REGULATORY ENVIRONMENT FOR MEDICAL DEVICES IN NEW ZEALAND

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REVIEW ARTICLE

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ABSTRACT

Medical Devices are one of the most important health intervention tools available for the prevention, diagnosis and treatment of diseases and for patient rehabilitation. Although the Medical Devices market in the New Zealand region is very diverse, the existing regulations should be further developed to a greater extent for development of the country's healthcare sector. Medsafe, the drug and medical device authority of New Zealand has taken steps towards this introducing a web-based online database however, only for the notification of devices in the market which means, there is no premarket assessment for all devices that get sold in the market. The notification process is comparatively very easy and the documentation that is prioritized by Medsafe is only the evidences of the device registration in other countries, like the FDA clearance, the CE certificate or the ARTG listing.

Keywords: Medical Devices, New Zealand, Medsafe, WAND, MTANZ.

INTRODUCTION

Medical Devices are no longer the concepts of future and the world today rely on various medical devices directly or indirectly for the purpose of healthcare and diagnosis. These devices are currently being built into everyone's life by the manufacturers via simplest of the consumer electronics such as smart watches and smartphones which have the functionality to trach and sense the health-related activity of the user. Be it heart rate, be it the number of calories being burnt, be it the count of steps a person takes to travel a distance a sensor in a smartphone can measure to the devices that monitor the activities of the heart, portable x-ray devices and ultrasound scanners, technology has been playing a major role in advancement of these devices and serving the healthcare sector massively.

However, no device can be authenticated unless being regulated by a regulatory authority devised by the respective health ministries of different nations of the globe. The advancement of technology making the devices simpler with maximised capabilities poses challenges to the regulators who are responsible for registration of these devices and health of the people who use it. Today, the Food and Drug Administration (FDA) of United States has been most successful in comparison with any other regulatory bodies in framing out the medical device regulations. The FDA has also issued regulations that cover the Mobile Apps that can be considered medical devices, in the recent past. The European Medicines Agency (EMA) has also successfully laid out regulations for medical devices in the continent of Europe. Australia's Therapeutic Goods Administration (TGA) also, does not fall back on this context.

As of 2015, almost all developed nations have their dedicated guidelines for the regulation of medical devices. A few developed economies including the island country New Zealand haven't been very successful in laying down the regulations for medical devices. This article sheds light on the current aspects of medical device regulation in New Zealand and aims at suggesting changes to the regulation system followed in the nation.

New Zealand currently does not have detailed regulations for medical devices. The responsibility for ensuring the supply of 'approved' medical devices lies entirely with the customer. A company submitting a tender to supply devices for public health is required to demonstrate that the device is already approved

for use in Australia or the US, or is CE marked. (1)

The Web-Assisted Notification of Devices (WAND) system, though being an advanced online databasing system, fails to serve the functions similar to that of the regulatory environment of other countries. The steps to be followed for entering the database or registering a medical device on the database are relatively easy and less complicated. The document requirement is minimal too, with priority being given largely at the evidences of certification of the same device in other markets, preferably United States, Europe or Australia. This means, an FDA clearance or a CE marking certificate for a device gains a direct and relaxed entry for the device into the New Zealand market.

There have been few cases where Medsafe has failed to ensure the safety of its patients regarding medical devices and few proposals for overhauling the regularly system for medical devices have been made in the recent past. These proposals have been discussed later in the article.

OBJECTIVES

The focus of this article is to define the regulatory environment for medical devices in New Zealand and to explain the pathways for marketing authorisation for medical devices in New Zealand. The objectives of the article are-

- To explore the regulatory environment of New Zealand.
- To define and elaborate the regulations for medical devices in New Zealand supplemented by official documents.
- To explain the process for marketing authorisation for medical devices in New Zealand in detail.
- To suggest the implementation of a more stringent pathway for medical device registration in New Zealand

DISCUSSION

Medsafe oversees the medical device market of New Zealand. The device to be registered must be listed in Medsafe's Web Assisted Notification of Devices (WAND) database within 30 days of a person or organization becoming the sponsor of the device and device market entry. Pre-market approvals of devices are not required by Medsafe, but manufacturers must provide proof of compliance with US, Canadian, EU or Australian medical device regulations in order to gain market entry in New Zealand. (2)

Medsafe expects the suppliers of medical devices to be familiar with the related definitions in the Medicines Act 1981 to ensure the products they supply are appropriately regulated. The supply of products as medical devices that are medicines may breach the Act. (3)

For the scope of this article, legal definitions for the following have been taken from the Medicines Act which provides the legal definition.

Therapeutic Purpose

A product is regulated as a medical device or a medicine if the manufacturer or sponsor claims or implies a therapeutic purpose for it. The legal definition of therapeutic purpose is contained in Section 4 of the Medicines Act 1981 and states.

Therapeutic purpose means any of the following purposes, or a purpose in connection with any of the following purposes:

a. preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or

b. influencing, inhibiting, or modifying a physiological process; or

c. testing the susceptibility of persons to a disease or ailment; or

d. influencing, controlling, or preventing conception; or

e. testing for pregnancy; or

f. investigating, replacing, or modifying parts of the human anatomy

The legal definition of therapeutic purpose provides the framework for understanding the concept. Understanding how these clauses apply to medical devices is important to the definition

of a medical device. A therapeutic purpose, either claimed or implied, for a product may result in it being determined to be a medicine or a medical device. (3)

Medicine

The term 'medicine'

a. means any substance or article that -

   i. is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

   ii. achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and

b. includes any substance or article -

   i. that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or

   ii. of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of the Medicines Act; but

c. does not include -

   i. a medical device; or

   ii. any food within the meaning of section 2 of the Food Act 1981; or

   iii. any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or

   iv. any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or

   v. any animal remedy; or

   vi. any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of the Medicines Act.

Medical Device

Only products that meet the legal definition of a medical device are regulated as medical devices.

a. means any device, instrument, apparatus, appliance, or other article that -

   i. is intended to be used in, on, or for human beings for a therapeutic purpose; and

   ii. does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

b. includes a material that -

   i. is intended to be used in or on human beings for a therapeutic purpose; and

   ii. does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

c. also includes -

   i. anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and

   ii. any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of the Medicines Act; but

d. does not include a device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared

by regulations not to be a medical device for the purposes of the Medicines Act.

Medical Device Registration in New Zealand

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. (4)

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.

The Sponsor's Role

The Sponsor in the New Zealand would correspond to importer, exporter or local manufacturer who has the legal responsibility for a medical device supplied in New Zealand. This responsibility includes ensuring that medical devices are notified to the WAND database in accordance with the Regulations.

The legal definition of a sponsor is contained in Regulation 3 of the Medicines (Database of Medical Devices) Regulations 2003 and states;

Sponsor, in relation to a medical device -

a. means -

   i. a person in New Zealand who exports, or arranges the exportation of, the device from New Zealand:

   ii. a person in New Zealand who imports, or arranges the importation of, the device into New Zealand:

   iii. a person in New Zealand who manufactures the device in New Zealand, or arranges for another person to manufacture the device in New Zealand, for supply (whether in New Zealand or elsewhere); but

b. does not include a person who -

   i. exports, imports, or manufactures a device; or

   ii. arranges for the exportation, importation, or manufacture of a device -

   iii. on behalf of another person who, at the time of the exportation, importation, manufacture, or making of the arrangements, is a resident of, or is carrying on business in, New Zealand.

The interpretation of the above definition establishes the following criteria for a sponsor;

- A sponsor is based in New Zealand and must has a local presence (registered business or principal place of business in New Zealand).
- A sponsor imports, exports, or manufacturers medical devices in New Zealand.
- A sponsor may arrange for a New Zealand based third party to manufacture a medical device on its behalf for supply anywhere.
- A sponsor must have a presence in New Zealand. Organisations without a New Zealand presence cannot be sponsors.
- A sponsor is NOT an individual or organisation that purchases products

from a New Zealand based sponsor for resale within New Zealand.

In this regard, the examples of sponsors may include, a New Zealand entity (individual or organisation) importing devices into New Zealand for sale to the local market; a New Zealand hospital directly importing a device from an overseas manufacturer; a healthcare professional making a one-off importation of a small number of devices, one of which he/she keeps, and reselling the balance; a New Zealand entity parallel importing any medical device into New Zealand for sale to the local market; a New Zealand entity importing a range of medical devices into New Zealand which it repackages as first aid kits for resale; a New Zealand entity contracting a New Zealand third party to produce a first aid kit to the entity's specifications.

The examples of entities that are NOT considered as Sponsors are, Overseas companies supplying product directly to New Zealand organisations (The importer is the legal sponsor.) and any organisation or individual that purchases medical devices from a sponsor or that purchases medical devices that have been supplied by a sponsor.

A sponsor has the following responsibilities to take care of-

- Ensuring that the device is safe for its intended purpose.
- Notifying information about the medical devices to the WAND database within 30 working days of becoming the sponsor.
- Ensuring correction of information on the WAND database if the same is inaccurate or incorrect within 10 working days of the information ceasing to be accurate or correct.
- Maintaining distribution records of the devices supplied so that in the event of a recall or corrective action the sponsor can contact all affected users.
- Advising Medsafe of any recall or corrective action affecting medical devices supplied by that sponsor in New Zealand immediately.
- Ensuring that the labelling of the medical devices complies with the Regulations.
- Ensuring that any advertising for medical devices supplied by that sponsor complies with the requirements of the Medicines Act and Regulations.

Role of a Medical Device Manufacturer

Individuals and organisations manufacturing medical devices in New Zealand should ensure the devices are correctly notified to the WAND database. Manufacturing includes assembling of kits of medical devices (i.e., first aid kits) as well as device fabricators.

The Medicines Act 1981 and Medicines (Database of Medical Devices) Regulations 2003 do not provide a definition of a medical device manufacturer. In the absence of an explicit definition, common use of the term would be presumed. The following guidance is provided.

Manufacturer includes a person or organisation that carries on the business of assembling, producing, or processing goods, and includes -

- any person or organisation that holds itself out to the public as the manufacturer of the goods:
- any person or organisation that attaches its brand or mark or causes or permits its brand or mark to be attached, to the goods:

New Zealand Medical Device Legislations

The Medicines Act 1981 and its Regulations describe the regulatory scheme for the supply of medical devices in New Zealand. However, some medical devices may be affected by other legislation which must also be complied with before the devices may be legally supplied. Following is a summary of the key Acts and Regulations that may impact on the sale of medical devices. Other Acts and Regulations may also need to be complied with. It is the supplier's responsibility to ensure that its products comply with all applicable legislation. (5)

The following acts cover the legislations for Medical Devices

- Medicines Act 1981
- Medicines Regulations 1984
- Medicines (Database of Medical Devices) Regulations 2003

Risk Classification of Medical Devices

Medical devices are rated by their potential risk from Class I (low) to Active Implantable Medical Device (AIMD, high). The Regulations require a sponsor to determine the correct risk classification of its medical devices. Recent or planned changes to risk classification systems in Europe and Australia mean there are now differences between risk classifications in those regulatory regimes and New Zealand. (6)

Following the principles of the Global Harmonisation Task Force (GHTF) the New Zealand Regulations have five risk classes and two sub-classes. These classes are based on the potential risk posed by the medical device when used as intended by the manufacturer. The classes are summarised below in Figure 1.

Class	Risk	Example
Class AIMD	High	Implantable Pacemaker
Class III	High	Drug Eluting Cardiac Stents
Class IIb	Medium-High	Ventilators, Orthopaedic Implants
Class IIa	Medium-Low	Hypodermic Needles
Class I sterile	Low	Non-Medicated Sterile Dressings
Class I measuring	Low	Volumetric Urine Bag
Class I basic	Low	Reusable Surgical Instruments

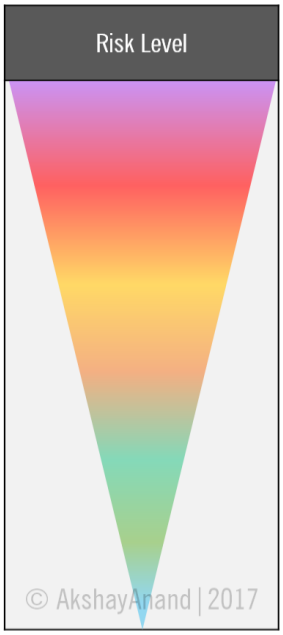

Figure 1: Risk Classification of Medical Devices in New Zealand

Determining the risk classification is a simple process of working with Schedule 2 of the 'Medicines (Database of Medical Devices) Regulations 2003' and using a process of elimination to determine the correct classification.

Schedule 2 sets out the 22 rules that are used to determine the risk classification of devices.

- Rule 1 provides the definitions for transient, short term and long term use of a device.
- Rules 2 through 5 relate to non-invasive medical devices.
- Rules 6 through 9 relate to invasive and implantable medical devices.
- Rules 10 through 13 relate to active implantable medical devices.
- Rules 14 through 22 relate to special kinds of medical devices.

The process of elimination should be used to determine the risk classification. The process begins by working through the 22 rules, commencing at Rule 22 "Medical devices that are mammary implants", and work backwards to Rule 2. By commencing at Rule 22 and working backwards higher classifications are eliminated and correct classification is reached easily. Devices that are not eliminated by any rule are determined to be Class I. If it is unable to determine the risk classification, the manufacturer of the device should be referred. Medsafe will not be able to make a determination as to the risk classification of a medical device.

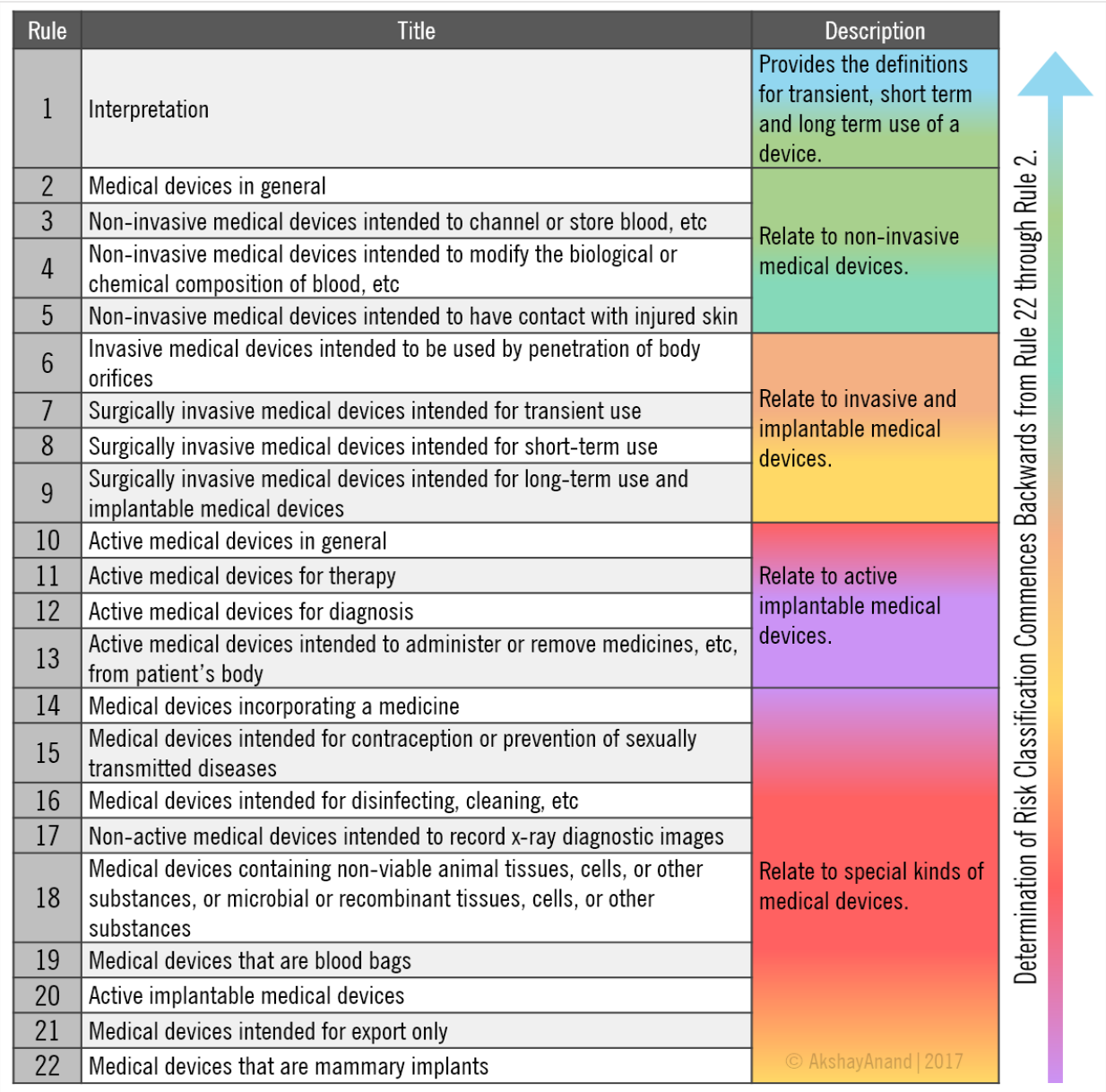

Figure 2: The 22 Rules for Risk Classification

For example, consider a cardiac guide catheter used to assist with the delivery of other medical devices to the heart. The catheter is a single use device that is inserted via the femoral artery. The catheter is in place within the patient for approximately 1 hour.

- According to Rule 1 the device is for transient use.
- Rules 22 to 8 do not apply
- Rule 7(1) describes the device
- Rules 6 to 2 do not apply

By the process of elimination, the guide catheter has a risk classification of IIa.

The Web Assisted Notification of Devices (WAND) Database

For medical devices to be legally supplied in New Zealand they must be notified to the WAND database. Notification of medical device information to the WAND database is free and there are no on-going fees. Devices must be notified to the WAND database within 30 calendar days of a person or organisation becoming the sponsor of the device. (7)

The WAND database was established by the Medicines (Database of Medical Devices) Regulations 2003 to collect information about medical devices supplied in New Zealand. It is a mandatory requirement for importers, exporters and local manufacturers to notify their medical

devices to the database. WAND is not an approval system for medical devices.

There is no approval system for medical devices under the Medicines Act 1981. There is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand. Notification to the WAND database does not mean or imply that a medical device has been assessed by Medsafe in terms of quality, safety, efficacy, or performance.

It is, though, a mandatory requirement for importers, exporters and New Zealand manufacturers to advise the Director-General of Health, via the WAND database, of the devices that are supplied here.

The WAND database holds information about all medical devices supplied in New Zealand and is used by Medsafe to respond to information about medical device safety issues. If there is a safety issue with a device the WAND database is used to identify all sponsors of that device.

Medsafe has a role to monitor post-market activity in relation to medical devices and to take action when required to ensure devices continue to meet legislative requirements with respect to safety. Medsafe used the information in WAND to identify sponsors of products when necessary in order to make contact when post market issues have been raised through international or local reports. There are no charges associated with the database. All information is submitted free of charge to the WAND database.

How to access the WAND database?

Access to the WAND database is restricted to sponsors of medical devices. New sponsors need to apply for access to the WAND database to begin the notification process. There is no public access to the WAND database. The WAND database is a secure online database that can only be accessed via a 5-digit Sponsor ID and password.

The database is managed by Medsafe and applications for access to the database must be made to Medsafe. Access is only available to New Zealand based entities (organisations or individuals) that import, manufacture or export medical devices. The only information in the database visible to any sponsor is the information it has entered about its products.

Organisations and individuals that need to apply for access to WAND should complete the application form below and return it to Medsafe for processing. Both Part 1 (Sponsor Details) and Part 2 (WAND Administrator Access) of the application form need to be completed. The completed form may be submitted to Medsafe by post, fax or email (details appear on the application form). Forms that are incomplete, incorrect, or illegible will be returned without access being granted.

A sponsor must have a presence in New Zealand. Organisations without a physical presence in New Zealand cannot be sponsors. Correctly completed application forms will be processed within 10 working days of receipt by Medsafe. Once an application has been accepted the sponsor will receive a Sponsor ID and password to access the WAND database.

The WAND Process

The registration of medical devices in New Zealand is mainly based on the notification of the device by the manufacturer or the importer on the WAND database. There are five key steps in the WAND process. (8)

1. Determining whether a product is a medical device
2. Requesting access to the WAND database
3. Notifying details of the manufacturer to the WAND database
4. Notifying details of the medical devices to the WAND database
5. Maintaining the information notified to the WAND database

These key steps for notifying the device on the WAND database have been depicted in Figure 3 and explained below.

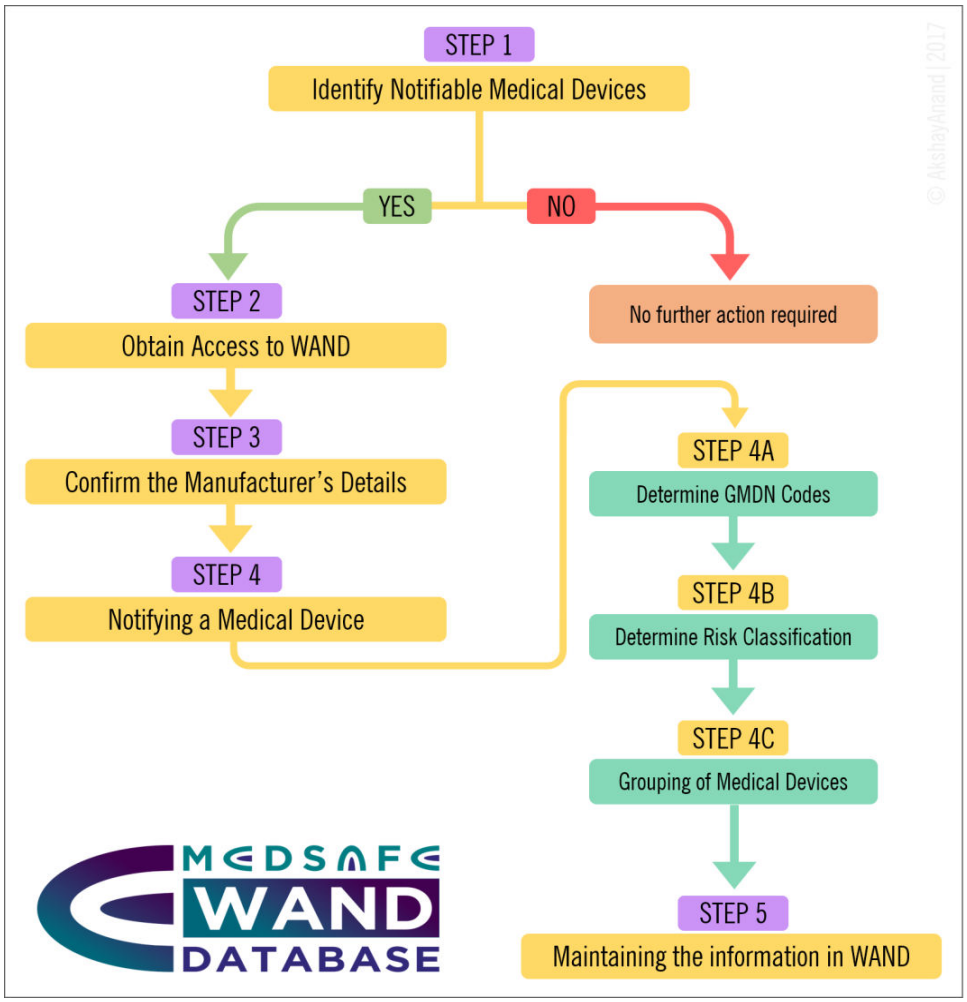

Figure 3: Key Steps in the WAND Process

Step 1: Identify Notifiable Medical Devices

- Is the product intended to be supplied a medical device as defined by the Medicines Act, and not exempted by Schedule 1 to the Medicines (Database of Medical Devices) Regulations 2003?
- If the answer is 'NO', no further action is required.
- If the answer is 'YES', advance to Step 2.

Step 2: Obtain Access to WAND

- Submit the 'Access Rights to WAND' form, Sections One and Two, from the Medsafe website.
- Receive a unique WAND User ID and password from Medsafe.

Step 3: Confirm the Manufacturer's Details

- Confirm the manufacturer's details are correct in WAND.
- If the manufacturer is not present, notify details of the manufacturer for inclusion in the database

Step 4: Notifying a Medical Device

- Verify that the desired manufacturer's address is already registered with Medsafe.
- Complete the on-line Medical Device Notification form.
- Click 'submit' on the final draft to send the notification to Medsafe.

Post completion of Step 4, use Information from manufacturer; or the Classification Guide that is available on the notification form. Check whether the devices are able to be grouped together for notification to WAND.

- **Step 4 A:** Determine GMDN Codes

- **Step 4 B:** Determine Risk Classification
- **Step 4 C:** Grouping of Medical Devices

Step 5: Maintaining the information in WAND

- Ensure presence of accurate information on the database.
- Update or correct information within 10 working days of a change occurring.

Proposal for New Regulatory Scheme by 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 promotes policies for a legal, regulatory and economic environment to advance access to innovative medical technologies. (9)

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) presented a proposal for a new regulatory scheme for registration of medical devices. 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. (10)

MTANZ saw the New Zealand's opportunity to establish a regulatory scheme that is comprehensive, effective and efficient, reflecting its small therapeutic market and not creating barriers for New Zealanders to access life-saving technology in a timely manner.

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

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

b. The regulatory authority (Medsafe) can designate third-party conformity assessment bodies whose certification is acceptable to be able to include a device in WAND.

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

d. Regulatory approvals from other jurisdictions to be utilized.

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

f. Allowance of adequate transition period for the industry to comply with the new regulations.

g. A regulatory scheme that is limited to efficiency costs only.

CONCLUSION

The WAND database explained here, though being advanced system for medical device listing, fails to serve as a direct registration pathway. WAND does not stand to the robustness in other markets' registration processes. The CE marking system of EU offers a strict and highly regulated marketing authorisation environment. The FDA also has its own, sturdy pathways for registration of devices. Australia possesses a similar but better system to New Zealand's. The risk-classification of devices slightly differ in New Zealand, bearing a total of seven classes of devices compared to Australia's six, Europe's five and United States' three classes.

New Zealand has a relatively small but growing medical device manufacturing sector made up of around 60 companies. The largest is Fisher & Paykel, which produces high quality equipment mainly for export but there are several smaller companies focused on niche areas that are also developing their export profile. According to MTANZ, the industry generates a revenue of around NZ$1.4bn (USD 1.1bn) per annum, and it expects this to double in the next 3-5 years. (11)

New Zealand depends majorly on Australia and Europe for laying out its regulations on the medical devices. It borrows the concept of WAND from Australia's ARTG and is solely dependent on Europe's CE marking to directly authorise the devices to its market. Other that the CE certificate, providing any proof of a valid registration of the same device in any other country or market to the Medsafe, grants an

authority to market the devices in New Zealand. This system may be prone to loopholes and must be overlooked and need to be overhauled for the safety of patients or the users.

For achieving this, MTANZ or the Medical Technology Association of New Zealand, in 2012 proposed a new regulatory framework for medical devices in New Zealand. It believes that the medical device regulation should ensure acceptable patient safety standards while maintaining timely access to innovative technologies. (12)

MTANZ wholeheartedly supports the need for medical devices in New Zealand to demonstrate that they meet an internationally recognized standard for safety and performance. The health and safety of the New Zealand public remains our highest priority. The MTANZ believes that with the implementation of the proposed pathway, the industries get a clear, predictable and effective regulatory system specifically tailored for medical devices that ensures:

- The highest level of safety for patients
- Timely access to the latest, innovative technologies
- The trust of its stakeholders
- The sustainability of national healthcare systems
- Active R&D and innovation in New Zealand.

While it is anticipated that a new regulatory framework and new medical device legislations will be enforced in New Zealand in the near future, until this time the easy system of WAND continues to exist, allowing the relaxed pathway for the medical devices to enter the New Zealand market. Medsafe will have to adapt the proposal of MTANZ for a potent system of medical device regulation or should come up with a newer stringent system to regulate the device market.

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DISCLAIMER

The views and opinions expressed in this article are those of the author and do not reflect or represent the views of the company the author works for in any manner.

CONFLICT OF INTEREST

The author declares that there are no conflicts of interest.

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