Australia: Analytical and Clinical Chemistry

Monique Roos
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Summary

With a population totaling approximately 20 million people, Australia has a high per capita income and standard of medical practice. Together with the expectation of state-of-the-art medical treatment by an educated population, there is demand for a full range of sophisticated and innovative medical products.

Pathology testing plays a critical role in the diagnosis and monitoring of illness and medical treatments in Australia. It accounts for approximately US$1.2 billion of the Australian annual healthcare budget. While the ageing of the population is having a significant impact on the number and type of health care services delivered, there has been a significant increase in pathology test ordering rates by GPs. It is expected that with the increasing emphasis on prevention and management of chronic disease, there will continue to be an increase in pathology ordering by GPs.

Market Demand

Australia has a government-funded healthcare system. National expenditure on health is 9.8 percent of GDP. In 2004-05, the government funded approximately 70 percent of the US$69 billion spent on total health expenditure. Australia's expenditure on healthcare to GDP ratio is comparable to Canada, Austria and Norway. Australians generally enjoy good health and have a range of health care services available to them. The life expectancy of Australians places the country among the top five nations in the world.

The pathology services industry provides a range of testing and analysis services for the medical professions, public and private hospitals and other healthcare organizations. The major services that this industry provides include biochemistry, anatomical pathology, hematology, microbiology, immunology and cytopathology. The major customer base comprises doctors and hospitals. Other customers include community health centers, dental practices and veterinary clinics.

During the past five years, the largest change in management activity by GPs has been in the ordering of pathology tests. GPs are now more likely to order pathology during patient encounters. Although there has been a significant increase in the number of pathology tests ordered by GPs, there has been a relatively small increase in the proportion of problems for which pathology is ordered. There has been a move away from ordering a single test per problem to ordering an average of two per problem tested. The major increase has been in orders for chemical pathology and hematology. The increases are reflected in pathology ordered for diagnostic and preventive care and to a lesser extent in monitoring pathology.

According to the Australian Institute of Health and Welfare, in 2005-06, the proportion of encounters generating pathology test orders increased between 1999-00 and 2005-06 from 14 percent to 16 percent of encounters, and the total number of pathology tests ordered increased by almost 25 percent in 2005-6 compared to 2001-02.

The most common pathology tests ordered are chemistry (56.4 percent of all pathology tests), hematology (19 percent) and microbiology (14.4 percent). There are many factors that have contributed to the increase in pathology test ordering rates by GPs. These include an increase in management rates of chronic diseases such as diabetes and increases in the number of people taking medications (for example lipid lowering agents). Other factors that may have been influential include a greater availability of tests, increased patient expectations, more knowledgeable patients, and the fear of litigation by medical practitioners.

Market Data

The Australian health system is complex with many types of service providers and a variety of funding mechanisms. Almost 70 percent of the US$69 billion spent on total health expenditure is funded by the Australian government (federal, state, territory and local governments). One of the Australian Government's major national subsidy schemes is the Medicare Benefits Schedule that pays for medical services including those performed by pathologists.

Pathology testing plays a critical role in the diagnosis and monitoring of illness and medical treatments. The Australian government funds over 92 percent (or US$1 billion dollars a year) to support pathology services under the Medicare Benefits Schedule.

There are 450 pathology laboratories in Australia employing 11,300 people. The industry has a total turnover of approximately US$1.2 billion. Private pathology operators conduct most pathology testing. The structure of the industry is moving from a large number of "small player" partnership-based professional practices to a few larger corporate pathology services firms.

In 2005-06, the ten problems for which pathology was most frequently ordered were:

Diabetes
Hypertension
Lipid disorders
General check-up
Female genital check-up
Weakness/tiredness general
Urinary tract infection
Blood test not otherwise specified
Pregnancy
Microbiology/immunology not otherwise specified

Best Prospects

Drivers for growth for particular tests include the health and demographics of the population. Similar to the U.S., Australia is experiencing an ageing population. Growth in the demand for pathology services is expected to continue as the "baby boomer" generation ages, particularly as its members move into their seventies. The elderly are large users of pathology and most of their conditions can only be diagnosed through blood tests. As the range of diagnostic services available increases, so does the demand for these services.

The leading causes of death include cardiovascular disease and cancer. The Australian Government has identified seven national health priority areas that pose a significant burden of disease:

Asthma
Cancer control (lung, colorectal, melanoma, prostate, breast, cervical, and non-Hodgkin's lymphoma)
Cardiovascular health
Diabetes
Injury prevention and control
Mental health
Arthritis and musculoskeletal conditions

The more common problems managed in general practice for which pathology is frequently ordered and that have seen a significant increase includes: cardiac check-up, hypertension, menopausal problems, diabetes, and ischaemic heart disease.

The industry is continually increasing its use of advanced technologies to speed up delivery of service to its customers and to produce cost efficiencies. Growth markets, which are not funded by the government through Medicare, include occupational tests, sports drug tests and clinical trial tests.

Key Suppliers

As the market for clinical laboratory and diagnostic instruments is mature and highly competitive, innovative products, pricing and quality are key factors for success. In 2003, in preparing to develop a new regulatory framework for in vitro diagnostics (IVDs), the Australian Government commissioned a study into the IVD industry. Results of the study revealed that more than 95 percent of IVDs were imported and less than 5 percent were locally manufactured. In addition, suppliers of IVDs reported that less than 5 percent of their IVD sales came from home use IVD products. Most importers reported their source of IVDs to be either the U.S. or the European Union.

Prospective Buyers

There is a trend towards corporatization in the pathology industry. The Australian pathology industry has undergone significant structural change over the past twenty years and is now dominated by a small number of large corporate providers. In addition to consolidation, there is a continuing trend towards vertical integration of pathology providers with private hospital providers. It is estimated that the four largest pathology companies account for at least 83 percent of industry revenues. These large companies tend to run central laboratories and have a network of collection centers.

The major customer-base of pathology practices is comprised of referring doctors (70%) and hospitals (20%). Many Australian doctors and scientists have spent some time studying in the U.S. and are therefore already familiar with U.S. products. Some hospitals have entered into agreements with private providers for the provision of pathology services.

In the study into the IVD industry commissioned by the Australian Government, the majority of pathology laboratories (both private and public laboratories) reported that more than 95 percent of their annual turnover was related to IVD testing or related activities. It is expected that with the increasing emphasis on management of chronic disease and prevention, there will be a continuing increase for pathology tests.

Market Entry

The Australian Therapeutic Goods Administration (TGA) regulates medical devices. In January 2002, the TGA initiated the development of a new regulatory framework for IVDs that is harmonized with international best practice and adopts the Essential Principles developed by the Global Harmonization Task Force (GHTF).

The IVD framework will complement the new regulatory system for medical devices that was introduced on October 4, 2002. IVDs will be regulated as a subset of medical devices and will include all commercial and "in-house" IVDs. All IVDs will need to conform to Essential Principles for quality, safety and performance. IVDs are classified into four classes, based on risk, with levels of regulatory oversight commensurate with the risk posed.

The Australian system uses elements of the European system, however, differs in the classification system, and is similar to the Canadian framework. The Mutual Recognition Agreement with the European Union that is currently in place will include IVDs once the legislative framework is implemented. A Memorandum of Understanding with Canada on quality systems is currently in development and will eventually include IVDs.

All IVDs will have to be entered onto the Australian Register of Therapeutic Goods (ARTG) as a basis for approval to supply in Australia. Applications to be entered onto the ARTG must be lodged by an Australian-based Sponsor that accepts responsibility for the goods in Australia.

Further information on Australia's regulatory system for IVDs can be can be obtained from:
http://www.tga.gov.au/devices/ivd-overview.htm

Under the U.S. - Australia Free Trade Agreement, which went into force on January 1, 2005, medical devices will continue to attract no import duty.

Market Issues & Obstacles

Pathology services in Australia operate in a capped funding and highly regulated market. Pathology services are reimbursed by the Australian Department of Health and Ageing according to the Medicare Benefits Schedule and are a significant contributor to healthcare costs. As approximately 92 percent of pathology tests conducted in Australia are reimbursed directly by the Australian government under Medicare, the government tries to limit the excessive use of pathology services for which a Medicare benefit may become payable and which is not reasonably necessary for the adequate medical care of the patient.

Consequently, the Australian Government has entered into agreements with the Australian Association of Pathology Practices and the Royal College of Pathologists of Australasia to cap pathology expenditure under Medicare benefits arrangements. The Australian government limits the growth of the government's expenditure on pathology services to five percent per annum. Under Medicare, through the use of "Item Test Coning", regardless of how many different tests a doctor may request for a patient, only the three most expensive tests will be eligible for Medicare reimbursement. Medicare benefits are not payable in respect of a pathology service unless the service was rendered by or on behalf of an Approved Pathology Practitioner, was rendered in an Accredited Pathology Laboratory, and the proprietor of the laboratory is an Approved Pathology Authority.

According to the Australian Association of Pathology Practices, while this has been a difficult process for providers, the pathology profession has agreed to the capped funding of Medicare pathology services which have delivered the following benefits:

- continued fee-for-service for this medical service
- certainty in outlays to the government
- agreed annual growth rates
- industry stability during a period of unprecedented consolidation and corporatization.
- professional survival for pathologists and scientists
- improved efficiencies in delivery of services

However, capped funding has produced some difficulties, including:

- reduced margins in pathology practices
- a potential adverse effect on quality by requiring more for the same amount of money
- dampened entrepreneurship by limiting the return on investment
- potential to constrain growth and risk long-term sustainability

Trade Events

Many Australian suppliers and distributors of clinical laboratory and diagnostic products attend the annual American Association for Clinical Chemistry (AACC) and the American Society for Microbiology conferences in the U.S., as well as Medica in Germany.

Resources & Key Contacts

Australian Commonwealth Government Department of Health and Aged Care
GPO Box 9848
Canberra City ACT 2606
Tel: +61 2 6289 1555
Fax: +61 2 6281 6946
Website: www.health.gov.au

Therapeutic Goods Administration (TGA)
Narrabundah Lane
Symonston ACT 2609
Tel: +61 2 6232 8444
Fax: +61 2 6232 8241
Email: tga-information-officer@health.gov.au
Website: www.tga.gov.au

For More Information

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