



# Australia – Life Sciences Market

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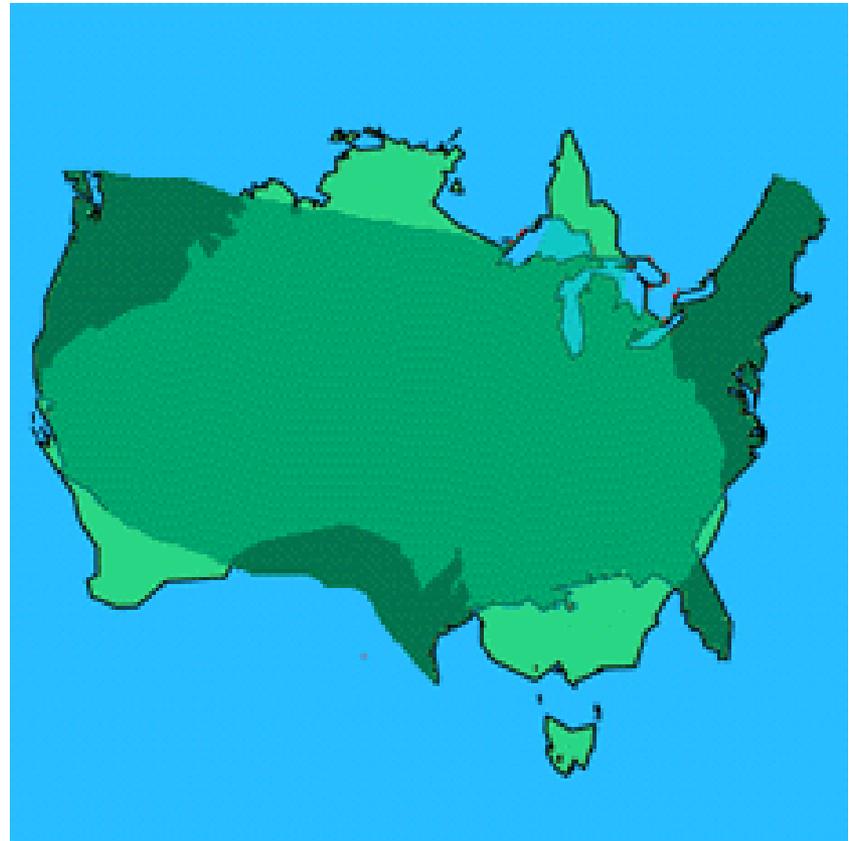
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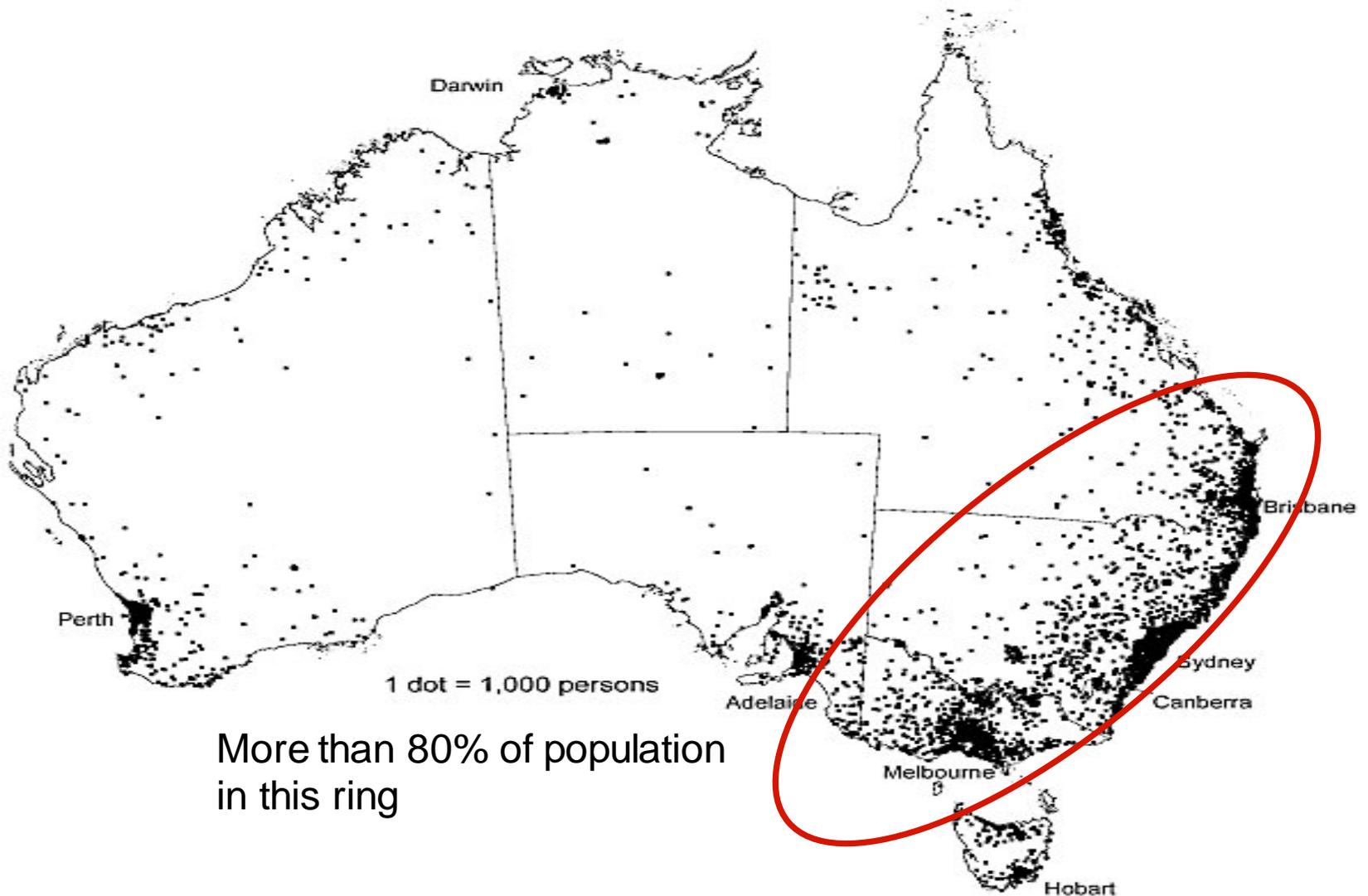


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# Geographical Size



# Population Density



More than 80% of population  
in this ring

# Basic Facts

- Population – 23 million
- World's 12<sup>th</sup> largest economy
  - stable political environment & strong economy
  - 23 years of economic growth
  - forecast GDP growth rate 2014: 3%
  - unemployment: 6.0%
- Relatively strong Australian Dollar
  - but has fallen 11% in the last year
  - exchange rate: AUD1.00 = USD0.87



# Economic Drivers



- Located in the world's fastest growing economy region
- 4<sup>th</sup> largest economy in the Asia Pacific region
- Reliance on mineral and commodity exports

# U.S.-Australia Trade Relationship

- U.S./Australia Free Trade Agreement since 2005

- January 2015 marks 10<sup>th</sup> anniversary of the FTA
- Our 12<sup>th</sup> largest export market



- Australia buys more goods from the U.S. than from any other country
- Major Australian trading partners: China, U.S., Japan

# Australia's Life Sciences Industry

- Healthcare System Overview
- Hospitals
- Health Trends
- Regulatory Requirements
- Medical Eq.
- Pharmaceuticals
- Complementary Medicines
- Dental Eq.
- Biotechnology
- Health IT
- Veterinary Eq.
- Opportunities

# Healthcare System Overview

- Mix of public and private sector funding
  - complex mix of public/private reimbursement
  - Government-funded healthcare scheme
  - approx. 50% of Australians have private health insurance
- Government primary purchaser of medical products
  - 70% of sales to the Public/Government sector
  - 30% of sales to the Private sector
- Costs of maintaining a public healthcare system is a concern
  - hospital administrators directed to choose the best product available at the lowest cost

# Healthcare System (cont'd)

- 9.5% of GDP spent on health
  - comparable to United Kingdom, Spain & Greece vs U.S. (17%)
- High per capita income
  - demand for full range of sophisticated medical equipment
- Educated population
  - expectation of state-of-the-art treatment

# Hospitals

- 750 public; 590 private
- Public hospitals – large, more complex care
  - intensive care, emergency, major surgery, organ transplants, renal dialysis and specialist outpatient clinics
- Private hospitals – less complex non-emergency care
  - 67% of admissions involving elective surgery
  - shift and now providing more complex services e.g. intensive care, cardiac & oncology units

# Health Trends

- Life expectancy is among the highest in the world
  - 80 yrs men; 84 yrs women
- Leading causes of death include cancer and circulatory system diseases such as heart disease
- 2012: 63% of adult Australians were overweight or obese
  - Obesity's growing prevalence foreshadows increases in the occurrence of chronic conditions such as diabetes, asthma, and higher healthcare costs

# Regulatory Requirements

- Therapeutic Goods Administration (TGA) [www.tga.gov.au](http://www.tga.gov.au)
- Regulation of medical devices
  - based on the Global Harmonization Task Force (GHTF) model and closely aligned with the European Union (EU) system for medical devices
  - no recognition of FDA product approvals
  - firms should obtain CE Mark prior to exporting to Australia
- Australian Sponsor applies for TGA approval and listing of product on the Australian Register of Therapeutic Goods (ARTG)

# Medical Eq.

- Ninth-largest export market for U.S. medical products
  - more than 95% of medical devices are imported
  - approx. 60% of these products are from the U.S.
  - other main sources include Germany & Ireland
- Mature market for medical products
  - sophisticated, competitive & price-sensitive
  - new to market companies may experience strong competition from other U.S. companies or multinationals already in the market

# Pharmaceuticals

- One of the top areas of business investment in Australian R&D
  - Australia often chosen by global medicines industry to conduct clinical trials
  - industry is the largest high-technology exporter
- Pharmaceutical Benefits Scheme (PBS)
  - patients pay \$32.00 or \$6.00 for concession card holders
  - Federal Govt. subsidizes remaining cost
  - listing involves a rigorous clinical and cost-effectiveness evaluation against already available alternatives
- Most prescribed medicines broadly reflects the burden of disease in Australia
  - cardiovascular, glaucoma, cancer, respiratory disorders, mental illness, auto immune disorders, high blood pressure, cholesterol

# Complementary Medicines

- Complementary Medicines
  - vitamin, mineral, plant or herbal, naturopathic and/or homeopathic preparations some aromatherapy preparations, and nutritional supplements
- Sophisticated and competitive market
  - 254 complementary medicine companies and 59 manufacturing facilities
  - Australian firms export to more than 20 countries
  - 10,000 complementary medicines on the market
  - 1,800 new complementary medicines listed on the ARTG each year
- Ageing population
  - a move towards pro-active healthcare & preventative therapy
  - growing popularity of “integrated” medicines where “East meets West.”
  - growth categories:
    - provide scientific evidence to support efficacy; products aimed at the ageing baby boomer market; products that help people maintain their health

# Complementary Medicines Regulation

- Regulated as medicines
  - evidence of pharmaceutical GMP
  - <http://www.tga.gov.au/industry/cm.htm>
- Lower risk medicines
  - **Listed** on the ARTG (Aust L)
  - Assessed for quality and safety but not efficacy
  - Only contain low risk, pre-approved ingredients
  - Not make any indications (therapeutic use) for the treatment of a disease or condition
  - Sponsor must certify they hold evidence to support indication and claims
- High risk medicines
  - **Registered** on the ARTG (Aust R)
  - Assessed for quality, safety & efficacy

# Dental Eq.

- Dependent on imported products
  - market is mature, sophisticated and competitive
  - strong demand for full range of innovative products
  - local manufacturing < than 3% of dental products sold
- United States is second-largest supplier after Germany
- Opportunities
  - state of-the-art dental technology; products for ageing population; and cosmetic & preventative procedures

# Biotechnology

- Approx. 420 biotechnology companies
  - agricultural biotechnology, biomedicines, biopharmaceuticals, stem cell sciences, environmental biotechnology and diagnostics
  - biomedical strongest sub-sector with well established focus on therapeutics, diagnostics & vaccines
  - world-class science and medical research, & capacity for international partnerships
- Scientific American Worldview Scorecard 2014
  - ranks Australia as number four in the world for biotechnology innovation
  - measures countries' biotech performance according to productivity, intellectual property protection, intensity, enterprise support, education/workforce, foundations, and policy and stability
- Emerging trends
  - foodtech and cleantech

# Health IT

- Government's National E-Health Strategy - 2008
  - National E-Health Transition Authority (NEHTA)
    - personally controlled electronic health records (PCEHR) – 2012
- Pursuing solutions to grow a sustainable healthcare system
  - improve health outcomes and respond to increasing cost & demand pressures; greater demand for personalized care; and an ageing population
  - health system serves urban centers, remote and rural areas, and indigenous communities across a vast geographic region
  - solutions need to be integrated and interoperable with the current architecture

# Veterinary Eq.



- Sophisticated market for animal health products
  - More than 66% of Australians own pets
- APVMA - Australian Pesticides and Veterinary Medicines Authority (APVMA): [www.apvma.gov.au](http://www.apvma.gov.au)

Veterinary chemicals:  
prevent, diagnose, cure or alleviate a disease, condition cure or alleviate an injury; modify the physiology  
incl. vitamins, minerals and additives if they are used for above
- AQIS – Australian Quarantine and Inspection Service  
<http://www.agriculture.gov.au/biosecurity>
  - Import permit required for:
    - Animal Feed - including pet food & treats, stock feed, aquaculture feed, and bait
    - Veterinary Products - such as therapeutics and medicines

# Opportunities

- Technology & Products:
  - significantly improve clinical outcomes and/or reduce costs
  - serve an ageing population
  - high level of uptake of innovative technology
- Many clinicians have spent time in the U.S.
- Australia's chronic disease burden is similar to the U.S.:
  - asthma, cancer (incl. lung, colorectal), type 2 diabetes, coronary heart disease, stroke, arthritis, osteoporosis, depression, chronic obstructive pulmonary disease (COPD), chronic kidney disease, oral disease
- Continuing need for high quality & innovative medical equipment and products
  - innovative and high-quality U.S. products are well-received





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