Australia’s National Medicines Policy

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Australia’s National Medicines Policy

- Endorsed by parliament in 2000

Goal:
- To meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved

Objectives

• Timely access to the medicines that Australians need, at a cost individuals and the community can afford
• Medicines meeting appropriate standards of quality, safety and efficacy
• Quality use of medicines; and
• Maintaining a responsible and viable medicines industry
Figure 1: QUM and the National Medicines Policy

National policies related to health

Quality

Quality, safety & efficacy

Use of medicines

Equity of access

Viable & responsible pharmaceutical industry

Healthy consumers

Industry and trade policies
Medicines meeting appropriate standards of quality, safety and efficacy

- Achieved via the Therapeutic Goods Administration (est 1958)
- Approves for marketing
  - Prescription medicines
  - Over-the-counter medicines
  - Complementary therapies
- Current policy development, harmonisation of regulatory arrangements with New Zealand
Maintaining a responsible and viable pharmaceutical industry

- Industry development program established in 1988
- Pharmaceuticals Partnerships Program (P3)
- Provides $150 million over 5 years to support R&D
- Australian industry has achieved an average annual growth rate of 11% over the last five years
- Exports have risen from $1.13 billion in 1999 to $2.8 billion in 2004-05
Quality Use of Medicines

- National Strategy for Quality Use of Medicines
- Established 1992
- In response to strong consumer lobby

National Prescribing Service

- Newsletters & prescribing feedback to all GPs
- New drugs program
- Academic detailing, clinical audits, case studies,
  - over 50% of GPs voluntarily participate each year
- Consumer program
- Information lines
- Health professional curricula
- Over $100 million over 4 years

\[\text{http://www.nps.org.au/}\]
Quality use of medicines

- Medication reviews: community based (26,000 annually) & aged-care (all beds nationally)
- Medication Disposal Service (250 tonnes annually)
- National Therapeutic Guidelines
- Australian Medicines Handbook
- Consumer Medicine Information
Ensuring equitable access at a cost the individual and community can afford

- **Australia’s Pharmaceutical Benefits Scheme**
  - Universal access to necessary medicines
  - Initiated in 1950, with 139 life saving and disease preventing medications available free
  - Today, ~ 600 medicines (1500 formulations, 2600 products)
  - Accounts for over 90% of all community medicine use in Australia
Australia’s Pharmaceutical Benefits Scheme

- 288 require prior authorization
- Consumers pay a proportion of total costs
  - $4.70 for social security beneficiaries
  - $29.50 for general beneficiaries
- Safety net system
  - Maximum social security beneficiaries annual costs $253.80 per family, then supplied free.
  - Maximum costs of $960.10 per family per annum for general beneficiaries
Assessment of medicines for reimbursement

- Pharmaceutical Benefits Advisory Committee (PBAC)
  - Statutory committee established under the National Health Act
  - Health minister cannot list a medicine under the scheme without a positive recommendation from the PBAC
Assessment of medicines for reimbursement

- Sponsor (usually industry) makes requests for listing, including type of listing (e.g. generally available, restricted or prior authorization)
- In assessing medicines for listing, the PBAC is required by legislation to consider:
  - Comparative efficacy
  - Comparative safety
  - Cost-effectiveness (mandatory since 1993)
    - Cost-minimisation assessment or cost-effectiveness assessment, includes whole of health costs
Some questions
Will our access policies restrict industry R&D?

- Pharmaceutical R&D in Australia grew at a rate of 16% per annum from 1998/99 to 2000/01

- Compared to overall growth in R&D expenditure of 3.5% (1996/97 – 2002/03)

Source: Evaluation of the Pharmaceutical Industry Investment Program 2003; Shanks and Zheng 2006
Globally pharmaceutical R&D is increasing as a proportion of all health expenditure.

USA, Canada, Germany, France and Japan (WHO 2004)
Is cost-effectiveness assessment a form of price constraint?

Or does it reflect value for money and reward innovation for health gain?
Medicines fast tracked by FDA or labelled innovative by Canada because of health gain

- Agalsidase beta
- Amprenavir
- Drotrecogin alfa
- Emtricitabine
- Enfuvirtide
- Imatinib
- Etanercept
- Fosamprenavir
- Gefitinib
- Lopinavir/ritonavir
- Infliximab

- Riluzole
- Docetaxel
- Interferon gamma
- Peginterferon alfa
- Pemetrexed
- Apomorphine
- Anastrozole
- Imiglucerase
- Oxaliplatin
- Tenofovir
- Verteporfin
<table>
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<tr>
<th>Proprietary Name (INN))</th>
<th>FSS $US</th>
<th>Big 4 $US</th>
<th>AUS (PBS) $US</th>
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Australian prices are commonly higher for new medicines which offer health gain

- When considering all 22 products, Australian prices were higher than FSS and Big 4 on 64% of occasions
- Australian prices were lowest on 27% of occasions
Does reference pricing restrict access?

- The PBAC cannot reject a medicine that proves cost-equivalent
- Thus, you do not see in Australia only some medicines from a class on the schedule
  - For example, there are 12 NSAIDs listed (30 formulations, 71 products);
  6 SSRIs (12 formulations; 60 products)
  20 antidepressants in total (42 formulations)
- We do not tender for lowest price product within a class
New molecular entities have significant market share in Australia.
Conclusion

- Australia’s National Medicines Policy is about holding the balance between all aspects of the pharmaceutical system
- This is a local and a global challenge
Conclusion

• “In the final analysis, medicinal drug policies are concerned with more than drugs. They are fundamentally about people and their relationships with one another. They are concerned with achieving a balance: between economic growth and social justice; wealth and poverty; regulation and freedom; risk and certainty; incentives and sanctions; costs and benefits; suspicion and trust; isolation and involvement”.

Mary Murray, Ken Harvey