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**White Paper**

**Proposal for a New Zealand Regulatory Scheme for Medical Devices**

**March 2015**

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**CONTENTS**

1. **Executive Summary**
2. **About the Medical Technology Association of NZ**
3. **Aim of the paper**
4. **The current NZ regulatory requirements for medical devices**
5. **Background**
6. **EU Notified Bodies and Competent Authorities**
7. **A proposed regulatory scheme for medical devices in NZ**
8. **Conclusions**

**1 Executive Summary**

Following the cessation of efforts to establish a joint therapeutic agency with Australia and the need to upgrade the current *Medicines Act 1981,* the Medical Technology Association of New Zealand (MTANZ) presents this paper. MTANZ has always supported the requirement for medical devices entering the New Zealand market to demonstrate that they meet an internationally-recognised standard for safety and performance.

New Zealand now has the opportunity to establish a regulatory scheme that is comprehensive, effective and efficient, reflects our small therapeutic market and does not create barriers for New Zealanders’ to access life-saving technology in a timely manner.

A New Zealand regulatory scheme would be based on the European Essential Requirements and have the authority to perform similar to a European Competent Authority:

* enforces regulations by investigating allegations received about possible non-compliance with the regulations
* investigates post-market surveillance reports received from device manufacturers, users and the public
* maintains a register of manufacturers and distributors

How the new regulatory agency is funded will be crucial for suppliers of medical devices. The New Zealand medical device sector would be firmly against a therapeutic agency being fully funded by industry. The major arguments against full industry funding relate to the general problem of excessive costs in relation to benefits under a statutory monopoly with mandatory purchase. This could be a recipe for cost excesses and mediocre performance. The solution is to introduce performance related incentives where possible and to ensure that costs are related to efficient cost and marginal benefit – the lowest cost that the service can be provided under an efficient system.

**2 About the Medical Technology Association of New Zealand (MTANZ)**

The Medical Technology Association of New Zealand (MTANZ) was first established in 1979 and is the only industry body representing medical technology manufacturers, importers and distributors of medical devices in New Zealand.

MTANZ aims to increase awareness of the medical technology industry in New Zealand and to ensure patients benefit from the innovative medical devices available today and into the future. MTANZ supports New Zealand researchers and manufacturers in developing medical devices for international markets.

MTANZ represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. MTANZ promotes policies for a legal, regulatory and economic environment to advance access to innovative medical technologies.

**3 Aim of the paper**

In November 2014 the Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator. The New Zealand Government will now upgrade New Zealand’s therapeutic products regulations with a comprehensive, effective and efficient regulatory scheme.

The paper aims to:

1. Propose a model for the regulation of medical devices entering the New Zealand market based on internationally recognised certifications/approvals.
2. Propose that a regulatory scheme supports quality, safety and performance of medical devices supplied in New Zealand.
3. Propose a regulatory scheme that demonstrates efficiency costs.
4. Propose a regulatory scheme that fosters and supports innovation in research, development and manufacture of New Zealand medical technology.

**4 The current NZ regulatory requirements for medical devices**

Currently, all devices placed on the New Zealand market for sale are mandated by the *Medicines (Database of Medical Devices)* *Regulations 2003* to be “notified” to the Medsafe’s Web Assisted Notification of Devices (WAND) database within 30 days of being placed on the New Zealand market. The sponsor of the medical device must be a New Zealand legal entity with a physical address in New Zealand. Also, New Zealand manufactures need to be registered as “sponsors” in order to supply the New Zealand market.

While this is not a registration process, the WAND database does capture devices and sponsors in the New Zealand market. The public District Health Boards (DHBs) and most private hospitals, require a supplier to provide evidence through the Product Evaluators Hospitals NZ (PEHNZ) process that their medical device is notified on the WAND database, has a European CE Mark, and/or USA FDA approval and/or is included in the Australian Register of Therapeutic Goods (ARTG) before being procured by the healthcare provider.

WAND could very effectively become a registration process with minimal compliance costs while still ensuring medical devices placed on the New Zealand market meet internationally recognized standards for safety and performance through the attachment of appropriate international certification/approvals evidence to WAND application.

**5 Background**

The Global Harmonisation Task Force (GHTF), was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry founded in 1992. At its inception GHTF was comprised of representatives from five founding members (Australia, Canada, European Union, Japan and United States), each of which actively regulated medical devices using their own unique regulatory framework. The GHTF was established to address global issues:

* The need to harmonise national standards in order to minimize regulatory barriers
* Facilitate trade and improve access to new technologies
* Reduce the cost of implementing regulations for Governments and local industry

The purpose of GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this was accomplished was via the publication and dissemination of harmonised guidance documents on basic regulatory practices, which could be adopted/implemented by member national regulatory authorities.

In late 2011 GHTF was replaced by the International Medical Devices Regulators Forum (IMDRF). IMDRF aims to accelerate the international medical device regulatory convergence started by GHTF. The GHTF model was fundamentally based on the European regulatory system adopted in the early 1990s, and included the following key elements:

1. Pre-market evaluation:
2. Definitions of key terms, including ‘medical device’ and ‘manufacturer’
3. Rules-based risk classification system
4. Conformity assessment procedures to be followed by manufacturers, including the requirement to implement a Quality Management System (QMS) and post-market surveillance system
5. Standards and Essential Principles to demonstrate the safety & performance of medical devices, including requirements for labelling
6. Post-market surveillance & vigilance
7. QMS & auditing
8. Clinical safety & performance

The GHTF system encourages manufacturers of medical devices to apply internationally harmonised standards to the design and manufacture of their product to demonstrate compliance with the Essential Principles. This includes compliance with the international QMS standard (ISO13485), for all but the lowest risk (Class I) medical devices. This standard requires manufacturers of medical devices to establish and maintain the high quality of design, manufacturing and post-market monitoring necessary for medical technology.

Assessment and certification of a manufacturer’s QMS occurs before manufacturers can supply their products. Continued adherence to the QMS requirements is also assessed through regular surveillance inspections. This continuous monitoring and surveillance ensures that medical devices are manufactured to their specification and continue to perform as intended.

Once conformity assessment certification has been obtained, the manufacturer signs a ‘Declaration of Conformity’ declaring that they have applied the relevant conformity assessment procedures, and that the devices comply with GHTF Essential Principles for safety and performance.

GHTF prescribes a risk-based system for the assessment of conformity to the Essential Principles. The greater the risk carried by the product (in terms of how invasive within the human body it is, the duration of use and the risk it poses to users), the more stringent the conformity assessment procedure that needs to be applied by the manufacturer.

The GHTF Essential Principles are expected to form the basis of New Zealand medical device regulations.

**6 EU Notified Bodies and Competent Authorities**

This European-style model works well to cater for the enormous diversity of life-improving medical treatments and technologies provided to patients. Europe’s current medical device legislation makes a more targeted and effective use of competent authority and regulator resources.

In the EU conformity assessment of medical devices is undertaken by Notified Bodies (NB). These bodies are impartial, independent third-party commercial organisations specifically designated to monitor and review conformity assessment procedures applied by medical device manufacturers. Each member state of the EU has a Competent Authority (e.g. in the United Kingdom the Competent Authority is the Medicines and Healthcare Products Regulatory Agency (MHRA)), which is responsible for implementing the European laws (‘Directives’) nationally, and designating Notified Bodies (e.g. in the UK BSI and SGS are Notified Bodies) within their respective nation.

The member state Competent Authority will assess a resident Notified Body’s organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in activities related to medical device assessments.

If a Notified Body meets the criteria, the Competent Authority recommends that it is listed on the Official Journal of the European Commission (OJ). Notification stipulates the specific directive areas in which the Notified Body has been approved (e.g. medical devices or consumer electronics). It is not uncommon for a notification to also list specific product groups, which the Notified Body is approved to assess (e.g. active medical devices or implantable medical devices). The designating Competent Authority is responsible for periodically assessing the resident Notified Bodies to ensure continued compliance with the standards for assessment.

Competent Authorities are also responsible for post-market monitoring of medical devices. Under the EU Directives a manufacturer of medical devices supplied in the EU must report adverse events involving medical devices to the Competent Authority of the nation where the event occurred. It is the Competent Authority’s responsibility to investigate, monitor and trend adverse events so they can initiate recalls or provide advice to the health system of other Competent Authorities and regulators around the world.

The European Commission has established a new framework for the designation and supervision of Notified Bodies operating under the EU Medical Devices/Active Medical Devices Directives and partnering with a Competent Authority will provide the greatest insight into the competence of a range of Notified Bodies.

In September 2013 regulation on the designation and supervision of notified bodies was adopted, examples of new measures include:-

* A Member State shall only designate or re-designate a Notified Body after a joint assessment conducted with experts from the Commission and other Member States. The assessment reports shall be made available to all other Member States.
* Member States are required to carry out surveillance and monitoring of the Notified Bodies at certain intervals to ensure that they continuously live up to the requirements. If this is not the case, the Member State must withdraw the designation as Notified Body.
* Knowledge and experience requirements of the staff of the Notified Bodies are clarified.

In 2014 20 joint mandatory assessments under the Regulation are expected and of the five which took place earlier in 2014 one application for a new Notified Body to be designated was refused.

Other recommendations surrounding audits and assessments have also been adopted such as random unannounced manufacturer audits and rotation of auditors to ensure impartiality, in 2014.

In addition existing international collaborations such as the IMDRF Medical Devices Single Audit Program (MDSAP) and the Mutual Recognition Agreement (MRA) with the EU may also support the reliance by Medsafe on the conformity assessment procedures undertaken by European Notified Bodies.

These recent “improvements” to the European system provide additional confidence in the way that Notified Bodies fulfil their responsibilities.

**7 A proposed regulatory scheme for medical devices in New Zealand**

The key features of a proposed New Zealand regulatory scheme for medical devices would contain the following:

1. *The regulatory authority (Medsafe) should become a Competent Authority.*

The competent authority is in control of two main elements:

* 1. Firstly they set the public safety requirements and intervention mechanisms and
  2. Secondly, they select and control competent, scientific certification bodies to do the technical and scientific review

Ultimate control remains under the jurisdiction of the Competent Authority.

This concept would translate in the legislation where Medsafe would have two broad tasks:

1. Setting and monitoring public health and safety requirements such as essential safety and performance requirements, clinical investigation, product classifications, product, technical and manufacturing standards, vigilance and market surveillance;
2. Selecting, empowering, monitoring and evaluating competent testing and certification organizations, (mainly Notified Bodies) who must have the latest in scientific and technical competence, and be capable of checking both manufacturers and their medical devices in accordance with the regulations.
3. *The regulatory authority (Medsafe) is able to designate third-party conformity assessment bodies whose certification is acceptable to be able to include a device in WAND*.

With Medsafe as the Competent Authority, the use of certification issued by designated 3rd party conformity assessment bodies would enable Medsafe to ensure the best skilled and competent reviewers are assessing products coming into New Zealand. The majority of medical devices supplied in New Zealand will be supported by CE certification from a European Notified Body.

Similar to the current DHB process, Medsafe would accept the CE certification from these designated conformity assessment bodies without any further review and the New Zealand sponsor would upload the conformity assessment certification in to an enhanced WAND database.

(For a New Zealand manufacturer that only supplies the domestic market, conformity assessment would be delegated to a designated 3rd party conformity assessment body)

1. *Enhancement of the Web-Assisted Notification of Devices Database (WAND)*

The WAND database has provided an effective way of recording the medical devices available for supply in New Zealand and the associated sponsor responsible for the supply of the goods and post-market surveillance activities.

It is proposed that the WAND database be maintained and enhanced by the addition of evidence of certification/approval by a designated international regulatory authority/Notified Body. It is proposed that sponsors be required to undertake a thorough review of all WAND listings to remove any that are no longer required, to check and verify that the information in each entry is correct and current and attach appropriate evidence of conformity assessment or approval for each listing that covers the product in its scope.

If regulatory authority was to maintain a ‘preferred’ Notified Body (NB) list (those that they have designated), then this would serve as a point of difference between those manufacturers using NBs recognised as competent, and those using NBs of unknown competence.

1. *Regulatory approvals from other jurisdictions to be utilised*

In addition to the generally accepted European CE certification, it is proposed to allow manufacturers to use other equivalent regulatory approvals from recognised competent regulators.

For example, this could be in the form of:

* US FDA Pre-Market Approval (PMA) which is considered to be comparable to the European Design Examination (DE), together with US FDA 510K approvals for Class I/Is/Im/IIa/IIb medical devices.
* Inclusion in the ARTG from TGA
* Health Canada product licence

Similar approvals should be accepted from the USA, Australia and Canada (and, in the future, Europe) for IVD medical devices.

1. *The regulatory authority to focus resources to post-monitoring and compliance*

The basic principle of a post market system is to trend and monitor events that cause serious injury or death or have the potential to cause serious injury or death on reoccurrence, and to ensure these events are reported to the regulator.

No amount of rigour in the pre-market review process can predict all possible device failures or incidents arising from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur. Increasingly, more emphasis is being placed on post-market surveillance and vigilance and its input into risk management. Rather than heavily resource assessment of pre-market requirements, there should be an appropriate balance of resources directed to post market activities.

Post-market surveillance ensures that medical devices in use continue to be safe and effective and this requires shared responsibility by all stakeholders. Shared responsibility includes communication and participation by the manufacturer, sponsor, distributor, government, user and the patient.

Currently adverse events are reported to Medsafe and an investigation of the alleged adverse event, relating to the device, is conducted by the manufacturer. Medsafe does review these reports and provides feedback to the manufacturer as required. The system is working as desired to ensure safe and effective use of the devices.

In extreme cases, dependent upon the outcome of the investigation and risk of the adverse event in relation to patient safety, the manufacturer may be required to conduct a field action.

1. *Transition period*

Whether the above mode of registering medical devices in New Zealand, or an alternate framework, is adopted, it will be important to allow an adequate transition period within which the industry must comply with the new regulations for products that are on the market immediately prior to the new Regulations coming into force. Given the impact, not only to industry, but also the Regulator, a period of *five* years should be considered appropriate. Further, there should be no additional costs associated with transitioning products to the new framework as this could act as a disincentive to register existing products early in the transition period.

1. *A regulatory scheme that is limited to efficiency costs only*

A New Zealand regulator should not have automatic access to industry funding revenue, but seek funds from Parliament through normal budgetary processes using efficiency dividends, benchmarking and market testing third party competition. The protection of health and welfare of the New Zealand population should be a shared responsibility between Government and the industry.

Governance issues should include a requirement to operate through a consultative committee that encompasses stakeholder representation, an independent chairman, an ability to monitor agency efficiency, access to adequate information and transparent reporting processes. There needs to independent reviews of industry funding arrangements and independent dispute resolution processes

A process of measurable performance targets for the provision of the regulatory services, including penalties for non-performance would have to be part of any regulatory scheme to ensure timely assessments are completed.

While any new regulations would need to make reference to the conducting of clinical trials and articulate advertising principles for medical devices, the current New Zealand processes for both are already well defined and are appropriate for the New Zealand market.

**8 Conclusions**

MTANZ believes the proposals put forward in this paper will help support a New Zealand regulatory scheme for medical devices that is efficient and effective for New Zealand. It is important the New Zealand public has confidence in the safety and performance of medical devices supplied to the domestic market and that the regulatory scheme supports the research, development and manufacturing of medical devices in New Zealand.

It is to be noted that the WAND notification process for medical devices was established in 2004 to capture products on the New Zealand market. It has been a low “touch” scheme and has not historically led to any issues regarding public health and safety that have not impacted other regulated markets ( such as Australia and Europe). As such, it would appear that this “White Paper” proposal offers an appropriate balance of risk and benefit for a New Zealand regulatory scheme.

A New Zealand regulatory scheme must have minimal regulatory burden and support technology innovation introduction that improves health outcomes for New Zealand and contributes to economic growth.

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