

Australia's National Medicines Policy

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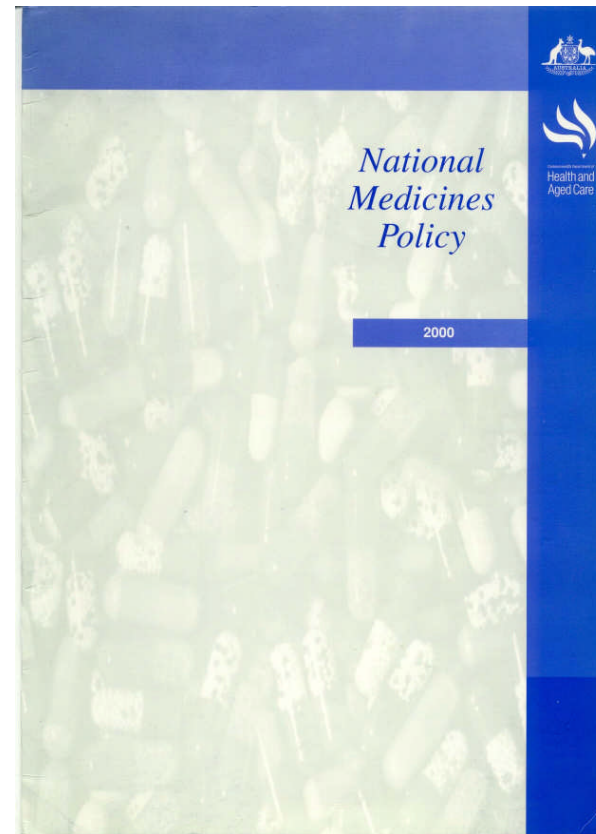


Australia's National Medicines Policy

- Endorsed by parliament in 2000

Goal:

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



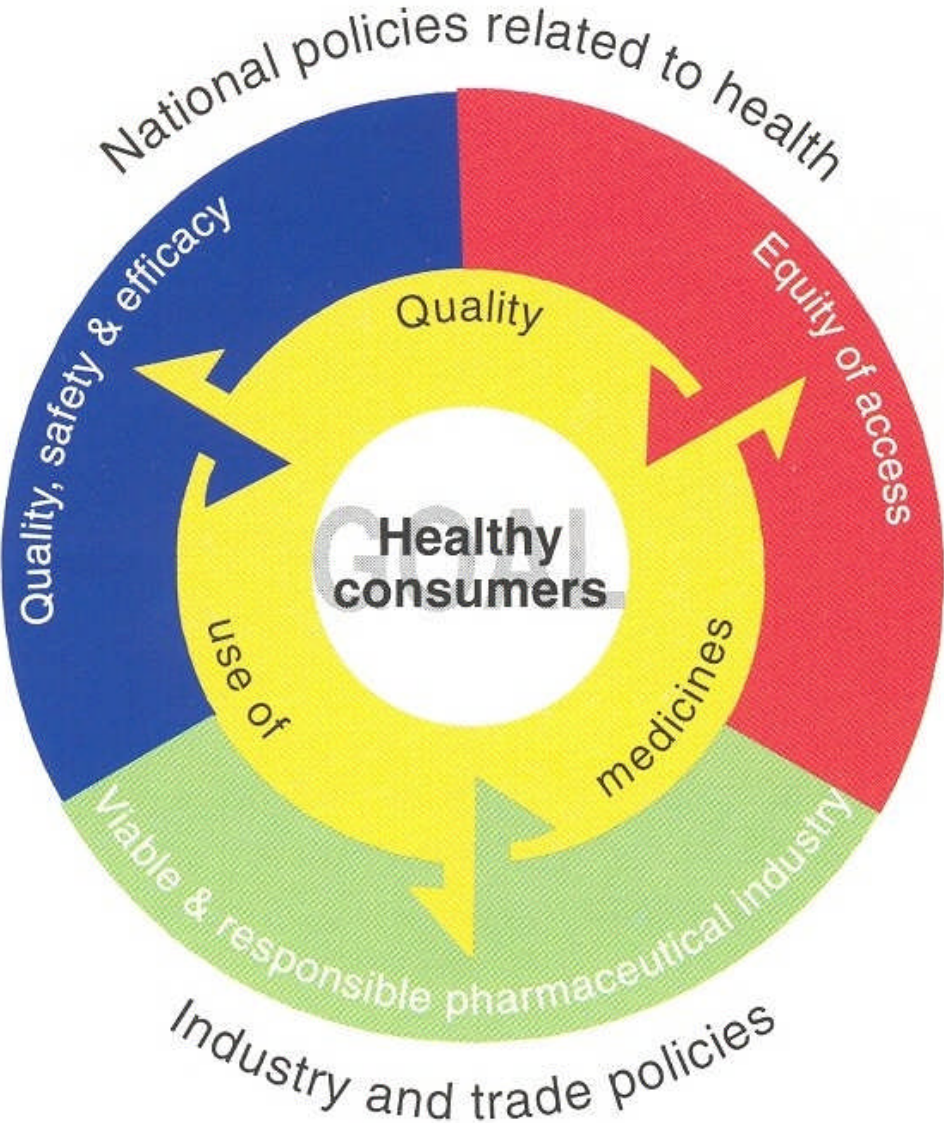
<http://www.health.gov.au/nmp/objectives/policy.htm>

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



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



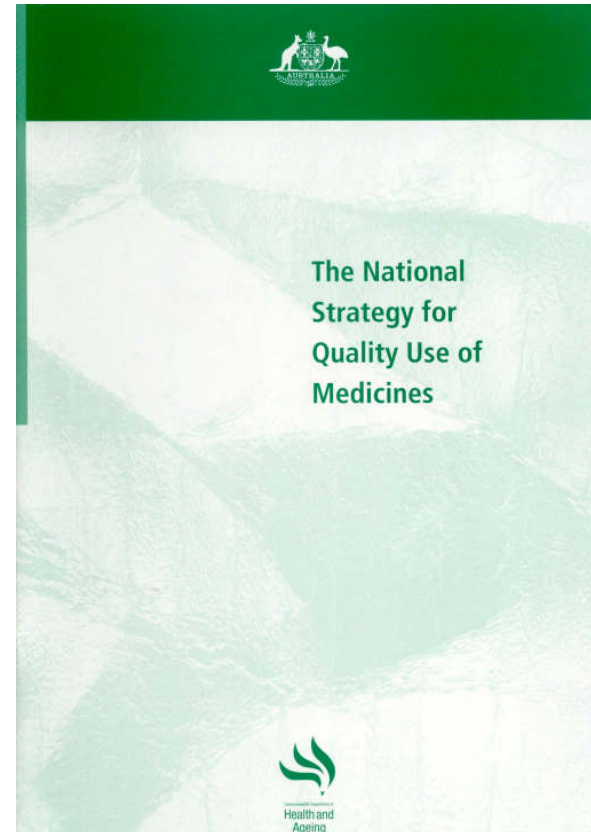
Maintaining a responsible and viable pharmaceutical industry

- 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



<http://www.health.gov.au/nmp/quality.htm>



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

NPS NEWS
National Prescribing Service Newsletter

18 2001
ISSN 1447-9421 October 2001

Inside ▶
COX-2 inhibitors: Selective but still NSAIDs
A complementary update: Glucosamine

Osteoarthritis—have COX-2s changed its management?

Nonsteroidal anti-inflammatory drugs (NSAIDs) are used widely to treat pain and inflammation. The rapid uptake in prescribing of the new COX-2 (Vioxx[®])—has newer drugs and drugs truly safe reduce the risk. Inside we answer these new questions with osteoarthritis.

Practice Visits Program
National Prescribing Service Limited

Non-drug
The aim of therapy and stiffness, improve individual's quality step in treatment.
Weight loss is on placed on weight-
Physiotherapy is flexibility of the at the joint, and provide individual's capabilities cause pain or further precipitate latent.
Occupational therapy devices include a affected knee), or
Educating the patient is very important, such as seeking relief pain. Educating the patient to provide support telephone contact the person's over a trial of superficial transcutaneous electrical relief during episode.

Management of URTIs and acute bronchitis in general practice
National Prescribing Service Limited

- Uncomplicated URTIs and acute bronchitis in general practice are most often caused by
- Most bacteria in particular
- Antibiotic outweigh
- Use antibiotic spectrum
- It is unnecessary. E.g. In acute and cover
- The management made explicit should be now available

Audit of provision of over-the-counter NSAIDs
National Prescribing Service Limited

Using this form This form can be used by graduate/trainee pharmacists and non-pharmacist staff as well as by the pharmacist. It acts as a guide to the information that should be used to appropriately advise on OTC NSAID use for adults. Tick all applicable boxes to indicate answers.
NB If the customer's answers result in a tick in any box with a heavy red border , graduate/trainee pharmacists and non-pharmacist staff should refer the customer to the pharmacist for advice.

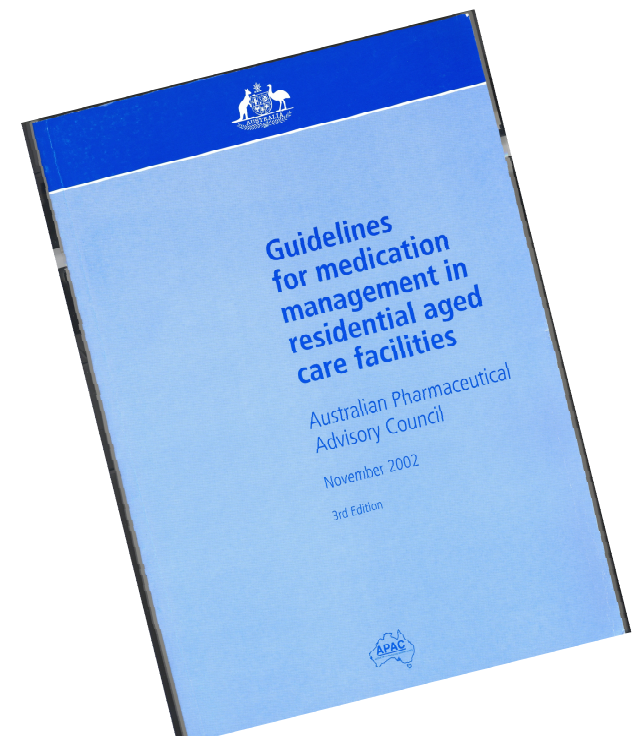
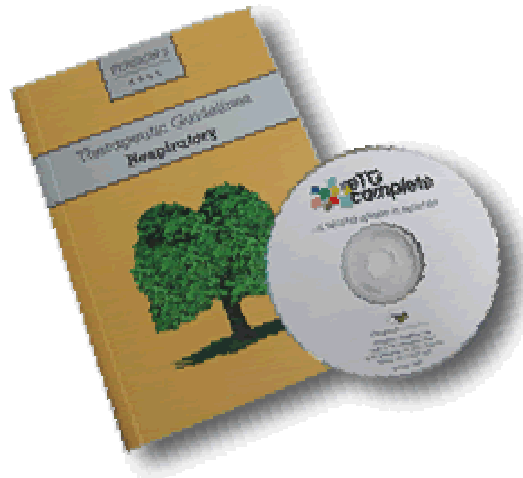
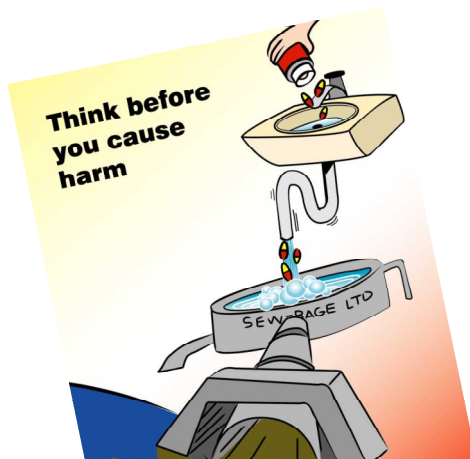
Auditing the request	Therapeutic notes from guidelines ^{3,4}
Did the customer ... make a direct request for an NSAID? <input type="checkbox"/> present with a symptom-based request for which you considered an NSAID? <input type="checkbox"/>	assess symptoms
Who is the patient? adult 13-65 years <input type="checkbox"/> older adult >65 years <input type="checkbox"/> customer not asked <input type="checkbox"/>	NSAIDs ↑ risk gastrointestinal (GI) ulceration & renal impairment
What are the symptoms? fever <input type="checkbox"/> headache <input type="checkbox"/>	paracetamol recommended paracetamol or aspirin usually recommended



• <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



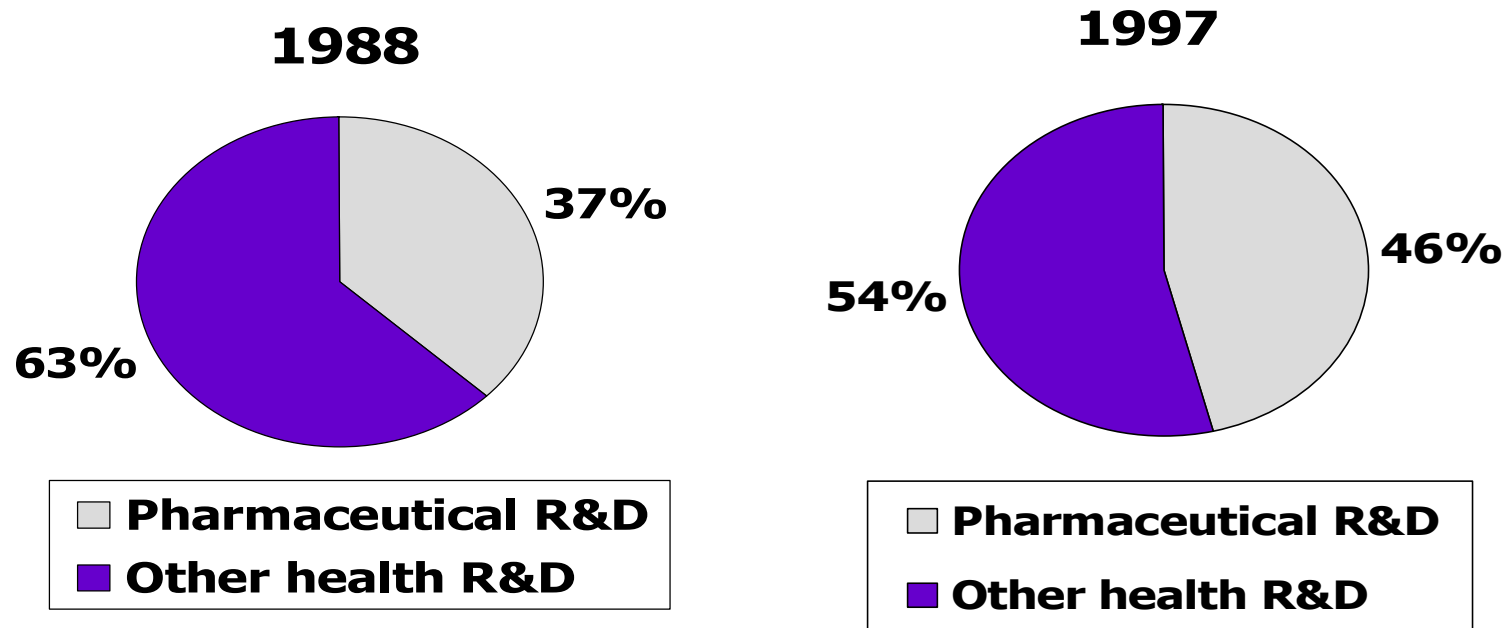
Will our access policies restrict industry R&D?

- 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



Proprietary Name (INN)	FSS \$US	Big 4 \$US	AUS (PBS) \$US
Agalsidase beta	3016	-	4626
Amprenavir	32	23	15
Anastrozole	189	142	123
Apomorphine	63	-	15
Docetaxel	790	-	900
Drotrecogin alfa	892	657	1263
Emtricitabine	167	-	216
Enfuvirtide	1707	1282	1697
Etanercept	360	360	625
Fosamprenavir	519	386	436
Gefitinib	1548	1196	2841
Imatinib	2412	1835	2891

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



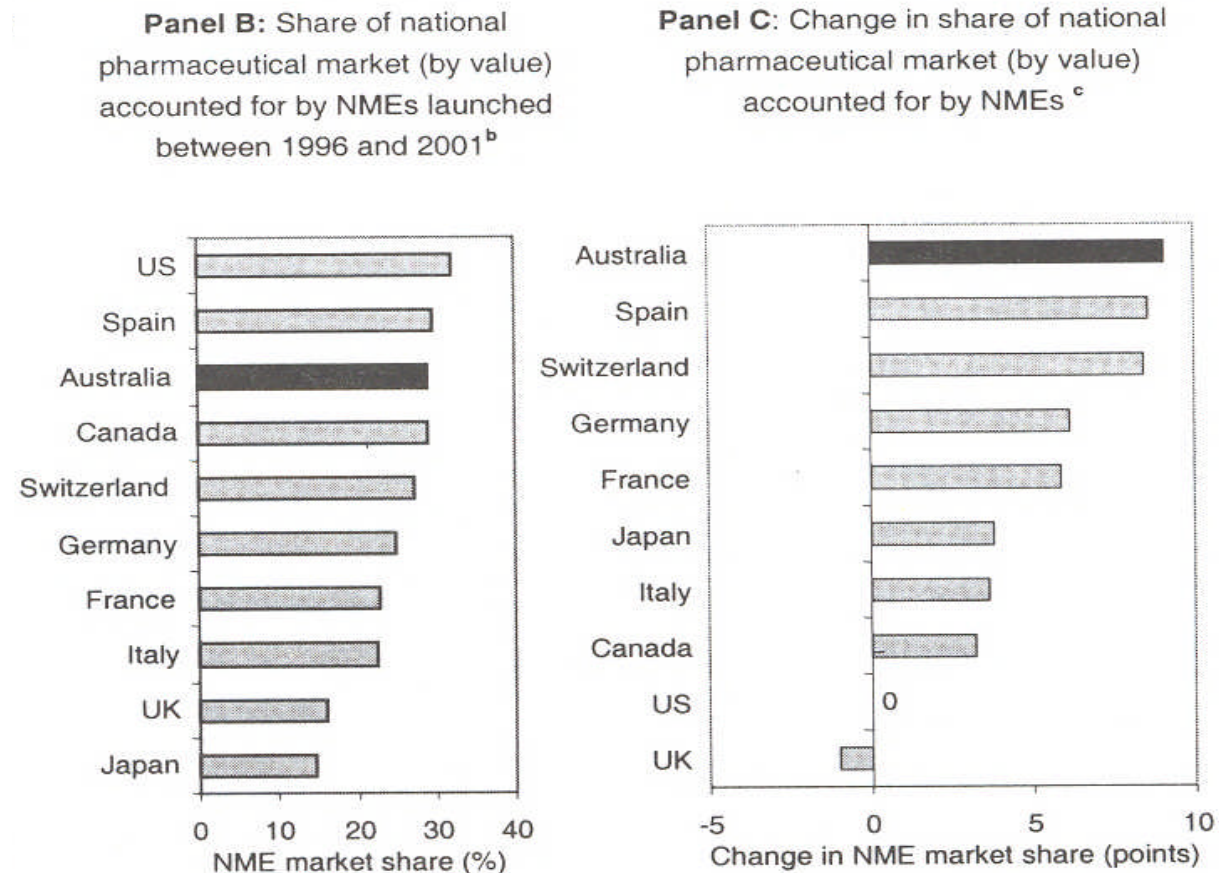
Does reference pricing restrict access?

- 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

Figure 3.1 Measures of the penetration of new molecular entities in different countries



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

