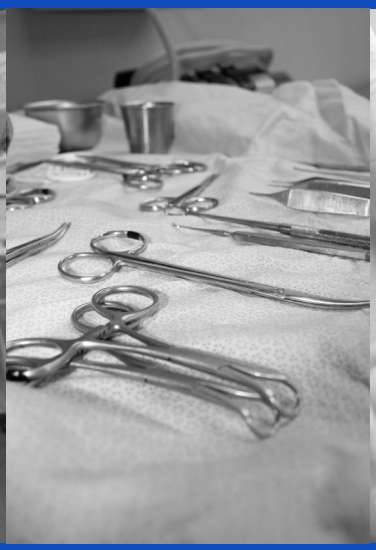
medical technology
ASSOCIATION OF NEW ZEALAND

Medical Technology

A GUIDE TO MARKET ACCESS IN NEW ZEALAND


Helping you find the answer in the medical and healthcare sector

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Contents

1. Introduction

We have prepared this *Guide to Market Access* to help you navigate the New Zealand healthcare environment and to chart a course for success. We have designed the document as a single, straightforward resource to help importers, distributors and manufacturers.

New Zealand has a comprehensive public and private healthcare system with no one clear pathway of access to the healthcare providers. We have tried to simplify this complex landscape and to provide you with clear directions.

As with any democracy, regulations are a moving target. For example, the public sector procurement system is under review and we will update this document as changes are introduced.

Although the cost of medical devices to the healthcare system is comparatively small at approx 2 – 5 percent of total health spend, administrators are keenly focused on containing costs while delivering a high level of healthcare. Further reforms by government will continue to shape procurement of medical equipment into the domestic market.

New Zealand is heavily reliant on imports of medical equipment and supplies, with approximately 97% of all equipment imported.

On a world scale New Zealand is still seen as a small domestic manufacturer of medical equipment. Fisher and Paykel Healthcare is our largest success story. Our medical technology manufacturing sector is developing and we will continue to put emphasis into growing this sector. Science, innovation and trade were among the top six key drivers highlighted in the Government's Growth Strategy to improve economic performance for NZ. The 2010 budget included $321 million funding over the next four years for Research, Science and Technology and this will create opportunities for the medical technology sector.

New Zealand has all the raw materials and the ideal environment for a successful medical technologies sector. We have some magnificent people including: talented clinicians and engineers; world class universities and research institutes, as well as an educated workforce. We have a regulatory environment that allows for clinical trials and fast introduction of innovative technologies, and we have a world class health system.

To compete on a world stage the medical technology sector and all the stakeholders need to collaborate and move away from the fragmentation model that sees us working in silos. Collaboration through innovation hubs is currently a 'work in progress'. These innovation hubs will provide the opportunity for industry, universities, and District Health Boards to work together towards developing products and services for the benefit of the NZ healthcare system, New Zealanders as patients and the NZ economy.

1. Introduction

Access to the DHBs is crucial for the growth of our local medical technology manufacturers. To succeed on a world scale we need to have access to our local hospitals and clinical teams to prove the value of NZ technological advances. We need reference sites from within NZ to validate products before we take them into international markets.

Information is power. We trust the information in this publication will empower you to achieve success in the New Zealand medical technology market.

Chandra Selvadurai
President
MTANZ

2. The Healthcare Market

2.1 The Medical & Healthcare Market Overview

New Zealanders receive healthcare through a mixture of public and privately-funded services. The public healthcare system is mainly funded through general taxation.

New Zealand's population stood at 4.37 million in August 2010. Other useful demographics on the New Zealand population can be found at the NZ Statistics Department.

In 2007, total health expenditure (public and private) was worth $16.2 billion (Source: Ministry of Health). Publicly-funded healthcare represented a 79.2 percent share of this total, with private healthcare holding a share of 20.8 percent.

Total health expenditure in 2007 represented 9.1 percent of GDP which is the same as the OECD weighted average. New Zealand public health spending currently represents around 7 percent of GDP. Treasury estimates this amount will double by 2050 unless steps are taken to curb the increase.

In May 2010, Vote Health received an increase of $512 million but it is only marginally above the level health officials calculate is necessary to keep up with inflation and population growth. So, public health providers are being told to tighten their belts and increase efficiencies. Vote Health for 2010/11 stands at just under $13.574 billion.

A complex network of organisations and people deliver health and disability services in New Zealand.

The Minister and Ministry of Health develop national policy, provide leadership and monitor District Health Board performance. They also work with DHBs, primary health organisations, non-government organisations, Crown entities, health professionals and others across the system to achieve health goals for New Zealanders.

2.1.1 District Health Boards

There are 20 DHBs in New Zealand. They were set up in 2001 under the New Zealand Public Health and Disability Act 2000. DHBs are responsible to the Minister for providing, or funding the provision of, health and disability services in their district. Funding is allocated via a population-based formula by the Ministry of Health. This includes funding for primary care, public health services, aged care, and services provided by other non-government health providers including Māori and Pacific providers.

Each DHB is responsible for organising healthcare in the district and meeting the standards and goals set by the Ministry of Health. DHBs range in population size from about 30,000 at the smallest to over 500,000 for the largest.

2. The Healthcare Market

DHBs currently have discretion on procuring medical devices. Government has, however, encouraged them to share procurement services to gain efficiencies and some DHBs have set up such arrangements, for example, HealthAlliance in Auckland. In July 2010, the Minister expanded Government drug buying agency Pharmac's role to include procurement of medical devices. Over time the Minister intends Pharmac to become responsible for managing the prioritisation, assessment, standardisation and procurement of all medical devices. Meanwhile, the new Health Benefits Limited (HBL) is expected to begin the process of nationally procuring a range of medical devices that are already used in public hospitals.

2.1.2 Hospitals

There are around 220 hospitals (public and private) in New Zealand. The major regional public hospitals are:

Northland Base Hospital

North Shore Hospital

Waitakere Hospital

Auckland City Hospital

Middlemore Hospital

Waikato Hospital

Palmerston North Hospital

Wellington Hospital

Christchurch Hospital

Dunedin Hospital

Southland Hospital

2.1.3 Primary Care

The Government introduced non-profit, community-based Primary Health Organisations (PHOs) in 2002 to implement its primary healthcare strategy. PHOs comprise doctors, nurses and other health professionals in the community (such as Māori health workers, health promotion workers, dieticians, pharmacists, physiotherapists and midwives). PHOs serve the health needs of their enrolled populations. They contract to DHBs on a per capita basis to provide primary healthcare services. Patients usually pay a subsidised fee to visit a GP unless, like children under six, they are entitled to free care.

There are around 70 PHOs currently. In early 2010, however, the Minister announced the PHOs would be restructured and reduced to 40 to free up money for more patient care and a wider range of health services. PHOs currently cost around $715 million a year with about $541 million going directly to GPs in patient subsidies and the rest on specific health programmes.

2.1.4 ACC

The Accident Compensation Commission is another government agency which funds health and disability services particularly in relation to accidental injury. ACC, which was introduced in 1974, supplies 'no fault' accident insurance coverage which is intended to compensate people for medical bills and loss of wages. It is funded by employer and employee levies.

2.1.5 Private hospitals

Around 1.3 million or about a third of New Zealanders have health insurance. The work performed at private surgical hospitals is primarily funded by medical insurers with around 20 percent funded by ACC or other sources.

Private hospitals are also contracted by the DHBs to perform surgery when they require additional capacity.

There are 36 private surgical hospitals in New Zealand. They performed 164,000 elective procedures in 2008-2009.

New Zealand's only national private hospital network is Southern Cross Healthcare Group. Other key private surgical facilities are:

MercyAscot – Auckland

Wakefield Hospital – Wellington

Bowen Hospital – Wellington

St George's Hospital – Christchurch

Mercy Hospital – Dunedin

Boulcott Hospital – Lower Hutt

Ormiston Hospital - Botany

Royston Hospital – Hastings

Braemar Hospital – Hamilton

Kensington Hospital – Whangarei

QE Health – Rotorua

2.1.6 Dental Industry

In 2007, there were 1867 dentists in New Zealand. Three in four dentists were self-employed in private practice, with the remainder as employees of private practices, District Health Boards (DHBs), the School of Dentistry and so on. Of those self-employed, one in three dentists were in sole practice.

There were 345 active dental technicians in 2007. In 2006, there were 225 hygienists and 633 dental therapists servicing the school system which caters for all children 16 years and under.

Most dentists work on a commercially-focussed environment and funding is usually by the patient, ACC or medical insurer.

New Zealand is currently well served for dentists and there is much competition. So, practices are keen to adopt new and more sophisticated technology to stay ahead of the competition and meet patients' expectations.

2.1.7 NZ Medical Technology market

The medical technology industry in New Zealand has an annual turnover of $1.3 billion. (2008/2009)[1], earns an export income of $333 million (2007/2008)[2] and employs in excess of 6000 people. Local manufacturing produces earnings of $554 million (2007/2008)[2]. The medical technology industry invested $56.6 million in research and development in 2007/2008[2].

The $1.3 billion market can be split with approximately $350 million spent on medical technologies in the private hospital system in New Zealand with a further $950 million spent in the public health system[1]. The domestic market is estimated to see real growth of between 2 to 3.5 percent each year for the next five years.

The New Zealand market for medical technology is approximately 0.25% of the global market. New Zealand's small size means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into New Zealand or invest in development of a new technology in New Zealand. This sector has, however, had recent revenue growth of between 14-16 percent per annum.

There is comparatively little domestic production of medical equipment in New Zealand. Those companies who do manufacture locally, like Fisher and Paykel Healthcare, focus heavily on export markets. Most imported medical equipment comes from the US and Europe. Australia and Japan are also leading suppliers, with a small number of products now being imported from China.

[1]Ultrafeedback Market Barometer

[2]New Zealand Medical Technologies – A Sector Overview

2.2 Public Sector Procurement

As discussed in the previous section, public hospitals are managed by the 20 District Health Boards (DHBs) in New Zealand. As public sector bodies, the DHBs follow Government procurement policies and rules. These are fully detailed in a recent document from the Ministry of Economic Development, "Supplying New Zealand Government – A guide for suppliers on how to bid for government contracts".

The procurement system relating to medical technology is currently under review as the Minister wants to bring some medical device procurement into a national system under PHARMAC and the new Health Benefits Limited with the aim of gaining cost efficiencies and better value for money. As soon as further information becomes available we will update this section.

Meanwhile, the following section will outline the current DHB procurement processes and rules.

2.2.1 Procurement process

Procurement is another term for buying goods and services. Although the DHBs must follow Government policies on procurement, their practices, requirements and systems in this area may vary and this can be confusing and frustrating for suppliers at times. More recently, there has been a move towards more consistent and collective procurement between the DHBs to gain efficiencies and reduce bureaucracy.

District Health Board New Zealand (DHBNZ) was formed in 2000 to provide a sector group through which DHBs could coordinate their activities at a national level on selected issues.

The role of DHBNZ is changing and its employees who were engaged in procurement are now based in the new Health Benefits Limited (HBL). DHBNZ will continue to exist but as the DHB CEO Forum - not procurement contracts. The DHBs are working more on regional procurement but HBL will eventually work on national contracts.

MTANZ has been working with DHBNZ for past two years to improve the supply chain and to reduce inefficiencies. As a result, millions of dollars worth of efficiencies have so far been identified. In particular, MTANZ and DHBNZ believe there are gains to be made through greater use of the electronic trading, standard contracts and more streamlined tender processes.

For example, Counties Manukau and Waitemata DHBs announced in June 2010 that they were gearing up to launch software that would fast-track procurement.

HealthAlliance, the DHBs shared services agency, has developed electronic tendering software with New Plymouth firm Tenderlink that lets suppliers submit tender bids and DHBs assess them online.

Bringing together DHB staff and clinicians to assess tender bids can be complicated and time-consuming at present, and moving the process online is expected to save time and money and means decisions on tenders are made sooner.

2.2.2 Procurement or Purchasing

Procurement is the strategic, long-term supplier relationship as opposed to Purchasing which is the daily processing of purchase orders and operational management of suppliers.

Generally, a Procurement department is made up of five key areas:

- Consumable Clinical Product Sourcing
- Capital Product Sourcing
- Services
- Clinical Product Co-ordination
- Product Catalogue Administration

Most DHBs have their own Procurement Policy and Procedures based upon the Government policies and rules.

2.2.2.1 Consumable Clinical Product Sourcing

Any product that is deemed consumable (e.g. thrown away once used) and used in a clinical setting. For example, needles and syringes, gloves, fluids, drapes and so on.

2.2.2.2 Capital Product Sourcing

The DHBs have been going through a major rebuilding and refurbishing programme since the late 1990s and there are still major opportunities here. Capital Product Sourcing can be split into two sections one being the day -to-day purchase of large capital items such as IV pumps and instruments.

The other area is when a hospital is refurbishing and replacing old technology or equipment, for example, a new Cath lab, renal unit or wards. This is project based and may occur every five to ten years.

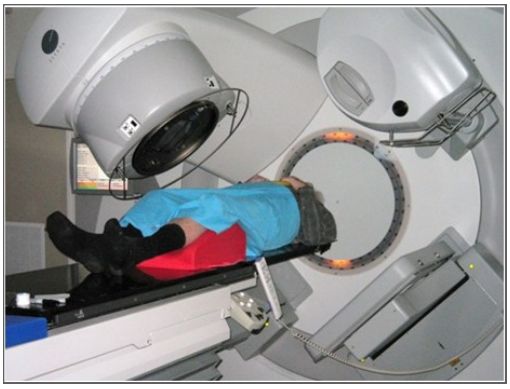
2.2.2.3 Services

This category covers anything non-clinical such as recruitment, vehicles, waste management, electricity and pest control.

2.2.2.4 Product Catalogue Administration

When contracts are signed with suppliers their product details such as Product, part number, description, unit of measure and price are loaded onto the hospital's ordering system, thus restricting purchases to only those products that have been negotiated and approved.

2.2.3 New Product Introduction Procedures



The majority of DHBs and larger private hospitals demand that companies adhere to strict procedures when introducing new products into their environment. Product Evaluation Health New Zealand (PEHNZ) represents around a dozen of the major health providers in New Zealand. The organisation exists to enable healthcare consumers receive the best value from clinical products bought by healthcare facilities, encompassing quality, effectiveness and service costs. PEHNZ also provides a communication channel that promotes the flow of ideas, advice, product update and alerts, practice changes and technology trends nationally. It acts in partnership with the Ministry of Health, healthcare agencies and the medical industry to oversee regulation, management and handling of product to minimise both clinical and commercial risk.

Product Evaluators, who may also be known as Clinical Product Coordinators, are members of PEHNZ. No company should introduce a new product into a hospital without it first being discussed with the Product Coordinator/Evaluator.

Where employed, these Product Evaluators co-ordinate any new product launch into their hospital. Their role in this process can include any, or all, of the following:

- Gathering all the relevant new product and company details (either electronically or in hard copy) on what is generally known as a 'PEHNZ form'. These forms may be obtained from the procurement department and request details such as product code, full product description, unit of measure, TGA certificate and/or CE mark or FDA approval, WAND number (see reference under Legislation section) and date of notification, manufacturing certificate, promotional literature, pricing and company contacts;
- Taking the new product to a 'New Product' committee (also called Product Optimisation Committees) for approval by both procurement and clinical staff;
- Assessing 'product' fit into hospital. They will require knowledge of current product used and whether the new product is expected to 'replace' or 'be used in addition to' it.

Always clarify internal procedures with hospital procurement staff prior to any new product launch. Those company personnel not conforming to the DHB/hospital processes risk being banned from the site if new products are promoted without approval.

If your company is launching a new product at a trade conference it is a good idea to advise procurement staff of this forthcoming activity. They are then fully informed should one of their clinicians enquire about product availability on return from the conference.

2.2.4 Infection Control – NZ Standards

New Zealand Standards provide a basis for consistent and acceptable minimum levels of quality, performance, safety and reliability. In 1998 the Ministry of Health commissioned Standards New Zealand to project manage the development of six new Standards. Since then, Standards NZ has increased its involvement in health sector projects and produced Standards and workbooks in areas from day-stay surgery to dementia care. These documents aim to enhance best practice to ensure the safety of patients and the delivery of consistently high quality healthcare.

Standards which may be of interest in the area of medical devices are:

AS/NZS 4187	Reprocessing of Medical Equipment Standard
NZS 8134	Health and Disability Sector Standards
NZS 8142	Infection Control Standard
SNZ HB 8142	Infection control Audit Workbook
SNZ HB 8149	Flexible Hollow Endoscopes Handbook
NZS 8164	Day-Stay Surgery and Procedures Standard

Sterilisation Standards applicable to medical devices are covered by Standards New Zealand.

Further useful information may be found at http://www.standards.org.nz/ or click here

2.2.5 Medico-electrical registration

The majority of electromedical devices are imported into New Zealand and as such the manufacturer will most likely have referenced IEC, ISO or other internationally-based standards to assist in bringing the product to the market.

Within New Zealand there are three key standards that assist in assuring electrical safety in patient care:

AS/NZS	3003	Safe installation
AS/NZS	2500	Safe procedures
AS/NZS	3551	Safe electromedical devices

2.2.6 Bidding for contracts

DHB procurement generally falls into two tiers; lower and higher value contracts. An open and competitive process is the preferred approach when government buys goods and services. This isn't, however, always the most appropriate process for all types of procurement. There are several factors that come into consideration including the:

- Total value of the procurement;
- Overall risk to the DHBs business if the contract performs poorly;
- Nature and complexity of the product or service;
- Availability of competitor product

As the DHBs are spending taxpayers' money the rules are there to ensure that they purchase goods and services at 'best value' in an honest, open, fair and transparent way. Suppliers are advised to contact the Procurement departments early in their business relationship and to maintain that contact to best understand the requirements of a particular DHB.

2.2.6.1 Is the tender worth going for?

Deciding whether to go for a tender is a vital skill. Tendering for contracts you have no realistic chance of winning wastes your time and that of the purchaser. The market place is extremely competitive and in order to win the work you must be able to put in the time required to pull together a professional tender together. This is a strategic decision for your business.

You must ask yourselves the following questions: does the tender match you experience? Does it match your staffing and facilities level? Will it fit your company profile? Does it need capital investment? Do you need to have policies in place such as Health and Safety and environmental standards? Do you need any additional accreditation or certification? Have you any case studies of similar work?

Other questions could include: does this opportunity match your marketing strategy? Will it make sufficient profit? How will it affect your cash flow? Does this take up space capacity or warrant investment in new plant?

You should always ensure you have plenty of time to complete the tender response before the deadline; if you are late it will not be accepted.

It may be worth hiring a specialist writer on contract to assist you in preparing your tender documents as they should be clearly set out, attention-grabbing and compelling.

2.2.6.2 Stages of the process

Finding opportunities to tender

If the DHB has a local approved supplier list make sure your company is on them. At least make contact with the DHB Procurement departments so they know about you and your products.

Search the GETS (Government Electronic Tenders Service) website at www.GETS.govt.nz to see the latest government tenders (including DHBs). It's a free service run by the Ministry of Economic Development. Contracts worth $100,000 or more for goods and services and $10million for construction work are advertised on GETS. The website also shows details of recent contracts awarded.

Expressions of interest (EOI) form

This is usually the very first stage of a tender process. The DHB will ask you for an overview of your organisation and high-level information on your capability to deliver the product. It's usually followed by a Request for Information (RFI) or Request for Tender (RFT).

Request for information (RFI)

An RFI is usually a set of questions to help the DHB gain more information on, or a better understanding of, the suppliers in the market. It helps the DHB determine the range of possible solutions, technologies and goods or services available.

Request for proposal (RFP)

DHBs will issue an RFP if they want to receive proposals for goods or services. They are usually open to innovation in the type of product requested. Suppliers are invited to submit proposals giving details of their product and its ability to deliver the outputs and outcomes, along with the proposed prices.

Request for tender (RFT)

An RFT is usually issued if the DHB wants tenders for products that are easy to define. There is little room for flexibility or innovation. RFTs are used mostly for products with highly technical requirements. The DHBs will expect detailed information on how your goods meet the specific requirements, along with proposed prices.

Further details of typical documents and tips for submitting responses or tenders may be found in "Supplying New Zealand Government – A guide for suppliers on how to bid for government contracts".

Tender evaluation

DHBs are looking for a professional and reliable option to do business with. You must prove that you are able to meet this criterion. Tenders are evaluated by a formal panel, scored against the criteria and this will enable you to see how much 'weight' should be given to each of your sections.

In most cases the process is competitive unless there are good reasons to the contrary. DHB procurement must be based on 'value for money'; this means evaluating the quality and other relevant attributes of the goods. A judgement is based on the best combination of the cost of a product, spread over its lifetime, and its ability to meet, but not necessarily exceed user requirements. This is normally achieved through comparing suppliers' prepared bids, and by generally 'testing the market'.

Feedback

If you're unsuccessful in a contract bid, or even if you're successful, it's a good idea to ask for a debrief. The debrief should give you some outline of your bid's relative strengths and weaknesses which will allow you to improve your future responses and tenders.

2.2.7 Clinical Environments

Behaviour in hospital environments sometimes requires training as staff selling or 'working' within clinical settings need a basic understanding of how they operate. One example of this is DHB Operating Theatres which have protocols that visitors must follow. MTANZ in conjunction with the Clinical Nurse Educator at Auckland City Hospital conduct four hour seminars in the Adult and Trauma Operating Theatre for surgical representatives from member companies. There are 16 attendees per seminar and 3-4 seminars a year. Contact MTANZ for further details. Other areas which may require clinical setting knowledge include ICU, NICU, Dialysis or other high tech areas. Discuss what is required with clinical staff.

2.3 Independent Sector Procurement

Beyond the DHBs and PHOs, there is a thriving independent sector made up of private hospitals, rest homes, post natal care clinics, independent GPs, clinics and occupational health services. The New Zealand independent health sector was worth around $3.37 billion in 2007 and purchases similar equipment to the public health sector. Under the National Government there has been a move to reduce public sector surgical waiting times resulting in greater use of private facilities to increase capacity.

Specialists in New Zealand are free to choose to divide their time between the public and private sector, allowing them to gain a range of clinical experience and to supplement their income. The advantage to suppliers is, of course, that specialists will be exposed to a wide range of medical devices and consumables and be in a position to make knowledgeable comparisons.

Private surgical hospitals deliver many similar services to DHB hospitals and have similar purchase requirements from MRI scanners to latex gloves. They may, however, be more likely to purchase some of the more

sophisticated and advanced equipment in a bid to compete for market share, to improve efficiency and to attract the leading specialists. The private sector will also look for quality and competitive pricing.

Members of the New Zealand Private Surgical Hospitals Association (NZPSHA) may be found here: http://www.nzpsha.org.nz/members.php

The NZPSHA promotes excellence in healthcare and its members provide procedures for approximately 152,000 patients every year, representing around 60% of all elective surgery performed in New Zealand. This proportion of elective surgery is growing in response to the increasing needs of New Zealand's ageing population and the constraints on the ability of the public sector to meet those needs.

2.3.1 Procurement processes

The larger hospital groups, like Southern Cross Hospitals (SCH), have purchasing strategies and will schedule the purchasing of key items. You should contact the National Office procurement department to find out when your particular group of products are up for renewal and to ensure you are included in the process.

SCH is New Zealand's largest private hospital network with 14 private surgical hospitals. Its rigorous procurement policies and processes are a good example to illustrate the expectations and requirements in this sector.

SCH's Procurement department will provide you with guidelines to assist you in working with them. Again, it is advisable to contact the Procurement department and to develop a relationship with them as soon as you can to smooth your access to their hospitals.

Although private hospitals are not obliged to follow the same system as their public sector counterparts, they do have to keep in mind their need to obtain value for money and to standardise pricing and options where possible.

Specialists who work at SCH may also work in the DHBs and may have particular preferences for equipment and consumables built up from their public experience. SCH tries to cater for these preferences to a degree but the options are limited to the items required by the majority of users in order to gain economies of scale.

The organisation also uses a centralised catalogue system for all hospitals and encourages users to buy off the catalogue.

To avoid potential risks, ensure regulatory compliance, and to facilitate a multi-disciplinary approach to the introduction of new products, suppliers to Southern Cross Hospitals are required to:

- Contact the Procurement department first if they wish promote clinical products within SCH;
- Consult Procurement to affirm the clinical need, obtain regulatory documentation (WAND notification/ PEHNZ forms and explore any existing contractual obligations;
- Leave samples with the Clinicians for the purpose of viewing only – samples are not be used for patient care until the new product process is complete;

- Consult with SCH Procurement on evaluations and follow the organisation's process. Note: any cost associated with evaluation will be negotiated by Procurement;
- Ensure that all equipment for loan or evaluation is accompanied by a compliance form, service manual and have a current electrical safety check label or sticker attached, prior to use. At completion of evaluation the supplier will be responsible for uplifting equipment;
- Only verbally advise SCH staff of the list price of a clinical product. All written quotes for capital and new consumable items and subsequent price negotiation must be undertaken with Southern Cross Hospitals Procurement;
- Negotiate contracts relating to the supply of medical consumables, capital equipment and services with the SCH Procurement Manager;
- Comply with the MTANZ Code of Practice Guidelines;
- Arrange a time that is convenient with SCH Department Managers prior to arrival when providing product support / in-service;
- Comply with Health and Safety regulations by signing in/out when visiting Southern Cross Hospitals and affix a 'Visitor' identification badge;
- Liaise with the Operating Room Manager to ensure they are informed and follow the correct procedure prior to access to the operating room;
- Inform SCH and Procurement of staff changes. Suppliers also need to inform their new employees of the Southern Cross Hospitals Supplier Guidelines.

Other hospital groups may have slightly different policies and processes so again it's worthwhile contacting their procurement departments to find out what they require.

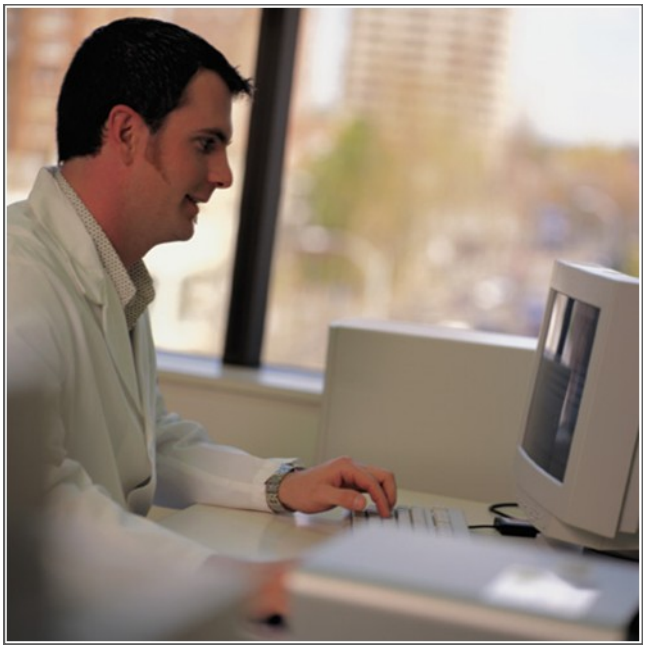
2.4 E-Commerce in the Healthcare Sector

MTANZ has been leading a health sector e-commerce initiative for several years in partnership with Tranzsoft Group and the Pacific Health Exchange (PHE). This initiative is focused on reducing supply chain costs and increasing efficiencies for suppliers and customers through electronic trading.

MTANZ believes significant benefits may be achieved through more extensive use of e-commerce in this sector in future years. The fragmented and incompatible way in which the DHBs have previously adopted Information Technology systems has been a barrier to faster development of e-commerce in this sector. As a supplier to this market you need to be aware of this inconsistency and to adopt systems that will be compatible with the major players at least.

The current formation of the Government's Health Benefits Limited should provide a greater opportunity to develop a national model for e-commerce.

2.4.1 Data Exchange Technology and Pacific Health Exchange



Currently, around 5 DHBs and 27 medical suppliers are using Tranzsoft's Data Exchange Technology and the PHE to translate, transmit and deliver documents between disparate Electronic Resource Planning systems (ERPs). Regardless of the business application a supplier and its trading partners are running, Tranzsoft facilitates the translation so that each partner can trade using their chosen communication method and their chosen data format for each document type. This includes data from diverse systems such as Oracle, JDE, Peoplesoft, SAP, Finance One, IBA, BizTalk, Exonet, Propella, MYOB and many more. Tranzsoft track and record each transaction with time and date stamps. Any incomplete transactions are detected and reported.

Documents commonly handled include purchase orders, invoices, shipping notices, bills of lading and custom documents. This technology is often referred to as Electronic Data Interchange (EDI). Tranzsoft and the PHE e-Business gateway exchanges business transactions electronically between the various organisations.

In the past, MTANZ had identified that out of every order placed by hospitals there was much duplication due to wrong pricing, units of measurement, addresses, back orders, credits and reconciliations. These inefficiencies have been significantly reduced through using the PHE and Data Exchange Technology.

2.4.2 Proposed National Strategy

Tranzsoft has recently proposed a national strategy for Health Benefits Limited that would encompass:

- Electronic trading with suppliers (EDI)
- Track and Trace of Loan Equipment and Consignment Stock
- National Products Catalogue using UNSPSC coding
- Collaborative Procurement

Tranzsoft has developed LOCUS WMMS to track and trace loan equipment and consignment stock. It allows a supplier to see consumed items and replenishment in real time. Valuable loan equipment is also tracked from supplier to customer and returns. This system lowers administration costs and manual processing and reduces exposure to cost of "lost" items.

Similarly, a National Products Catalogue would simplify the process for providing all item details to all DHBs and other public health providers. It would reduce the effort and cost involved in communicating product, price to public health institutions. There would be less ordering errors and costs associated with processing invoice reconciliation, credit claims and returns. Overall, it's believed it would significantly reduce the time and cost of introducing new products onto the market.

The Collaborative Procurement System is a SaaS (Software as a Service) hosted solution using Web 2.0 technology. It presents a single, online shopping portal where a range of suppliers offer products, services or contracts to single or multiple customers. Customers view this collaboration through an easy to use and familiar style of online shop front. This system can also be deployed as a corporate procurements system integrated with existing financial systems.

Products can be searched for, earmarked, put into shopping baskets, wish lists saved and final orders processed electronically. All the time underlying rules ensure that the customer only has access to products from authorised suppliers, and are buying at their own price breaks. Automated and preset rules and controls within the portal remove the ability for random and uncontrolled procurement. This system streamlines procurement and has many benefits for both supplier and purchaser.

We will update this document as further information on a national strategy or new developments come to hand.

For more information or to get started, contact Tranzsoft on +64 9 448 2075, e-mail information@tranzsoft.com or check out the website at http://www.tranzsoft.com

2.4.3 Electronic tendering software

Meanwhile, as mentioned earlier in this document, HealthAlliance, the shared services agency for CMDHB and WDHB, has developed electronic tendering software with New Plymouth firm Tenderlink that lets suppliers submit tender bids and DHBs assess them online.

The software lets people evaluate a tender by logging in from any PC. It guides them through a structured assessment process, prompting them to give marks based on pre-set criteria. The software, which provides an electronic paper trail of the whole procurement process is expected to be used for all purchases eventually but will be phased in for simpler tenders at first.

Tenders will still be advertised through the GETS service online but potential suppliers will be redirected to the procurement software to download relevant documents and submit bids. HealthAlliance is asking suppliers to register to use the software.

The Ministry of Economic development is reportedly investigating software that will let government departments hold reverse auctions online to get discounts on goods and services. In this type of auction the role of the buyer and seller are reversed, the objective of this auction is for the buyer to get the lowest price possible. It is the sellers who compete to obtain business. As with all auctions, set your price limit before you start bidding.

2.5 Evaluation and Ethical Agencies

If you are introducing a new medical product into the New Zealand market you will need to provide scientific evidence of its clinical effectiveness, likely benefits and risks. A DHB or private sector hospital will expect to be able to assess the quality of your product and compare it to other products on the market. They will also want to be assured of its safety profile.

Imported medical devices are likely to have this sort of evidence from established markets overseas. If, however, the product is being developed in New Zealand then you will need to include clinical trials as part of your product development process.

It is important to note the term 'clinical trials' describes the process of testing a medicine or medical device for efficacy or safety for use. Where a medical professional wishes to try a product to check its suitability for use in a particular situation this is not a clinical trial and the term clinical assessment is more appropriate.

Clinical trials may also be essential if you want to market your product into other markets overseas. A hospital in the USA, for example, is unlikely to buy a New Zealand-made device that has not been tested and does not have a proven track record in its domestic market.

Again, it is best to make contact with your customer's procurement department as early as possible to find out what their usual evaluation process is and what is required. You don't want to find out that it is going to take six months to approve when you are just about to launch.

New Zealand's Parliamentary Health Select Committee is currently inquiring into improving New Zealand's environment to support innovation through clinical trials.

2.5.1 Ethics Committees

Ethics Committees were established by the Minister under Section 11 of the New Zealand Public Health and Disability Act. The role of Ethics Committees is to protect the right of the individual.

The objectives of Ethics Committees are:

- To safeguard the rights of health and disability support service consumers and participants in research and to protect them from harm;
- To protect and promote the wellbeing of Maori as taonga and foster mechanisms for Maori input into ethical review;
- To ensure the ethical aspects related to health and disability related research are adequately considered;
- To ensure the innovative aspects of innovative procedures, both therapeutic and diagnostic are adequately considered;

- To foster the awareness of ethical principles and practices within health and disability service providers, researchers and the community;
- To consider any matter of ethics relevant to the delivery of health and disability services;
- To facilitate health and disability related research for the well being of society;
- To assure the public that the above are being done

Importantly, if you are a medical device manufacturer considering clinical research you should seek an appraisal of the research by an accredited Ethics Committee before proceeding with it. You must be advised in writing by a properly authorised person that the proposal is considered to meet appropriate ethical standards.

All proposed health and disability research investigations must be submitted for appraisal by an accredited Ethics Committee where the investigation:

- Involves health and/or disability service consumers, healthy volunteers, or members of the community at large; and compares an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognised as established either by virtue of their recent development, discovery, or use in new or unfamiliar ways; or
- Involves access to health records for the purposes other than direct patient care or internal clinical audit. Any access to health information should be in accordance with the provisions of the Privacy Act 1993; or
- Seeks to further scientific or professional knowledge by means of questionnaires, interviews or other techniques of information gathering, or by means of laboratory analysis of human blood, tissues etc., of living people, cadavers or discarded body tissues (e.g. placenta).

You will find further information on Ethics Committees here: http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-home?Open&m_id=1

3. Medical Technology Development in NZ

3.1 Partnerships and Networks

You don't need to go it alone in developing medical technology in New Zealand. There are resources, consultants, potential partners and networks available to assist you. Indeed, MTANZ's Emerging Medical Technology Group (EMTG) sees greater collaboration, particularly between industry, universities and hospitals, as the key to New Zealand companies being able to compete strongly in global medical technology markets.

The following sections are designed to outline the partnerships and networks that are available and how to access them.

3.2 Innovation Hubs

Innovation hubs are a relatively recent concept in New Zealand. Essentially, Innovation Hubs help innovators to develop, test and trial technology in hospitals and community-based healthcare environments. The Hubs connect innovators and clinical people and resources, and help facilitate the development, innovation and commercialisation process.

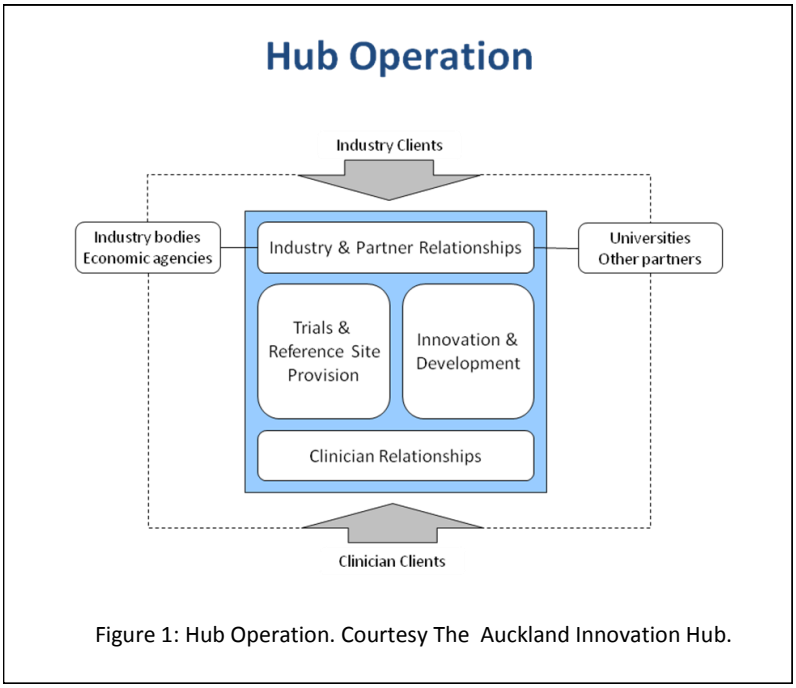


Figure 1: Hub Operation. Courtesy The Auckland Innovation Hub.

While pharmaceutical breakthroughs are primarily made in the laboratory, innovation in medical technology tends to be made at the point of care and through working with clinicians. One of the first Innovation Hubs in New Zealand is being established in Auckland and has been initiated by Counties Manukau District Health Board (CMDHB), working with Waitemata DHB and other northern DHBs and healthcare organisations. The Auckland Hub will also work closely with universities, polytechs and crown research institutes. It intends to work with three types of clients – multinational healthcare companies, established NZ health technology companies, and clinicians/innovators/firms with ideas at an early stage.

The Auckland Hub is expected to commence operations in late 2010 with a small number of 'proof of concept' projects. More widespread promotion of the hub services will occur in 2011.

The Hub will be a separate business to its partner organisations, with its own commercial board. Activities will focus on development and innovation, purposely separated from DHB procurement processes, to foster a collaborative environment. A number of medical technology companies have already shown interest in working with the Hub for clinical trials, clinical advice on product development, access to DHB resources and to network

with other medical technology companies. Although early-stage funding and support has been provided by the foundation partners, it is intended that the Hub will become self-funding in the medium term.

Meanwhile, moves are also underway to develop an Innovation Hub based in Canterbury. The proposed Canterbury Health innovations Hub would be a joint venture between the Canterbury Development Corporation (CDC) and Canterbury District Health Board (CDHB). At the time of writing, the parties involved were considering piloting the project on a small scale to prove the concept.

In Wellington, Capital and Coast DHB, Victoria University Wellington and the Medical Research Institute have recently launched the Health Education Research Collaborative Centre known as "The HERCC" on the Wellington Hospital campus. Its focus is a little different to the Auckland and Canterbury hubs.

The intention is for the HERCC to be a centre for different disciplines of post-graduate medical research and an education centre. Grow Wellington has been a key player in the establishment of the HERCC. The HERCC plans to include a Clinical Trials Unit where it will undertake Phase 2,3, and 4 clinical trials primarily with the Health Research Council of New Zealand and pharmaceutical-sponsored studies.

The various hubs may be linked and could share core infrastructure and expert resources.

The Innovation Hubs are expected to help health technology firms access expertise; to provide a commercialisation pathway and opportunities for inventors and clinicians; to offer firms local reference sites to help them win international sales; to enhance networking between companies, suppliers, customers and investors, and to generate revenues for the health system and industry.

The Hubs are also expected to foster a feasible and practical environment for innovation; enhance recruitment and retention of people in the industry and health sector; spread products into the New Zealand health system; help improve patient care and reduce healthcare costs.

3.3 The Knowledge Base

The Knowledge Base is a broad term to describe public sector research and teaching organisations, including universities and specialist research institutes or trusts.

Many of these organisations have a business arm or interface to market their services and collaborate in practical ways with industry.

Selecting which organisation to work with will depend on the type of assistance you need, your location, and what specialist expertise you need.

A good starting point is the MTANZ Directory which details the capabilities of various organisations for clinical trials both for multi-nationals and domestic companies.

3.3.1 CCREP

One of the largest clinical research organisations in New Zealand is The Centre for Clinical Research and effective practice (CCRep). This is an independent charitable research trust whose key objectives are to undertake, conduct and promote clinical research, evidence based practice and educational activities within the South Auckland region.

CCRep works in partnership with the Counties Manukau District Health Board (CMDHB) and is co-located with Middlemore Hospital, one of the largest tertiary teaching hospitals in New Zealand. As a result of this partnership, CCRep can access all the services and facilities of CMDHB for the purpose of conducting clinical trials and health-related research projects.

CCRep offers a range of services from organising reference groups and desk research to performing and analysing research. Its personnel have conducted hundreds of clinical trials over ten years of operation and are experienced in medical devices and biotechnology.

3.3.2 Auckland Uniservices

Auckland Uniservices currently manages over 80 clinical trials and is the largest research and development company in the Southern Hemisphere. Uniservices manages the University of Auckland's intellectual property and is responsible for all research-based consultancy partnerships and commercialisation.

Uniservices' Clinical Trials Research Unit (CTRU) provides expert research services – advice on study design, randomisation, web-based data management and biostatistics – to external clients. CRTU also performs specialist health research with the core focus on innovative intervention trials.

3.3.3 Industrial Research

Industrial Research Limited (IRL) is a Crown Research Institute that specialises in medical technology research, among other sectors. IRL's specialist areas of expertise in the field of health technology are the development and implementation of assistive devices for rehabilitation and mobility as well as diagnostic and imaging technologies ranging from biosensing and ultrasound to nanofluidic modelling.

3.3.4 Other research contacts

University of Canterbury

Otago Innovation

Massey University

AUT Enterprises

Victoria University

Waikatolink

3.3.4.1 NZACRes

The New Zealand Association of Clinical Research (NZACRes) was founded in August 2004 as a non-profit organisation. It is a constituent organisation of the Royal Society of New Zealand. NZACRes aims to provide a forum for clinical researchers in science, healthcare and industry in New Zealand – for exchanging experience, sharing expertise and networking.

3.3.5 Masters of Engineering in Medical Devices and Technologies

An example of the collaboration and co-operation between academic institutions and industry is the new Masters of Engineering in Medical Devices and Technologies degree that has been developed by the Auckland and Otago Schools of Medicine and the Auckland and Canterbury Schools of Engineering. The programme seeks to unlock the innovative potential of an interdisciplinary approach to developing new medical technologies for export. The programme starts in January 2011.

3.4 Funding

You've got the ideas and the enthusiasm but you need funding to get your projects off the ground and into the marketplace. This is often a challenge and the current recession hasn't made the task any easier. Many medical technology companies have, however, proved it can be done.

The Government's 2010 Budget included $321million funding over the next four years for Research, Science and Technology and this will create opportunities for the medical technology sector.

This funding is particularly targeted at "medium to large research intensive firms which can show that their activities result in wider benefits to New Zealand."

There are many types of funding available for either capital or revenue expenditure, or a combination of both, and the most common sources are:

- A grant requiring no cash match by the SME;
- Part funding with cash match by the SME at some level;
- Funding with the capture of 'in-kind' support i.e. the cost equivalent of time spent by an SME;
- A range of support, which is free to the SME but is in the form of a number of specified hours of consultant's advice;
- The raising of funds through the commercial route i.e. bank, venture capital or business angels.

3.4.1 Angel investment and Venture Capital

An angel investor is an individual who provides capital and, often, expertise to early stage businesses which can't source traditional sources of business funding. Angels typically invest their own capital, and often provide valuable management advice, mentoring and access to important contacts and markets. They do not require equity or shares in the business in return for their investment.

Angel investors usually seek businesses with innovative products or solutions that have international market potential, which makes medical technology ideal for this type of investment.

According to the Angel Association New Zealand, increasingly, angel investors are forming angel networks and groups to share research and pool their investment capital. They can operate as a collective of private investors who band together to increase their 'deal flow' (the number of investment opportunities they see). These groups connect high-potential start-up ventures, with willing investors to facilitate the funding and success of emerging companies.

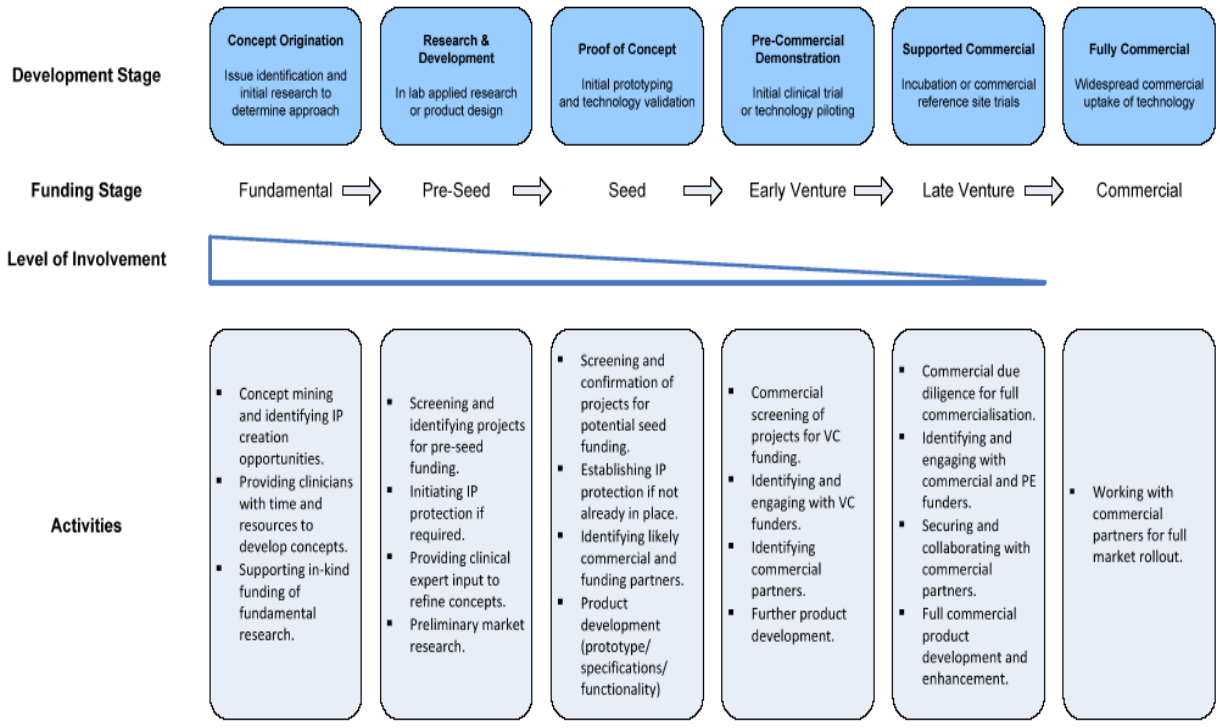
Venture Capital is a specific type of funding aimed at providing finance in return for equity or shares for businesses with a potential high return on the investment in the medium or long-term. These investments are usually high risk – high gain. VCs usually raise finance from institutional investors or high net worth individuals.

3. Medical Technology Development in NZ

Venture capital funds (VCs) work with a portfolio of investments with different degrees of risk and different potential returns. It is risk capital, which means that unlike a bank providing a loan, VCs are prepared, if necessary, to write off an investment. VCs work on the basis that some of their investments will fail but the returns they make on the successful ones will provide an overall profit. VCs usually have access to larger sums of investment finance but the market in New Zealand is small.

To realise the potential of their investments VCs have to sell their shares, typically using a management buy-out (MBO), initial public offering (IPO) on the Stock Exchange or a trade sale as exit strategies. VCs are focused on the return on investment and will, from the beginning, drive the company to the most lucrative exit strategy. That means even if they do not have a majority shareholding, the VC will make sure that they control the timing and mechanism of exit. Usually they seek to exit after three to five years. Consequently, they do not usually become involved until the proof of concept or seed funding stage.

Fig 2 Sources of Funding by Development Stage flow chart. Chart courtesy Auckland Innovation Hub.



Angel Association New Zealand

The Angel Association New Zealand is an organisation that aims to increase the quantity, quality and success of angel investments in New Zealand and in doing so create a greater pool of capital for innovative start-up companies. Angel Association has around 16 member investor groups, some of whom have a particular interest in medical technology sector investment.

The primary objectives of the Angel Association are to:

- Promote the growth of angel investment in New Zealand, including encouraging and educating entrepreneurs, new angel investors and angel groups;
- Ensure the ongoing success of the industry through developing industry strategy, encouraging collaboration between members and providing education for those involved.

Current members

A list of the current members of Angel Association, their particular interests and contact details are here: http://www.angelassociation.co.nz/index.php/membership/members

3.4.2 Requirements for Finance

For a medical technology SME to access finance, it will need to:

- Establish credibility in the healthcare technology sector;
- Demonstrate technological and management capabilities;
- Demonstrate a need for its product or service;
- Provide evidence of efficacy and risk management;
- Develop a comprehensive Business Plan, including a sales and marketing plan;
- Evaluate any export opportunities;
- Be prepared to release equity and share control

3. Medical Technology Development in NZ

Planning

A business plan that clearly defines your business goals and strategy for achieving those goals is an essential tool in accessing finance.

In a recent *National Business Review* article, health investment expert David Clarke of Cranleigh Merchant Bankers offered some valuable advice to entrepreneurs:

"It's very hard to get investment traction without strong governance structures. Many of these entrepreneurial healthtech companies are strong in technology but not so strong in the commercial aspects of building a business."

He says they need to start by asking themselves, "What is our claim? What's the unique benefit of our product to our relevant customer segment(s)? What problem is it solving? Is it urgent and important? And, will they pay what you need for your product/service?"

"They need to focus on market niches – there's no point in taking on Apple to build a better iPhone, for example. And they need to be able to convey their message succinctly."

Investment Readiness

Investment readiness means being able to give a potential investor the level and quality of information that shows that the company is knowledgeable, professional and credible in its chosen marketplace. From the investor's point of view, this vastly reduces the perceived element of risk.

NZTE Escalator Service

New Zealand Trade and Enterprises' Escalator service helps qualifying NZ businesses get investment-ready. Typical of the available resources is its Investment Ready Guide.

Principally, and depending upon the level of support applicable to each qualifying business, the Escalator service offers:

- Assessment and advice on investment readiness for a business or entrepreneurial opportunity;
- Deal preparation and deal broking;
- Investment specific workshops;
- Helpdesk and online information (Freephone 0800 822 748) or email info@escalator.co.nz

The Escalator service is supported by NZTE and delivered by a consortium of leading private sector advisors. Any New Zealand business seeking to raise up to a maximum of $5 million is eligible to apply. Every application for Escalator support is initially reviewed for its suitability, and if successful at that stage, is sent to an advisor for a needs assessment (a review analysing business needs and the deal options available), potentially leading to deal broking services being offered.

These evaluation and support services are underwritten by NZTE and provided to clients at no cost. A success fee applies of 6% for capital raised or non-equity deal concluded, payable to the broker only after capital has been raised or a non-equity deal completed.

In a typical year Escalator receives around 350 applications, provides specialist advice to 200 businesses, prepares 62 firms for potential deals and aims to raise $20 million from the private sector.

3.4.3 Foundation for Research, Science and Technology (FRST)

Each year the New Zealand government sets aside, or 'votes', a certain amount of money for research, science and technology in its budget.

This money is called Vote RS&T and the Foundation for Research, Science and Technology, which reports to the Ministry of Research, Science and Technology, invests the majority of the Government's Vote RS&T funds, working alongside the Royal Society of New Zealand and the Health Research Council.

FRST's current priority research areas include:

- High value manufacturing and services: Research to develop new technologies, materials, products, processes and services for the manufacturing and technology sectors;
- Health and society: Research to improve health and social well-being.

FRST may be a useful source of funding for pre-seed Research and Development. Further detail about FRST may be found here http://www.frst.govt.nz/index.php

3.4.4 The New Zealand Venture Investment Fund Limited (NZVIF)

The New Zealand Venture Investment Fund Limited (NZVIF) is a Crown owned company established under the Companies Act 1993 and incorporated in June 2002. Based in Auckland, the company is governed by a private sector board of directors and managed by a dedicated management team.

VIF is contracted by the New Zealand Government to administer the Venture Capital and Seed Co-investment Programmes. Key services provided across both programmes include:

- Establishment of new Venture Capital Funds under the Venture Capital Programme and formation of new co-investment partnerships under the Seed Co-investment Programme;
- Implementation of best practice investment arrangements and documentation;
- Programme administration including monitoring programme and fund activity and performance;
- Fostering development and growth of the New Zealand venture capital and early stage investment markets;
- Attracting early stage and venture capital investment into the New Zealand market through facilitating education initiatives and effective stakeholder management;
- Preparation of reports and advice on the New Zealand venture capital and early stage markets;
- Reporting to Government on Programme performance.

The Seed Co-Investment Fund

The Seed Co-Investment Fund (the Fund) is managed by The New Zealand Venture Investment Fund Limited (NZVIF), and is an equity investment fund aimed at small to medium sized businesses at the seed and start-up stage of development that have strong potential for high growth.

The key objectives of the Fund is to enhance the development of angel investor networks, stimulate investment into innovative start-up companies, and to increase capacity in the market for matching experienced angel investors with new, innovative start-up companies.

The Fund commenced in July 2005 and provides $40 million of matched seed funding to support the further development of early-stage investment markets through a co-investment fund alongside selected Seed Co-Investment Partners.

Key Features of the Seed Co-investment Fund

- A total of $40 million will be available for investment through the Fund over a 5-6 year period;
- The Fund will operate for a period of 12 years in total, with an expected investment period of 5-6 years;
- Seed-stage and start-up investments will be eligible for the Fund;
- Investment alongside selected private investor groups ("approved co-investors");
- $4 million total per co-investment partner;
- Investments through the Fund would be limited to a maximum investment of $250,000 in any one company or group of companies; with the possibility of another $250,000 in follow-on capital at the discretion of NZVIF;
- 50/50 matching private investment is required for the Fund to invest;
- To act as a direct investor on the same terms as the co-investment partner;
- Any investments must be made in New Zealand businesses. A New Zealand business is defined as having the majority of assets and employees in New Zealand at the time that the initial investments is made;
- To act as a direct investor on the same terms as the co-investment partner;
- The Fund will exclude investment in property development, retailing, mining and hospitality industry businesses.

Future Calls for Applications

For further information contact Richard Palmer, Investment Director on Tel: 09 951 0170 or Email: venture@nzvif.co.nz.

The Seed Co-Investment Partners below have been selected by NZVIF for their investment networks and dedicated team with strong talents and a commitment to building early stage New Zealand companies.

Chrysalis Capital Partners	Cure Kids Ventures
Ice Angels	Manawatu Investment Group
Powerhouse Ventures	Sparkbox
Upstart Angels	Pacific Channel

3.4.5 Further sources of information on funding

Further resources or information for companies seeking New Zealand Venture Capital and/or Private Equity may be found at the New Zealand Venture Capital Association.

The NZVCA's mission is to develop a world-best venture capital ("VC") and private equity ("PE") environment for the benefit of investors and entrepreneurs in New Zealand.

A good source of information on angel investment and latest news is NZAngels.com

3.5 Support

New Zealand is a great environment for budding medical technology companies to develop and thrive. We have talented clinicians and engineers; world class universities and research institutes, as well as an educated workforce. In recent years, however, there has been a growing realisation that, despite these raw ingredients, no company can be expected to succeed on the world stage on its own. Medical technology entrepreneurs need support from a wide range of organisations and agencies and they need to collaborate with other stakeholders to fully realise their potential and to accelerate their growth.

So, who can help? Your first stop should be the **Medical Technology Association of New Zealand** (MTANZ). Its range of member services are outlined on its website where you will also find its Industry Directory which lists medical technology manufacturers, suppliers to the sector, regional agencies, Government agencies, research organisations, professional services and other services.

Contact: Phone +64 9 917 3645.

As more and more medical devices become computerised, there is a need to collaborate with the IT sector and that's one of the reasons the **NZ Health IT Cluster** was formed.

The New Zealand Health IT Cluster is an alliance of organisations interested in health IT, comprising software and solution developers, consultants, health policy makers, health funders, infrastructure companies, healthcare providers, and academic institutions - who have agreed to work collaboratively**.** The Cluster leads collaborative health projects to allow members to showcase their expertise and develop their capabilities.

Contact: Phone +64 4 472 4691

New Zealand Trade and Enterprise can help companies who want to commercialise medical devices in offshore markets.

4. Regulatory Affairs

Medical devices are highly regulated – with good reason as lives depend upon their safety and reliability. The medical industry in New Zealand has operated in an environment of self-regulation for a number of years. It is therefore important that suppliers are conversant with the legislation that impacts their business.

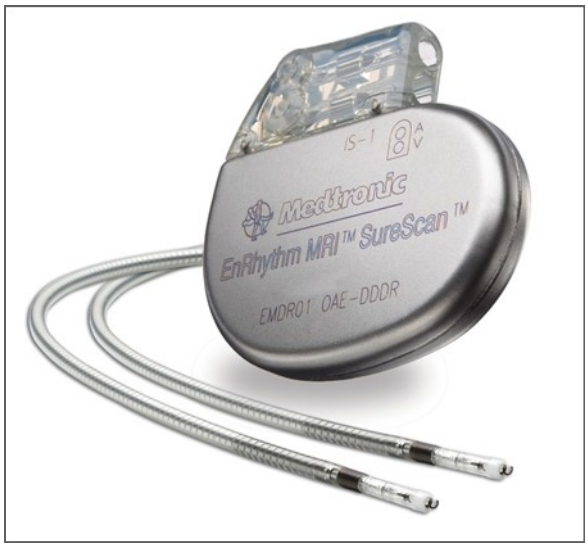
Rapid growth in the global market for medical devices has created a need to harmonise national standards in order to minimise regulatory barriers, facilitate trade and improve access to new technologies.

Harmonisation also reduces the cost of implementing regulations for governments and local industry. The Global Harmonisation Task Force (GHTF) was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America to address these issues.

The purpose of the GHTF is to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. The GHTF also promotes technological innovation and facilitates international trade.

For further information visit the GHTF website http://www.ghtf.org/.

4.1 Definitions



What is a medical device?

According to Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) a medical device is:

Any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose; and includes bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilizing the dressing; but does not include-

Any ultrasonic therapy apparatus within the meaning of section 2 of the Physiotherapy Amendment Act 1953:

Except in section 38 of this Act, any irradiating apparatus within the meaning of section 2 (1) of the Radiation Protection Act 1965:

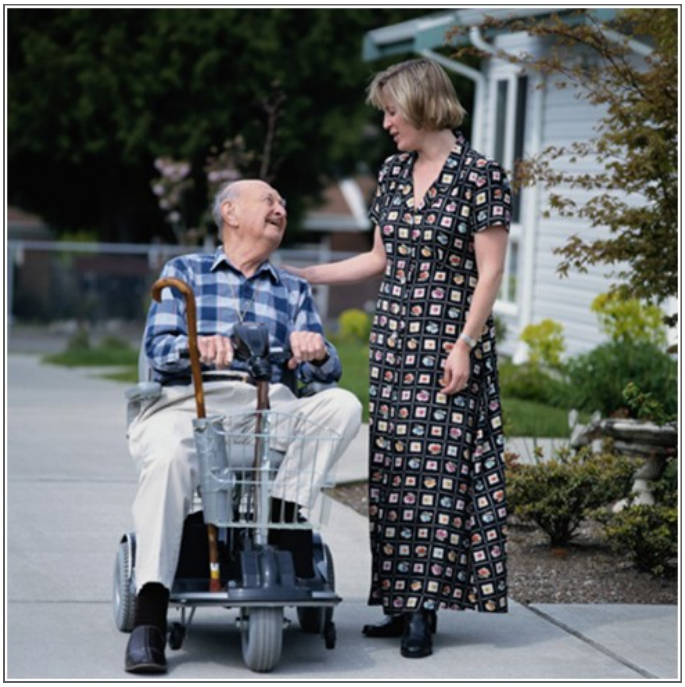
Any article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of article that is not a medical device for the purpose of this Act.

4. Regulatory Affairs

The Global Harmonisation Task Force has the following harmonised definition for medical devices (see GHTF document SG1/N029R11).

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, 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 purposes 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 for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.



Note: An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, it should be subject to the same procedures and GHTF guidance documents as apply to the medical device itself.

Note: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, reagents and the like may be covered by separate regulations.

Note: Products, which are considered to be medical devices in some jurisdictions but for which there is not yet a harmonised approach, are:

- aids for disabled/handicapped people;
- devices for the treatment/diagnosis of diseases and injuries in animals;
- spare parts for medical devices;
- devices incorporating animal and human tissues which may meet the requirements of the above definition but be subject to different controls.

A country may develop its own guidance document for any detailed descriptions they may require.

Further useful definitions may be found in the Frequently Asked Questions on the WAND part of the Medsafe website.

4.2 WAND database

From January 2004, under the Medicines (Database of Medical Devices) Regulations 2003 a sponsor (i.e. any New Zealand-based person or organisation that is manufacturing or importing medical devices for supply in New Zealand, or exporting medical devices) is required to enter details into a medical device database within 30 days of commencing supply or export of a new medical device. This database, held by the Director General of Health is called WAND (Web Assisted Notification of Devices).

This database is additional to other regulatory requirements, and is used to help with post-market surveillance and tracking. Its contents are not available to the general public.

WAND is a notification database only, and is reliant only on information provided by sponsors about their products. Inclusion of a notification on WAND does NOT indicate approval or any other endorsement of the device by Medsafe.

The proposed Therapeutic Products and Medicine Bill to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) is on hold. New medical device legislation to establish a pre-registration and post-market process will be introduced into New Zealand in the near future.

For further information and to obtain instructions for WAND notification:
http://www.medsafe.govt.nz/regulatory/wand.asp

4.3 Medical Device Classifications

Medical devices are classified and regulated according to risk, specifically risk to the patient or user. It makes sense, for example, that a complex implantable such as a pacemaker is subject to more stringent rules than a pair of spectacles.

Entry of devices on the WAND is based on the European risk-based classification guidelines. Classification guidelines for various countries and regions, including EU, may be found on pages 40 and 41 of this document.

The classification rule relating to New Zealand may be found here:

http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html

DHBNZ has recently decided to adopt the United Nations Standard Product and Services Code (UNSPSC) as the National Code and work is underway to code and classify all medical technology products in New Zealand.

Classification of a medical device is determined by the manufacturer. It is, however, your responsibility to ensure you classify your device correctly when entering it on the WAND database. As a sponsor, you also need to make sure that all the associated processes, procedures and documentation are in place. If you need help, the Government's regulatory agency Medsafe, may give some guidance. You are, however, advised to seek independent legal advice if necessary.

4.3.1 Global Medical Device Nomenclature (GMDN)

The GMDN, is endorsed by the GHTF as the global nomenclature to be used by regulators for the classification and registration of medical devices. It is intended:

1. To give a common generic description for every general term that describes characteristics of a medical device. This is to be used for identifying similar devices to those involved in an adverse incident report;
2. To identify a device, using the generic term, for having been awarded a specific design or other certificate;
3. To serve as a basis for E-commerce – to provide a generic basis for purchasing individual types of manufactured devices, by establishing a heading for comparison of products from different manufacturers.

Further information on the GMDN can be found on their website.

The GMDN code is established by the manufacturer and the sponsor is responsible for entering it on the WAND database in New Zealand.

4.4 Standards

Medical device companies need to understand standards systems, the standards development process and their use in conformity assessment. Most standards are voluntary. Such standards may, however, be mandated by an organisation, company, professional body, government or trade agreement.

The formal definition of a standard that should be adopted in the medical device domain is given by the International Standards Organisation (ISO):

> Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose.

In our increasingly global village the needs and benefits of international standardisation are becoming increasingly obvious. Incompatibility between different consumables and medical devices or replacement parts are costly and a hindrance to companies wanting to buy or sell internationally.

According to the World Health Organisation, standards can serve different purposes. They can:

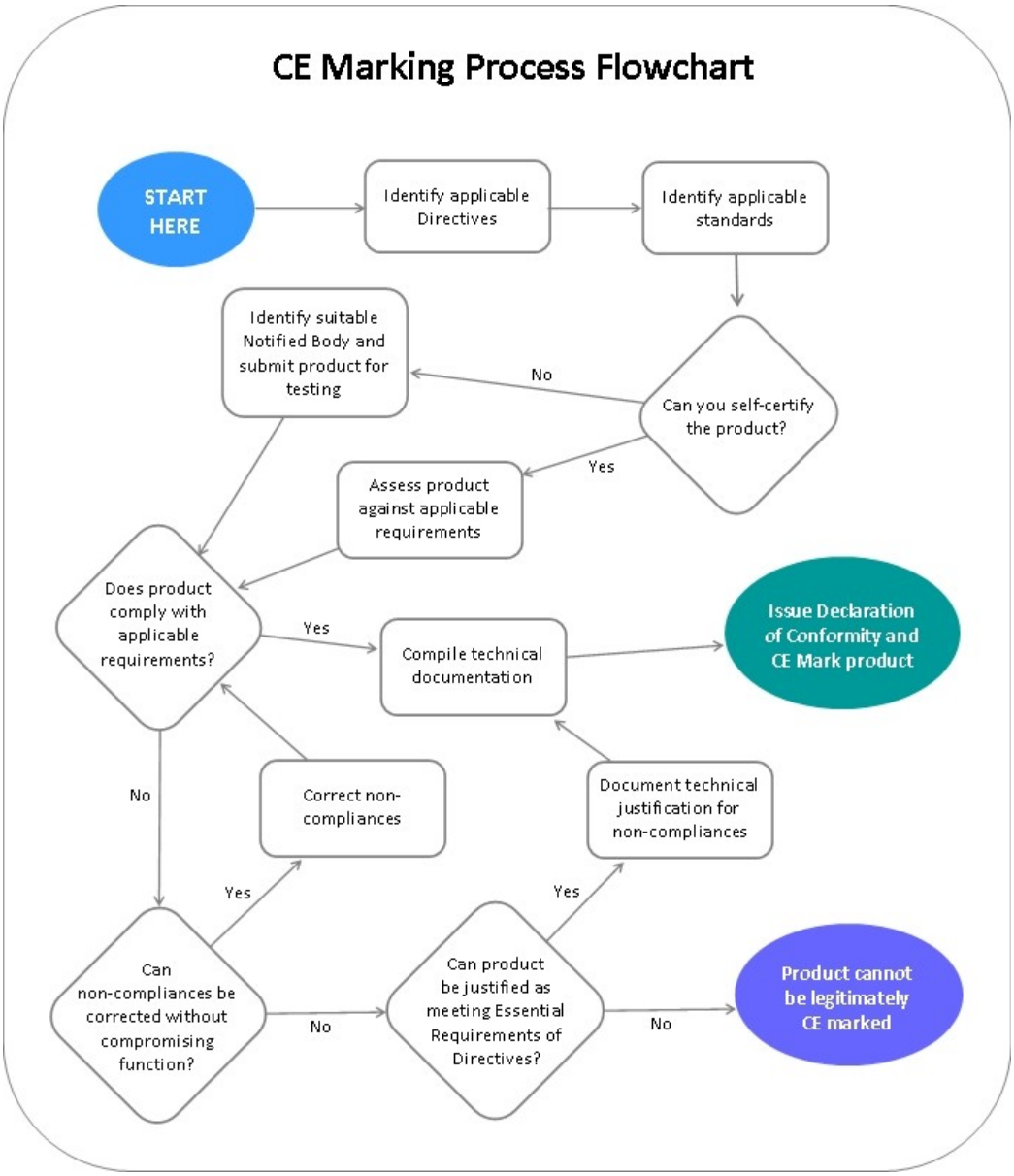
1. Provide reference criteria that a product, process or service must meet.
2. Provide information that enhances safety, reliability and performance of products, processes and services.
3. Assure consumers about reliability or other characteristics of goods or services provided in the marketplace.
4. Give consumers more choice by allowing one firm's products to be substituted for, or combined with, those of another.

Standards which may be of interest in the area of medical devices are:

AS/NZS 4187	Reprocessing of Medical Equipment Standard
NZS 8134	Health and Disability Sector Standards
NZS 8142	Infection Control Standard
SNZ HB 8142	Infection Control Audit Workbook
SNZ HB 8149	Flexible Hollow Endoscopes Handbook
AS/NZS 3551	Safe electromedical devices
NZS 8164	Day-Stay Surgery and Procedures Standard

Click on links for further information regarding New Zealand Standards and International Standards

4.5 CE Mark



If you want to sell a medical device in the European market it must have a CE mark. The CE marking certifies that a product has met the relevant EU consumer safety, health or environmental requirements. In the case of a medical device it must meet the requirements of the Medical Devices Directive (MDD). Active implantable devices (e.g. pacemakers, implantable infusion pump) are covered by a separate directive, the Active Implantable Medical Devices Directive (AIMDD).

Before your product can bear CE marking you must set up a technical file and sign an EU Declaration of Conformity to say that the product(s) conform to the MDD. This is a self-certifying process. The documentation, however, has to be made available to authorities on request.

4. Regulatory Affairs

Once you have demonstrated your product can meet the required standards you can apply for a CE mark. This will also be recognised in some other markets. Most countries, however, have slightly different regulations so it's worthwhile getting specialist advice.

A useful reference is the flow charts produced by Emergo Group which are available here: http://www.emergogroup.com/files/uploads/brochures/Medical-Device-Regulatory-Process-Chart-EUROPE.pdf

The routes to compliance depend on the classification of the product. (Note that the full classification rules are given in Annex IX of the MDD).

Class I devices are low risk. Examples are stethoscopes, hospital beds, wheelchairs. The manufacturer has to produce a technical file, including product test results to relevant standards. In addition, manufacturers of sterile products and devices with a measuring function must apply to a Notified Body for certification of the aspects of manufacture relating to sterility or metrology. A Notified Body is an organisation appointed by the national accreditation authorities and "notified" to the European Commission to approve products covered by the MDD.

Notified Bodies have usually grown out of the local Standards organisations and are not of equal standard. To identify the Notified Body that is best for your organisation you need to research the market by talking to other medical device manufacturers who have already been through the process. MTANZ provides networking opportunities or can put you in touch with other members or experts who may be able to help.

Class IIa are low-medium risk devices, with examples such as hearing aids, electrocardiographs, ultrasonic diagnostic equipment. As for Class I, the manufacturer produces a technical file, but in addition a conformity assessment must be carried out by a Notified Body, according to one of the following routes (at the manufacturer's choice):

Examination and testing of each product or homogenous batch of products

Audit of the quality assurance system (e.g. ISO 13485)

Class IIb are medium-high risk devices, with examples such as surgical lasers, infusion pumps (non-implantable), ventilators, intensive care monitoring equipment. Routes to compliance are the same as for Class IIa, with the addition of Type Examination of the product by the Notified Body, except for the quality assurance route (ISO 13485), where Type Approval is not necessary.

Class III devices are high risk. Examples are balloon catheters, prosthetic heart valves. Routes to compliance are:

Audit of the full quality assurance system (ISO 13485) and examination of the design dossier by the Notified Body;

Type Examination of the product together with examination and testing of each product or homogenous batch of products.

Products shipped must bear the CE marking to show compliance with the directive. If a Notified Body is involved in the approval, the number of the Notified Body must also appear adjacent to the CE marking.

Additionally, the product must be shipped with a Declaration of Conformity.

4.6 US Quality System Regulation

To sell medical devices in the US market you need to:

- Apply for an Establishment Registration and device listing;
- Meet the requirements of the US Quality System Regulation (QSR);
- Apply to the Food and Drug Administration to classify your device;
- Seek the relevant approval for your device.

Unlike the European system, the US works on the basis of self-declaration for compliance with the QSR (Except for Class 3). Companies are subject to random audits by the FDA. So it pays to do everything by the book and seek expert advice. A useful starting point is to view the documents on the MTANZ website.

A useful reference is the flow charts produced by Emergo Group.

4.7 Guide to Regulatory Processes for Medical Devices for Other Regions

Australia
Canada
China
Japan
Mexico
Russia
Korea
Brazil

4.8 Commercial Legislation

There are a number of pieces of legislation which influence how medical device suppliers manage their business in New Zealand. These include:

- The Commerce Act 1986
- The Fair Trading Act 1986
- The Consumer Guarantees Act 1994
- The Privacy Act 1993

4.8.1 The Commerce Act 1986

The Commerce Act aims to promote competition on New Zealand markets. The Act prohibits a range of restrictive trade practices which substantially lessen competition, and business acquisitions which create or strengthen dominance in the market.

These prohibitions apply to all commercial organisations, including State Owned Enterprises (SOEs) and government departments. Restrictive trade practices include:

- arrangements between competitors that substantially lessen competition in a market;
- arrangements between competitors that reduce competitiveness of another rival;
- arrangements that lead to prices being fixed among competitors;
- a company dominant in the market using its position to prevent competition;
- suppliers fixing the prices at which goods may be sold by other traders.

4.8.1.1 Representative responsibilities

Company representatives have certain responsibilities under the Commerce Act:

- never discuss pricing with competitors;
- don't call your competitors and ask what they are charging and why;
- don't pass on price lists to competitors;
- don't remain in meetings of trade associations or with competitors when prices are being discussed;
- don't signal price changes to competitors;
- don't threaten or in any way disadvantage a reseller because the reseller advertises or sells at discount prices;
- don't enter into any arrangement with a customer not to supply a competitor of that customer.

4.8.2 The Fair Trading Act 1986

The Fair Trading Act 1986 protects consumers and ethical traders from dishonest trade practices. Its aim is to ensure that information available is accurate so that consumers can make informed choices and are protected from unsafe goods.

It applies to all aspects of the promotion and sale of goods and services, from advertising and pricing to sales techniques and finance agreements. It applies in addition to industry specific legislation like the Medicines Act.

The Act complements the Commerce Act by ensuring that buyers have accurate information about goods and services with which to take advantage of the competition in the market place.

The Fair Trading Act also provides for the enforcement of Product Safety Standards and Consumer Information Standards.

4.8.3 The Consumer Guarantees Act 1993

The Consumer Guarantees Act generally applies after a sale is made (whereas the Fair Trading Act generally applies before a sale is made). It sets guarantees or minimum standards that must be met for goods and services normally bought by consumers. It also provides for remedies for failure to meet the guarantees. If guarantees are not met, or remedies not provided, a customer can seek redress under the Act by directly approaching the business concerned or taking action in the Disputes Tribunal or a court.

The Act covers the supply of medical products for medicinal purposes to private individuals. Where a company supplies a product to an end-user there is no obligation to do anything more than provide a product that will perform as described. However, the situation may become more complicated when a company or their representative make express statements or claims about the product. If a claim is made that the product will ensure a particular result, then the company could be held liable under the Act.

4.8.4 The Privacy Act 1993

The Privacy Act 1993 aims to protect individual privacy. It affects the collection, storage, use and disclosure of information about any individual. Such matters as the giving and obtaining of references, the use of customer lists, and the credit checks on individuals are covered by the Act.

4.8.4.1 Health Information Privacy Code 1994

This code of practice applies specific rules to agencies in the health sector to better ensure the protection of individual privacy. With respect to “health information” collected, used, held and disclosed by “health agencies” the code substitutes for the information privacy principles in the Privacy Act.

It is important that any supplier respects the privacy of any patient information it may come across in its dealings with health agencies.

4.9 Health Legislation

In addition to Commercial legislation is legislation directly related to the health industry including:

- The New Zealand Health and Disability Act 2000
- The Health and Disability Commissioner Act 1994
- The Health and Safety in Employment Act 1995
- The Health Practitioners Competency Assurance Act 2003
- Hazardous Substances and New Organisms Act (HSNO) 1996

4.9.1 The New Zealand Health and Disability Act 2000

The New Zealand Health and Disability Act 2000 was brought in to reform the public funding and provision of health and disability support services. It ushered in the establishment of District Health Boards, Primary Health Organisations and a population-health focus. The Act encourages cooperation and collaboration between health agencies.

4.9.2 The Health and Disability Commissioner Act 1994

This Act promotes and protects the rights of health consumers and disability consumers. The Health and Disability Commissioner is appointed by the Minister of Health to investigate and resolve complaints relating to infringements of consumer rights in health.

4.9.3 The Health and Safety in Employment Act 1995

The purpose of this Act is to prevent harm to employees at work. The amendment of the Act in 2002 clarified a number of points including that:

- *Persons selling or supplying plant for use in a place of work to take all practical steps to ensure plant is designed, made, maintained and installed so that it is safe for use. This applies to the hire or leasing of plant, but not the sale of second hand plant or plant sold as is.*
- *Duties of employees expanded to include the requirement to use personal protective equipment supplied.*

4.9.4 Health Practitioners Competence Assurance Act 2003

The main purpose of this Act is to protect the health and safety of members of the public. It provides mechanisms to ensure that health practitioners are competent and fit to practise their profession.

4.9.5 Hazardous Substances and New Organisms Act (HSNO) 1996

The purpose of the Hazardous Substances and New Organisms (HSNO) Act 1996 is to protect the environment, and the health and safety of communities, by preventing or managing the adverse effects of hazardous substances and new organisms. The HSNO Act is all-embracing. It covers all new organisms and hazardous substances.

The Environmental Risk Management Authority (the Authority) was established under the Hazardous Substances and New Organisms (HSNO) Act 1996. The main role of ERMA is to make decisions on applications to import, develop, or field test new organisms; or to import or manufacture hazardous substances. A new organism could be a plant, animal or microorganism coming into New Zealand for the first time or a new species developed through genetic modification.

Hazardous substances could be explosive, flammable, corrosive, toxic or eco-toxic. For hazardous substances, the Act takes a `cradle to grave' approach and allows the Authority to set controls on how substances are contained, labelled, stored, used, transported or disposed of. Substances may be reassessed if new information warrants it.

4.10 MTANZ/MTAA Code of Practice

Ethical standards and compliance with applicable laws are critical to the medical technology industry's ability to continue its successful collaboration with healthcare professionals. To enhance this relationship the Medical Technology Association of Australia (MTAA) and MTANZ have jointly developed a Code of Practice to facilitate ethical interactions with practitioners and others within the medical technology industry. A copy of the Code may be downloaded here: http://www.mtanz.org.nz/CodeofPractice/tabid/84/Default.aspx

4.11 Medical Device Incident Report Investigation Scheme

This scheme is a joint venture between the Australian Therapeutic Goods Administrations (TGA) and Medsafe. It is intended to help maintain the standard of devices used in health care through the voluntary cooperation between users, government and industry.

In New Zealand, doctors and other health professionals are encouraged to report all medical device faults. Consequently, New Zealand has the highest rate of voluntary reporting in the world.

Medsafe will investigate a problem when they consider it to be of significance. This may depend on the number of incidences or the health implications of the fault. Medsafe has an established network to notify hospitals of any information on medical devices.

A faulty medical device is reported by using the Medical Device Incident Report form on the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) website. http://www.medsafe.govt.nz/profs/defect/device.asp