Sector Overview and Opportunities

Australia is a significant size market for Canadian medical technology, with the advantage of a comparable regulatory framework, and a State-based system of healthcare delivery with many parallels to the provincial system across Canada. Major Australian distributors who have been interviewed by the Consulate General of Canada have expressed interest in speaking with Canadian technology companies, because of the perception that high quality research and development is undertaken in Canada, and the products would have passed stringent regulatory requirements.

A rapidly aging population, and the spectrum of chronic disease problems that mirror the healthcare challenges of Canada, provide opportunities for Canadian companies to access a relatively predictable export market to diversify their client base.

However, stiff competition from low cost producers from Asia makes it difficult for Canadian companies to compete in the low value, high volume, commodity end of the market. Instead, emerging technologies in specialised niche areas are likely to be the better proposition. Opportunities exist for molecular and invitro diagnostics, and devices for monitoring or therapeutic purposes. Strong impetus at Federal and State government levels to implement e-health solutions is also providing opportunities for software and devices used in telehealth, and the integration of a paperless, digital environment within healthcare institutions.

Value of the medical technology industry in Australia

Total revenue for the Australian medical technology industry for 2009-10 was calculated to be in the order of $7.6 billion. The value is higher if invitro diagnostic devices (IVDs) are included (~$8.4 billion), and both IVDs and dental products are included (~$9.2 billion). The Australian medical technology industry is expected to grow at a Compound Annual Growth Rate (CAGR) of 9% per annum over the next five years.

Imports and exports of medical technology in Australia

Nearly all medical technology products manufactured in Australia are exported, while the majority of medical technology products used in Australia are imported. In 2010, the value of medical technology imports was $3.3 billion and the value of medical technology exports was $1.2 billion. The comparative values for medicinals and pharmaceuticals were $9.5 and $3.9 billion respectively.

There are over 500 medical technology companies in Australia with products registered on the Australian Register of Therapeutic Goods (ARTG). This number does not include IVD companies (of which there are
approximately 60) or dental (of which there are over 50). There are 53 medical technology companies listed on the Australian Securities Exchange (ASX) with a combined market capitalisation of $2.4 billion. The majority (>75%) of companies in Australia are independent distributors or Australian affiliates of international companies.

The majority of medical technology companies are located in NSW (54%), followed by VIC (24%), QLD (11%) and WA (7%).

The medical technology industry in Australia employs approximately 17,500 people. The majority of Medical Technology Association of Australia (MTAA) member companies (77%) employ between 20-100 staff.

**Regulation of medical technology in Australia**

All medical technology products sold in Australia are regulated by the Therapeutic Goods Administration (TGA). There are over 35,000 medical devices listed on the ARTG (including IVDs and dental) (the number of individual items is likely to be far higher).

The regulation of medical devices is based on risk assessment. Devices are classified according to the risk they present to the human body. Therefore an invasive device has a higher risk to a patient than a device that is not implanted. The device classification reflects this risk. This determines the level of regulatory oversight, including the level of evidence required before the device can be approved for supply on the market.

The general classification for medical devices is as follows:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Risk Level and Regulatory Requirements</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low</td>
<td>Wheelchairs, ostomy pouches, crutches, hospital beds</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Low to Medium</td>
<td>Electrocardiographs, contact lenses, hearing aids</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Medium to High</td>
<td>Non-implantable insulin infusion pumps, long term urinary catheters, modern wound care devices designed to penetrate the dermis</td>
</tr>
<tr>
<td>Class III</td>
<td>High</td>
<td>Heart valves, aneurysm clips, cortical electrodes, medical devices containing medicines, silicone breast implants, blood bags</td>
</tr>
<tr>
<td>Active Implantable Medical Devices (AIMD)</td>
<td>High</td>
<td>Pacemakers, neurostimulators, implantable cardiac defibrillators, cochlear implants</td>
</tr>
</tbody>
</table>

To comply with TGA regulation in Australia, manufacturers of medical devices have to undertake assessments of their own manufacturing processes to assure that their products comply with a prescribed set of essential safety and performance principles. All devices are required to have varying levels of clinical evidence depending on their classification. Manufacturers of all medical devices have to undertake risk analyses to determine the residual risk when the device is used. Clinical evidence has to be developed if any residual risk cannot be eliminated so that the manufacturer can demonstrate that the benefit of using the device outweighs any residual risk. For Class I items, clinical evidence may therefore not be needed if it is possible to determine that benefit outweighs risk (e.g. the risk of rare allergic rash in the case of a Band Aid). Companies must produce detailed technical documents to prove that there is no residual risk if they claim that clinical data is
unnecessary. It is normal to expect that the level of clinical evidence required for an approval by the TGA will increase as the risk classification increases.

Manufacturers of medical devices classified higher than Class I also require independent certification that their manufacturing processes meet internationally acceptable manufacturing standards.

The level of evidence required for pre-market assessment of medical devices can be complicated. It is often not practical to use similar techniques for the development of medical devices as required of pharmaceutical companies to prove medicines are safe and effective. For example, the use of double blind randomised clinical trials is not practical or ethical for testing an implanted medical device. The safety and efficacy of a medical technology depends not only on the product itself but also on how it is used. The need to adjust for user characteristics complicates the design and analysis of clinical studies.

The only compliance certification accepted by the TGA, other than that issued by the TGA, is CE certification before an approval to supply medical devices in Australia. Even so, the TGA can and does sometimes require more evidence, especially clinical evidence, before an approval is granted. The Australian legislation prescribes what products and manufacturers are required to have TGA certification.

All medical device manufacturers and sponsors have to comply with post-market vigilance and monitoring requirements. The three major components of post-marketing activities are the manufacturer’s post-marketing surveillance system, post-marketing monitoring of market compliance by the TGA and internationally agreed vigilance programs.

The TGA also has a voluntary reporting system for people who use medical devices to report problems with those devices.

In 2010 the number of clinical trials commenced in Australia with the interventional code ‘treatment device’ was 75. Almost 400 device trials were registered in Australia between the years 1999-2011. Of these, 68% had Australia as the primary sponsor and 73% conducted research in Australia. The primary purpose of medical technology trials was treatment (91%). Australian trials of medical technology cover a wide range of conditions.

**Healthcare funding in Australia**

**Medicare**

Medicare is funded from taxation (a 1.5% of taxable income Federal Medicare Levy), and subsidises healthcare for all Australians. Medicare provides subsidies for prescribed medicines, free or subsidised treatment by practitioners such as doctors or dentists, substantial grants to State and Territory governments to contribute to the costs of providing free access to public hospitals, and specific purpose grants to State/Territory governments and other bodies.

The Commonwealth Medicare Benefits Schedule (MBS) lists a wide range of consultations, procedures and tests, and the Schedule fee applicable for each item. Proposed listings of new medical procedures and new technologies on the Schedule are assessed by the Medical Services Advisory Committee (MSAC) on the basis of evidence of safety, cost-effectiveness and benefit to patients. Although Schedule fees are used to calculate Medicare benefits entitlements, doctors can charge whatever fee they wish, provided the service is not ‘bulk-billed’ (ie billed directly to Medicare without a patient co-payment).
Pharmaceuticals

Medicines or pharmaceuticals prescribed by doctors and dispensed in the community by independent private sector pharmacies are directly subsidised by the Commonwealth Pharmaceutical Benefits Scheme (PBS). The PBS provides subsidies for about 800 different pharmaceuticals. Additional drugs are added when assessed as meeting safety, quality, effectiveness and cost-effectiveness criteria. Around 75% of all prescriptions dispensed in Australia are subsidised under the PBS. The other major source of subsidised medicines is public hospitals which provide medicines to inpatients free of charge and do not attract subsidies.

Private Health Insurance

The Commonwealth regulates insurance offered by registered health insurance organisations to ensure that the principle of community rating is maintained. This means that health funds must charge everyone the same premium regardless of the health status or claims history of the individual. Patients with private health insurance may choose to be private patients in a public hospital, in which case private health insurance will cover all or nearly all of the charges. Private insurance benefits can also contribute to payment of the costs of allied health/paramedical and other costs (for example, surgically implanted prostheses) incurred as part of the hospital stay.

The Commonwealth Government has introduced measures designed to encourage people to take up private health insurance and decrease the pressure on the public system. One measure was the introduction of a 30% rebate on private health insurance in January 1999. Another initiative is Lifetime Health Cover, which is designed to encourage people to take out hospital cover early in life and maintain their cover. People who join a health fund before they turn 31 years of age and who stay covered pay a lower premium throughout their lives relative to people who delay joining. Patients with private health insurance are able to receive reimbursement for implantable devices from the Prostheses List (see below for further information on the Prosthesis List).

Consumable medical technology

Medical consumables are provided to patients in the community through a variety of Commonwealth and State and Territory schemes as outlined below. In some cases there may be inequity of access depending on where the patient lives.

Federal schemes are [5]:

Repatriation Pharmaceutical Benefits Scheme (RPBS): Administered by the Department of Veterans’ Affairs (DVA). Provides access to certain medications and dressings for treatment of entitled veterans and war widows. The range of items is more comprehensive than is available through the PBS and includes assistive devices.

Rehabilitation Appliances Program (RAP): Administered by the DVA. Provides aids and appliances to eligible members of the veteran community to help them maintain their independence. A range of appliances are provided through six product groups (continence, mobility function and support, oxygen, diabetes, personal response systems, Continuous Positive Airway Pressure (CPAP)).

National Diabetes Services Scheme (NDSS): Administered by Diabetes Australia and delivers diabetes-related products at subsidised prices, information and support services to approximately 910,000 people with diabetes each year.
Stoma Appliance Scheme (SAS): Provides stoma related products (medicines and appliances) to individuals who have undergone either a temporary or permanent surgically created body opening (stoma). Approximately 30,000 people receive products under the scheme.

Continence Aids Payments Scheme (CAPS): The CAPS assists individuals with permanent and severe incontinence to meet some of the costs of continence products.

Epidermolysis Bullosa Dressing Scheme: The only Federal scheme for modern wound care devices assists patients with Epidermolysis Bullosa. Up to 200 patients will be assisted.

**State / Territory Schemes are:**

**ACT:**
- ACT Equipment Scheme
- Domiciliary Oxygen Scheme
- Continuous Positive Airway/Variable Positive Airway Pressure (CPAP/VPAP) Scheme
- ACT Spectacles Subsidy Scheme
- Breast Prosthesis Scheme

**NSW:**
- Program of Appliances for Disabled People (PADP)
- Aids for People in DAHDC Accommodation Services

**NT:**
- Territory Independence Mobility Equipment (TIME) Scheme

**QLD:**
- Medical Aids Subsidy Scheme (MASS)

**SA:**
- Independent Living Equipment Programme (ILEP)
- Disability SA Equipment Program

**TAS:**
- State wide Community Equipment Scheme
- State wide Continence Aids Scheme
- Spectacles and Intra-Ocular Assistance Scheme
- Home Oxygen Scheme
- Spinal Account

**VIC:**
- Victorian Aids and Equipment (A&EP) Scheme
WA:

- Community Aids and Equipment Program (CAEP)

**Implantable devices**

Hospitals: In public hospitals medical devices are purchased under state, regional or hospital arrangements and are provided free of charge for patient use. Access to surgical procedures may be constrained by budgets. In private hospitals medical devices are purchased by private hospital/hospital groups with categories of devices reimbursed by means of contractual arrangements with health funds, e.g. procedure banding or the Prostheses List.

National Procedure Banding Schedule: The schedule covers theatre fees and consumables used in operating theatres according to the complexity of the procedure.

**Prostheses List**

Under the Private Health Insurance Act 2007, private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service. Items on the Prostheses List include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue. The list does not include prosthetics, external breast prostheses, wigs and other such devices. The Prostheses List lists the benchmark benefit to be paid by the private health insurers for each group of products.

The Prostheses List contains over 9,500 prostheses and is in three parts: Part A – Prostheses; Part B – Human Tissue (includes products that are substantially derived from human tissue); and Part C – Non-implantedDevices.

Products meeting all of the following criteria are eligible for consideration for inclusion on the Prostheses List:

1. The product must be included on the Australian Register of Therapeutic Goods; and
2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment; and
3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist); and
4. The product should:
   - be surgically implanted in the patient and be purposely designed in order to:
     - replace an anatomical body part; or
     - combat a pathological process; or
     - modulate a physiological process; or
   - be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted; or
   - be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and
5. The product has been compared to alternate products on the Prostheses List or alternate treatments and:
   o assessed as being, at least, of similar clinical effectiveness; and
   o the cost of the product is relative to its clinical effectiveness.

The Prostheses List is an important source of access to medical technologies. For example, 75% of insulin pumps are purchased by health funds which cover the cost of pumps for people with Type 1 diabetes. Over 90% of gastric reduction and gastric bypass procedures for obesity are performed in private hospitals and patients without private health insurance are often unable to access bariatric surgery.

Joint replacement procedures can be performed in public or private hospitals. The National Joint Replacement Registry (NJRR) reported 82,823 joint replacements in 2010. The majority were for knees (53%) and hips (42%). Since 2001, the number of knee and hip replacements has increased by 67% and 40% respectively.

In 2010 benefits were paid for 1.6 million prostheses by registered health insurers, at a total value of $1.3 billion. These data (for private patients in both public and private hospitals) are shown below.

<table>
<thead>
<tr>
<th>Prostheses Category</th>
<th>Number of gap and no gap permitted prostheses</th>
<th>Sum of no gap and gap permitted benefits paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Stents</td>
<td>18,357</td>
<td>$54,023,733</td>
</tr>
<tr>
<td>Cardiac Defibrillators</td>
<td>3,041</td>
<td>$95,477,487</td>
</tr>
<tr>
<td>Cardiac Pacemakers</td>
<td>14,711</td>
<td>$69,379,537</td>
</tr>
<tr>
<td>Hips</td>
<td>71,549</td>
<td>$182,502,920</td>
</tr>
<tr>
<td>Knees</td>
<td>88,458</td>
<td>$195,676,370</td>
</tr>
<tr>
<td>Lenses</td>
<td>66,159</td>
<td>$29,312,737</td>
</tr>
<tr>
<td>Other</td>
<td>1,422,456</td>
<td>$701,494,869</td>
</tr>
<tr>
<td>Total</td>
<td>1,684,731</td>
<td>$1,327,867,652</td>
</tr>
</tbody>
</table>

General health trends in Australia

The average life expectancy in Australia is 79 years for males and 84 years for females. The projected leading specific causes of burden of disease and injury are coronary heart disease, anxiety and depression, Type 2 diabetes, dementia, stroke, lung cancer, chronic obstructive pulmonary disease (COPD), adult-onset hearing loss, colorectal cancer and asthma [6].

Australia has 1,317 hospitals (57% public, 43% private). There are 4.9 million admissions to public hospitals and 3.3 million admissions to private hospitals each year. Additionally, there are over 51,000 public admissions for hospital-in-the-home care (1% of public hospital admissions) annually. Just over half of all Australians (52%) are covered by general treatment private health insurance [7].

Healthcare expenditure in Australia

In 2008-09 health expenditure in Australia was $112.8 billion [8]. Governments directly fund almost 70% of healthcare. The Commonwealth funds 43% of healthcare (16% of which is raised by the Medicare Levy). State
governments contribute an additional 26% and individual payments make up about 17% \[^9\]. More than two thirds of all health expenditure is associated with chronic disease management (approximately $75 billion).

Salaries for medical and nursing staff represent 52% of admitted patient costs. Other costs are made up of medical and drug supplies, diagnostic and allied health services and administration costs. Medical supplies make up 9% of costs \[^10\]. Medical technologies comprise approximately 5% of expenditure (similarly in the US, expenditure on medical technology makes up 5% of total health care costs, in the EU the percentage is slightly higher at 6%).

Consequently reduction in expenditure on medical technology offers only limited potential to contain total expenditure \[^11\].

The cost of prostheses represents only a small part of a hospital’s total budget (around 3% in a public hospital) \[^12\].

In 2008-09, expenditure on aids and appliances was $3.3 billion. Of this, 71.5% was funded by individuals’ out-of-pocket expenditure \[^13\].

### Changing the Australian healthcare system

A number of changes are set to occur over the next five years that will change the way that healthcare is delivered in Australia. There is a shift towards the provision of medical services in the home – many medical technologies have remote monitoring capabilities and can be used in the home. Up to $620 million will be invested from July 2011 to 2015 to provide Medicare rebates for online video consultations (telehealth) across a range of specialties. An eight year investment of $43 billion will fund the rollout and operations of the National Broadband Network (NBN). The availability of high speed affordable internet will provide a number of indirect benefits to the healthcare system (e.g. enabling rapid delivery of test results and medical data). Additionally, over $466 million will be invested over the next two years in the first release of a personally controlled electronic health record.

### Challenges facing the Australian healthcare system

- The number of people aged 65-84 years will double and the number of people aged over 85 will quadruple by 2050 \[^14\].
- The number of aged care places will need to double by 2030 in order to meet demand.
- Current spending on aged care will double by 2049-50 \[^15\].
- There is a shortage of informal care-givers, nurses and doctors \[^16\].
- Rapid growth in chronic diseases is expected in the areas of diabetes, mental illness, cardiovascular disease, cancer and joint disorders.
- Type 2 diabetes is expected to become the leading cause of disease burden and it is estimated that by 2030 approximately 75% of Australians will be overweight or obese \[^17\].
- The annual loss of workforce participation from chronic disease in Australia is around 537,000 person-years of participation in employment and approximately 47,000 person years of part-time employment \[^18\].
- Approximately 12% (n=864,000 in 2008-09) of patients who present at an emergency room are non-urgent, usually with minor illnesses or stable chronic conditions and minor complicating symptoms.
- 9.3% of potentially preventable hospitalisations are due to chronic ailments, which could be prevented or managed through effective, timely care (usually non-hospital).
- Over 30% of Australia’s total burden of death, disability and disease can be accounted for by risk factors (e.g. smoking, obesity) \[^19\].


**References**

This market profile draws primarily from the content of Medical Technology Association of Australia Key Facts and Figures 2011 which is available from [www.mtaa.org.au](http://www.mtaa.org.au).

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**Foreign Affairs and International Trade  Canada**  
125 Sussex Dr.  
Ottawa, ON K1A 0G2  
Website: [www.tradecommissioner.gc.ca](http://www.tradecommissioner.gc.ca)

**Australian Medical Technology Industry Associations**

- Medical Technology Association of Australia
- IVD Australia

**Australian Medical Technology Distributors**

- Abacus Als PTY LTD
- Diagnostic Solutions PTY LTD
- Diagnostic Technology PTY LTD
- Device Technologies Australia PTY LTD
- Ebos Healthcare
- Fairmont Medical
- Immuno PTY LTD
- Life Bioscience PTY LTD
- Life Healthcare
- LMA Pacmed PTY LTD
- Mayo Healthcare PTY LTD
- Mosaic Medical (Asia Pacific) PTY LTD
- VWR International PTY LTD

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[1] The Government of Canada has prepared this report based on primary and secondary sources of information. Readers should take note that the Government of Canada does not guarantee the accuracy of any of the information contained in this report, nor does it necessarily endorse the organizations listed herein. Readers should independently verify the accuracy and reliability of the information.

[2] All monetary amounts are expressed in Australian dollars, unless otherwise indicated.


