

Executive Summary

Global growth in pharmaceutical and complementary medicines is underpinned by an ageing population with an increasing standard of living and greater expectations of health care in terms of quality and value for money. A study of the Queensland pharmaceuticals industry revealed data that suggests the state has the potential to capture a number of niche growth opportunities in areas including preclinical and clinical trials, generic medicines, complementary medicines and product/compound manufacturing. With targeted strategic investment in soft (e.g. human capital, capabilities, skills, industry networks) and hard infrastructure the state's pharmaceutical industry could expand over the coming years in line with global growth trends. Expansion opportunities are underpinned by:

- significant Queensland government investment since 1998 in biotechnology, health and medical research and development (R&D) and recent commonwealth government funding programs; and
- the growth and development of organisations and networks of organisations in a number of niche areas where a critical mass of skills, resources and infrastructure is emerging or established

For the purposes of this study the pharmaceutical industry was broadly defined to include the sub-sectors of prescription and non-prescription medicines and complementary medicines. Reference was also made to veterinary medicines and medical devices in the surveys and workshops. A generic value chain (based on a drug discovery model) was described with three major elements including scientific R&D; product/compound development and production and marketing/sales. Since the State's scientific R&D sector has been profiled in several other studies it was not a focus of this exercise. It was beyond the scope of the study to examine the wholesale and retail sectors of the industry.

Economic Profile

A major component of the study was the development of an 'economic profile' of the Queensland pharmaceutical industry. There was a high level of difficulty in obtaining discrete, consistent or complete data sets on pharmaceutical and related industries. The profiling exercise did reveal that:

- the pharmaceutical industry contributed \$8.2 bn of Australia's \$756 bn GDP in 2002/03 and the industry is expected to show a higher GDP growth rate than that for Australia as a whole (3.7%);
- the USA, UK and New Zealand are key export destinations for Australia's pharmaceutical manufacturing industry. Australia is a net importer of manufactured pharmaceutical goods (\$8.5 bn vs. exports of \$3.5 bn in 2003). The major foreign providers are the USA, the UK and Germany;
- the Queensland pharmaceutical industry employed over 19,000 people in 2001 (16% of the national industry total). This accounted for approximately 1.1% of Queensland's total employment. The retail sector dominates employment with almost 50% employed in pharmacies; and
- an analysis of the 2003 TGA database showed Queensland in "third place" in the country. A relatively high number of sponsors and manufacturers of complementary medicines was evident.

Global Trends

Global trends that are likely to have a significant impact on the Queensland industry include:

- double digit growth in the complementary and alternative medicines sector;
- growth in the production and consumption of generic pharmaceuticals;
- growth and global consolidation in biopharmaceutical drug development;
- the concept of personalised medicine (or pharmacogenomics);
- a switch to over-the-counter status for many medicines;
- outsourcing of key functions and activities by large pharma; and
- continuing developments in information management.

What did industry say?

A selection of 40 TGA registered companies and seven industry associations with operations in Queensland were surveyed as part of the study. Workshops and interviews were also conducted with industry and government participants to discuss particular issues including skills and training, industry features and opportunities and gaps in the Queensland industry. A number of commonly cited barriers to industry or company growth emerged:

1. Human resources: challenges in attracting and retaining appropriately qualified scientists and engineers with particular skills in regulatory compliance, applied analytical chemistry, Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP).
2. Regulatory compliance: tighter regulatory requirements were cited as creating challenges particularly for those in the area of complementary medicines. Overall, the changes were seen as positive for the industry in the long term.
3. Availability of contract manufacturing: with limited GLP or GMP compliant facilities in the state manufacturing activities in areas such as scale-up manufacturing of biopharmaceuticals or small molecules was either shifted off-shore or not undertaken due to the high cost of 'importing' such services from overseas providers.
4. Availability of contract research services: many companies outsourced R&D and preclinical and clinical trial work but could not source complete and high quality contract service providers locally.
5. Access to overseas markets: companies were interested in exporting and partnering with international companies but the capability or capacity to do so was limited in some cases.
6. Access to capital: one of the most commonly cited barriers to growth. To a large extent, failure to access capital is a function of the quality of a company's management, the product and the opportunity in question and therefore beyond the scope of any industry based initiatives.

Specific findings

1. The growth in sales of generic medicines and Queensland's existing strength in pharmaceutical manufacturing facilities could see the state build on this capacity and secure a position as a regional centre for generics manufacture. Without commenting on regulatory requirements, there is an opportunity to become a low cost/high quality global source for drug production, with a shorter term focus on winning market share in the generics sector.
2. Queensland has a clear leadership in complementary medicines in Australia and consideration should be given to exploring local sources of natural ingredient supply, as well as advancing the IP, clinical trialling and manufacture of such products.
3. An investment has been made by the Queensland government to develop a Clinical Trials Network. In order to capitalise on this investment Queensland industry should ensure that associated value-added services (e.g. contract research services for the development of lead candidates, mechanisms for efficient patient recruitment) are available for international drug development companies.
4. A 'networked pharma' model for Queensland would align the industry with the global trend towards outsourcing of R&D activities across multiple specialist organisations. The critical mass created by a formal network or cluster may assist in attracting drug development investment from large pharmaceutical firms. Increased partnering and collaboration between small companies would assist the state in building critical mass in specific industry segments.
5. Queensland industry participants should proactively seek international partnerships with a view to accessing the Commonwealth Government's P3 scheme.
6. Industry and the tertiary/vocational education sectors should collaborate to establish formal programs to improve skills development and transfer and graduate readiness over the long term.
7. As a general statement, Queensland does not have commercial contract research organisations or applied research laboratories of a sufficient size and capability to service local needs or build export markets in specific service areas. In particular a value chain gap exists in the general area of 'compound development', through contract research organisations. This is a critical precursor to scale-up manufacturing and preclinical and clinical trials.
8. Queensland and Australia have a limited capability to undertake GLP/GMP compliant scale up manufacturing of Active Pharmaceutical Ingredients (APIs).

The findings of this study (including industry feedback) illustrated that Queensland is well positioned to expand and further develop its pharmaceutical industry. This, in part, will be stimulated by Queensland's and Australia's cost competitiveness and attractiveness for in-bound investment. A range of industry opportunities are identified in this profile with key strengths including expansion in clinical trials, contract manufacturing, generic and complementary medicines. There is a range of intermediate goods and services and value adding opportunities along the value chain with Queensland's future role likely to be stronger in some of these areas than others.

All these forces for change present an opportunity for Queensland to be an important player in the global pharmaceuticals industry in its areas of relative strength and expertise. The realisation of these opportunities will require competition and also collaboration so that groups of players at different stages of the value chain can engage in ways that develop the necessary critical mass for the State.

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Preamble

The pharmaceutical industry is knowledge and skills intensive, rapidly growing and globalised¹. US based multinationals currently dominate the global industry although recent trends have seen certain high value functions such as new pharmaceutical drug development and clinical trials outsourced. This trend presents opportunities for niche players with appropriate capabilities to gain a greater share of the global pharmaceuticals market².

In recognition of opportunities such as these, various levels of government in Australia have committed to growing the pharmaceuticals sector and ensuring the country is well placed to create or take advantage of global opportunities. The Pharmaceuticals Industry Action Agenda (2002) was initiated to identify and leverage Australia's competitive strengths to grow the pharmaceutical industry. The action plan has aims to

“establish Australia as a global pharmaceutical hub, create a globally competitive operating environment, strengthen Australia's ability to commercialise research and project a positive culture, image and profile for growth”

Queensland has the potential to share in niche opportunities created in the sector by building on current strengths including competitive cost structure, stable local market conditions and skilled labour. The Queensland Government, through the Pharmaceuticals and Nutraceuticals Sectoral Development Unit (PNSDU) of the Department of State Development and Innovation (DSDI), has developed the Queensland Pharmaceuticals Action Plan. One of the key elements of this plan is to map and profile the pharmaceutical, complementary medicines and veterinary products value chains, particularly focusing on the elements where Queensland can build and sustain competitive strengths.

In line with phase one of the Queensland Action Plan, PricewaterhouseCoopers (PwC) was contracted to report on the scale and economic impact of the pharmaceutical sector in Queensland. The study aimed to:

- map and identify the components of the pharmaceutical value chain
- provide an economic profile of the industry in Queensland
- identify local and global trends within the industry
- conduct a SWOT analysis of the Queensland industry
- identify and evaluate barriers to or opportunities for expansion of the industry

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¹ Commonwealth of Australia (2002) Pharmaceuticals Industry Action Agenda

² IBIS World (2004). C2543 Medicinal and Pharmaceutical Product Manufacturing in Australia; April 21

Methodology

This profile of the Queensland Pharmaceutical industry was developed through the analysis of data collected from literature reviews, various industry reports, industry and internal workshops, industry surveys, the Australian Bureau of Statistics, the Queensland Office of Economic and Statistical Research and other secondary sources.

The following steps were taken in this study:

1. Definition of Pharmaceutical Value Chain

A definition was offered of a generic value chain (i.e. a chain generally applicable to prescription and non-prescription medicines, complementary medicines, veterinary medicines and medical devices). An attempt was made to identify the key market segments (based largely on the Therapeutics Goods Administration (TGA) terminology) represented in the Australian pharmaceutical sector.

2. Development of a profile of the value chain through primary and secondary research.

Secondary research included

- a limited review of the literature to identify global trends, regulatory issues, skills and training requirements, local initiatives and other relevant information.
- an economic analysis of the pharmaceutical industry using secondary data. The economic analysis examined contribution to the economy, trade, number of establishments, revenue and employment within, where possible, both the Australian and Queensland sectors.

Primary research included

- a survey of 40 TGA registered industry participants
- a survey of 7 relevant industry associations
- a half-day workshop on skills and training involving around 40 participants
- a half-day workshop on a SWOT analysis
- a half-day workshop on opportunities in the sector involving around 20 participants

3. Analysis of results to draw out a range of identified opportunities to expand the industry in Queensland

Survey Methodology

The forty participants in the survey of TGA registered companies was drawn from a list of 100 companies provided to PwC by the Department of State Development and Innovation (DSDI). Participants were not randomly selected and the survey was not intended to offer statistically significant data. Given the limited intended scope of the survey, participants were selected to ensure that a relevant cross section of organisations was canvassed. This included small, medium and large firms within each of the principal market segments within the industry, i.e. complementary and alternative medicines (CAM), veterinary products, generic and patented pharmaceuticals and medical devices). About 60 organisations were unwilling or unable to participate in the survey. The survey comprised both qualitative and quantitative questions addressing a number of topics including:

- economic analysis and business performance;
- current or anticipated skills requirements;
- research and development (R&D) plans and expenditure;
- view on impact of regulatory environment; and
- growth or development plans.

Representatives from seven pharmaceutical industry associations completed a separate and different survey. This survey included questions relating to:

- opportunities for the Queensland pharmaceutical industry;
- where Government could assist in expanding the industry; and
- challenges for the industry over the next five years.

Background to the Queensland Pharmaceutical Sector

In this section is presented a description of, or general background information on elements of the value chain, industry segments and relevant initiatives or developments within the local industry. It is provided as contextual information only and is not intended to be an exhaustive description.

The Australian Pharmaceutical Industry Structure

In 2002 the Federal Government released the Pharmaceuticals Industry Action Agenda³. In this document key goals aimed at doubling Australia's share of the global pharmaceutical industry by 2012 were presented. Actions developed in this agenda are expected to:

- Increase investment in Australia to capture innovation and knowledge
- Create a global hub for research, development and commercialisation
- Develop Australia as a key global exporter of goods and services

Several of the suggested elements of the 16 point plan have been initiated or implemented (see First Year Implementation Report⁴ at <http://www.industry.gov.au>; January 2004). For example:

- Education and skills issues – an industry led council established
- Preclinical and scale up capability study and workshops conducted
- Benchmarking study across value chain
- Taskforces – industry development; investment attraction; collaboration

Given the high level of activity at the Federal level it would be prudent for Queensland industry participants to keep abreast of developments at the Federal level and contribute where relevant.

The Australian pharmaceuticals industry consists of manufacturers, research institutions, biomedical research and development firms and associated service sectors. A generic value chain for the industry is presented in Figure 1. The chain has three major elements and 15 general activities. The end product output from the industry can be segmented based on the product classification systems used by the TGA (see Figure 2).

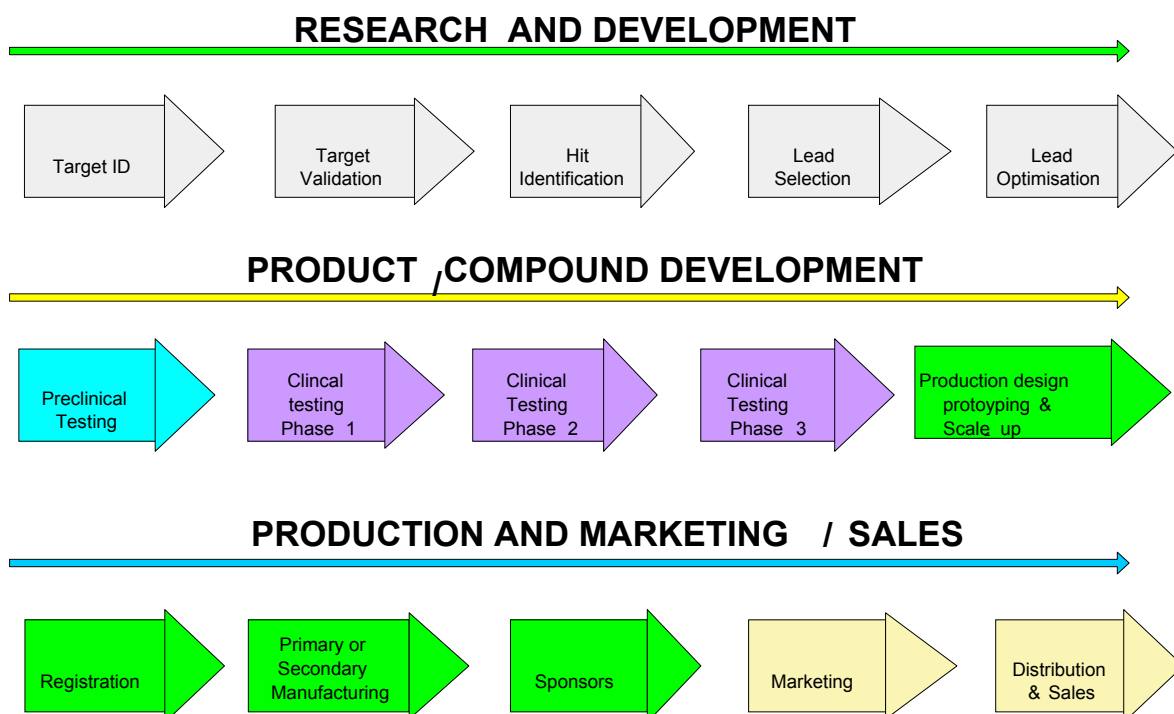


Figure 1 A generic value chain for the pharmaceutical industry

³ Commonwealth of Australia (2002) Pharmaceuticals Industry Action Agenda: Canberra

⁴ see First Year Implementation Report at <http://www.industry.gov.au> January 2004; accessed 6 September 2004

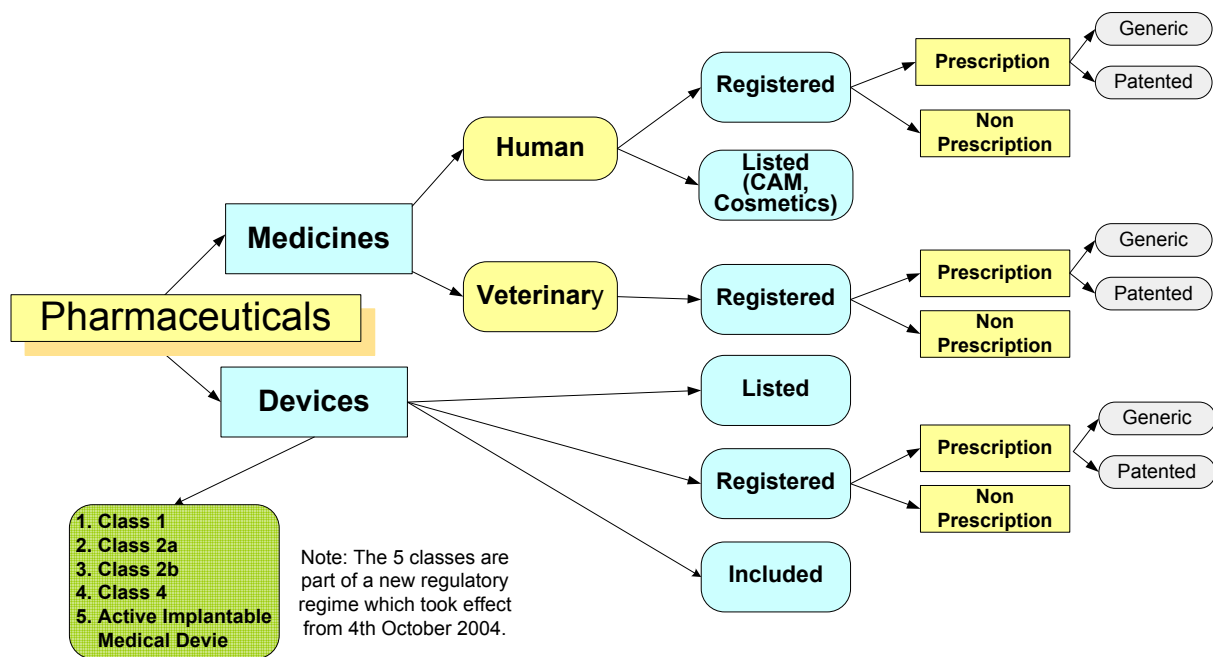


Figure 2 Pharmaceutical product segmentation (adapted from TGA classification system)

The pharmaceutical and nutraceutical industries have several well defined sub sectors and these are as follows:

Medicines are defined as products that are represented to, or likely to, achieve its principal intended action by pharmacological, chemical, immunobiological or metabolic means in or on the body. Medicines can be classified as prescription, non prescription or complementary.

Prescription Medicines

Those drugs or preparations only available from a pharmacist with a doctor's prescription or an authorised health care professional in a hospital due to factors such as the nature of their ingredients, side effects or cost. These products can be either generic or patent protected. *Example: Anti-depressants, contraceptive pills, antibiotics, strong painkillers.*

Non-prescription Medicines

Otherwise known as Over-the-Counter (OTC) medicines, these drugs or preparations are bought by consumers for self treatment and contain well known established ingredients with a long history of use. They are widely available in pharmacies and some products are also available in supermarkets and health food stores. Again they can be either generic or patent protected products. *Example: Cold & Flu Tablets, sunscreens and analgesics*

Complementary Medicines

These products, which include herbal medicines, traditional chinese medicines and homeopathic medicines are used as alternative or complementary treatments for conditions such as osteoarthritis, acne, psoriasis. *Example: Glucosamine*

Also included are nutraceuticals, being vitamin, mineral or other nutritional supplements.

Example: Vitamin C

See below for an expanded description of complementary medicines.

Veterinary Medicines

Veterinary medicines are those drugs or preparations that are specifically used for the treatment of animals. Include both prescription and non prescription medicines and can also be either generic or patent protected. *Example: Antibiotics*

Medical Devices

Medical devices are any instrument, apparatus, appliance material or other article used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap. See below for an expanded description of medical devices. Devices also covers products used for investigation, replacement or modification of the anatomy and control of conception. *Example: Syringes, Heart Valves*

Regulatory Framework

The Queensland pharmaceutical regulatory environment is controlled by

- (a) the Therapeutics Goods Administration (TGA) (a unit of the Australian Government Department of Health and Ageing) and
- (b) the Australian Pesticides & Veterinary Medicines Authority (APVMA). The APVMA is the government authority responsible for the assessment and registration of pesticides and veterinary medicines and for their regulation up to and including the point of retail sale.⁵

The *Therapeutic Goods Act 1989* sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia. The objective of the Act is to provide a national framework for the regulation of therapeutic goods and ensure their quality, safety and efficacy. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. It aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances⁶.

The TGA adopts a risk management approach with higher risk medicines (Registered: including prescription and non-prescription) being individually evaluated for quality, safety and efficacy. Lower risk medicines (Listed) are individually assessed by the TGA for quality and safety but not efficacy. Sponsors of listed medicines must however provide evidence to support the indications and claims made for these medicines.

Overall control of therapeutic goods by the TGA is exerted through three main processes⁷:

- Pre-market assessment of product safety, quality and efficacy;
- Licensing of manufacturers to assure product quality; and
- Post-marketing monitoring of product safety and quality, and surveillance to check for compliance.

1. Pre-market assessment

- Products assessed as having a higher level of risk (prescription medicines, some non-prescription medicines and medical devices) are evaluated for quality, safety and efficacy. Once approved for marketing in Australia these products are included in the Australian Register for Therapeutic Goods (ARTG) as 'registered' products and are identified by an AUST R number.
- Products assessed as being lower risk (many non-prescription medicines including most complementary medicines and low risk medical devices) are assessed for quality and safety. Once approved for marketing in Australia, these products are included in the ARTG as 'listed' products and are identified by an AUST L number.
- In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are taken into account.

2. Licensing of manufacturers

Australian manufacturers of therapeutic goods must be licensed. Their manufacturing processes must comply with principles of good manufacturing practice (GMP). The aim of licensing and standards is to protect public health by ensuring that medicines and medical devices meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

3. Post-marketing vigilance

Post marketing activities include investigating reports of problems, laboratory testing of products on the market and monitoring to ensure compliance with the legislation.

Recent Regulatory Developments

There are several recent issues that could have major implications for the TGA and the regulatory framework in which Queensland's pharmaceutical industry operates. These issues include changes at the TGA as a result of the Pan Pharmaceutical product recall in 2003, the proposed Trans-Tasman TGA and the Free Trade Agreement between the US and Australia.

5 www.apvma.gov.au; accessed July 28, 2004

6 www.tga.gov.au; accessed July 28, 2004

7 <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm>; accessed July 12, 2004

Amendments to the Therapeutics Goods Act

As a consequence of the regulatory action involving Pan Pharmaceuticals Limited, a number of amendments were made to the *Therapeutic Goods Act 1989* to further ensure the quality, safety and efficacy of therapeutic goods that are supplied in Australia or exported from Australia⁸.

The amendments provide the TGA with greater powers in relation to manufacturing practices and recall procedures. The existing requirements placed on manufacturers and sponsors of therapeutic goods were tightened. The amendments

- increased maximum penalties for a range of existing offences;
- created a range of new offences such as falsifying documents relating to therapeutic goods regulation;
- expanded compulsory public notification and recall provisions;
- inserted a 'fit and proper person' test in relation to manufacturing licences and conformity assessment certificates;
- require better identification of therapeutic goods in the event of a recall; and
- require inclusion of manufacturer details on the labels of medicines.

The Pan case highlighted the need for more clearly defined responsibilities, obligations and accountability of both manufacturers and sponsors of therapeutic goods. The changes provide more assurances for the community. However, compliance costs for some companies are expected to increase.

A New Trans-Tasman Therapeutics Goods Agency

The New Zealand and Australian Governments have agreed to establish a trans-Tasman therapeutic products agency. 1 July 2005 is the target date for the joint agency to replace the Australian TGA and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

New Zealand's existing system is acknowledged as outdated and unsustainable⁹. Examples of the problems with Medsafe include:

- controls on medical devices are minimal and inadequate to manage public health and safety risks e.g. virtually no requirement for devices to meet specified safety and performance standards, and
- for most complementary medicines there is no requirement for pre-market assessment of ingredient safety or product quality.

Beyond the primary policy objective to manage the risks to public health and safety from avoidable harm associated with the use of therapeutic products, the Joint Scheme seeks to:

- progress closer economic relations between Australia and New Zealand;
- facilitate trans-Tasman trade in therapeutics products; and
- facilitate exports of therapeutic products beyond Australia and New Zealand.

Therapeutic products will be regulated under two categories, medicines and medical devices. The same regulatory elements will be applied to all therapeutic products, regardless of whether the product is a prescription medicine, an over the counter medicine, a complementary medicine or a medical device. The manner and extent of regulation will depend on the type of the product and the level of risk associated with its use – the lower the risk, the lighter the controls¹⁰.

The US-Australia Free Trade Agreement

In February 2004 Australia and the United States announced the 'agreed text' of the Free Trade Agreement (FTA) between the two countries. Once finalised, there are a number of components of the agreement that could have implications for organisations in the Australian pharmaceutical sector. It is beyond the scope of this report to provide detail on the relevant components or assess their likely impacts. There are numerous publications providing informed comment on the FTA including a series of papers by the law firm Allens Arthur Robinson.¹¹

- **Generic Drug Manufacturers:** Under one article of the FTA the TGA must reject an application for marketing approval from a generic drug manufacturer if the equivalent innovator drug is covered by a patent. If the generic manufacturer submits that the patent is invalid or not infringed then the patentee will be notified of that submission

8 Source: <http://www.health.gov.au/pubs/annrep/ar2003/2/1/tga/1-3.htm>; accessed July 12, 2004

9 www.jtaproject.com/Downloads/Key%20Documents/FactSheets1to6.pdf; fact sheet 2; accessed July 12, 2004

10 www.jtaproject.com/Downloads/Key%20Documents/FactSheets1to6.pdf; fact sheet 3; accessed July 12, 2004

11 <http://www.aar.com.au/pubs/>

and they have a set period in which to lodge an infringement action. The TGA would delay approving the generic drug until the outcome of the infringement action was known and this will likely increase approval costs for the applicant.

- **Patent Extension:** The FTA intends to compensate patent holders for delays taken in granting a patent by extending the term of the granted patent beyond the standard of 20 years from the date of filing of the completed specification. Market entry by some Australian generics manufacturers could conceivably be delayed as a result of timing differences in the expiration of patents on the same drug in different parts of the world.
- **Pharmaceutical Benefits Scheme (PBS):** Australia will make a number of changes to the PBS to improve the transparency and timeliness of the product listing process. This includes an appeal process to allow companies to seek a review of decisions concerning inclusion of a particular medicine in the PBS.

Biotechnology R&D

Queensland has a biotechnology industry based on established scientific research infrastructure. In the context of this report the biotechnology sector is seen largely as contributing to the R&D components in the pharmaceutical value chain (see Figure 2). Through its Bioindustries Strategy the Queensland Government aims to position and promote the State as a centre of excellence in biotechnology. The biotechnology industry in Queensland has been described and characterised in previous government sponsored reports¹². According to the Australian Biotechnology Report (2001) of the 190 core biotechnology companies in Australia, 47% were involved in human health and 13% in genomics/proteomics or bioinformatics.

A notable collaborative R&D unit in Queensland is the AstraZeneca and Griffith University Natural Product Discovery unit. Astra Zeneca through their alliance has invested over \$100 million since 1993¹³. The unit investigates plants and marine organisms collected from Australia's rain forests and oceans in the search for novel medicines. The centre employs more than 45 scientists, technicians and information technologists and is recognised as one of the top 5 natural product discovery institutes in the world and the largest and most successful collaboration of its type in Australia. Since the unit began in 1993, the unit has found approximately 700 bioactive compounds from over 35,000 specimens collected from Queensland's rainforests and the Great Barrier Reef. About 40% of these compounds are new to science.

Australia is one of the 12 mega-diverse countries on earth¹⁴. Queensland has a range of competitive strengths that set it apart from comparable developed countries. The combination of megadiverse natural resources and a highly developed research and education infrastructure provides a valuable platform for the growth of the complementary and alternative medicine (CAM) industry in this state. Queensland's biodiversity includes 19 terrestrial bioregions and 17 marine bioregions, as well as five world heritage regions covering 40 million hectares. The unique species of flora and fauna in Queensland are being screened for novel chemicals for use in CAMs and insecticides and herbicides¹⁵. CAMs include herbal medicines, vitamin and mineral supplements, other nutritional supplements and traditional/Chinese medicines, homeopathic medicines and aromatherapy oils.

There are numerous Institutes, Centres and Research groups contributing to the pharmaceutical value chain and it is beyond the scope of this report to note these. Information on many of these entities can be found in the Queensland government's publication *Biotechnology in Queensland* (2004) or *Science and Research Infrastructure: A Directory of Queensland's Strengths* (2004) or via AusBiotech (www.ausbiotech.org)

Medical Devices

According to the TGA, medical devices are any instrument, apparatus, appliance material or other article (whether used alone or in combination, and including the software necessary for its proper application) for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or
- control of conception.

¹² For example: Queensland Bioindustries 1999-2004: Realising the Potential; Queensland Biotechnology Report 2003; Biotechnology in Queensland, Australia 2004; Public Register of Biotechnology Organisations June 2004; <http://www.sdi.qld.gov.au/innovation/publications/biotechnology/default.asp> accessed July 30 2004

¹³ <http://www.astrazeneca.com.au/article/502023.aspx>; accessed 28 July 2004

¹⁴ <http://www.sd.qld.gov.au/dsdweb/httdocs/global/content.cfm?ID=62> accessed July 30, 2004

¹⁵ <http://www.sd.qld.gov.au/innovation/biotechnology/default.asp> accessed July 30,2004

A device is one

“that does not achieve its principal intended action by pharmacological, immunobiological or metabolic means, but which may be assisted in its function by such means. Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, X-ray equipment, heart rate monitors, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves.”

Devices are classified into five categories based on the manufacturer’s intended use, the level of risk associated with the device and the degree of invasiveness in the human body (see Table 1 below).

Table 1 TGA Categories of Medical Devices

| Category | Example |
|------------------------------------|---|
| Class I | Beds, Cotton Wool, Scalpels, Wheelchairs |
| Class IIa | Hearing Aids, Catheters, Dental Drills |
| Class IIb | Blood bags, Condoms, Ventilators |
| Class III | Breast Implants, Heart Valves, |
| Active Implantable Medical Devices | Implantable Electrodes & Pulse Generators |

Complementary Medicines

Complementary medicines (also known as alternative medicines) are a group of diverse medical and health care practices and products that are not presently considered to be part of conventional medicine. Figure 3 gives an indication of the diverse range of products which can be considered in the context of complementary and alternative medicines.

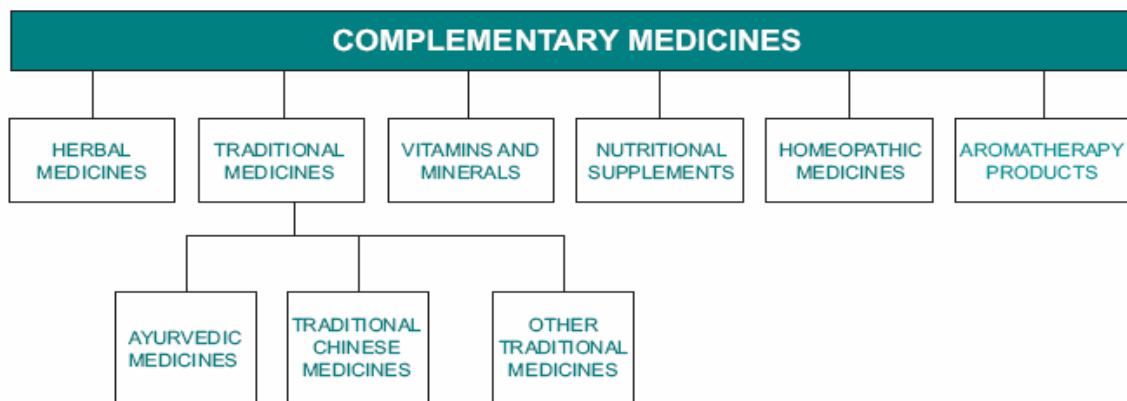


Figure 3 Classes of Complementary Medicines¹⁶

The use of complementary and alternative medicine (CAM) in Australia is extensive with over 50% of the Australian population using some form of complementary medicine.¹⁷ There is a growing focus on CAM in Australia and worldwide by a range of stakeholders including government, the World Health Organisation, western medical practitioners and private health insurance companies.¹⁸

As illustrated in Figure 4, The number of listed complementary medicines on the Australian Register of Therapeutic Goods (ARTG) is well in excess of registered complementary medicines (i.e. deemed higher risk and therefore demonstration of efficacy required) and the other two categories.

¹⁶ Source: Randerson, D, Regulatory Requirements and Commercialisation in the Australian Context, Forum on Herbal Medicine and Sustainable Health Development, Brisbane, 7 September 2004.

¹⁷ MacLennan, M.D. et al., (2002) The escalating cost and prevalence of alternative medicine, Preventative Medicine, 35: 166-178.

¹⁸ O'Brien, K, Complementary and alternative medicine: the move into mainstream health care, Clinical and Experimental Optometry 2004;87:2:110-120.

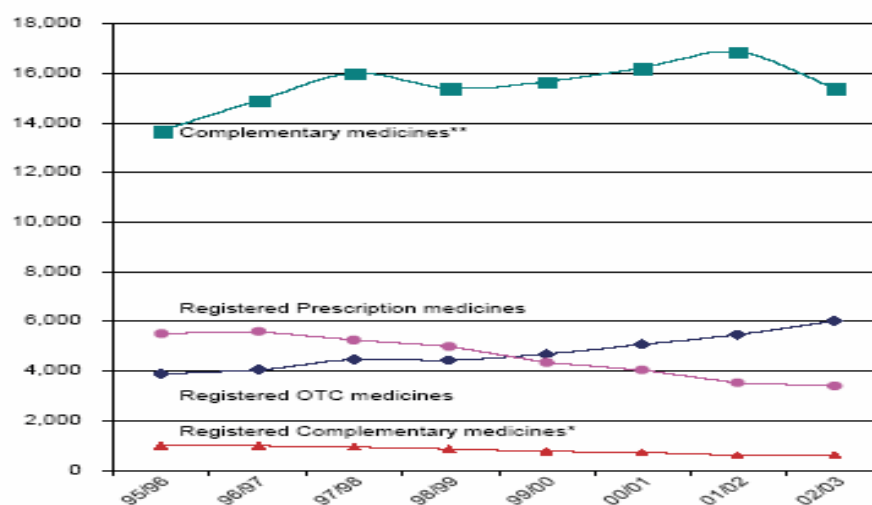


Figure 4 Products on ARTG 1995 - 2003.¹⁹

Complementary medicine is increasingly being taken much more seriously by orthodox medicine in Australia as is illustrated by the Australian Medical Association's recent adoption of a formal policy on complementary medicine which advocates registration of complementary therapists, further education for general practitioners, and more funding for research. The policy recognises the widespread and increasing use of complementary therapies, and their acceptance by many general practitioners²⁰.

Similarly, the Pharmaceutical Society of Australia (PSA) has recognised the significant and growing use of complementary medicines in Australia reflecting consumer preferences for such products and is supportive of this trend with the caveat that consumers can be assured of access to high quality, safe and efficacious products as well as relevant information concerning their use.²¹

Complementary medicines also gained significant publicity due to the Pan Pharmaceuticals issue which resulted in the closure of Australia's biggest contract manufacturer of complementary medicines and the subsequent national recall of 1600 products. In response the Federal Government set up the *Expert Committee on Complementary Medicines in the Australian Health System*²² to examine the sector.

Amongst the industry related findings of the Expert Committee in 2003 were:

- incentives are needed to encourage innovation and research in complementary medicines;
- there is a need for dedicated government funding for complementary medicines research;
- the disparity between public funding for prescription/over-the-counter (OTC) medicines research and complementary medicines research needs to be addressed; and
- relatively few sponsors use the registration process for complementary medicines.

Veterinary Products

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian government authority responsible for the assessment and registration of pesticides and veterinary medicines and for their regulation up to and including the point of retail sale. The APVMA evaluates the safety and performance of chemical products intended for sale, making sure that the health and safety of people, animals and the environment are protected. The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals in partnership with the States and Territories and with the involvement of

¹⁹ Source: Randerson, D, Regulatory Requirements and Commercialisation in the Australian Context, Forum on Herbal Medicine and Sustainable Health Development, Brisbane, 7 September 2004.

²⁰ www.abc.net.au/science/news/health/HealthRepublish_495340.htm, accessed 9 September 2004, Health and Medical News in Science, ABC Online.

²¹ www.psa.org.au/ecms.cfm?id=56, accessed 9 September 2004, Policy – Complementary Medicines.

²² Commonwealth of Australia (2003) Complementary Medicines in the Australian Health System. Report to the Parliamentary Secretary to the Minister for Health and Ageing.

other Australian government agencies. As at August 2004 the APVMA had just over 150 Queensland organisations registered on its database²³.

Queensland Government Support

DSDI is working with pharmaceutical companies throughout Queensland to identify opportunities and plan for the future growth of the industry. DSDI is implementing the **Queensland Pharmaceuticals Action Plan** which is also supported by Queensland Health, Departments of Employment & Training, Premier & Cabinet, Primary Industries and Education Queensland.

The following activities are being pursued: -

Research and Profiling – map and profile the pharmaceutical and nutraceuticals supply chains to determine the economic impact of the sector to Queensland's areas of competitive advantage and to identify future opportunities for the industry.

Develop Niche Sectors – develop strategies to encourage the development of niche sectors in Queensland including pharmaceuticals, complementary medicines, and veterinary pharmaceuticals.

Facilitating Industry Growth – assist industry to benefit or take advantage of emerging opportunities such as increasing manufacturing capabilities; collaborative R&D projects, locally based clinical trials work and export opportunities etc.

Leveraging Infrastructure – develop and implement strategies to maximise the benefits back to industry of publicly funded R&D infrastructure such as the Queensland Clinical Trials Network, Pharmacy Australia Centre of Excellence, the Queensland Institute of Medical Research, etc.

Industry Support Funding – assist firms to access and gain maximum returns from State Development & Innovation's Queensland Industry Development Scheme (QIDS) as well as the Federal Pharmaceuticals Partnerships Program (P3) and Commercial Ready schemes.

Intellectual Property Issues – engage the Federal Government with respect to patent law and trade matters to ensure that the interests of Queensland manufacturers are well represented.

Skills and Training – in conjunction with DET, consult with industry and other stakeholders such as ANTA, DET, TAFE, universities and Education Queensland to plan for current and future industry skills and training requirements, through a *Pharmaceutical Skills Formation Strategy*.

Investment Attraction – as part of a targeted Investment Attraction program, focus on attracting global pharmaceutical R&D, manufacturing and Asia Pacific operations to Queensland and pursuing emerging opportunities.

Cross Sector Industry Collaboration Opportunities – develop and implement strategies to facilitate cross-sector industry collaboration by leveraging existing strengths in pharmaceutical value chains such as the biotechnology and primary industry sectors.

Coordination – coordinate relevant meeting groups regarding the pharmaceutical industry, including Queensland Government Pharmaceuticals Reference Group, DSDI Pharmaceuticals Reference Group and relevant Industry Associations.

Australian Government Support

The Australian Government, through the Department of Industry, Tourism and Resources (DITR), in partnership with the pharmaceuticals industry has developed the 'Pharmaceuticals Industry Action Agenda (PIAA), Local Priority, Global Partner'. The PIAA sets down a 10-year growth strategy for industry and government with the vision of doubling Australia's share of the global pharmaceuticals industry by 2012 by increasing investment in Australia to capture innovation and knowledge; becoming a global hub for research, development and commercialisation; and developing Australia as a key global exporter of goods and services.²⁴

The PIAA details 10 actions that are necessary to be implemented to achieve the industry's vision. One of the key actions is the establishment of the Pharmaceuticals Partnership Program (P3)

²³ Information provided by APVMA via Queensland DSDI

²⁴ Commonwealth of Australia (2002) Pharmaceutical Industry Action Agenda

Pharmaceuticals Partnership Program

The Pharmaceutical Partnerships Program (P3) will provide \$150 million over five years in competitive grants to the pharmaceuticals sector²⁵. Its focus is to develop medicines for global markets and encourage multinational firms to foster partnerships with local companies. It is expected to promote additional R&D throughout the entire pharmaceutical value chain including biotech, originator and generic medicines companies. Successful applicants receive 30 cents in the dollar for each additional dollar they spend on increasing their eligible R&D in Australia.

According to AusIndustry, eligible R&D under the scheme would normally include drug discovery including biological screening, synthesis extraction of therapeutic substances, drug formulation, preclinical and phase I, II and III trials, clinical trials of a registered drug in a new indication, formulation, route of administration or dosage, laboratory evaluation of likely commercial production processes and the obtaining of industrial rights including patents.

Industry Trends and Future Outlook

Total estimated global pharmaceutical sales exceeded \$US430 billion for the 12 months to June 2003²⁶. North America and Europe accounted for 50% and 25% of sales respectively. The most significant customer sectors represented were retail pharmacies (67%) and hospitals (15%). Sales of pharmaceuticals affecting the central nervous system made up the largest contribution by disease state followed by preparations for neoplasms, the endocrine and metabolic systems.

The global pharmaceutical industry has demonstrated strong revenue growth over the past decade in spite of dynamic regulatory and market conditions²⁷. It is expected that demand for pharmaceuticals in developed and some developing countries will continue to rise due to ageing populations, rising incomes, higher expectations about quality of life and increasing consumer demand for the best medicines.

Numerous trends have been identified or predicted that will impact on the Australian and global industry over the next 5-10 years. There are various sources for the points made below^{28,29,30,31}.

Growth in Biopharmaceuticals Development

Biotechnology has emerged as a source of new pharmaceuticals, and genomics-based technology will result in feasible products. As biotechnology companies increasingly deliver new products to market, investors will more readily accept the risks and possible returns associated with biomedical research.

There is a switch in focus away from traditional chemical therapeutic methods in favour of biotechnology (utilising living organisms to create new products and processes). The authors noted key areas including genomics, genetic engineering, combinatorial chemistry, robotics, DNA research and enzyme engineering. Such new approaches have driven the trend of collaborative alliances between global players and the smaller biotechnology firms.

Personalised Medicine

Pharmacogenomics and the use of screening technology to identify exactly who will respond to a specific drug may challenge the prevailing "blockbuster" business model that currently dominates the life sciences and pharmaceutical industries³². In the blockbuster model, lengthy and costly clinical trials are required to prove a drug candidate's safety and efficacy on the population at large, which includes both responders and non-responders to a given drug. Once the drug is approved, this cost can typically only be recovered through annual sales of more than \$1 billion.

The development process of the future will begin with a better understanding of disease at the molecular level. Characterising proteins and their interactions is thought to be the key to understanding and treating disease. Consequently, the need for 'targeted treatment solutions' will focus discovery and development into areas that are driven by a better understanding of disease states through biological research. New pharmaceuticals that emerge will target specific conditions that affect smaller patient groups.

25 <http://www.ausindustry.gov.au/> accessed 28 July 2004

26 IBM Consulting Services (2002). Pharma 2010: the threshold of innovation.

27 Standard and Poors (2003). Healthcare Industry Survey: Pharmaceuticals.

28 Commonwealth of Australia (2002) Pharmaceuticals Industry Action Agenda; Canberra

29 IBIS World (2004). C2543 Medicinal and Pharmaceutical Product Manufacturing in Australia, 21 April

30 IBM Consulting Services (2002). Pharma 2010: the threshold of innovation.

31 Standard & Poor's (2003) Industry Surveys, Healthcare: Pharmaceuticals: Vol 171, No 50, Section 1

32 PwC July 2004

By targeting a specific responder population beginning at the drug research stage, pharmacogenomics could dramatically reduce the costs required for clinical trials and reduce or eliminate harmful side effects. This approach would also eliminate the need for broad-based marketing and sales efforts that are typically required to recover huge R&D investments. At the same time, such a highly targeted drug would ultimately be more valuable but marketed to a smaller patient population.

Increased use of e-commerce solutions to streamline value chains will allow manufacturers to market direct to the consumer (e.g. pharmacist, health care provider). In 2000 IBM Business Consulting Services released Pharma 2010: The Threshold of Innovation³³. One of the key findings in the report was companies that know how to make 'targeted treatment solutions' will deliver bigger shareholder returns. To make targeted treatment solutions the industry must make changes at every stage in the Pharma value chain:

"...the industry must be able to manage the complexity associated with working on multiple disease areas and multiple product types that use different research, development, manufacturing, marketing and sales techniques and serve different markets. Some pharmaceutical companies have already started focussing on particular disease pathologies and expanding their range with the acquisition of diagnostics operations. A few companies have also produced targeted treatments, but none has produced an entire package of targeted treatments and services for a specific disease area."

Products that target clinically defined populations, aiming to modify disease as opposed to controlling symptoms will increase in profile.

Global Consolidation

Globalisation of markets is reducing lead time in drug development, eroding first mover advantages and facilitating the rapid entry of followers. Consequently, consolidation activity within the industry may increase as organisations attempt to lever scale economies and impose barriers to entry. This could result in global manufacturing hubs. The wider use by more countries of pharmaco-evaluation of pharmaceuticals to contain expenditure will squeeze prices and global revenues. As such a key driver of consolidation includes the need to reduce R&D costs as competition within the industry intensifies.

Growth in Generic Pharmaceuticals

There are two significant factors contributing to a positive outlook for the growth in generics (i.e. those products based on innovative drugs for which the primary patent has expired). Firstly, patents on many innovative drugs are due to expire between June 2005 and 2010. Secondly, several established demographic trends favour greater consumption of generic pharmaceuticals: an ageing population; an increase in the average life expectancy and increased incidence of chronic lifestyle diseases. These demographic trends threaten to burden health care systems as the demand for supportive treatment increases. In a general sense it is also becoming increasingly difficult to find new blockbusters.

The Standard & Poor's pharmaceuticals industry survey in 2003³⁴ noted a predicted strong growth in the generic drug market. In contrast to single digit growth in sales of branded products (8-9%), global sales of generic drugs were expected to grow 20% in 2004 from \$29 billion in 2003. Growth in generics should remain at double digits through 2007.

Business Review Weekly recently published an estimate of market share by the generics manufacturers in Australia³⁵ (see list below). The largest supplier of generic drugs in Australia is Alphapharm, owned by the multinational Merck. In the next 12 months, two big-selling drugs will come off patent in Australia: Merck's cholesterol-reducing Zocor (the generic ingredient is simvastatin) and Pfizer's antidepressant Zoloft (sertraline). In 2003, Australian sales of these two were \$347.8 million for Zocor and \$94.2 million for Zoloft.

Table 2 Market share of key players in generic drug manufacturing in Australia

| Company | (%) |
|-----------------------|------------|
| Alphapharm | 71 |
| Arrow Pharmaceuticals | 12 |
| Hexal | 7 |
| Douglas Laboratories | 6 |
| Mayne | 4 |

33 IBM Business Consulting Services (2002) Pharma 2010: The Threshold of Innovation; Future Series, IBM

34 Standard & Poor's (2003) Industry Surveys, Healthcare: Pharmaceuticals: Vol 171, No 50, Section 1

35 Quinlivan, B (2004) Fever Symptoms, Business Review Weekly, 2 September: p. 45

Switch to Over-the-Counter Medicine

Any drug that can safely be used by consumers without physician management can be given regulatory body approval to be available without a prescription. Various industry stakeholders are asking regulators to consider approval of an increasingly wide variety of medications for over-the-counter sale. Since 1976 almost 90 prescription drugs have become OTC medicines³⁶.

Growth in Complementary and Alternative Medicine

Consumers are increasingly embracing complementary medicine motivated by a desire to have input and control of their health coupled with an increasing focus on prevention and wellness, and a perception that these products present an opportunity for an inexpensive form of 'health care insurance'.

In Australia and worldwide, there is an increasing awareness and focus on complementary and alternative medicine from western medicine and allied health practitioners, insurance companies, regulatory bodies and consumers. According to the Expert Committee on Complementary Medicines in the Australian Health System³⁷ the current annual retail turnover of CAMs (as at 2002-03) was estimated to be \$800 M with an additional 20% of Australian output exported.

A survey conducted by the RP Scherer Corporation (now Cardinal Health) in 2001 found that 70% of Australians used a natural healthcare product at least once a year and also suggested that 80% of GPs were referring patients for complementary treatments³⁸.

MacLennan (2002)³⁹ estimated a higher expenditure on CAMs in 2000 of \$1.67 billion, representing an increase of 120% over 7 years and further estimated that 52.1% of the population used at least one non-medically prescribed complementary medicine in 2000.

An illustration of reported complementary medicine usage in Australia over certain years from various data sources^{36,39,40} is shown in Figure 5. This data is largely anecdotal but it offers support for global industry predictions.

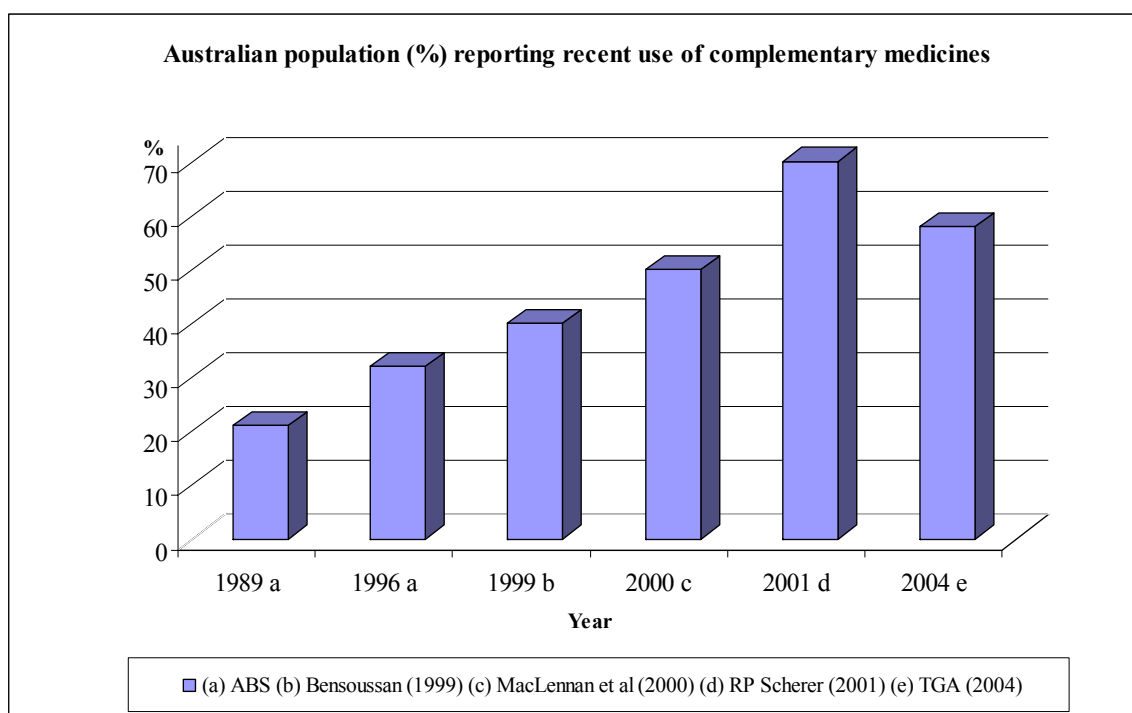


Figure 5 Consumers reporting use of complementary medicines.

36 Standard and Poors (2003). Healthcare Industry Survey: pharmaceuticals.

37 Commonwealth of Australia (2003) Complementary Medicines in the Australian Health System. Report to the Parliamentary Secretary to the Minister for Health and Ageing.

38 RP Scherer Australia (2001) Vitamins, Minerals, Herbal and Nutritional Supplements - Consumption Data, October.

39 MacLennan, M.D. *et al.*, (2002) The escalating cost and prevalence of alternative medicine, *Preventative Medicine*, 35: 166-178

40 Weir, D (2004) Supporting Consumers Quality Use of Complementary Medicines, Complementary Medicines Summit, Sydney, September.

The market for Complementary and Alternative Medicines is also showing a number of changes over time with increases in aromatherapy products, herbal medicines and mineral supplements (Table 3):

Table 3 Uses of Alternative Medicines - 1993 and 2000.⁴¹

| | 1993 | 2000 |
|---------------------------|------|------|
| | % | % |
| Vitamins (not prescribed) | 37.6 | 36.4 |
| Aromatherapy oils | 3.5 | 15.3 |
| Herbal Medicines | 9.9 | 13.4 |
| Mineral supplements | 9.2 | 10.6 |
| Evening Primrose oil | 7.8 | 8.0 |
| Ginseng | 3.0 | 5.0 |
| Homeopathic medicines | 4.4 | 4.3 |
| Chinese medicines | 1.8 | 3.2 |
| Menopause products | 1.4 | 1.6 |
| Other | 3.6 | 4.9 |

Demand for complementary medicines is expected to be positively influenced by trends such as ageing populations, an increase in average life expectancy and the growth in chronic lifestyle diseases^{42,43}. Interest in CAM continues to grow as the broader community increasingly accepts preventative medicine as a means of improving and maintaining general health and well being. The CAM workforce is itself substantial and growing - with a 12-fold increase in the size of the CAM workforce between 1970 and 1986.⁴⁴

Networked Pharma and Outsourcing

Multinationals will become less vertically integrated with increased outsourcing at all stages of the value chain. As multinationals seek more strategic alliances in drug discovery and development, there will increasingly be more contributors to the development and manufacture of pharmaceutical products. There will be an even stronger emphasis on human resources as a highly mobile source of competitive advantage.

Information Management

High speed computing will facilitate much of the global consolidation predicted. Pervasive computing and networked communities will enable closer monitoring of clinical trials through the exploitation of advances in bandwidth, mobile telecommunications and radio frequency technologies. As a result, modelling and simulation will enable monitoring of drug interactions in whole body systems.

Given advances in information management communication with regulators will likely begin earlier in the development process. With greater access to clinical trial information, fuelled by computing advances and e-data capturing, regulators will receive 'rolling dossiers' of trial results. This will reduce the time to market.

Although the transition to electronic data (e-data) capture is underway most clinical trials remain paper based. The transition to e-data will likely reduce human error and streamline the data capture process resulting in significant cost reductions in the development process.

41 Adapted from MacLennan, M.D. et al., (2002) The escalating cost and prevalence of alternative medicine, *Preventative Medicine*, 35: 166-178

42 Wondur Holdings Pty Ltd (2000). *New Pharmaceutical, Nutraceutical and Industrial Products: the potential for Australian agriculture*.

43 Standard and Poors (2003). *Healthcare Industry Survey: pharmaceuticals*. *ibid*.

44 Parliament of Victoria Social Development Committee, *inquiry into alternative medicine and the health food industry*, 1986. Cited by Hall, K, Giles-Corti B., *Complementary therapies and the general practitioner – a survey of Perth GPs*, *Aust Fam Phys* 2000;29:602-606.

Economic Profile of the Pharmaceutical Industry

Snapshot of Queensland and Australian Pharmaceutical Industries

Contribution to Economy

- Australia's pharmaceutical industry contributed approximately \$8.16 billion to gross domestic product (GDP) in 2002/03. The contribution to GDP from certain segments of Australia's pharmaceutical industry is expected to grow at a higher average compound annual growth rate (CAGR) over the next five years compared to Australia as a whole (CAGR of 3.7%):
 - pharmaceutical, cosmetic and toiletry retailing segment: CAGR of 6.2% pa
 - medicinal and pharmaceutical product manufacturing segment: CAGR of 5.3% pa
 - pharmaceutical and toiletry wholesaling segment: CAGR of 3.9% pa

Trade

- The USA, New Zealand and the United Kingdom are key export destinations for Australia's pharmaceutical manufacturing industry.
- Australia's three major foreign providers of pharmaceutical manufacturing goods are the United States of America, the United Kingdom and Germany. Whilst Australia exports a large amount of pharmaceutical goods to a number of Asian countries, it does not source a large amount of pharmaceutical goods from this region.
- In 2003, Australia's pharmaceutical manufacturing industry exported \$3.36 billion (including re-exports) and imported \$8.46 billion (including re-imports).

Employment

- Australia's pharmaceutical industry employed 120,000 people in 2001. The pharmaceutical, cosmetic and toiletry retailing segment (dominated by pharmacies), employed over 52,000 people in 2001.
- The Queensland pharmaceutical industry employed over 19,000 people in 2001, accounting for approximately 1.1% of Queensland's total employment.
- In the medicinal and pharmaceutical product manufacturing segment, average revenue per employee in Queensland in 2001 was \$165,000, whilst in New South Wales it was \$394,000.

Revenue

- Of the six segments used to proxy the pharmaceutical industry, the pharmaceutical and toiletry wholesaling segment recorded the largest amount of revenue in 2002/03, at over \$12.28 billion. The pharmaceutical, cosmetic and toiletry retailing and the medicinal and pharmaceutical product manufacturing segments recorded \$7.56 billion and \$7.27 billion respectively.
- In 2002/03 the scientific research segment contributed approximately 58 cents to GDP per dollar of revenue, a larger contribution per dollar than all of the other segments used to proxy the industry.
- Over the next five years revenue is forecast to grow strongly in the following segments
 - pharmaceutical, cosmetic and toiletry retailing segment: average CAGR of 5.8%)
 - the medicinal and pharmaceutical product manufacturing segment: average CAGR of 4.9%)
 - the pharmaceutical and toiletry wholesaling segment: average CAGR of 4.6%)

Number of Establishments

- In 2001 the total number of pharmaceutical establishments across the six ANZSIC codes used to proxy the industry was estimated at 9,298 in Australia and 1,700 in Queensland.
- The average turnover of medicinal and pharmaceutical product manufacturing establishments was approximately \$29.4 million, whilst the average turnover of retail pharmaceutical establishments was \$1.2 million in 2000/01.

These observations have been compiled based on data sourced from the ABS and IBISWorld. Specific references can be found throughout the chapter. The 'Information Sources' section outlines a number of limitations of the data presented.

The purpose of this section is to provide context as to the profile of the Queensland pharmaceutical industry. Information is presented on the total contribution that the industry makes through such measures as gross domestic product (GDP) and gross state product (GSP), exports and imports, employment, revenue generation and the number of establishments.

The pharmaceutical industry is a broad industry sector comprised of a diverse range of sub sectors and various value chain elements. This economic profile represents an examination of the industry at its more aggregate level of manufacturing, wholesaling and retailing matching the format data on the industry that has traditionally been collected.

Statistics based on Australian and New Zealand Standard Industrial Classifications (ANZSIC) are employed in this section. ANZSIC codes are industry groupings that were developed for use in Australia and New Zealand for the production and analysis of industry statistics.

ANZSIC codes categorise industries into four levels including Divisions (the broadest level), Subdivisions, Groups and Classes (the finest level). The industry statistics presented in this report are based on classes (4 digit ANZSIC codes). The pharmaceutical industry as a whole does not fall into one Divisional ANZSIC grouping. Therefore a selection of ANZSIC codes has been used as a proxy for the industry. Table 4 sets out the ANZSIC codes used to present industry statistics.

Table 4 ANZSIC Codes Used to Profile the Pharmaceutical Industry

| Industry | ANZSIC |
|--|--------|
| Scientific research | L7810 |
| Medicinal and pharmaceutical product manufacturing | C2543 |
| Medical and surgical equipment manufacturing | C2832 |
| Cosmetic and toiletry preparation manufacturing | C2546 |
| Pharmaceutical and toiletry wholesaling | F4796 |
| Pharmaceutical, cosmetic and toiletry retailing | G5251 |

In conducting this study it was found that discrete, consistent or complete data sets on the pharmaceutical and related industries was difficult to obtain. Comparison of key economic measures between Queensland and Australia or the other states was often not possible or not an exercise that would be likely to yield reliable or valid results. The group of ANZSIC codes did not definitively capture the entire pharmaceutical industry. The industry categories that exist overlapped and did not always represent the sub-sectors examined. For instance, the scientific research ANZSIC code, (L7810), includes medical and health science along with a range of non-pharmaceutical research such as agricultural and computing research. For example, the ANZSIC scientific research category includes a significant amount of research outside of pharmaceuticals.

Data was compiled and examined on key economic measures including industry contribution (through gross domestic product (GDP) and gross state product (GSP)), exports and imports, employment, revenue generation and the number of establishments.

Information Sources

Key data sources included the Australian Bureau of Statistics (ABS) and IBISWorld industry reports. Information at the Australian level is presented first where possible followed by state data.

IBISWorld data was used as the basis for many of the statistics provided on Australia's pharmaceutical industry. IBISWorld is a research organisation that provides commercial information for a large range of industries. IBISWorld's data is categorised according to ANZSIC industry classifications. As IBISWorld compiles information based on analyst research and estimations in addition to ABS data it represents more up-to-date data than is available through the ABS which compiles statistics on an irregular/longer cycle basis.

Data was sourced from the following IBISWorld reports:

- L7810 – Scientific Research in Australia, published 23 December 2003
- C2543 - Medicinal and Pharmaceutical Product Manufacturing in Australia, published 3 February 2004
- C2832- Medical and Surgical Equipment Manufacturing in Australia, published 16 June 2004
- C2546 – Cosmetic and Toiletry Preparation Manufacturing in Australia, published 2 July 2004
- F4796 - Pharmaceutical and Toiletry Wholesaling in Australia, published 29 January 2004
- G5251 - Pharmaceutical, Cosmetic and Toiletry Retailing in Australia, published 7 January 2004
- Business Environment Overview – Gross Domestic Product (GDP), Real GDP
- Business Environment Overview – Inflation, Inflation - Deflators and CPI

ABS data was used to provide a state level profile of the pharmaceutical industry in Australia. The ABS is Australia's official statistical organisation. In most cases, IBISWorld do not publish a state-by-state breakdown of data and therefore, throughout this chapter, less recent ABS data has been used to form many of the observations regarding the industry's economic profile in Queensland.

ABS publications employed throughout this section include:

- ABS, Manufacturing Survey by 4 digit ANZSIC by all states in Australia, 1999/2000
- ABS, International Trade - Exports by 4 digit ANZSIC by State of Origin by Country of Destination by Quantity and Value (FOB), 2003
- ABS, International Trade Imports – Imports by 4 digit ANZSIC by Country of Origin by State of Destination by Quantity and Value (FOB), 2003
- ABS, Australian National Accounts, State Accounts, 5220.0, 1999-2000
- ABS, 2001 Census of Population and Housing, Number of Persons by 4 digit ANZSIC by all states and Australia
- ABS, Census of Population and Housing: Selected Education and Labour Force Characteristics for Statistical Local Areas, Queensland, 2017.3, 2001

This data allowed conclusions to be drawn on the profile of the pharmaceutical industry in Australia and Queensland. Although care has been taken to use the best available data to profile the industry, some distortions may be present due to inherent limitations of the data as noted below:

- The pharmaceutical industry had been proxied using a compilation of ANZSIC codes. It is unlikely that the data captures the entire pharmaceutical industry. Similarly the data includes some activities that are not related to the pharmaceutical industry.
- A large proportion of the information provided on the Queensland industry was derived from the Australian Bureau of Statistics Manufacturing Survey, which only provided statistics on the manufacturing segment of the industry:
 - businesses included in the manufacturing survey were those that were predominantly involved in the manufacturing industry, however some may have engaged in other activities; and
 - in some cases establishments that undertook limited manufacturing activities and were primarily non-manufacturing businesses were excluded from this data.
- Data presented at the state level has the potential to be distorted where companies have 'head office' operations in one state and key operational activity in another.

These limitations should be kept in mind when reading the profile of the pharmaceutical industry in both Australia and Queensland.