The Future of Clinical Research in Australia

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Australian Pharmaceuticals Industry Facts and Figures

The Australian pharmaceuticals industry:

- has an annual turnover of approximately **$17 billion**;
- employs over **34,000** exceptionally talented Australians;
- generates nearly **$4 billion** in export earnings; and
- spends over **$750 million** on research and development

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Medicines Australia's 2007 Industry Economic Survey

- In September 2007 Medicines Australia conducted a member survey to obtain information about the industry's activities in Australia.
- **36** member companies responded to the survey
- Respondents account for nearly **80 per cent** of total value of wholesales pharmaceuticals in Australia.
- The survey covered reporting data from 2005 and 2006 calendar years.

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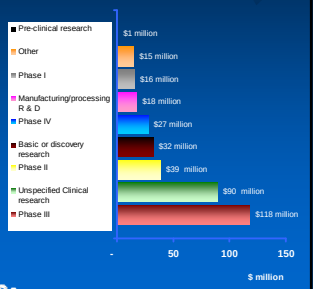
R&D investment is growing

- In **2005**, respondents spent approximately **$320 million** on R&D. In **2006**, respondents spent approximately **$380 million**
- Phase III clinical trials account for a majority of R&D expenditure
- Phase I growing, but tyranny of distance from HQ



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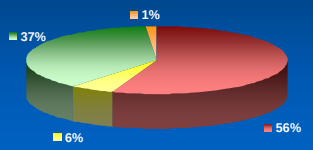
R&D Collaborations

- Respondents conducted **43%** of their R&D in collaboration with Australian hospitals and universities.



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Global industry picture

- Dearth of new molecules – FDA approved 22 in 2006; 53 in 1996 – TGA similar decline
- Increasing cost R&D – more trials; more subjects; greater complexity
- Higher cost per molecule approved – now more than $1 billion
- Competing drivers - desire for faster access at lowest possible cost whilst minimising risk

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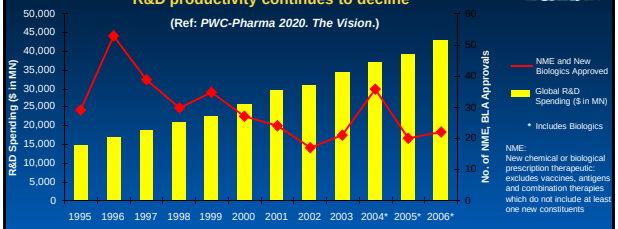
Why is cost (value) so important?

R&D productivity continues to decline

(Ref: *PWC-Pharma 2020. The Vision.*)



Over 10 years:

- **R&D investment doubled, reaching >$55bn p.a. (75% of global spend) in 2006**
- **FDA approved medicines declined by 60% - 53 in 1996, 22 in 2006**

Source: FDA/CDER Data, PhRMA data, PwC analysis

The Challenge for the Australian Pharmaceuticals Industry

- The global innovative pharmaceuticals industry is undergoing massive restructuring.
- Multinationals are relocating manufacturing and research and development facilities to emerging economies, such as India and China, which offer considerable (and growing) advantages in both capabilities.
- There is need for urgent action. In a few years, the advantages that some emerging economies enjoy now could well constitute insurmountable obstacles to the viability of the pharmaceuticals industry in Australia.

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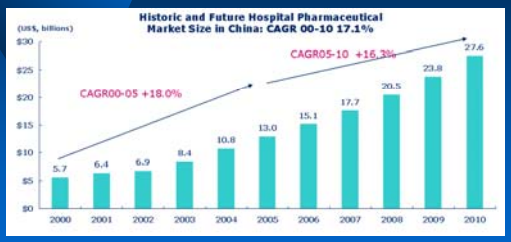
Pharmaceutical Forecast - China

By 2010, the Chinese pharmaceutical market may reach around US$28 billion (IMS forecast). China pharma market is forecasted to become the world fifth largest by 2010 and the largest by 2050



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MNC R&D Investment in China

- **April 2007 Eli Lilly committed US$100 million for research in China**
- **May 2006 AstraZeneca announced it intends to invest US$100 million in R&D in China over the next three years**
- **October 2006 Pfizer opened a US$2.5 million research and development (R&D) centre in Shanghai**
- **November 2006 Novartis announced it will build its eighth global research center in China at an investment of US$100 million**
- **GSK will launch its 23rd global research and development center in Shanghai - US$40 million**

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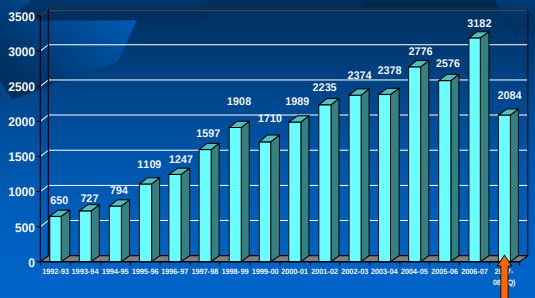
Clinical trials in Australia – Notifications to TGA



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Note: only three quarters of 07-08

Perceptions at odds

- Industry believes Australia's competitiveness in clinical trials is **under intense threat**.
- **37%** of **industry** respondents at a recent Forum expect the number of clinical trials in Australia to increase. **41%** think that activity will decline and **23%** think activity will not grow further.
- **80%** of **Government** (or related bodies) respondents expect the number of clinical trials in Australia to increase.
- There is a dramatic difference between how the industry and the Government see the future.

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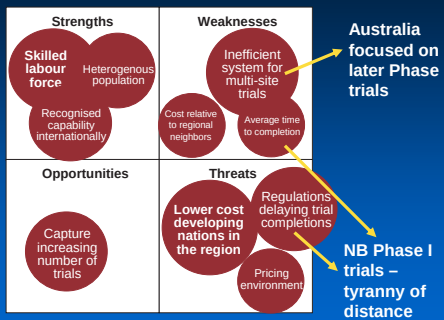
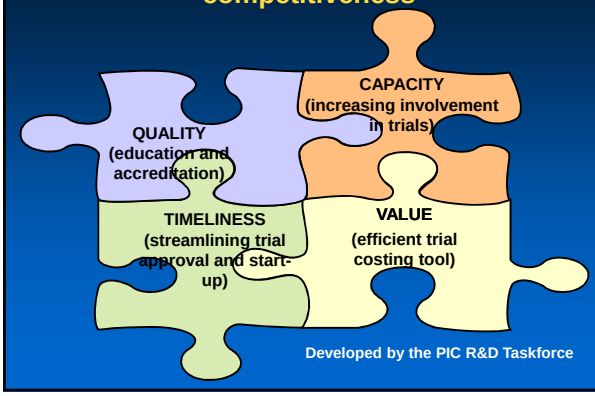
SWOT ANALYSIS — CLINICAL RESEARCH IN AUSTRALIA



Source: The Allen Consulting Group, Drivers of Pharmaceutical Investment, 2005

The Four Pillars – Improving Australia's competitiveness



Developed by the PIC R&D Taskforce

How can we compete?

Competing globally – Four pillars: Quality, Timeliness, Capacity, Cost

Timeliness

- HREC approval of multi-centre clinical trials – slow and inefficient
- Streamlined approval clinical trials
  - States – especially NSW, Victoria, Qld
  - $5.6m over 4 years to NHMRC to develop a national model

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How can we compete?

Quality

- Quality data = education & accreditation of clinical research staff
- Maintain a qualified and competent clinical research workforce in Australia – assure quality research
- Ensure access to e-medical records – data validation

Capacity

- Increase awareness, understanding and interest in clinical trials conducted in Australia
- Particularly considering the informed consent process
- Increase the pool of subjects interested in trials

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How can we compete?

Cost = Value

- Transparent and Efficient trial costing model – a national costing model with the aim of standardizing how studies are budgeted - procedures, tests, hospitalisation, ethics review, pharmacy service and overhead etc.
- NOT standardisation of the actual costs

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Implications for the future

- Secure the existing R&D base
- Secure clinical trial regulatory environment
- Address fragmented research base and low private venture capital investment
- Incentives for partnerships and collaborations

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Government Incentives for R&D investment

- P3 Scheme – small number of companies rewarded; finishes in 2009
- No follow-on incentive program agreed
- 175% premium tax concession – IP ownership rule changed, but will it be enough?
- Competing with Korea, Singapore, China, India, E. Europe

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Innovation Review & PISG

- In the context of global rationalisation of R&D investment
- Senator Carr announced a Review of the National Innovation System and established the Pharmaceuticals Industry Strategy Group (PISG)
- Only avenues to achieve further Industry Development Program
- Challenge of convincing Government of the need for further programs

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Conclusions

- Australia faces difficult challenges to remain globally competitive
- Need for policy partnership between industry, research community and regulators
- Work together at both the macro and micro level
- Greater competitiveness of clinical research required in the challenging global environment

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Questions

Thank you

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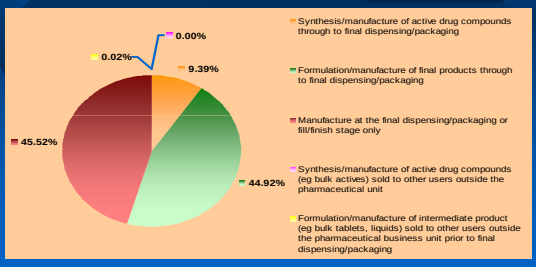
Industry Survey: Manufacturing

•Companies manufactured over **$4 billion** worth of ex-factory good in Australia **in 2006**, and **increase of 21% from 2005**.



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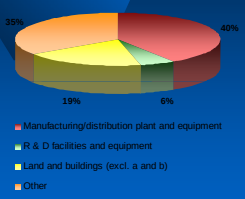
Industry Survey: Capital Expenditure



•Companies reported spending over **$155 million** on capital expenditure in 2006, which is **11.5%** higher than capital expenditure in 2005.

•The average nominal growth rate of capital expenditure since 2004 has been approximately **6.2%** (compared to and average of **19%** for the whole of the Australian manufacturing sector).

•The pharmaceuticals manufacturing sector has shown volatility in capital expenditure. **The innovative pharmaceuticals industry's level of capital expenditure is significantly lower than in the mid-1990s.**

•Annual capital expenditure has **declined** approximately **50%** since the mid-1990s.

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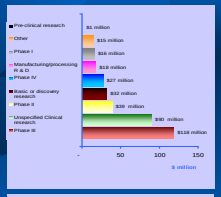
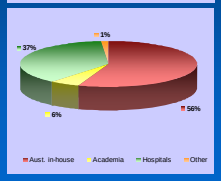
Industry Survey: Research and Development





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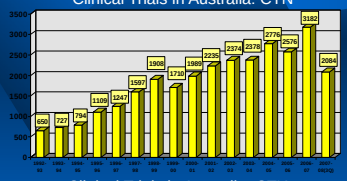
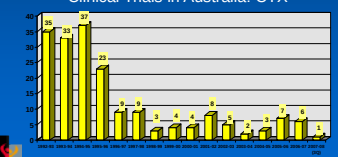
Industry Survey: Clinical Trials

Clinical Trials in Australia: CTN



Clinical Trials in Australia: CTX



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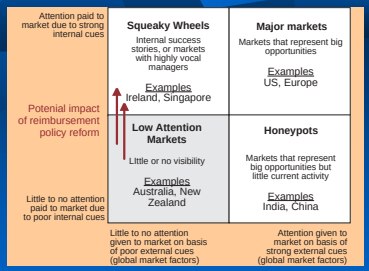
MARKET CLASSIFICATIONS ACCORDING TO SOURCES OF GLOBAL ATTENTION



Source: The Allen Consulting Group adaptation of London Business School's Sources of Global Attention framework, see, Birkinshaw, J., and C. Bouquet, 2005, *Getting the Attention You Need: Strategies for the Australian Subsidiary*, London Business School in association with CEO Forum.

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The Allen Consulting Group, Drivers of Pharmaceutical Investment, 2005

Industry Survey: Drivers and Barriers to Investment in Australia

Companies identified the following as the most positive influences on leverage with head office:

•Quality of labour
•R&D environment
•Location of Australia in Asia Pacific
•Drug registration

Companies identified the following as the most negative influences on leverage with head office:

•PBS listing
•PBS prices/controls
•12.5% pricing measure
•Policy towards generics

Companies identified the following as the most positive influences on development in Australia:

•Quality of labour
•Patents/intellectual property
•Economic environment
•R&D and political environment

Companies identified the following as the most negative influences on development in Australia:

•12.5% pricing measure post-PBS reform
•PBS prices/controls post-PBS reform
•12.5% pricing measure pre-PBS reform
•PBS listing & prescribing post-PBS reform

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Pharma Industry Policy

- Pharmaceutical Partnerships Program (P3) ends July 2009
- No industry development program to follow
- Has been IDPs since 1988 – PIDP (Factor (f)), PIIP, P3
- Positive Industry policy to balance impact of PBS