** These undergo extensive biochemical testing, with a primary focus on pharmacodynamics, pharmacokinetics, and clinical trials to ensure safety and efficacy.
    - **Medical Devices:** These require evaluations based on mechanical, electronic, or software performance, alongside biocompatibility assessments for implants or in-body devices. In the case of IVD's, they are based on clinical and analytical evaluations. The pace of innovation is faster, demanding a more flexible regulatory approach, which can be futureproofed for emerging technologies, particularly in the Digital Health space.

2. **Risk Management:**
    - Medicines typically have well-defined chemical compositions and predictable biological effects, whereas medical devices can range from simple bandages to complex surgical robots, each with distinct risk profiles and safety concerns.
3. **Innovation and Market Access:**
    - The medical device industry benefits from a flexible regulatory framework that can quickly adapt to technological advancements, promoting faster market entry and innovation cycles compared to the more static pharmaceutical sector.

**Regulatory Framework Exemplars:**

1. **Australian Therapeutic Goods Administration (TGA):**
    - The TGA has distinct regulations for medical devices under the Therapeutic Goods (Medical Devices) Regulations (2002), together with a separate Chapter (Chapter 4—Medical devices) within the Therapeutic Goods Act (1989) and many other medical device specific pieces of subordinate legislation. This framework aligns with international standards and is designed to ensure that medical devices meet safety and performance criteria specific to their category and intended use.
    - In contrast, medicines are regulated under the "Therapeutic Goods Act 1989," focusing on ensuring the safety, quality, and efficacy of pharmaceutical products through rigorous clinical testing and post-market surveillance.
2. **European Medical Device and IVD Regulation (MDR/IVDR) :**
    - The European Union implemented the Medical Device Regulation (MDR) in 2017, which came into full effect in 2021 and is currently progressing through its transition period. The EU then implemented the Invitro diagnostics regulation (IVDR) in 2022 which is also in its transition period. Both the MDR and IVDR provide a comprehensive regulatory framework specifically for medical devices and IVDs, addressing aspects like clinical evaluation, risk classification, and post-market surveillance to ensure high standards of safety and performance.
    - Pharmaceuticals in the EU are regulated under separate legislation, primarily the "Directive 2001/83/EC" and the "Regulation (EC) No 726/2004," focusing on the authorization and monitoring of medicinal products for human use, with a distinct set of requirements for clinical trials and market approval.

By establishing distinct legislative frameworks, both the TGA and the EU ensure that the unique characteristics and regulatory needs of medical devices and medicines are appropriately addressed, promoting patient safety, fostering innovation, and improving access to effective healthcare solutions.

**'Co-mingling of medicines and medical device legislation in the TPA caused scenarios where medical devices in New Zealand would have been subject to more stringent requirements than those enforced by the TGA in Australia'**

Since the TGA model is widely regarded as an international exemplar in medical device regulation, these additional regulatory burdens are unnecessary and counterproductive. For instance, under the Therapeutic Products Act and the 2018/2019 exposure draft, there are licensing requirements for

facilities and the wholesaling of medical devices. Such requirements do not exist under the TGA legislation, which focuses on ensuring safety and efficacy without imposing excessive regulatory obligations. This divergence highlights the importance of tailored regulatory frameworks that reflect the distinct needs of the medical device industry, preventing unwarranted administrative and financial burdens that could stifle innovation and access to medical technologies.

## RECOMMENDATION THREE

**'Adopt a Regulatory Recognition Model for Medical Devices in New Zealand'**

Adopting a regulatory recognition model for medical devices in New Zealand offers numerous advantages. This approach leverages the assessments and approvals of trusted international regulators, such as the FDA, TGA, and EU MDR/IVDR, to streamline the approval process and ensure the safety and efficacy of medical devices. Adopting a regulatory reliance program for medical devices is similar to what the current government is proposing for medicines.

**Benefits for New Zealand**

1. **Overcoming Capability and Capacity Challenges:**

    - **Lack of Experience:** New Zealand has not previously had a dedicated regulatory system for medical devices, leading to gaps in expertise and infrastructure. Leveraging approvals from well-established regulators helps bridge this gap.
    - **Building Capacity:** A regulatory recognition model allows New Zealand to build its regulatory capacity over time while ensuring that immediate needs are met without compromising safety or efficacy.

2. **Efficiency and Timeliness:**

    - **Faster Approvals:** By recognising the certifications from international regulators, New Zealand can significantly reduce the time required to approve medical devices, ensuring quicker access to new technologies for healthcare providers and patients.
    - **Reduced Administrative Burden:** The model minimises redundant evaluations and paperwork, streamlining the regulatory process and making it more efficient.

3. **Ensuring High Standards:**

    - **Global Best Practices:** Accepting approvals from reputable regulators ensures that medical devices in New Zealand meet high international standards of safety, performance, and quality.
    - **Consistency:** This approach provides a consistent and reliable framework for manufacturers and healthcare providers, fostering trust and confidence in the regulatory system.

4. **Economic and Market Benefits:**

    - **Attracting Innovation:** A streamlined and efficient regulatory process makes New Zealand an attractive market for both global and local medical device manufacturers, promoting innovation and investment in the medical technology sector.
    - **Supporting Local Industry:** By reducing regulatory burdens, local manufacturers can bring their products to market more quickly and compete effectively on a global scale.

5. **Leveraging Global Expertise:**
    - **Draw on global knowledge** - A regulatory reliance model enables New Zealand to draw on the extensive global expertise of well-established regulators in regions such as Europe, Australia, the USA, Japan, Canada, and Singapore. This collaborative approach is common in jurisdictions where shared knowledge facilitates timely review of premarket assessments.
    - **Cyber-security and Artificial Intelligence (AI)** – One area where we can benefit from additional expertise is in the domains of cybersecurity and AI in medical devices. Other jurisdictions have more advanced legislation and standards in these areas, most notably Singapore and the UK in areas of cybersecurity, and Europe recently passed the legislation on AI. By utilising regulatory reliance, we can access this expertise to ensure that these products are safe and fit for use in our marketplace. This approach allows for the review of complex issues that require specialised knowledge, which may not be readily available in New Zealand.

**Regulatory Recognition Exemplar - Singapore:**

The Health Sciences Authority (HSA) of Singapore uses a regulatory recognition model that acknowledges approvals from reputable international regulators. This model allows the HSA to expedite the registration process for medical devices by relying on the evaluations and certifications conducted by trusted regulatory bodies, such as the FDA, TGA, and European MDR/IVDR. Leveraging a regulatory recognition model has enabled the Singapore HSA to develop into an internationally respected and established regulatory body, which is now recognised as a reference country by the TGA.

**Success Factors:**

1. **Efficiency:** By recognising and leveraging the approvals from established regulators, Singapore's HSA can significantly reduce the time required to bring medical devices to market.
2. **Resource Optimisation:** The HSA can focus its resources on high-risk or novel devices that may require additional scrutiny, ensuring optimal allocation of regulatory efforts.
3. **Global Standards:** Ensuring that medical devices meet international standards by accepting approvals from trusted regulatory bodies guarantees a high level of safety and efficacy.
4. **Market Competitiveness:** The streamlined approval process makes Singapore an attractive market for medical device manufacturers, encouraging innovation and investment in the region.

Adopting a regulatory recognition model for medical devices in New Zealand offers a pragmatic and effective solution to the challenges posed by the lack of existing regulatory infrastructure and experience. By leveraging the expertise and approvals of trusted international regulators, New Zealand can ensure the timely availability of safe and effective medical devices, support the growth of its medical technology industry, and provide high-quality healthcare solutions to its population whilst still maintaining the sovereignty of decisions made for the benefit of the New Zealand public.

With this model in place, we anticipate that the NZ regulator will promptly verify the accuracy of the conformity certificates and subsequently issue an approval to the product sponsor, permitting importation, local supply and, when needed, exportation. There should be a publicly accessible database of medical device approvals, providing information on the types of products available in the market and their respective sponsors. This visibility is crucial for post-market activities, such as tracing adverse events. It will enable the NZ regulator to concentrate more on post-market

monitoring, including the review of real-world evidence, clinical signalling, and continuous evaluation.

Document 5

**MTANZ RECOMMENDATIONS to MINISTRY OF HEALTH**
**New Legislation to Replace the Medicines Act 1981**
26 August 2024

MTANZ propose the following recommendations for the new legislation to replace the Medicines Act 1981.

1. Define 'Therapeutic Use' in the definitions section of the proposed Act and align with the TGA's definition which is:

   ***"Therapeutic Use"*** means use in or in connection with:
   a. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
   b. influencing, inhibiting or modifying a physiological process in persons; or
   c. testing the susceptibility of persons to a disease or ailment; or
   d. influencing, controlling or preventing conception in persons; or
   e. testing for pregnancy in persons; or
   f. the replacement or modification of parts of the anatomy in persons.

2. Have individual definitions for Medical Devices and Invitro Diagnostics (IVDs) as per IMDRF GHTF/SG1/N071:2012 also in the definition section of the proposed Act:

   ***"Medical Device"*** means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
   - investigation, replacement, modification, or support of the anatomy or of a
   - physiological process,
   - supporting or sustaining life,
   - control of conception,
   - disinfection of medical devices,
   - providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

   ***"In Vitro Diagnostic (IVD) medical device"*** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

3. ***"Controlled Activities"*** - Controlled activities for medical devices and IVDs, such as wholesaling and supply chain management, should fall under the Manufacturer's or Sponsor's responsibility where appropriate. While we recognise the importance of monitoring risks related to product integrity (storage) and product traceability (recalls), we do not believe these should be classified as controlled activities. Instead, they should be required as conditions of registration, as is the case in Australia.

Document 6

# ‘Medical Device Transition Period’

## Introducing Medical Device Regulations in New Zealand

Written by the MTANZ Regulatory Special Advisory Group – October 2024

## Introduction

This report outlines a structured transition period for implementing medical device regulations in New Zealand focusing on alignment with global standards and the International Medical Device Regulators Forum (IMDRF) recommendations. The framework includes a grandfathering provision for existing medical devices and In Vitro Diagnostic (IVD) medical devices (collectively referred to as “medical devices”) to ensure supply continuity for New Zealand patients, and a phased transition to mandatory Regulator notification or approval depending on risk classification.

## Transition Period Overview

The transition period for implementing medical device regulations in New Zealand spans nine years, beginning with a three-year grandfathering phase that allows existing medical devices on the Web Assisted Notification of Devices (WAND) database and medical devices currently exempt under Schedule 1 of the *Medicines (Database of Medical Devices) Regulations 2003* (“the Regulations”) but previously supplied in the New Zealand market to remain on the market, contingent upon a Manufacturer/Sponsor declaration confirming their safety.

The following six years will see mandatory Regulator approval based on both regulatory reliance and non-reliance models for non-IVD medical devices, starting with Class D medical devices in years four and five, extending to Class C in years six and seven, and to Class B in years eight and nine. For IVD medical devices with classifications aligning with the IMDRF, the transition should align with non-IVD medical devices, also commencing with Class D products. During this period of the transition, lower class medical devices that are not yet required to undergo mandatory Regulator approval will continue to be introduced to the market by way of a Manufacturer/Sponsor declaration.

Class A products, due to their low risk, will follow a self-declaration model under the Manufacturer’s QMS commencing in year 9 of the transition period.

This structured approach aims to ensure device safety, enhance Regulatory oversight, minimise disruption to current safe device supply, mitigate risk to patients and align New Zealand’s framework with global best practices.

It is Industry’s expectation that the Regulator will be able to select any medical device for an audit at any stage through, and after, the transition period based on (to be determined) risk factors.

This strategic approach will foster a smoother transition and support the long-term sustainability of the medical device and IVD market in New Zealand.

**Duration: 9 Years**

## Phase 1 Grandfathering Provision

The grandfathering phase will allow existing medical devices listed on the WAND database and those currently exempt under Schedule 1 of the Regulations but previously supplied in the New Zealand market to remain on the market while providing Sponsors with a structured timeline for compliance.

During the grandfathering stage, Sponsors will notify the Regulator of their intent to continue to supply via an online portal. Note: Infrastructure will need to be in place for this portal. Notification will be made by grouping devices into similar kinds of devices based on risk classification, GMDN code, and Manufacturer. The Sponsor must declare that the product:

- has been supplied within the last 12 months (sold, exported, sampled, donated or for research)
- is currently listed on WAND or meets the requirements of the exemption under Schedule 1 of the Regulations
- complies with a harmonised set of Essential Principles (e.g., IMDRF)
- is correctly classified
- has not been requested to be removed from the market in more than one jurisdiction (Australia, EU, or the USA) due to safety-related issues or other legal infringement(s).

Notifying the Regulator will offer insight into the devices currently available in New Zealand. This transparency will provide the Regulator with the advantage of having visibility to the variety of devices in the market, allowing for more effective resource planning and allocation as the mandatory approval or notification phase approaches. By understanding the volume and types of devices being supplied, the Regulator can establish the required framework including targeted post-market surveillance and vigilance activities. This will also allow the Regulator to gain a better understanding of resource requirements and the skill sets those resources will need to have.

**Duration: 3 Years**

## Phase 2-5 Transition to Regulator Approval and Self Declaration

The transition to Regulator approval or notification will be implemented in phases according to risk classification.

1. Phase 1 (Year 1-3): Grandfathering provision begins.
2. Phase 2 (Year 4-5): Mandatory Regulator approval begins for Class D
3. Phase 3 (Year 6-7): Mandatory Regulator approval begins for Class C
4. Phase 4 (Year 8-9): Mandatory Regulator approval begins for Class B
5. Phase 5 (Year 9 onwards): Manufacturer Self-Declaration begins for Class A

During the Mandatory approval period, Manufacturers/Sponsors will need to submit documentation by the reliance or non-reliance models for assessment, as applicable. The Regulator will approve devices based on correct documentation being supplied, verification of classification and documentation is current and meets the stated requirements.

Document 6

The regulatory framework should be administered by the Regulator through the development of an online portal. Sponsors can submit applications to the Regulator through this portal, upload documentation, make declarations and obtain approval information.

The Regulator should establish legislative timeframes for approvals. Below are the recommended approval timeframes for each risk class:

- Class A (Lowest Risk): Effective immediately upon self-declaration.
- Class B/C: 20 business days.
- Class D (Highest Risk): 20 business days.

**Duration: 6 Years**

**Risk classification** is based on IMDRF classification framework which categorises medical devices and in vitro diagnostics (IVDs) into 4 classes based on their potential risks:

- Class A: Low-risk devices and IVDs (e.g., tongue depressors, simple tests) requiring minimal regulatory oversight. Also known as Class I in other jurisdictions.
- Class B: Low-Moderate-risk devices and IVDs (e.g., diagnostic ultrasound equipment, tests for non-critical conditions) needing more comprehensive safety and efficacy data. Also known as Class IIa in other jurisdictions.
- Class C: Moderate-High-risk devices and IVDs (e.g., pacemakers, tests for serious conditions) that demand extensive clinical data and rigorous scrutiny. Also known as Class IIb in other jurisdictions.
- Class D: High-risk devices and IVDs (e.g., implantable devices, tests for life-threatening diseases) subjected to the most stringent regulatory requirements and extensive evidence. Also known as Class III in other jurisdictions.



## Reliance Model (RM)

The RM is a process where the Regulator accepts the safety, efficacy, or quality evaluation made by an approved regulatory authority. This approach aims to streamline regulatory pathways and promote global harmonisation, minimising duplication of efforts and enabling quicker access to safe and effective medical devices in various markets.

| Classification | Premarket Requirements | Post Market Requirements |
|---|---|---|
| **A**<br>**Low Risk** | Declaration of Conformance: Sponsors to submit a Manufacturer declaration attesting to compliance with safety and performance standards. | Post market obligations for reporting and field actions. |
| **B**<br>**Low-Moderate Risk** | International Registration evidence from a recognised regulator. This can include registration certificates from Australia, Canada, EU, Japan, Singapore, USA, or could also be MDSAP or ISO 13485 Certificate. | Post market obligations for reporting and field actions. |

| | | |
|---|---|---|
| **C**<br>**Moderate-High Risk** | International Registration evidence from a recognised regulator. This can include registration certificates from Australia, Canada, EU, Japan, Singapore, USA.<br><br>Manufacturers of implantable devices are also required to submit Patient Information Leaflet (PIL) and Patient Information Card (PIC), unless specifically excluded from these requirements. | Post market obligations for reporting and field actions.<br><br>Three-year reporting requirement, once approved, to monitor ongoing safety and performance for implantable devices. |
| **D**<br>**High Risk** | International Registration evidence from a recognised regulator. This can include registration certificates from Australia, Canada, EU, Japan, Singapore, USA.<br><br>Manufacturers of implantable devices are also required to submit Patient Information Leaflet (PIL) and Patient Information Card (PIC), unless specifically excluded from these requirements. | Post market obligations for reporting and field actions.<br><br>Three-year reporting requirement, once approved, to monitor ongoing safety and performance for implantable devices. |

**Rationale for ISO 13485.** Adopting ISO 13485 as a standard is critical for ensuring consistent quality and safety in medical devices.

ISO 13485 is the standard that specifies requirements for a quality management system. Conformity assessment is the process of verifying that a standard or technical specification was applied in the design and manufacturing of a device, which can include compliance with ISO 13485. Generally, obtaining ISO 13485 certification can be more costly upfront due to the need for documentation, audits, and potential process changes. However, the cost of conformity assessment varies depending on the scope and complexity of the device.



## Non-Reliance Model (NRM)

The NRM pathway is an option where no overseas approval is available. This alternative pathway ensures that devices can still be evaluated for safety and efficacy within the local regulatory framework, ensuring access while maintaining compliance with medical device standards.

| Classification | Premarket Requirements | Post Market Requirements |
|---|---|---|
| **A**<br>**Low Risk** | Declaration of Conformance: Sponsors to submit a Manufacturer declaration attesting to compliance with safety and performance standards. | Post market obligations for reporting and field actions. |

| | | |
|---|---|---|
| **B**<br>**Low-Moderate Risk** | ISO 13485 Certificate<br><br>And<br><br>Manufacturer Declaration that the device meets the Essential Principles. | Post market obligations for reporting and field actions. |
| **C**<br>**Moderate-High Risk** | ISO 13485 Certificate<br><br>And<br><br>Manufacturer Declaration that the device meets the Essential Principles.<br><br>Manufacturers of implantable devices are also required to submit Patient Information Leaflet (PIL) and Patient Information Card (PIC), unless specifically excluded from these requirements. | Post market obligations for reporting and field actions.<br><br>Three-year reporting requirement to monitor ongoing safety and performance for implantable devices. |
| **D**<br>**High Risk** | ISO 13485 Certificate<br><br>And<br><br>Manufacturer Declaration that the device meets the Essential Principles.<br><br>Manufacturers of implantable devices are also required to submit Patient Information Leaflet (PIL) and Patient Information Card (PIC), unless specifically excluded from these requirements.<br>***For certain High-risk devices, the non-reliance pathway is inappropriate**. | Post market obligations for reporting and field actions.<br><br>Three-year reporting requirement to monitor ongoing safety and performance for implantable devices. |



## Recommendations

**Priority Recommendations:**

- **Conformity Assessment**: Develop New Zealand's equivalent Essential Principles and conformity assessment procedures.
- **Monitoring and Evaluation:** Establish a framework to assess compliance and effectiveness throughout the transition period.
- **Online Resources:** An online portal would be required to replace WAND and facilitate the regulatory submissions required. The IT platform should facilitate data retrieval and analytics. Comprehensive guidance documents, FAQs, and a dedicated help desk should also be established. This should be a cost-effective effort and ensure that cost is not passed to the sponsor or manufacturer.
- **Regulatory Statements:** Maintain a process allowing Sponsors to request documentation to support export and registration in overseas jurisdictions, e.g., Certificate of Free Sale or equivalent.
- **International Collaboration:** Engage with global Regulatory bodies for knowledge sharing and alignment with best practices. Consider joining IMDRF as affiliate member.

- **Post-Implementation Review:** Develop evaluation metrics and establish a process for continuous improvement of the Regulator.

**Other Considerations:**

- **Communication Strategy**: Develop a detailed plan to inform and consult with stakeholders about new regulations, including timelines and requirements.
- **Pilot Programs**: Implement trial runs to gather insights and refine processes before full-scale implementation. This could potentially involve a request for Sponsors to volunteer for involvement in the pilot programs.
- **Stakeholder Engagement**: Organise workshops, establish advisory groups, and maintain open lines of communication with stakeholders.
- **Pre-submission meetings and interactive review consultation meetings between the Regulator and the Sponsor:** Particularly for devices that do not have a clear classification or are new / novel or are being applied in higher risk environments / patient populations / etc.
- **Financial Support:** Explore grants and flexible payment plans to assist smaller NZ Manufacturers.
- **Support Resources**: Provide Manufacturers with guidance on ISO 13485 certification processes and resources for compliance.
- **Technical Assistance:** Offer consultation services to help Sponsors/Manufacturers navigate Regulatory requirements effectively.

Document 6

# Project Timeline