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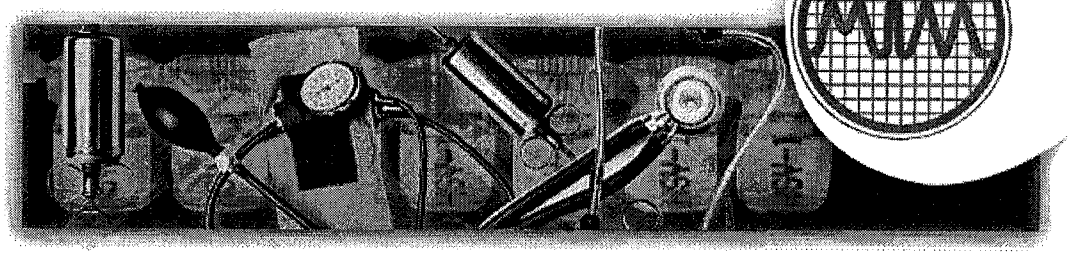
# SUBMISSION BY THE MEDICAL INDUSTRY ASSOCIATION OF AUSTRALIA INC

# TO THE

# HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON HEALTH AND AGEING

# INQUIRY INTO HEALTH FUNDING

MEDICAL INDUSTRY ASSOCIATION
OF AUSTRALIA



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# Introduction

The Medical Industry Association of Australia Inc (MIAA) welcomes the House of Representatives Standing Committee on Health and Ageing's Inquiry into Health Funding.

The MIAA represents manufacturers, importers and distributors of medical devices and diagnostic reagents in Australia.

MIAA members play a vital role in the Australian healthcare system by supplying non-pharmaceutical medical products to hospitals, medical professionals and patients.

Our members distribute over 85 percent of the non-pharmaceutical products used in the diagnosis, prevention or treatment of injuries or diseases. Products range from familiar items such as syringes and wound dressings through to high-technology implanted devices, hospital capital equipment, sophisticated diagnostic products, self-care items and laboratory consumables.

**Medical Devices and Diagnostic Industry**

A recent survey of MIAA membership found:

- MIAA represents more than 150 companies.
- More than 10,000 people are directly employed by the industry in Australia.
- It is estimated there are more than half a million different medical devices and diagnostic products.
- Domestic sales amounted to $2.9 billion in 2004.
- Export sales were $600+ million in that year.
- There are over 1100 sponsors who include medical devices on the Australian Register of Therapeutic Goods.
- Of these sponsors, 140 are members of MIAA and represent more than 85% of the dollar turnover in the industry.
- Member companies invest heavily in ancillary services including training doctors and other medical personnel, attendance during surgical procedures, patient education, servicing equipment and supply of supplementary equipment to support implant surgery.
- In 2003-04, MIAA conducted 50 professional development training programs for 1000 people employed in our highly specialised industry.

The MIAA and its members, therefore, have a deep interest in, and knowledge of, the Australian healthcare system.

We welcome the Committee's inquiry as it provides the Parliament and the governments the opportunity to examine and reform the healthcare system and public policy environment to improve its efficiency and effectiveness and to ensure the highest quality affordable healthcare is available to all Australians.

The MIAA also welcomes the decision of the Council of Australian Governments (COAG) on June 3, 2005 regarding the review to be undertaken by Senior Officers to examine how the health system can be improved by clarifying roles and responsibilities and by reducing duplication and gaps in services.

The MIAA will seek to be actively involved in this review process.

**This submission principally focuses on highlighting identified processes, regulations, funding issues and information gaps that should be addressed to improve the efficient and effective delivery of high quality healthcare to all Australians.**

In particular, MIAA draws the Committee's attention to the:

- benefits of **advances in medical technology**;
- imminent advances in **new technology** and their implications for the Australian healthcare systems, processes and patient outcomes;
- impact of **regulation and assessment procedures** on R&D, investment and the timely delivery of medical technology;
- **duplication and services gaps** under the current system and structure of healthcare delivery and funding;
- implication on **patient care** from the current system and structure of healthcare provision;
- existing **data deficiencies** that prevent proper measurement and planning for current and future costs and benefits of medical technology;
- **inefficient, ineffective and inequitable healthcare** processes in the present Australian healthcare system; and
- need for **incentives** for change and improvement to enhance healthcare in Australia.

## Benefits of Medical Technology

In undertaking its inquiry into health funding the MIAA urges the Parliamentary Committee to closely examine and acknowledge the benefits of medical technology.

There are two distinct dimensions to this point. The first is the patient benefit dimension, while the second dimension relates to the fostering and development of a high technology industry sector with substantial export growth opportunities.

All too often reviews of the Australian healthcare system focus on the cost of healthcare and ignore the benefits of medical technology. In fact, because the dollar cost of certain medical technology is easily identified it is regularly highlighted as a prime contributor to healthcare expenditure growth.

Unfortunately, discussion of the benefits of such technology is all too absent from much of the health policy debate in Australia.

Any proper examination of Australia's healthcare system must give due consideration to the benefits of medical technology and the offsetting savings it can generate.

In the broadest sense, medical technology has been responsible for significant reductions in mortality, morbidity (including disability) and improvements in quality of life in all age groups. In particular, many medical devices have reduced the use of some drugs, reduced hospital admissions and length of stay and allowed individuals to function normally. As a result, this has reduced the indirect costs for care of patients and the healthcare system.

A number of international studies have examined and quantified the direct benefits and cost savings as a result of advances in medical technology.[1]

For example, new data from the United States suggests that selected technologies have caused a 1-2 percent per year decrease in quality adjusted costs of specific disorders in the period 1960-1997. In terms of health benefits, the study also found that each extra year of life expectancy gained was associated with an increase of 3.5 percent of GDP share, and the implied value per year gained was US$93,000, an estimate that is consistent with many prior estimates of the value of one year of human life.

[1] For further information on these studies see the MIAA Submission to the Productivity Commission Study Into The Impact Of Advances In Medical Technology On Healthcare Expenditure In Australia (http://www.miaa.org.au/pdf/PC04.pdf).

Another study examined reductions in heart disease in the United States of America since 1970. This study found, with heart attacks and strokes treated with new technologies over this period, that the likely benefit from medical research is assumed to be 20 percent reduction in mortality, with another 13 percent associated with the use of new drug therapies and treatment protocols that reduced blood pressure and cholesterol.

At this point, it also worth noting that similar detailed studies of these kinds are not yet feasible in Australia, in part, because of a lack of investment in the national surveys required. The MIAA makes further observations on this issue later in this submission.

Nevertheless, it is clear that advances in technology have also aided clinicians in better management of chronic diseases, that for a long time have placed huge pressures on the healthcare system. Notably, medical devices have reduced the use of pharmaceuticals, reduced hospital admissions and length of stay and allowed patients to function normally.

For example, the application of a range of medical devices in the diagnosis and treatment of heart disease, Australia's most costly health disorder, have had a significant impact on healthcare, including:

- help reduce risk factors (e.g. blood pressure monitoring devices);
- reduce long term complications of often related chronic diseases;
- monitor symptoms and diseases (e.g. diagnostic devices for heart disease and stroke);
- distinguish patients who will benefit from drug therapy from those that will show no benefit due to genetic predisposition;
- aid diagnosis and treatment (e.g drug-eluting stents, and 'smart' cardiac defibrillators); and
- accelerate rehabilitation, enabling individuals to lead normal lives or attain a higher quality of life (e.g. ambulatory heart monitors).

**CASE STUDY: Cochlear Implant Developments, Impacts and Benefits**

Cochlear implants are a major medical break through, assisting approximately 2000 Australians who receive little or no benefit from traditional hearing aids. Independent studies show that, on average, an individual with severe to profound hearing loss is expected to cost society $US300,000 (or $AU577,000) over their life time. This includes reduced work productivity and the use of special education resources and programs.

Cochlear implantation benefits society as a whole as recipients are given a chance to achieve their potential and to contribute to the community. The benefits of the device extend beyond the medical and personal into reduced educational costs, enhanced employment opportunities, increased earnings and reduced reliance on social services.

Cochlear implants, therefore, represent an effective use of healthcare dollars.

A recent Australian study found significant quality of life improvements due to functional consequences of hearing improvements, such as increased ease of carrying out usual activities, mental and emotional well-being and improved relationships were greater than those due to amelioration of hearing disability.

The costs per quality-adjusted-life year range from:

- $5,070 - $11,110 for children
- $11,790 - $38,150 for profoundly deaf adults
- $14,140 - $41,000 for partially deaf adults

**CASE STUDY: Total Knee Arthroplasty Developments, Impacts and Benefits**

Recent developments in total knee arthroplasty have brought significant benefits to patient care and outcomes.

Where a total joint replacement is required, new devices enable a surgeon to perform a total knee replacement through an incision 80-120mm in length whereas traditional surgical techniques require an incision of 250-300mm in length.

Currently in the US where such instruments systems are used routinely average lengths of stay have fallen from 4 to 1.5 days. This provides for significant saving to the hospital. In addition, functional outcomes that are deemed important by patients are improved.

In Australia, a Gold Coast surgeon's study of approximately 150 patients during 2004, where the minimally invasive surgical technique was used and in 2003 where the surgical techniques were more invasive found the following differences in length of stay and total physiotherapist visits:

- length of hospital stay reduced by between 30% and 41%;
- the number of postoperative physiotherapy visits was reduced and there were savings in postoperative care costs;
- with the change in technique, patients are not only achieving their preoperative range of motion but also exceeding it by an average of 10 degrees; and
- patients regain independent motion much earlier with the new implant and technique.

The study clearly found that the new implant and surgical technique led to faster patient recovery and return to active daily life, and reduced hospital and rehabilitation costs.

Advances in medical technology, such as the Cochlear Implant and developments in knee arthroplasty, will continue at a pace and deliver improved clinical practice, patient outcomes and potential cost savings.

Research and development currently being undertaken by MIAA companies in key areas will have significant impacts on health outcomes and expenditures.

Immediate areas where emerging medical and diagnostic devices are likely to influence health expenditure and improved patient treatment and outcomes include:

- heart disease and stroke
- cancer
- Alzheimer's
- diabetes
- pain management
- hearing deficiency
- eye disease
- invasive surgery
- wound care

While these developments will have cost implications for healthcare budgets, it is critical that the benefits of such innovations be considered in this review.

In particular, where such innovations will have a beneficial impact on the location, number, price and net costs need to be actively considered in determining policy parameters.

The MIAA therefore submits and encourages the Committee to recognise that contrary to the popular contention, while new medical technology may cost more in some instances, it also contributes to savings in indirect healthcare costs. In fact, medical technologies can reduce the current growth rates of national healthcare expenditure through better diagnosis and treatment as well as the obvious gains in life expectancy and quality of life for everyone.

## Regulation of Medical Devices

Globally, the medical device industry is defined by regulations.

The medical device industry in Australia operates under a regulated environment provided by the *Therapeutic Goods Act 1989*, including the provisions provided by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* and the *Therapeutic Goods (Medical Devices) Relegations 2002.*

These provide the legislative basis for uniform national controls over goods used in the prevention, diagnosis, curing, or alleviation of a disease, aliment, defect or injury.

Three statutory committees have been established to provide advice on the regulation of therapeutic goods. They are the:

- Medical Devices Evaluation Committee (MDEC), which provides advice to the Federal Minister on issues relating to the safety, quality, performance and timely availability of medical devices. The Committee also provides advice on the policies, procedures and priorities that should be applied to the administration of the medical devices legislation.

- Therapeutic Goods Committee (TGC), which advises the Federal Minister on standards relating to therapeutic goods, as well as the raw materials, manufacturing processes and testing procedures used to make them.

- National Coordinating Committee on Therapeutic Goods, (NCCTG) consisting of representatives from States, Territories and the Commonwealth, which discusses many aspects of the regulation of therapeutic goods (including medical devices).

The MIAA accepts without question the need to regulate the safety of medical devices, drugs and other interventions.

Importantly, however, the MIAA draws the Committee's attention to the need to recognise the contributing role government policies affecting technology regulation, pricing, R&D, incentives, industry and trade have on healthcare and patient access to quality care and their outcomes.

This review should examine the existing legislative and regulatory regime to ensure it does not increase product development costs, patient and healthcare system costs or delay access to the latest medical device technology.

In particular, overlapping responsibilities of government bodies, delays in patient access to innovative devices and regulatory costs imposed on manufacturers can lead to direct funding implications on the Australian health system.

The MIAA has previously set out in detail a number of concerns in relation to the overlapping roles of five separate entities at a Commonwealth and State level in its earlier submission to the Productivity Commission's *Study into the Impact of Advances in medical technology on Healthcare Expenditure in Australia* (http://www.miaa.org.au/pdf/PC04.pdf).

In that submission the MIAA noted the following processes affecting the safety, efficacy and cost-effectiveness of the current regulatory regime:

- committees created in pursuit of controls over reimbursement of prostheses under Schedule 5 of the National Health Act;
- the Medical Services Advisory Committee (MSAC) and its advisory arm;
- the advisory committees of the National Health and Medical Research Committee (NH&MRC);
- the processes implemented by the Royal College of Surgeons and the State Health Ministers under Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S);
- the requirements proposed by the NSW Department of Health under its new intervention procedures in clinical practice; and
- any new regulatory requirements imposed by the proposed Trans-Tasman Agency.

Specifically, issues that arise from this regulatory and legislative regime involve:

- the need to recognise factors that distinguish prescribed drugs and medical devices and diagnostics;
- delays in assessment which add to development costs and patient access to new technology;
- overlapping responsibilities in assessment and review;
- lack of recognition of other comparable international regulatory authorities examination, assessment and approval of new technology;
- lack of clarity over priorities, assessment processes and timeframes;

- potential conflicts of interests and actions between regulatory authorities;
- impact of evidence gathering, reporting and assessment requirements; and

- layered approval processes as a result of different government health technology assessment groups.

It is clear to MIAA and its members that under the present healthcare system and structure there are significant inefficiencies and over-laps resulting in increased costs and delays in patient access to innovative medical devices and diagnostics.

Further, regulations affecting public access to breakthrough technologies should be subject to reasonableness tests. The need for effective government regulation of safety and efficacy is not in dispute. Given the global nature of the health sector and the use of medical technologies, it is essential that such government regulations not increase product development costs and the costs to consumers.

All regulations of safety and efficacy should be subject to government cost impact assessments, to ensure that regulatory hurdles already passed in nations with high standards are not repeated or extended in Australia, leading to delays in patient access to effective interventions already available in other nations. Equally, the imposition of the 100% cost recovery policies add to the cost burden of smaller medical device companies.

As noted in the case study below, the regulatory systems determine the relative speed with which drugs and devices come to market, and thus their relative impacts on treatment costs and shifts in the site of care. MIAA encourages the Committee to review differences in approval times for similar drugs and devices in different health systems and to comment on how any differences may be affecting change in the health sector.

As a starting point, to reduce costs and improve healthcare outcomes, the Parliamentary Committee is urged to investigate and recommend reforms to the existing legislative and regulatory regime to overcome these identified issues.

**CASE STUDY: Regulatory Approval Delays**

In 2002 MIAA supported the introduction of a new Australian medical device regulatory system harmonized with the European framework. Industry expected under the new system that costs would decrease and approval times would shorten due to the recognition of comparable regulatory approvals performed internationally.

Now into its third year, evidence from Australian medical device sponsors confirms that the new system is one of the most expensive in the world. MIAA believes this results from the TGA's expansive, risk-averse approach to regulation, combined with its 100% cost recovery policy.

Regulatory fees are not the only cost to industry under the new system. For importers of internationally approved high risk devices, approval delays caused by the TGA's lack of recognition of regulatory work approved elsewhere are affecting market access.

For Australian manufacturers the TGA's monopoly as the only regulatory approval body across all risk classes is proving to be slow and expensive when compared to other international regulatory agencies.

The Cochlear Nucleus Freedom System 4 serves as a good example to demonstrate these issues. It is but one example; however, it is a pointer to a wider problem. This device is manufactured in Australia and consists of an implantable component plus a speech processor which can be worn either behind the ear or as a body pack.

The following table compares international regulatory approval times for the various parts of this particular new device. The comparison clearly shows that when measured against other key regulators, approval through the TGA is both slow and expensive.

| | Australia | EU | FDA | Canada |
|---|---|---|---|---|
| Implant component | 12 months | 4 months | 8 months | 6 months |
| Speech processor (A) (ear pack) | 6 months | 4 months | Included in system submission | 6 months |
| Speech processor (B) (body pack) | Continuing after 3 months | 2 months | <1 month | Continuing after 1 month |

To include the Nucleus Freedom System 4 on the Australian Register of Therapeutic Goods, the costs were 3.6 times higher than in the EU. Cochlear estimates that the European market for this device is 10 times the size of the Australian market. Presuming the sales margins are comparable, then the market cost recovery ratio for regulatory fees is 36 times more difficult for Cochlear in Australia, compared to European fees in the EU market.

This is an indicator to a wider problem well known to industry. The slow and costly process inhibits the development of local industry and serves to deter inclusion of products in the Australian market, to the disadvantage of Australian health consumers.

## Australia's Multi-layered System of Healthcare

In addition to examining the current legislative and regulatory inefficiencies identified above, the MIAA welcomes a broader discussion and analysis of the suitability of the existing structures for the delivery and operation of the Australian healthcare system.

MIAA strongly believes that aspects of the current Federal, State and local system of healthcare funding and delivery has a significant adverse impact on patient care, administrative processes, efficiency, equity and cost-effectiveness.

As noted above, the MIAA also welcomes the recent decision of the Council of Australian Governments (COAG) to review the health system to examine how it can be improved by clarifying roles and responsibilities and by reducing duplication and gaps in services.

The MIAA will seek to be actively involved in this review process.

In general terms, the MIAA believes that many of the arguments put forward by the Australian Healthcare Reform Alliance deserve closer examination and consideration by Australian Parliaments and governments.

The Productivity Commission, in its *Review of National Policy Reforms*, put the argument for a national policy and strategy best when it noted that:

> "Where an activity is of national significance, where actions in one jurisdiction affect outcomes in others, or where policy and delivery responsibilities are shared, there will often be a value in adopting a national approach to reform." [2]

Further, in noting the variations in performance for the same service across jurisdictions, the Productivity Commission stated:

> "An integrated health services reform program within an agreed national framework would add much needed impetus to addressing structural problems of long standing that are preventing the healthcare system from performing at its potential." [3]

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[2] Productivity Commission, *Review of National Competition Policy Reforms,* Discussion Draft, Canberra, October 2004, p.261

[3] Productivity Commission, *Review of National Competition Policy Reforms,* Discussion Draft, Canberra, October 2004, p.267

Professor John Dwyer, Chair of the Australian Healthcare Reform Alliance, in his article *Federating Healthcare Would Mend Our Health System,* noted:

> "The healthcare system we need at the start of the 21st Century should be patient focussed (as opposed to provider focussed) and feature the integration of all various elements that must work together to supply our healthcare system. Improvements in quality, safety and cost effectiveness are rewards for doing so." [4]

He goes on to argue:

> "In our country it is proving to be impossible to provide such desirable and professionally achievable goals because of the wretched jurisdictional inefficiencies inherent in the fragmentation of healthcare responsibilities among our governments." [5]

He notes the unworkability of the present system whereby the Commonwealth Government is limited to providing healthcare by purchasing health from independent providers (doctors, nursing home providers, drug companies etc.) and support for the hospital system delivered by state governments.[6]

MIAA and its members concur with much of this argument. They have had ample practical experience where the current health system and structures offer inequitable access, inequitable treatment, delays in technology introduction and adoption, frequently resulting in less desirable patient outcomes.

The development of a truly national policy and strategy would ensure the rationalisation of resources, avoid unnecessary and costly duplication of service provision and administration, eliminate structural barriers to continuity of care, prevent blame shifting between jurisdictions and reduce delays in the introduction and use of new technology.

Most importantly, it would improve the efficiency and effectiveness of the delivery of healthcare to all Australians and improve patient outcomes.

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[4] Professor John Dwyer, *Federating healthcare would mend our health system,* Online Opinion, May 10, 2004, www.onlineopinion.com.au
[5] ibid.
[6] ibid.

## Data Deficiencies in Healthcare

Managing and forecasting healthcare costs can at best be imprecise even with accurate data due, in part, to changes in disease rates, technology and medical advances.

Determining the current and future healthcare expenditure in the Australian context is made more difficult due to significant data deficiencies.

These data deficiencies impede appropriate policy planning and response as well as the ability to identify different drivers of expenditure. It also prevents proper cost-effective analysis and masks the benefits of medical devices and diagnostics.

Specifically, unlike in other countries, notably the United States, there is no accurate data available in Australia to evaluate the disease-specific drivers of national healthcare expenditure.

In addition, for healthcare planning purposes it is not currently possible to examine data on the relationship between reimbursement methods and the cost of medical technology.

This lack of available data is principally due to the failure to invest in detailed national surveys and existing privacy regulations.

In particular, the MIAA draws the Parliamentary Committee's attention to existing privacy regulations that prevent any attempt to link existing data on MBS and PBS claims to data held by private health insurers.

A proper analysis of health funding seeking better planning, expenditure measurement and improved patient outcomes, requires the more accurate and timely collection and collation of such data.

The MIAA encourages the Parliamentary Committee to examine the need for and make recommendations regarding the appropriateness of conducting regular national surveys that would capture relevant information to improve Australia's healthcare planning, expenditure forecasting, cost-benefit analysis and patient outcomes.

**CASE STUDY: Obesity - How Improved Data Collection Could Benefit**

While there has been much attention in recent months on the issue of obesity in Australia, the lack of accurate data and proper surveys in this critical area is having a significant effect on the ability to measure its impact, and more importantly, manage and plan appropriate policy and medical responses.

Unlike in the United States, Australia has not undertaken risk factor surveillance which could be used to model the impact of obesity on disability for any associated disorders such as stroke, diabetes, heart disease and depression and its impact on the costs of treatment of those disorders.

US data suggest that severe obesity is associated with 60-68% higher healthcare costs than normal weight, and moderate obesity with 18-31% higher costs. The recent empirical analysis concludes that disability rates will increase by 1% per year more in the age group 50-69 than if there were no further weight gain.[7]

Such data might enable better forecasts of the future cost impacts of uncontrolled obesity and the health and economic benefits of different interventions.

A new study by Kaiser Permanente released in December 2004 observed cost reductions of US$800 per member from specific actions to reduce weight gain.

[7] R Sturm, JS Ringel and T Andreyeva." Increasing obesity rates and disability trends". *Health Affairs* 2004; 23(2): 199-205.

## The Need for Incentives

In addition to structural and regulatory reform to reduce duplication, gaps in services and inequities, there are a number of further incentives that governments should take to improve healthcare. Some of these would also support the development of Australian companies engaged in the medical device or diagnostics area.

As the MIAA has noted previously, chronic disease, ageing and disability require new strategies to fund technologies that reduce the consequences of disability.

The disease burden in Australia today is heavily weighted by the big killers (heart disease, stroke, cancer), the big disablers (musculoskeletal disorders, mental disease, diabetes), trauma due to falls and other accidents that can be prevented, and by chronic disorders that cause high, hidden losses of quality of life through pain, disability and loss of normal functioning.

Investment in medical technologies that avert or reduce disability has not had any priority in healthcare funding. Australia is facing a large increase in the economic and social burden of obesity, eye and hearing disorders, and the related costs of falls in the elderly and non-participation of the sight and hearing disabled in schools and society.

Innovative funding methods are needed to pay for breakthrough medical technologies. The next generation of medical technology is emerging daily in clinical practice, or is being developed in laboratories or in clinical trials around the world.

New medical technology may reduce the current growth rates of national healthcare expenditures if it facilitates better diagnoses and treatments not now available. More patients will be eligible for such interventions.

Any proposals to design funding methods to pay for new technologies should first identify unmet needs, provide fast-track funding for breakthrough interventions, restructure payment methods to achieve better health and functional outcomes, and indicate how higher investment in healthcare and in new technologies could produce gains in life expectancy and quality of life across all age groups and many disease conditions.

In particular, the Parliamentary Committee should examine and make recommendations to governments regarding incentives to:

- encourage R&D in medical technology;
- reform reimbursement systems to improve patterns of care and patient access to treatments;

- accelerate access to technology with demonstrable breakthrough impacts on the location, total costs, benefits and quality of care;
- reduce regulation and encourage better inter-agency coordination;
- streamline evaluation and assessment procedures;
- encourage risk reduction and preventative care strategies and programs, including public health promotion campaigns; and
- address shortages in medical specialists, including nurses and radiotherapists.

Internationally a number of countries have addressed these issues and provide a range of incentives to assist research and development, expansion of their medical devices industry and improve patient access to new technology.

**CASE STUDY: United States of America – R&D Tax Credits**

Since 1981, various forms of R&D tax credits have been in operation to provide benefits to American manufacturing companies performing R&D in the United States.

According to the Medical Device Manufacturers Association in the United States, this credit has stimulated additional spending by U.S. companies on research and development, which in turn increases the pace of innovation, raises productivity, and adds to economic and job growth.

The Association argues that a permanent tax credit for research and development empowers companies with the ability to plan for R&D expenditures far into the future. R&D is an inherently risky process. Improving the predictability of the tax structure will do much to ensure that the vibrant technological advances produced by the medical technology industry will be improved and more importantly, be retained in Australia.

A productive and efficient R&D infrastructure enables innovators to create new and better products to improve patient care. Smaller companies, in particular, rely on this tax credit to produce groundbreaking research.

The Association argues that a R&D tax cut allows companies to gain a tax advantage pertaining to expenses associated with research and development which correlates into technological innovation in products for patients.

It states research and development is and will continue to be the cornerstone of technological and scientific innovation. A tax credit would help encourage investment that leads to products that improve human healthcare and promote other technological advances.

The Medical Device Manufacturers Association in the United States argues that such a system enables a company to reduce its financial risk in costly, labor-intensive R&D investment that may or may not result in a new product or process. Since most companies have more ideas than research and development money, permanency of such arrangements provides a critically important incentive for funding the riskiest and often times most beneficial ideas. A permanent credit would allow companies to bring more products to market and increase employment.

**CASE STUDY: Germany - Industrial Investment**

The Industrial Investment Council (ICC) was established in 1997 by the Federal Government of Germany and the new eastern German states plus Berlin. Its mandate is to pinpoint investment opportunities in eastern Germany and create competitive advantages for it clients.

Its services include:

- Strategic planning;
- Market research and competitive analysis;
- Investment location selection and site visitation; and
- Project-specific financing and available government investment incentive.

The IIC's industry know-how encompasses the automotive, life sciences & chemicals, technology, services and manufacturing sectors. Its international team of advisors provide support for diverse companies at all stages of their investment processes. Interested investors can tap into the IIC's extensive network of contacts in business, public institutions and governmental finance ministries.

With a size of 19 billion euros (2001) the German market for medical devices is the third largest in the world, and by far, the largest in Europe. It is over twice as large as the second largest market in Europe - France.

Germany has historically been a centre for the development and production of cutting-edge medical devices. Companies such as Siemens, Biotronik, and Carl Zeiss Jena are at the forefront of new product development in their respective fields of activity.

According to the IIC, eastern Germany offers a vibrant medical devices industry with about 280 companies active in the treatment of various diseases, such as cancer, ophthalmological, neurological and cardio-vascular.

It also notes that that one of the factors making eastern Germany an excellent location for foreign investors is the numerous incentive programs for R&D, wage subsidies and training assistance that are available, as well as the highest investment incentives in the European Union for capital investments: cash incentives up to 50% (small and medium sized companies) or up to 35% (large companies).

**CASE STUDY: Canada – R& D Tax Incentives**

In February 2003, the Canadian Embassy in Berlin produced a report summarising the R&D tax incentives in operation in Canada and the advantages of doing research in that country.

It noted that promoting innovation is one of the most important tasks for any industrial society. Over the last 30 years, Canada has developed an extensive program of tax incentives for scientific research and development.

Both the Canadian federal government and the individual provinces allow businesses to save on R&D costs if they conduct them in Canada.

The federal R&D tax treatment now includes an immediate write-off of both current costs and R&D machinery and equipment costs, as well as a 20% tax credit. The rate of R&D tax credit increases to 35% for small companies.

It notes that these federal provisions have been generously strengthened by provincial R&D tax incentives. Eight of ten Canadian provinces offer their own incentive packages, relying mainly on tax credits. The tax credits significantly reduce the net cost of doing R&D in Canada and are designed to encourage risk-taking.

The result: The net after-tax cost of R&D expenditures ranges between 35 and 50 cents per dollar spent, depending on the type of corporation and the province where the R&D is conducted. The Canadian tax incentives are considered to be the most generous among the G-8 nations.

The Federal Government of Canada encourages R&D in Canada through the use of tax incentives. These incentives can function either as tax deductions or as tax credits. Under certain circumstances, the tax credits are refundable (paid out).

What type of R&D is eligible?

The Canada Customs and Revenue Agency (CCRA) defines eligible R&D costs as follows:

- R&D must demonstrate scientific or technological advancement. It must involve experimentation or analysis beyond standard practice and it must 'push the barriers'
- R&D must focus on areas of scientific or technological uncertainty where it is unclear whether, or how, the goals can be achieved.
- R&D must have scientific and technical content as evidenced by systematic, well-documented investigation, carried out by qualified personnel with relevant experience.

For example, the following activities may qualify for R&D benefits in Canada:

- new product development;
- development of new or improved materials;
- manufacturing process improvement;
- software development; and
- clinical trials of new drugs or medical devices.

# Medical Industry Association of Australia Inc Members

**MEMBERS**

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AGEN Biomedical
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Corin (Australia)
Craftmatic Australia
CYTYC (Australia)
Dade Behring Diagnostics
DePuy Australia
Dermal Technologies
Device Technologies Australia
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Incision Medical
Integrated Sciences
JDC-BIO
Johnson & Johnson Medical
Johnson & Johnson Pacific
KCI Medical Australia
Kimberly-Clark Australia
Life Therapeutics
Link Orthopaedics Australia
Linvatec Australia
LMT Surgical
LR Instruments
Mathys Orthopaedics
MDS Diagnostics
Med-Chem Surgical
Mede Group
Medical Specialties Australia
Medigard
Medigroup
Medipac Scientific
Medtronic Australasia
Mentor Medical Systems
Merck
Microgenics Diagnostics
Molnlycke Health Care
Mondeal Medical Systems
N Stenning & Co
Neich Medical
Occupational & Medical
Innovations
Ortho-Clinical Diagnostics
Otto Bock Healthcare
Oxoid
Pan Bio
Paul Hartmann
Point of Care Diagnostics
Portland Orthopaedics
Proteome Systems
Roche Diagnostics Australia
Rockeby BioMed
Sirtex Medical
Smith & Nephew
Smith & Nephew Surgical
Spectra-Medics
Spectrum Ophthalmics
St. Jude Medical Australia
Stryker Australia
Surgical House
Synthes Australia
Taylor Bryant
Terumo Corporation
Tornier
Tuta Healthcare
Tyco Healthcare Australia
Ulco Medical
Unitract
Unomedical
Ventana Medical Systems
Ventracor
Visiomed Group
Vital Diagnostics
W. L. Gore and Associates
Welch Allyn Australia
Zimmer Australia

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