

NZ Medical Technology Industry Report

Key facts and figures 2015



medical technology
ASSOCIATION OF NEW ZEALAND

Acknowledgements:

The information in this book has been obtained from a variety of sources. We are particularly grateful to the members of MTANZ who participated so strongly in the survey. Their high response rate underpins the validity of the data presented in this report.

We gratefully acknowledge the assistance of the Medical Technology Association of Australia Limited (2014) for allowing us to reproduce parts of its Factbook (2014) and relevant charts.



New Zealand industry survey development and deployment: Ms Janey Haringa, independent researcher.

Analysis and initial report writing: Mike Munley, MTANZ Business Development Manager.

Editing and design management: Brenda Saunders, Trio Communications, Auckland.

Suggested Citation

NZ Medical Technology Industry Report: Key facts and figures 2015.

Contact Details

E: info@MTANZ.org.nz

All correspondence: Medical Technology Association of New Zealand, PO Box 74116, Greenlane Central, Auckland 1546

Disclaimer

Every effort has been made to ensure the accuracy, correctness and reliability of the information provided in this paper. MTANZ does not claim that the information is free of errors.

Copyright © 2015 Medical Technology Association of New Zealand Limited (MTANZ)

To the extent permitted by law, all rights are reserved and no part of this publication covered by copyright may be reproduced or copied in any form or by any means except with the written permission of MTANZ Limited.



medical technology
ASSOCIATION OF NEW ZEALAND

Contents

1. MTANZ Industry Survey 2014/2015 Background	4
2. About MTANZ	6
What is a medical device?	7
3. Benefits of medical technology	8
Comparing medical devices and pharmaceuticals	9
Benefits of medical technology	9
4. General health trends in New Zealand	10
Implantable devices	12
5. The New Zealand hospital system	13
Private hospitals	14
Public hospitals	14
Health expenditure in New Zealand	14
Elective surgery	14
Medical technology and healthcare everywhere	15
Technology innovation and the patient	15
6. International health expenditure and trends	16
Relative costs of medical technology	18
Value of the global medical technology industry	19
7. Medical technology industry profile in New Zealand	20
Overview	21
Summary	21
Section 1: Company Characteristics	22
Section 2: Employee Information	24
Section 3: Local & International Business	25
New Product Launches	26
Section 4: Clinical Trials	27
Major Barriers to Undertaking Clinical Trials in NZ	28
Section 5: Risk Analysis	29
Additional Barriers that Prevent Business Growth in NZ	29
Plan to Overcome Business Hurdles	30
Section 6: Buyer Engagement	31
Section 7: Final Comments	32
References	33
Selected medical technology milestones(1816-2008)	34



1. MTANZ Industry Survey 2014/2015 Background

The medical technology industry (MedTech) faces multiple challenges in New Zealand, some are similar to challenges in other OECD countries, while others are unique to NZ.

The New Zealand medical technology industry, which includes medical devices, diagnostics and medical imaging equipment, comprises a diversity of manufacturers and suppliers of medical technology from emerging New Zealand companies to multi-nationals.

As in other OECD countries expenditure on healthcare in NZ has grown at a higher rate than GDP for two generations with no sign of abating.

Medical technology has become more sophisticated over this time and this iterative process has seen MedTech's contribution to healthcare, particularly hospital treatment, increase many fold. Thus, despite MedTech unit pricing levels generally holding below GDP or inflation in some categories, gross expenditure on MedTech continues to grow across the OECD.

More procedures require more devices whether driven by new techniques or patients living longer and needing more interventions. The overall burden of costs from these

burgeoning procedures is coming under increasing pressure irrespective of whether the payer is a government, an insurer, a private citizen or a combination of these parties. Added to this MedTech is currently converging with information technology especially as a conduit of individual patient 'micro-data' into big data applications.

In NZ MedTech faces unique challenges. While the vast majority (around 99 %) of medical devices are imported with most sourced from the USA (around 65 %) there is a vibrant eco-system of invention and innovation in NZ that has demonstrated potential to develop into a high value technical, manufacturing and services export sector.

That said the recent expansion of the Government's drug buying agency, PHARMAC, from pharmaceutical to medical device procurement is

a unique challenge potentially at odds with the desire to build a high value export MedTech industry.

With so many seemingly contradictory factors in play, MTANZ commissioned an industry survey in the last quarter of 2014 to establish the state of the industry, plans for 2015 and to benchmark attitudes to the emerging procurement environment.

The survey was developed and deployed by an Independent Researcher Ms Janey Haringa who recently completed her Masters thesis Characterising Early-Stage Medical Device Commercialisation in New Zealand.

In the following pages we have presented an examination of NZ healthcare and MedTech trends, as well as international spend and trends to put some context around the NZ survey results.

There is a vibrant eco-system of invention and innovation in NZ that has demonstrated potential to develop into a high value technical, manufacturing and services export sector.



2. About MTANZ

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

Medical technology covers a wide range of products used in the diagnosis, prevention, treatment and management of disease and disability. These products include everything from familiar items like syringes and wound dressings to sophisticated MRI scanners, pain management devices and customised titanium implants.

The medical technology ecosystem in New Zealand

The New Zealand medical technology industry is comprised of three distinct groups:

- New Zealand companies and New Zealand affiliates of multinational companies which undertake manufacturing in New Zealand for the domestic market and for export
- Affiliates of multinational companies which import into NZ and from time to time undertake clinical investigations in NZ and collaborations with NZ research institutions
- Independent distributors which import and distribute medical technologies.

What is a medical device?

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

A “medical device” is 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



medical technology
ASSOCIATION OF NEW ZEALAND

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.

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

3. Benefits of medical technology

Comparing medical devices and pharmaceuticals

Medical devices	Drugs
Industry Composition Over 80% small and medium - sized companies	Very large multi-nationals dominate
Active Components Generally based on mechanical, electrical and materials engineering	Based on pharmacology and chemistry; now encompassing biotechnology, genetic engineering etc Pharmacological properties and action of active ingredients are known, based on pre-clinical and clinical studies
Product Development Wide variety of products and applications –from thermometers to -x-rays Designed to perform specific functions and approved on the basis of safety and performance Often developed by health professionals	Products are usually in the form of pills, solutions, aerosols, or ointments Product development by discovery, trial, and approved on basis of safety and efficacy Products developed in laboratories by chemists and pharmacologists
How Products Work Most act through physical interaction with the body or body part	Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body
Intellectual Property Concerns Continuous innovation and iterative improvements based on new science, new technology and new materials	Extensive research and development of a specific compound or molecule; takes several years for a new drug to enter the product pipeline.
Product Life Cycle Short product life cycle and investment recovery period (~18 months on market) Little patient linkage possible. Data exclusivity is important	Intensive patent protection, including data exclusivity and patent, needed due to extensive product life cycle and long investment recovery period
Innovation Majority of new products bring added functions and clinical value based on incremental improvements	Usually large step innovation

Benefits of medical technology

Medical technologies benefit lives in many ways, for example¹

- The use of coronary stents (artificial tubes that keep the arteries open) has halved the number of people suffering heart failure or dying from heart attacks
- Patients who have an implantable cardiac defibrillator (ICD) have a 98% chance of surviving a cardiac arrest (versus only a 5% chance of survival without the device)
- Surgical procedures benefit from advances in medical technology e.g., the use of medical technology means endometrial ablation has a recovery time of just two to four days; the alternative (hysterectomy) necessitated six to eight weeks
- Cataract surgery once required a stay in hospital of three to five days, but can now be undertaken in a day-care facility
- Medical technology comprises 2-5% of national health expenditure. However, appropriate use of medical technology reduces hospital stays by an average of 13%.



4. General health trends in New Zealand



Current life expectancy for women is 83.2 years, compared with 79.5 for men.



The incidence of obesity in New Zealand has trebled since 1977.



Chronic conditions account for more than 80 percent of deaths.

New Zealand's life expectancy is among the highest in the world and stands on average at 81 years, one year above the OECD average. Current life expectancy for women is 83.2 years, compared with 79.5 for men.² While New Zealanders generally expect to live a relatively long life there are differences between population groups. In particular, Non-Māori are still expected to live longer than Māori by 7.1 years but that divide is also being reduced. The gap was 8.2 years in 2005-2007.

Statistics New Zealand says the disparity is due to several factors including socio-economic differences and smoking rates.

The leading causes of death in New Zealand are cancer and circulatory system diseases such as heart disease. There were 8891 deaths from cancer in 2011 (4650 males and 4241 females). Cancer was the leading cause of death for both males and females in 2011 in NZ.

However, a Ministry of Health report on cancer patients

between 1994 and 2011 shows survival rates after diagnosis have increased. The one-year survival rate, after patients were first told they had cancer, rose from 74.9% in 1998-99 to 78% in 2010/2011. The number surviving for five years after diagnosis rose from 57.7% to 63.3%.

Between 1980 and 2011, mortality rates for circulatory system diseases decreased. Specifically:

- ischaemic heart disease and cerebrovascular disease rates decreased by more than two-thirds (69.9 percent and 67.5 percent respectively)
- death rates for other forms of heart disease and chronic lower respiratory diseases halved (decreasing by 53.1 percent and 50.8 percent respectively).

This result can be attributed in no small part to advances in and the diffusion of medical technology. In 2011, Māori had a total mortality rate for all causes that was 1.8 times the rate for non-Māori (the age-standardised

rates were 663.2 and 374.8 respectively).

Obesity is now a major national health issue in New Zealand. The incidence of obesity in New Zealand has trebled since 1977. Today a third of New Zealand's population aged 15 years and over is obese.

In NZ, the obesity rate among adults, based on actual measures of height and weight, was 28.4% in 2012, up from 25% in 2003. It remains lower than that in the US (35.3% in 2012), but higher than that in most other OECD countries for which measured data are available. The average for the 16 countries with recent measured data was 22.7%.³

In 2011, an OECD review of the prevalence of obesity placed New Zealand as the third most obese country in the developed world – only the United States



The most common chronic condition in New Zealand is chronic neck or back problems.



Since 1999, the total number of registered joint arthroplasties at December 2013 was 200,816.



The number of disabled people in New Zealand last year rose to more than one million.

and Mexico were higher. The incidence of obesity varies among New Zealand's different socio-economic groups. Pacific peoples and Maori are much more likely to be obese. Similarly individuals living in socially deprived areas are more likely to be obese.⁴

Obesity's growing prevalence foreshadows increases in the occurrence of chronic conditions such as diabetes, CVD and asthma, and higher healthcare costs in the future.

Chronic conditions are the leading cause of illness in New

Zealand, and account for more than 80% of deaths.

They are the leading cause of preventable morbidity, mortality and unequal health outcomes (Ministry of Health 1999).

The most common chronic conditions in New Zealand (by diagnosis) are:

- chronic neck or back problems (one in four adults)
- mental illness (one in five adults)
- asthma (one in five adults aged 15-44 years)
- arthritis (one in six adults)

- heart disease (one in 10 adults).

An ageing population has contributed to the rise (around 4%) since 2001 in the number of disabled people in New Zealand, which last year rose to more than one million – almost a quarter of the population. (Statistics New Zealand 2013 Disability Survey).

Implantable devices

The frequency of device implantation is increasing in the New Zealand population.

Since 1999, the total number of registered joint arthroplasties at December 2013 was 200,816, which had been performed on 142,228 individual patients, of which

22,813 (16%) have died during the period.

The majority of procedures was for hips, primary (93,487 or 47%) and knees, primary (71, 503 or 36%).

The number of observed component years (ocys) contained within the NZ Joint

Registry is now in excess of one million.

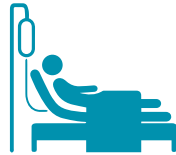
The increase of 18,046 registered joints for 2013 compared with the 17,127 in 2012 represents an overall annual gain of 5.3%, which is twice the percentage gain in 2012.⁵



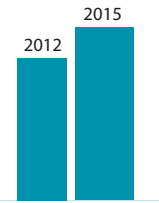
5. The New Zealand hospital system



Healthcare spend is dominated by public (83%) with private representing (17%).



The average length of stay declined by 16% from 3.75 days to 3.15 days.



Total health expenditure in New Zealand has increased from \$14 billion in 2012 to \$15.9 billion in 2015.

New Zealand has around 220 hospitals (private and public). Healthcare spend is dominated by public (83%) with private representing (17%). down from 24% ten years ago. New Zealand has 20 District Health Boards who manage public healthcare spend for the benefit of their populations.

Private hospitals

The New Zealand private hospital system has 154 operating theatres; 1,315 beds, 36 ICU beds and 470 day-stay beds. In 2013, private hospitals performed 162,218 procedures of which 10,180 were publicly-funded.

Private hospitals employ 4,400 staff. Approximately 29% of New Zealanders have some degree of private medical insurance cover. Around half of elective surgery in NZ is carried out in private facilities.

Public hospitals

Between 2001 and 2009 the number of discharges from New Zealand public

hospitals increased by 23% and the average length of stay declined by 16% from 3.75 days to 3.15 days over the same period. (Ministry of Health).

Health expenditure in New Zealand

In 2012-13, total health expenditure in New Zealand was just over \$14billion. In the latest Budget Government announced health spending would rise to \$15.9billion in the 2015-16 year.

Publicly-funded spending on healthcare has more than doubled as a share of gross domestic product (GDP) over the past 60 years, rising from around 3% in 1950 to 6.6% in 2011. (This is typical of countries in the Organisation for Economic Co-operation and Development (OECD).

Annual government spending on healthcare rose from \$583 per person in 1950 to \$2987 per person in 2011 (both figures in 2011 dollars). Health spending per person has

grown faster than GDP per person, in real terms, over this period. The trend has been particularly marked since the mid-1990s, but is now starting to level off⁶.

Elective surgery

Government has had the goal of increasing access to elective surgery since 2007/08 when the number of patients receiving elective surgery stood at 118,000 per annum.

This figure had increased to 162,000 patients per annum by 2013/14 – an increase of 37%. The Minister of Health has already announced plans to spend a further \$208 million on elective surgery over four years to continue to meet increased demand.

In particular, this funding is expected to provide an extra 2,500 orthopaedic procedures and 1,500 extra general procedures.

Medical technology and healthcare everywhere

The future of healthcare is in patient-empowering, information-leveraging technologies.⁷ These include smartphone apps, sensor-embedded smart devices and remote patient monitoring.

These have the potential to increase the efficiency of healthcare delivery and are blurring the line between medical devices and diagnostics and health IT. Combining patient empowerment and information/analysis may

lead to two breakthroughs:

1. Real time insights – timely information to assist health management, e.g. sensor monitoring of vital signs
2. Efficiencies – low-cost means of delivering healthcare efficiently.

Chronic disease accounts for around 75% of healthcare costs. Moving healthcare out of hospitals and into the home is one way of decreasing this cost.⁸

Everyday objects, including medical devices, are increasingly becoming sensor-embedded and wirelessly-connected. This has been termed the “medicalisation of consumer devices”.

In 2012 the UK’s National Health Service (NHS) began encouraging doctors to prescribe smartphone apps to patients. In 2011, 44 million health-related smartphone apps were downloaded worldwide.⁹

Technology innovation and the patient¹⁰

Technology enabler	Patient impact
Smart mobility	Ability to do the following from anywhere, at any time: <ul style="list-style-type: none"> • Communicate with medical professionals • Access health-related information to research conditions • Obtain healthcare from remote communities • Monitor/manage chronic disease • Fitness/wellness programmes and monitoring
Social networking	Tap into peer group knowledge to: <ul style="list-style-type: none"> • Compare costs of different providers and medical practices • Compare outcomes performance of different providers and medical practices • Obtain peer advice on treatment and living with chronic conditions
Cloud computing	Enables: <ul style="list-style-type: none"> • Delivery of “heavyweight” healthcare services and information to mobile devices • Personal healthcare ecosystems, including secure storage or patient information
Big data analytics	Enables: <ul style="list-style-type: none"> • Individualised healthcare services • Targeted wellness and prevention • Cost comparison of different providers.

A close-up photograph of a medical monitor displaying multiple ECG waveforms in yellow and red. The monitor is in the foreground, and a blurred background shows a person sitting on a hospital bed, suggesting a clinical setting.

6. International health expenditure and trends

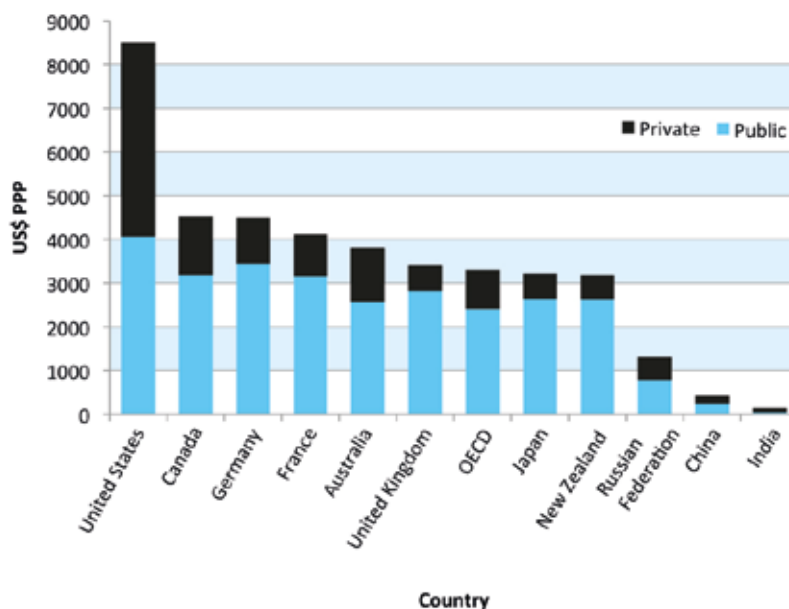
Total health expenditure as a percentage of GDP for 12 major economies.

Public and private health expenditure for 12 major economies as a percentage of GDP is shown right. The total NZ health spend as a percentage of GDP is just over half that of the USA.

However, as a proportion of GDP, New Zealand's health expenditure is above average for OECD countries. In 2010, total health expenditure in New Zealand was 10.1% of GDP compared to the OECD average of 9.5% of GDP. Only two countries – Portugal and Greece – spent a higher proportion of GDP on health and had a lower GDP per capita.

In dollar terms, New Zealand spends slightly less on health per person than the OECD average, and less than many of the countries we compare ourselves with, such as the United Kingdom and Australia (which to an extent reflects our lower national income).¹¹

As in many other OECD countries, health spending growth in New Zealand slowed down in recent years but still reached around 3% per year in real terms in 2010 and 2011, a higher growth rate than the average across OECD countries. This slowdown in health spending in NZ was driven partly by slower growth in pharmaceutical spending, due partly to the growing share of the generic market (which accounted for 33% of the pharmaceutical market in



Source: World Health statistics (2013).

2012, up from 27% in 2008).¹² OECD Health Statistics 2014 also shows that NZ has experienced a substantial expansion of its medical workforce since 2000. In 2012, NZ had 2.7 doctors per 1000 population, up from 2.2 in 2000. This nonetheless remains below the OECD average of 3.2.

- Annual sales of medical technology in Europe are approximately US\$95 billion (or 33% of the world market). Around 80% of sales are from the small and medium sized enterprises (SMEs) sector.¹³
- The medical technology sector employs around 500,000 staff in Europe.¹⁴
- The European medical technology industry is growing at over 5% per annum.¹⁵
- Each additional medical technology industry job created in the USA generates an additional 4.5 jobs across the country.¹⁶
- In the USA medical technology represents around 20% of total cost growth in healthcare (unlike NZ see next page). The largest components of the USA medical technology market are diagnostic imaging, cardiovascular procedures and in-vitro diagnostics (IVDs).¹⁷
- Despite the challenges of the current economic climate, net income for publicly held medical technology companies increased by 14% in the USA. This increase is less than the double digit figures of the past and financial performance is likely to continue to be challenged by low economic growth, austerity measures and imminent 2.3% medical device tax in the US.¹⁸
- Canada has approximately 1,000 medical device companies and employs around 26,000 people. The size of the Canadian device market was US\$6.3 billion in

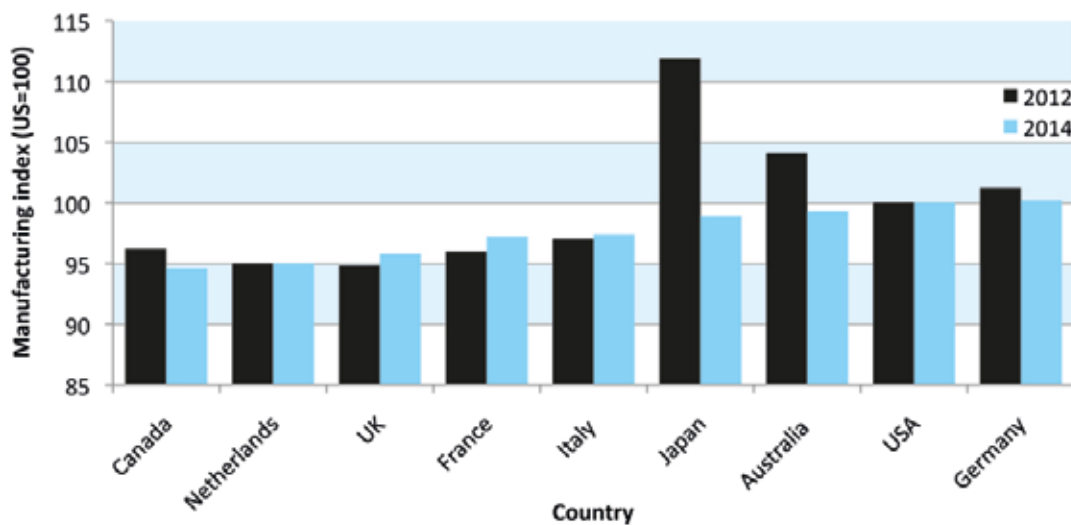
2011 and had device exports of US\$1.8 billion and imports of US\$6.5 billion.¹⁹

- Israel has 656 medical device companies. Israeli device companies are typically very small: 50% employ 5 or less people and nearly 70% of companies are still at the

pre-market or non-commercial stage of product development. These start-ups are viewed as drivers of innovation and are often supported by venture capital and other investments. Overall production revenue (exports and local sales) for Israel was US\$2 billion in 2011.²⁰

- KPMG performs an annual survey of manufacturing costs internationally including manufacturing costs for medical devices. The results of the manufacturing costs index for nine countries are presented below.²¹

Medical device manufacturing costs



Source: KPMG 2012.

Relative costs of medical technology

Medical technology is often erroneously blamed for the high and increasing cost of healthcare. Data from both local and international sources show that this assumption is incorrect.

Data from the World Medical Markets Fact Book 2012 (Espicom) which covers expenditure on medical devices in 66 countries shows that expenditure on devices is relatively low compared to other health costs.²²

Recent research suggests that medical technology of all kinds is only one of several factors that influence costs, and then largely by enabling more and better healthcare rather than increasing like-for-like costs.²³

The research points to a UK report that showed that the primary driver of healthcare costs was labour.²⁴ So, with their potential to impact positively on other major costs, such as labour, devices may be

part of the answer to, rather than the cause of, healthcare inflation.

Moreover, in NZ increased patients volumes (especially in elective surgery) driven by our aging population, chronic disease and relative affordability are the main reason the total cost of medical devices is increasing.

Pricing is relatively static and has grown below inflation.

Elective surgery volumes have grown by 37% from 2007/08 to 2013/14 which equates to 44,000 more operations over six years.

The medical device and diagnostics industry is

extremely competitive in NZ, ensuring that medical technology is a good bargain; spending on advanced medical technology is consistently a small and stable share of national health expenditure.

Expenditure remains between 5% - 6% demonstrating remarkable consistency and value despite a flood of new products that profoundly improved medical practice.

Value of the global medical technology industry

Globally, the medical technology market was valued at more than US\$350 billion per annum in 2013.

It is predicted that by 2018 global sales of US\$440 billion will be achieved.

The largest market is the United States with the New Zealand medical technology market estimated at US\$977 million – approximately 0.3% of the global market.

The largest market is the United States with the New Zealand medical technology market estimated at US\$977 million – approximately 0.3% of the global market.

A report by Evaluate MedTech that assessed data from 120 global medical technology companies reported that medical technology is set to outperform the prescription drug market with 4.5% growth per year (versus 2.5% per year for

the prescription medication market). The IVDs segment is the largest segment of the medical technology market. Research and Development (R&D) in medical technology is growing at 3.3% per annum.²⁵

Value of the global medical technology industry by segment

	Device area	Worldwide sales (2012) (US\$bn)	Worldwide sales (2018) (US\$bn)	CAGR+ % growth
1	In vitro diagnostics	43.6	58.9	+5.1
2	Cardiology	38.1	48.7	+4.2
3	Diagnostic imaging	36.1	45.1	+3.8
4	Orthopaedics	32.7	40.0	+3.4
5	Ophthalmics	23.6	32.9	+5.7
6	Endoscopy	17.7	24.2	+5.3
7	Drug delivery	17.7	22.0	+3.7
8	General & Plastic surgery	13.4	18.4	+5.4
9	Dental	12.6	16.5	+4.6
10	Wound management	11.9	14.7	+3.5
11	Diabetic care	11.8	14.4	+3.4
12	Nephrology	10.9	13.9	+4.1
13	Ear, Nose & Throat (ENT)	6.6	9.5	+6.2
14	Anaesthesia & Respiratory	6.1	8.5	+5.6
15	Neurology	5.3	8.0	+6.9



7. Medical technology industry profile in New Zealand

Overview

The 2014/15 industry survey seeks to collect accurate industry statistics in order to promote to our stakeholders the value and contribution our members make to the NZ economy.

Seven sections of questions were asked in an online survey encompassing: company characteristics; employee information; local and international business; clinical trials; risk analysis; buyer engagement and final comments regarding how the NZ medical device industry can increase its value for the NZ healthcare sector.

Eighty-eight MTANZ member companies were invited through email to participate. Sixty companies (70%) completed the survey.

Summary

MTANZ member companies are well established businesses, the majority of which have been successfully trading for well over

ten years. More than half of the respondents are NZ-owned companies that either distribute imported technology or, in the minority of cases, manufacture locally.

Multinational corporate subsidiaries are the largest in terms of sales volumes. However, locally-based companies continue to thrive.

The complex and innovative nature of medical technology requires close working relationships with healthcare providers and thus local well-established companies have built successful working relationships with the managerial and clinical staff within both the private and the public healthcare sector.

Single Use Technology (SUT), the largest MedTech category, only represents 10% of the total the range encompassed by medical devices.

This illustrates how medical devices and technologies vary profoundly, are rarely used in isolation (so must be

compatible), are highly adaptable to evolving processes and technological advances, and require technical transfer of expertise from the supplier to user in order to perform safely and adequately.

Staffing levels, expertise and capabilities reflect the ongoing relationship building and in use support required by the healthcare provider with over 40% of the 2366 full-time, employed staff selling, providing technical or clinical or executive level support.

Encouragingly, these key staffing areas are predicted to expand in 2015 or at least retain current levels suggesting a level of confidence in the immediate future despite these unknowns.

Note, to preserve like for like we have excluded the 1000+ staff at F&P Healthcare who are dedicated to export initiatives.

Multinational corporate subsidiaries are the largest in terms of sales volumes. However, locally-based companies continue to thrive.

Section 1: Company Characteristics

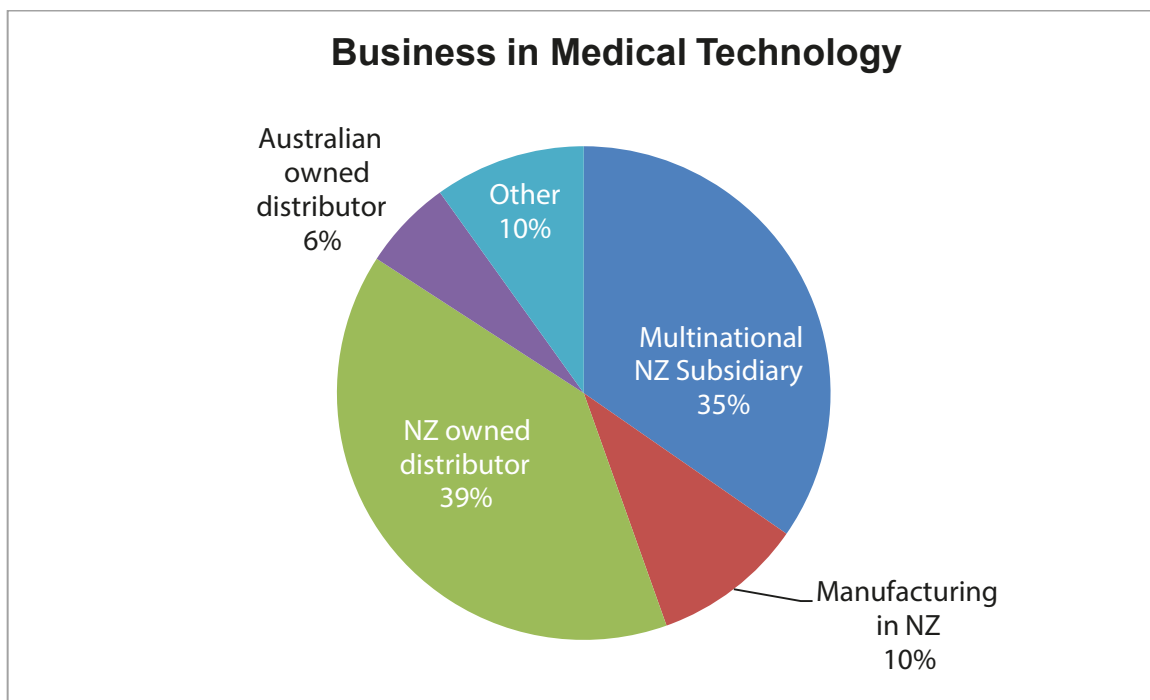
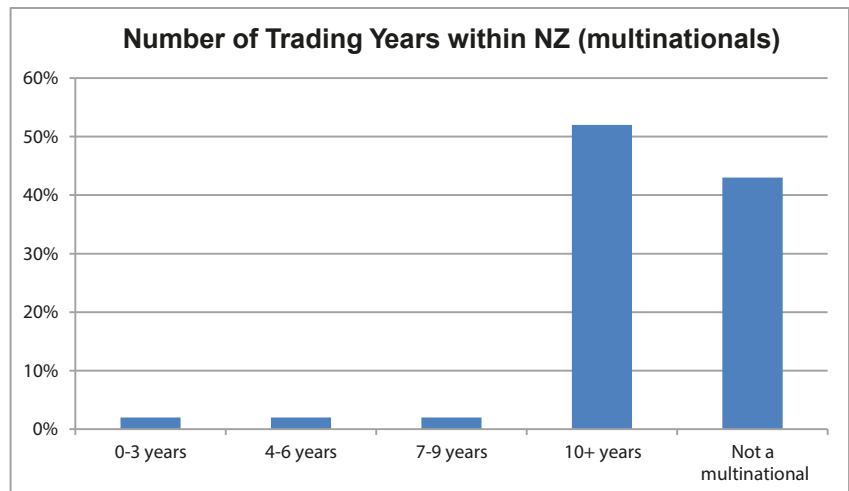
The majority of Medical Technology companies, whether locally-owned or divisions of multinationals, have been successfully trading in NZ for over a decade, some for significantly longer.

This length of tenure suggests the industry is well established and trusted within the healthcare sector. The industry shows resilience in the face of rapid change which continues at an increasing pace.

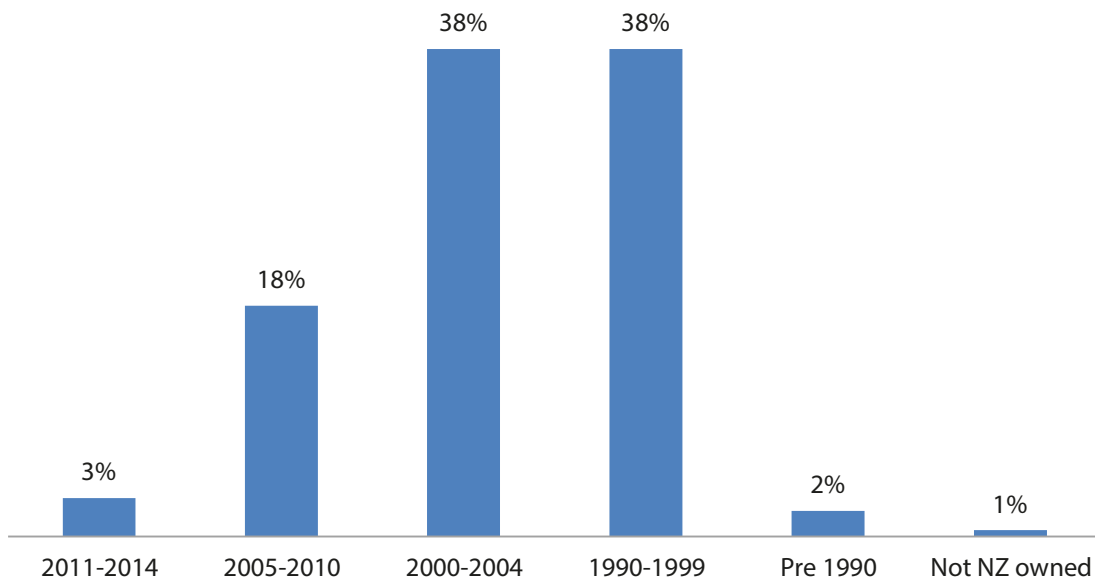
Further, the importance to the overall economy is reinforced by the large number of NZ-owned companies either distributing or manufacturing locally. The level

of technical ability and sophistication of these NZ companies is crucial to the development of a high value MedTech sector that may grow exports and expertise.

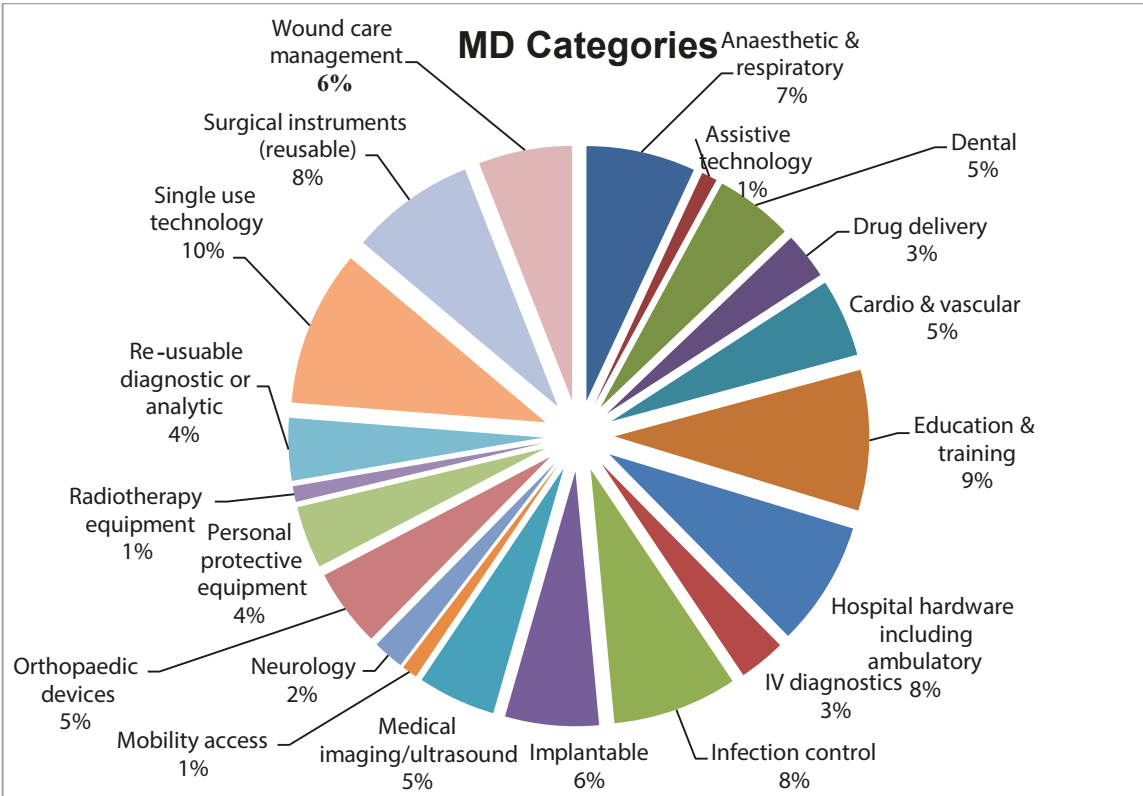
NZ and Australian-owned companies compete successfully across all the major medical device categories.



Date of Company Establishment (NZ owned)



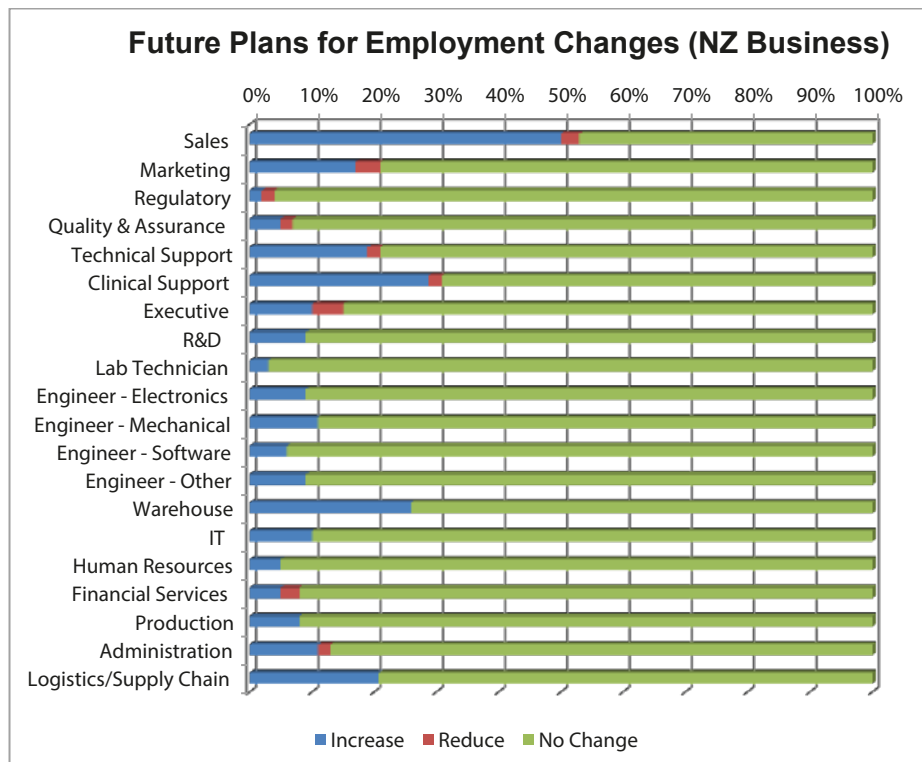
MD Categories



Section 2: Employee Information

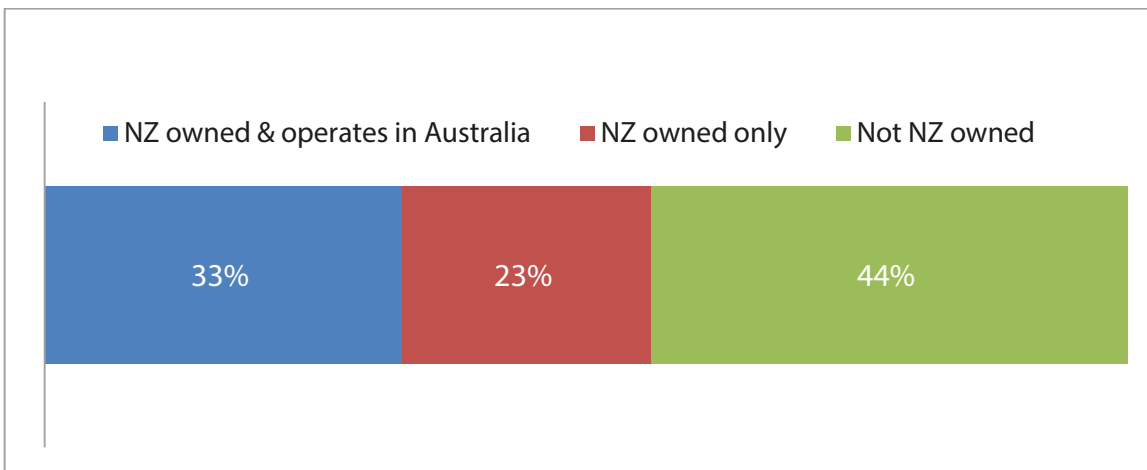
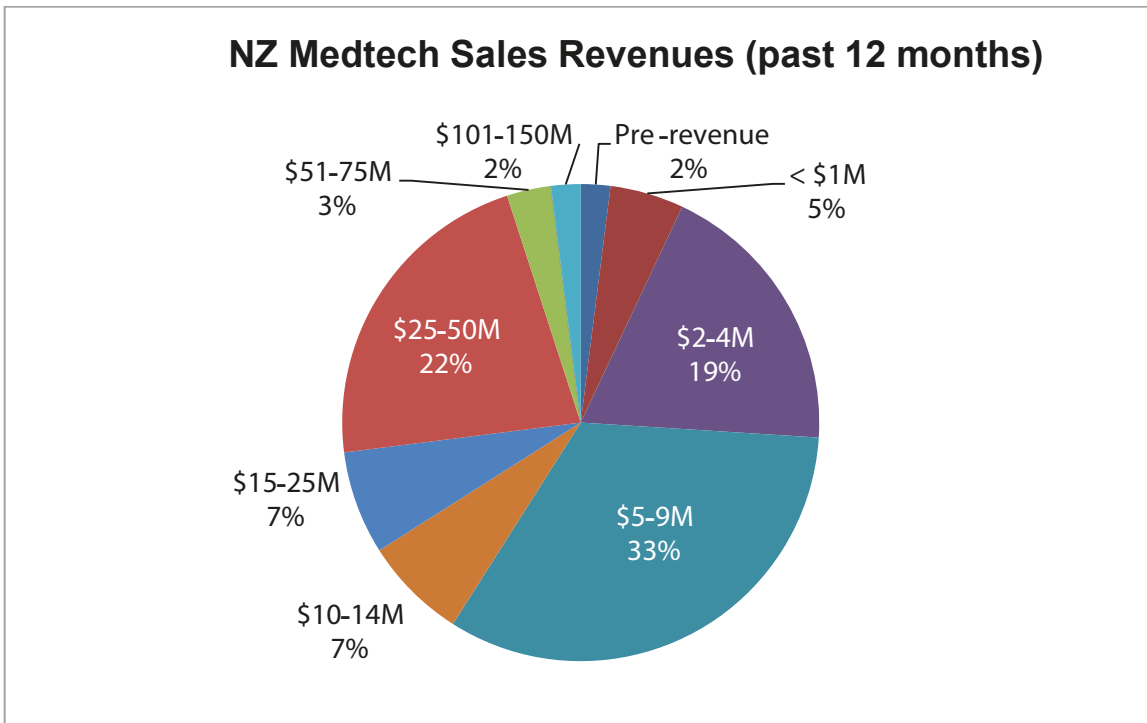
Across the 61 companies involved in this study, 2366 full time staff are employed against their medical device business. However, this does not include the 1000 full time staff who are employed by a single largest company F&PHC.

Staff Expertise	Proportion of All Employees
Sales	12%
Marketing	8%
Technical Support	8%
Clinical Support	8%
Executive	8%
Administration	8%
Warehouse	7%
Logistics/supply chain	7%
Regulatory	6%
Quality & Assurance	5%
Financial Services	5%
Engineer – Mechanical	4%
IT	4%
Engineer - Electronic	3%
Human Resources	3%
R&D	1%
Lab Technician	1%
Engineer – Software	1%
Engineer – Other	1%
Production	1%



Despite the rapidly changing environment and uncertainty over the procurement process MTANZ member companies are looking to employ more staff. Sales, marketing, technical support, clinical support, warehouse and logistics/supply chain are the six key areas where companies are planning to increase staff to support growth.

Section 3: Local & International Business



Total Sales

For NZ owned companies, the total sales outside of NZ over the past 12 months totalled \$81.37 million dollars not including the \$614 million by F&PHC and

\$6 billion by Ebos the majority of whose sales are pharmaceutical and/or wholesale distribution of medical devices sold by MTANZ members and thus double counted.

New Product Launches

There have been 1079 new medical device products launched in NZ over the last 12 months according to the survey.

Over 80% of these new product introductions were by NZ or Australian-owned companies. Underlining the crucial role the small and medium local players have in driving innovation.

Across the 61 companies, an average of 8% of current NZ sales revenue comes from new products over the last 12 months.

Additionally, companies on average plan to launch 12 new products in NZ over the next 12 months.

The volume of new products and the significant proportion of sales that new products account for is evidence of a rapid pace of innovation - much of it iterative. This rapid pace of innovation is projected to continue in the coming 12 months.

According to the TiN100 Industry Analysis 2014, the NZ healthcare sector had experienced 11.4% growth (\$124.5m) over the year and had reached total annual revenue of \$1.29billion. This sector also created 295 new jobs over the year.

The TiN100 is a good indicator for the success of the sector relative to other high-tech sectors – the goal is to increase the number and ranking of medical technology companies in this annually-produced list. Out of the seven healthcare companies in the top 100, a few medical technology companies stand out: Dynamic Controls; Fisher & Paykel Healthcare; Howard Wright, MedTech Global, Orion, Orthopaedic Synergy; and Trident.

Neither the industry nor the sector could sustain this level of new product launch without a close and trusting working relationship across all levels of the healthcare sector but, in particular, with clinicians.

The annual research and development spend by medical device manufacturers in NZ is \$66m per annum however this investment is only a part of the resources deployed to introduce innovation to NZ.

How the NZ medical device industry introduces new technology shows up in the statistics around clinical trials and product evaluation.

While NZ is acknowledged as a

centre of excellence for first in human trials of medical devices and technology, only a fifth of MTANZ members ran clinical trials recently or plan to do so in the coming year.

Trials, while critical to the development of devices, clearly are secondary to the launch of new products by MTANZ members with over 40% citing clinical trials as not applicable to their business needs.

However, what is clearly critical is the access and ability of MTANZ members to evaluation trials of new products within DHBs. Over two-thirds of MTANZ members have utilised new product evaluation trials within DHBs as part of the launch/go to market efforts.

Product evaluation risks are among the top three risks to businesses in MTANZ, ranked almost equal with procurement and funding policies and procedures. This suggests all three sides of the triangle need to be in balance for the industry to succeed in introducing new technology;

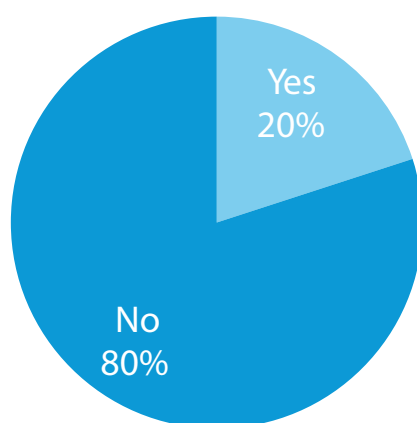
1. The device must be evaluated fairly - and deliver a benefit.
2. It must fit the funding requisite.
3. The procurement process must be able to accept the innovation.

Little wonder MTANZ members are concerned that the uncharted changes in procurement have the potential to unbalance one or more sides of this process. The number of product evaluations also reflects the close relationships MTANZ members have with clinicians and DHBs. This balance needs to continue to ensure innovation comes to market in a timely fashion.

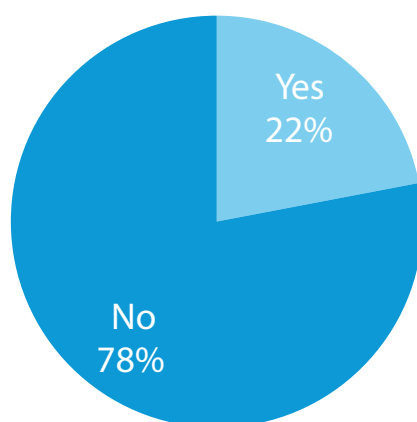


Section 4: Clinical Trials

Undertaken Clinical Trials in NZ (past 12 months)



Intentions to Undertake Clinical Trials (next 12 months)



Major Barriers to Undertaking Clinical Trials in NZ

Barrier	Number	Percentage
Clinical Trials N/A	25	41%
Funding & Costs	10	16%
Bureaucracy	6	10%
NZ Market Size	4	7%
Staff in NZ	3	5%
Delays (Timeframes)	2	3%
No Barriers	1	2%
No Answer	10	16%

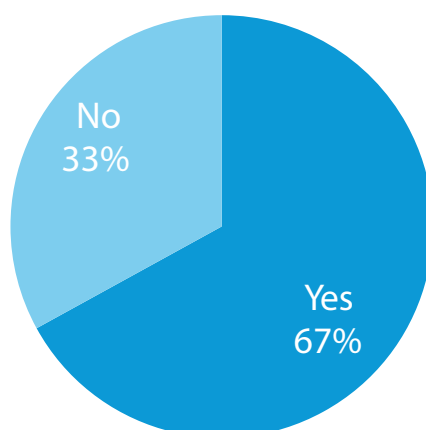
“Being a distributor this is not something we would normally do for cost, time and ROI reasons.”

“Costs and timing to set up.”

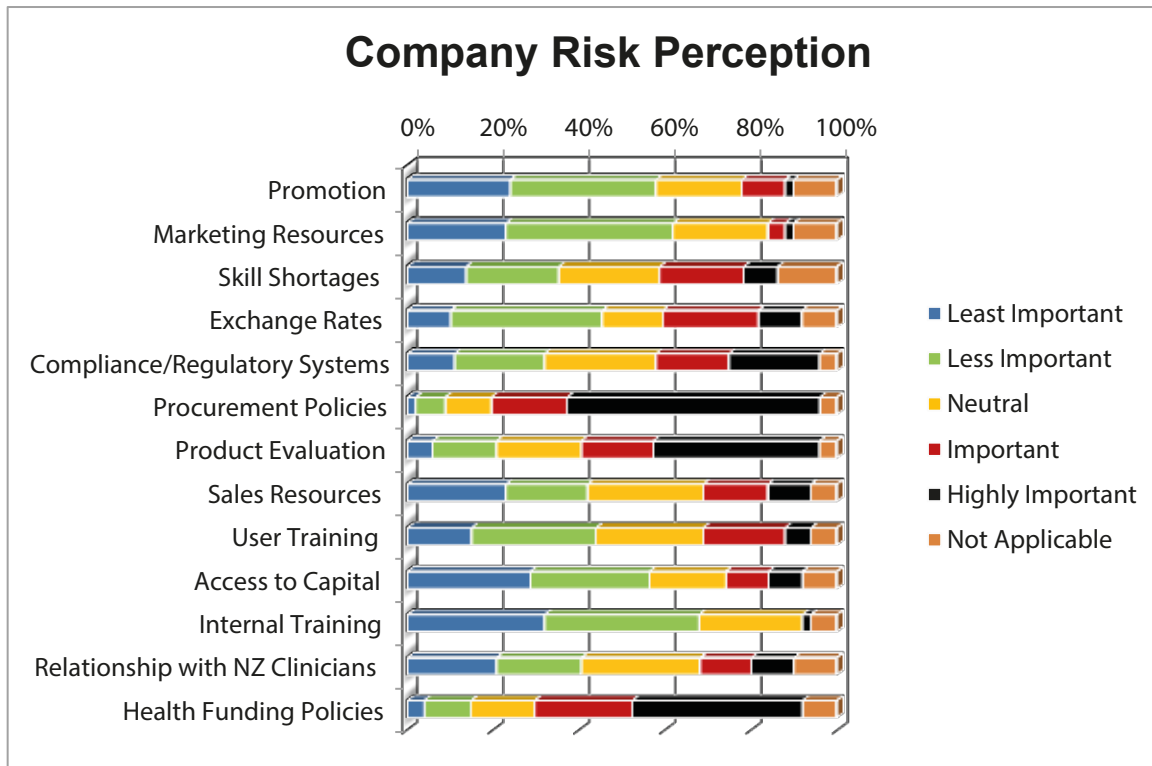
“Trial acceptance from procurement personnel.”

“Confused and overcomplicated bureaucratic process.”

Undertaking Product Evaluation to Launch New Products through DHBs (past 12 months)



Section 5: Risk Analysis



The most important constraints or problems that companies perceive may prevent growth for their business (red and black bars) are largely led by risks involving procurement policies, product evaluation and health funding policies. It is notable that these policies are currently in a state of flux.

Additional Barriers that Prevent Business Growth in NZ

Additional Barriers	Number	Percentage
1. Procurement Changes (PHARMAC/hA)	19	31%
2. Changes in the Market	8	13%
3. Single Supplier Contracts	4	7%
4. Other	4	7%
5. Not Applicable	4	7%
6. No Barrier	3	5%
7. No Answer	19	31%

1. Procurement Changes

“Uncertainty in government direction for procurement strategy.”

“Procurement is seen as road blockers to quantity driven vs. quality driven.”

“The introduction of Pharmac working off a fixed annual budget.”

“Acceptance of new technology by procurement organisations and their ability and willingness to investigate long term benefits of new technologies on their spend.”

2. Single Supplier Contracts

“Single product contracts.”

“National supplier agreements that encourage monopolies; the danger of the single supplier model.”

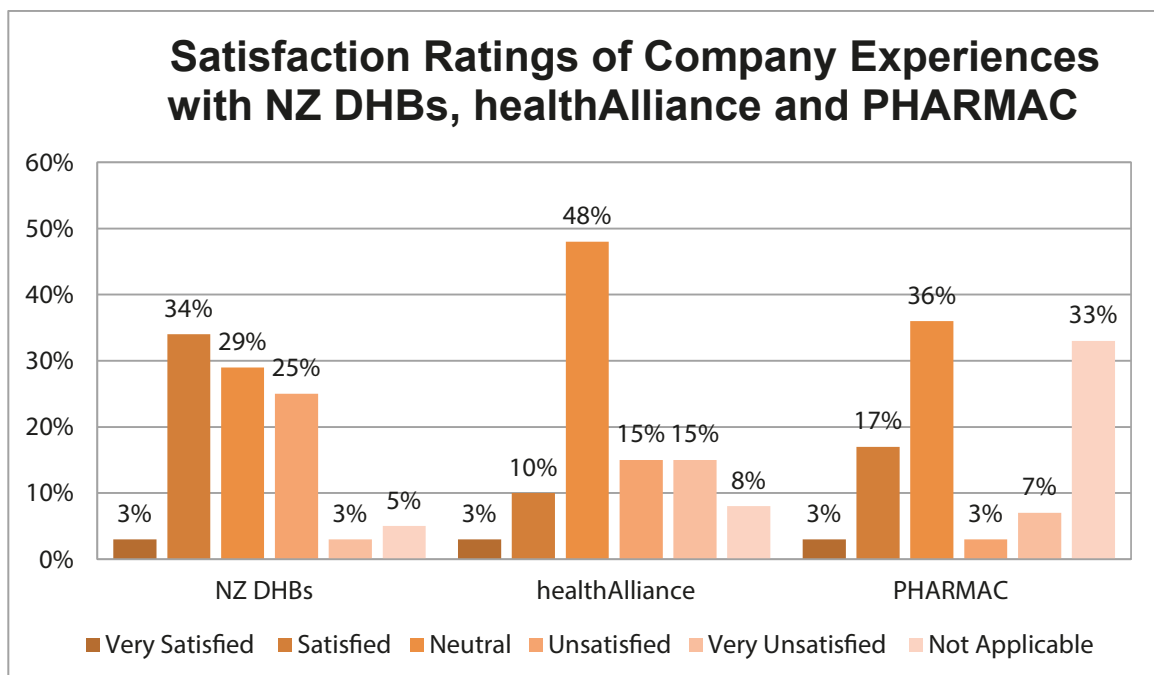
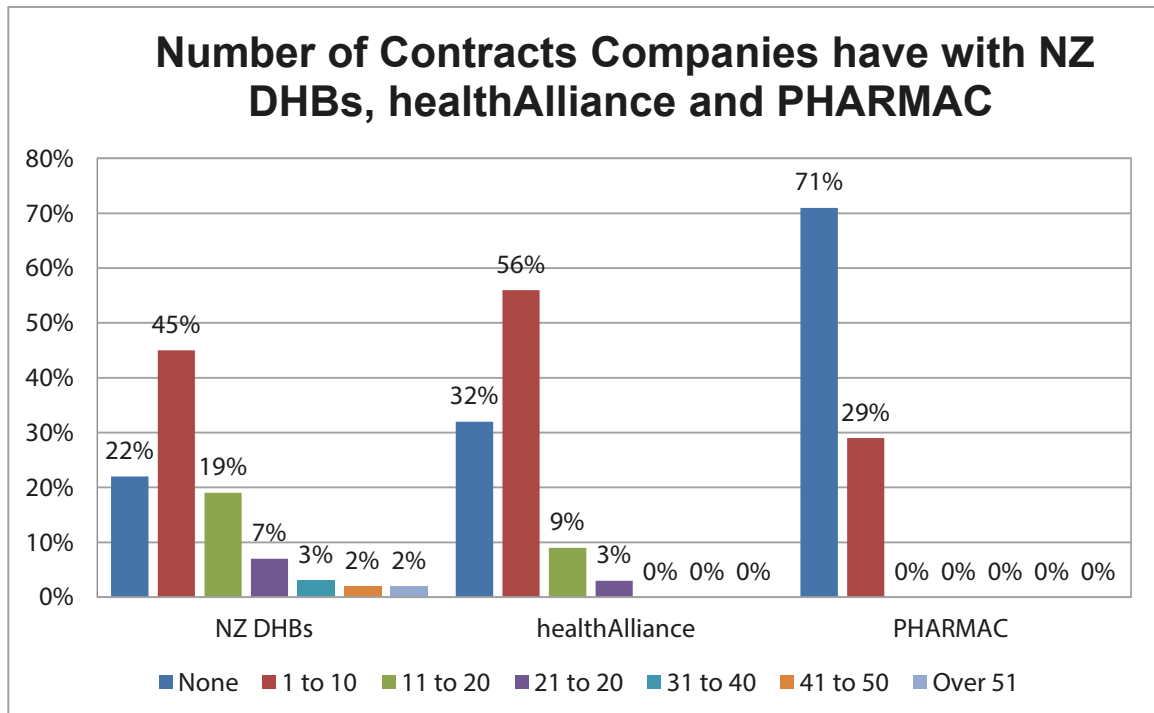
3. Changes in the Market

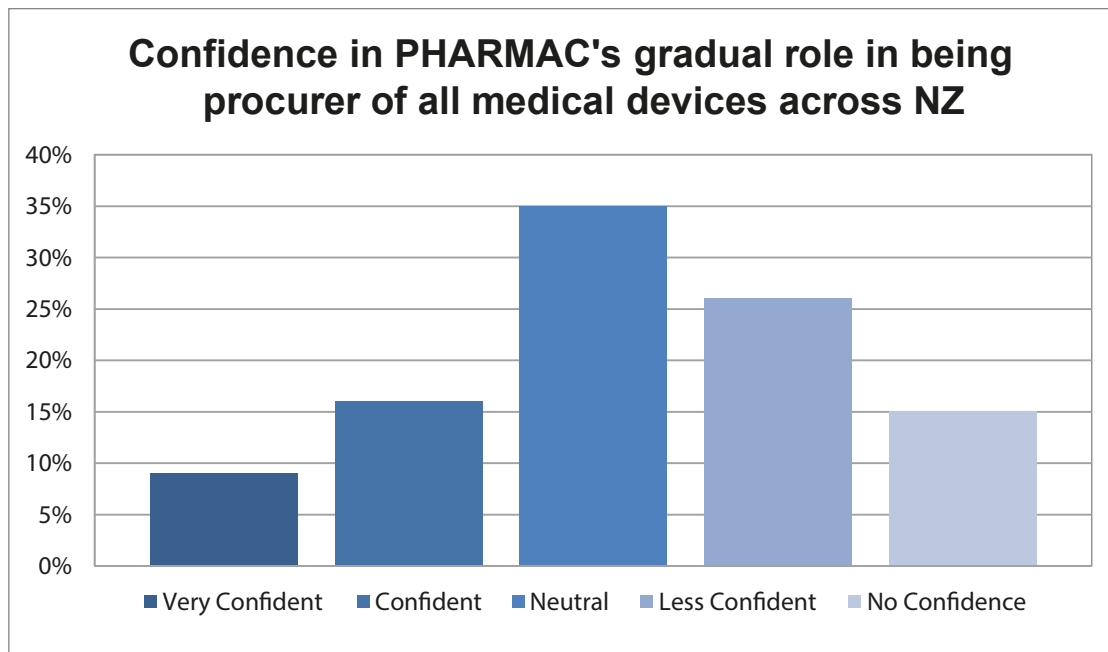
“Cross-border trade, both custom-made medical devices being manufactured in China and clinicians directly importing in.”

Plans to Overcome Business Hurdles

Plan to Overcome Hurdle	Number	Proportion
1. Increase Marketing & Customer Relationships	14	23%
2. Closer Engagement with Gov/Reg/Stakeholders	8	13%
3. Continue Current Strategy	6	10%
4. Greater Focus & Cut Costs	4	7%
5. Staff Training & Recruitment	3	5%
6. M/A with NZ companies	3	5%
7. Unsure	3	5%
8. Other	4	7%
9. No Answer	16	26%

Section 6: Buyer Engagement





The satisfaction ratings underscore the transition that the market is currently undergoing as the relatively satisfactory relationships are directly with DHBs with whom

members hold the majority of contracts.

This contrasts with low levels of satisfaction with healthAlliance and too few contracts and

transactions with PHARMAC to yet see trends. However, these base lines will be important to track over time as procurement both through hA and PHARMAC dramatically increases.

Section 7: Final Comments

Technological advances, empowered consumers, disruptive new entrants and rising demand by the aging population are ushering in a new era in healthcare. Medical technology is part of the solution – not the problem. The final thoughts from participants regarding how the NZ medical device industry can increase its value for the NZ healthcare sector.

What additional barriers could prevent the growth of your business in NZ?

"Constraints of national procurement agency trying to implement a strategy that isn't sufficiently developed to enable suppliers and DHB to achieve successful business outcomes efficiently."

"Cross border trade. Both custom-made medical devices being manufactured in China and clinicians directly importing medical devices."

"Increasing shift of unacceptable cost burden and risk to supplier."

"Resource required for

regulatory compliance."

"Antipathy and re-doing tests and evaluations that have been done internationally and accepted as standard; but power-hungry committees in NZ have to "approve or test" locally. A total waste of taxpayer's funding and eternal frustration for business."

"Acceptance of new technology by procurement organisations, and their ability and willingness to investigate long-term benefits of new technologies on their spend."

"Pharmac, Health Alliance focusing too much on unit costs not cost to treat. Health Alliance reducing access to clinicians. The short term focus of health managers around budgets today and not thinking how in 5-10 years we will be able to treat the numbers of patients requiring medical attention due to the aging population and the increase of chronic disease."

"Pricing decline forces us to not launch new products in NZ."

References:

- 1 Modified from www.eucomed.org/medical-technology/value-benefits
- 2 Statistics New Zealand report
http://www.stats.govt.nz/browse_for_stats/health/life_expectancy/NZLifeTables_HOTP12-14.aspx.
- 3 OECD Health Statistics 2014: How does New Zealand compare?
- 4 NZIER Report by Clough.P and Destremau. K; The wider economic and social costs of obesity: A discussion of the non-health impacts of obesity in New Zealand. January 2015.
- 5 New Zealand Joint Registry 15 year Report, NZ Orthopaedic Association.
<http://www.nzoa.org.nz/system/files/NZJR2014Report.pdf>
- 6 Statement of Intent 2012/2013 to 2014/15 Ministry of Health.
- 7 Ernst and Young. Pulse of the Industry. Medical technology report 2012.
- 8 Ernst & Young. Progressions. The third place: healthcare everywhere. Global Life Sciences report 2012.
- 9 Telecommunications: Mobile Healthcare and Medical App Downloads to reach 44 million next year, rising to 142 million in 2016. Finds Juniper Research Ltd. Telecommunications Weekly via VerticalNews.com
- 10 Modified from Ernst & Young (2013). MHealth. Mobile technology poised to enable a new era in healthcare (page 17).
- 11 NZ Treasury Report. Health Projections and Policy Options for the 2013 Long-term Fiscal Statement 2012.
- 12 OECD Health Statistics 2014: How does New Zealand compare?
- 13 www.eucomed.org/medical-technology/value-benefits.
- 14 www.eucomed.org/medical-technology/value-benefits.
- 15 www.eucomed.org/medical-technology/value-benefits.
- 16 The Lewin Group, Inc, State Impacts of the Medical Technology Industry, 2007.
- 17 Beever, C. & Karbe, M. The Cost of Medical Technologies. Maximising the Value of Innovation. Booz, Allen, Hamilton.
- 18 The Lewin Group, Inc, State Impacts of the Medical Technology Industry, 2007.
- 19 The World Medical Markets Fact Book 2012, Espicom, July 2012.
- 20 Medidata. Israel Medical Devices Industry. Market Overview. August 2012.
- 21 Medical Device Manufacturing Costs (Competitive Alternatives: KPMG's Guide to International Business Location Costs. 2012 Edition.
- 22 World Medical Markets Fact Book. (2012). Espicom Business Intelligence.
- 23 The Causes of Healthcare Inflation: MedTech's Urban Myth. The European Health Technology Institute for Socio-Economic Research, Belgium. December 2011. www.ehti.info.
- 24 Public Service Output, Inputs and Productivity: Healthcare, Office of National Statistics 2010. www.ons.gov.uk
- 25 Ibid.
- 26 Adapted from National Center for Health Statistics. Health, United States, 2009: In Brief – Medical Technology. Hyattsville, MD, 2010

Selected medical technology milestones (1816-2008)²⁶

- 1816 – Stethoscope invented
- 1842 – First surgical operation using anaesthesia with ether
- 1851 – Ophthalmoscope invented
- 1852 – Hyperdermic needle syringe with plunger invented
- 1855 – Laryngoscope invented
- 1895 – First documented medical use of x-rays in medical imaging
- 1896 – Sphygmomanometer (mercury-based blood pressure meter) invented
- 1901 – First electrocardiograph (ECG or EKG) machine
- 1920 – Band-Aid invented
- 1922 – Insulin first used to treat diabetes
- 1924 – First electroencephalogram (EGG) performed
- 1927 – First practical modern respirator (iron lung) invented
- 1943 – First electron linear accelerator designed for radiation therapy developed
- 1945 – First practical human haemodialysis machine developed
- 1947 – First stereotactic devices for human neurosurgery invented
- 1948 – Plastic contact lens developed
- 1949 – First implant of intraocular lens
- 1953 – Heart/lung bypass machine first used in surgery on humans
- 1955 – Ultrasound first used on pregnant women
- 1958 – First cardiac pacemaker implanted. Artificial heart valve developed
- 1962 – First hip replacement using a metal femoral head (hip joint) placed within a polyethylene acetabular cup (hip socket)
- 1965 – First portable defibrillator installed
- 1972 – Computed axial tomography (CAT) scan for brain invented
- 1975 – First recorded positron emission tomography (PET) image
- 1977 – First image of a human in a whole-body magnetic resonance imaging (MRI) scanner
- 1978 – First cochlear implant surgery
- 1982 – First permanent artificial heart implant
- 1985 – Implantable cardiac defibrillator (ICD) approved by US Food and Drug Administration (FDA)
- 2000 – First robotic system for general laparoscopic surgery approved by FDA.
- 2003 – Drug-eluting stent for clogged arteries approved by FDA
- 2004 – 64-slice CT scanner approved by FDA
- 2008 – Commercial hybrid PET/MRI scanner produced.



medical technology
ASSOCIATION OF NEW ZEALAND

MEDICAL TECHNOLOGY ASSOCIATION OF NEW ZEALAND
PO Box 74116, Greenlane Central, Auckland 1546, New Zealand
Ph: + 64 9 917 3645 Fax: +64 9 917 3651
Email: admin@mtanz.org.nz Website: www.mtanz.org.nz
