Pharmaceutical policies in Australia and New Zealand


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Editor-in-Chief, Journal of Pharmaceutical Policy and Practice
Salient features

- Medicines pricing policies in Australia and NZ
- Access to medicines in Australia and NZ
# Comparison of subsidised patient access in Australia and New Zealand

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Subsidized patient access system</th>
<th>Coverage</th>
<th>Patient co-payment</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Pharmaceutical Benefit Scheme</td>
<td>Universal coverage of subsidised medicines for Australian residents</td>
<td>AU$ 37.70 (adult) AU$ 6.10 (concession)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>PHARMAC</td>
<td>Universal coverage of subsidised medicines for NZ residents</td>
<td>NZ$5 Free for children</td>
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</table>

Medicines New Zealand

Contributing to good health outcomes for all New Zealanders
Pharmaceutical Management Agency of New Zealand (PHARMAC)

- Established in 1993 by Government
- Single purchaser of pharmaceuticals (PHARMAC)
- PHARMAC’s key role is to decide whether a medicine will be subsidised or not
- It negotiate prices with pharmaceutical manufacturers
- Pharmac uses rebates on list prices, reference pricing, tendering for generics and sole supply contracts, bundle agreements (where PHARMAC may list expensive new drugs in return for the manufacturer discounting the price of other products it supplies)
- The listed price in the Pharmaceutical Schedule for the new medicine may not include the the overall discount obtained by PHARMAC
Impact of PHARMAC on drug expenditure

Pharmac continued to run commercial processes to extract value from currently-funded medications, by reducing expenditure in the following areas:

- Pharmaceutical cancer treatments from 2011/12
- Vaccines from 2012/13
- Haemophilia treatments from 2013/14

The graph shows the net drug cost ($ millions) from 2003 to 2014, with actual expenditure and estimated expenditure at 2003 subsidies.
Medicines prices in NZ

There was general appreciation shown towards PHARMAC’s strategy of creating competition in order to achieve a lower purchasing price.

However

- PHARMAC policy on reference pricing (only one member of a therapeutic class is funded) negatively impacts on GPs clinical decisions (58% agree)
- Prices of non-subsidised medicines are high?

Medicines prices in Australia

- Reference pricing and value based pricing have been the main policies used for the pricing of subsidised medicines
- Overall, these policies have been effective in decreasing medicines prices
- However, there are still higher prices of generic medicines in Australia compared to other countries.

Access to generic medicines - Comparison of Australia & England

- Pricing comparison of Australia and England

- Analysis of drug reimbursement prices for 15 generic molecules (representing 45 different drug presentations) demonstrated that Australian prices were on average over 7 fold higher than England.

Medicines prices in Australia

• The high prices requested for new medicines may now represent the most pressing challenge faced by the Australian PBS

• Generic medicine price reforms have included mandatory price reductions and price disclosure cycles
  – The objective is to align PBS prices for generic medicines with pharmacy purchase prices.

Australia/NZ price comparisons with Europe
Price Comparison between NZ and European Countries

• New Zealand prices were found in the lowest quartile for five medicines and in the highest quartile for seven other products.
• Price differences between the originator products and generic versions ranged from 0% to 90%
• Medicine prices varied considerably between European countries and New Zealand as well as among the European countries.

Price Comparison between NZ and European Countries

- New Zealand’s prices ranked lowest in four cases
  - abacavir,
  - escitalopram generic version,
  - mycophenolate mofetil orginator version,
  - pioglitazone generic version
- The medicines in the highest quartile in New Zealand were
  - darunavir ethanolate,
  - indinavir,
  - insulin lipro,
  - sunitinib,
  - venlafaxine, (the latter being both the originator and the comparable generic version)
- For prasugel (highest price in New Zealand), the New Zealand price is 25% higher than that of the highest-priced medicine in the European countries.
# Price Comparison between NZ and European Countries

<table>
<thead>
<tr>
<th>No</th>
<th>NZ Lowest</th>
<th>NZ highest</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>abacavir</td>
<td>darunavir</td>
</tr>
<tr>
<td>2</td>
<td>escitalopram generic version, ethanolate</td>
<td>indinavir</td>
</tr>
<tr>
<td>3</td>
<td>mycophenolate mofetil orginator version</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>pioglitazone generic version</td>
<td>insulin lipro</td>
</tr>
<tr>
<td>5</td>
<td>sunitinib, and venlafaxine</td>
<td></td>
</tr>
</tbody>
</table>
Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished data)

- Official list prices per unit at ex-factory price level of 31 originator oncology medicines in 16 European countries, Australia and New Zealand were surveyed as of June 2013.

- Medicine price data for the European countries were provided by the Pharma Price Information (PPRI) service.

- Australian and New Zealand medicine price data were retrieved from the respective Pharmaceutical Schedules.
Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished data)

- Data availability was higher in the European countries compared with Australia and particularly New Zealand.

- Oncology medicines are highly priced.
  - None of the medicines surveyed had a unit price below €10 in the 18 surveyed countries.
  - Five medicines had an average unit ex-factory price between €250 and €1000, and seven medicines had an average unit price above €1000
Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished draft)

• Medicine prices varied across Europe, Australia and New Zealand.
• No relevant price differences of Australia and New Zealand in comparison with European countries were found
• However, these official list prices do not include discounts and similar arrangements that are in place for several of the surveyed medicines in a number of countries.
  – Issues and impact (If NZ prices are used as external reference prices in other countries, Brazil, South Africa etc)
Boxplot of medicine prices (ex-factory price per unit) indexed (price in the lowest priced country = 100), as of June 2013 (August 2013 for New Zealand), in 16 European countries, Australia and New Zealand

AU (n = 18) = blue diamond, NZ (n = 11) = red triangle
## Medicines pricing issues in Australia and New Zealand

<table>
<thead>
<tr>
<th>Countries</th>
<th>Evidence exist/what has worked</th>
<th>Challenges and Gaps in Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ</td>
<td>Low prices in government sector</td>
<td>• Research regarding prices of drugs not covered by Pharmac</td>
</tr>
<tr>
<td></td>
<td>Pharmac is monoposnly purchaser</td>
<td>• Impact of TPPA on prices</td>
</tr>
<tr>
<td>Australia</td>
<td>Generic medicine price reforms have included mandatory price reductions and price disclosure cycles</td>
<td>• High prices of generics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Price agreement for new medicines</td>
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</table>
Access to medicines situation in Australia and NZ
New Zealand
New Zealand

- New Zealand’s Access to medicines comparison with other countries
- General practitioners' perceptions regarding access to medicines in New Zealand
- Ethnic differences in access to prescription medicines because of cost in New Zealand.
- Identifying priority medicines policy issues for New Zealand.
New Zealand’s Access to medicines comparison with other countries

- PHARMAC funded fewer medicines than Finland’s public health system in 2007, 471 unique entities compared to 495. (Aaltonen et al. 2010).

- PHARMAC also funded fewer entities (503) than the Australian Pharmaceutical Benefit’s Scheme (567), the United Kingdom’s National Health Service (1016) and the United States Department of Veterans Affairs National Formulary (505) in 2007. (Ragupathy et al. 2012a).
The range of new prescription medicines in NZ and Australia in the period 2000 to 2009 were compared. A separate comparison of Australia and New Zealand found that PHARMAC only subsidised 59 (43%) of the 136 new prescription medicines subsidised by the Pharmaceutical Benefits Scheme between 2000 and 2009. Conversely, only four medicines were subsidised by PHARMAC but not the Pharmaceutical Benefits Scheme.

The remaining 77 medicines that are reimbursed in Australia but not in NZ cover a wide range of therapeutic areas, including some diseases for which there are no reimbursed medicines in NZ.
Moodie P, Metcalfe S, Poynton M

• Different time periods, metrics and opportunities to
  – Wonder and Milne have used a long time period to gather their data.
  – Had they reviewed the last 2 years, where the Government has invested significant new money in pharmaceuticals, the lists would have looked significantly different with some 59 new medicines funded in New Zealand during that period.

• There are also differences between the two countries in opportunities for funding.

• Also Pharmaceutical suppliers decide when they will bring products to market in each country
A qualitative evaluation of general practitioners' perceptions regarding access to medicines in New Zealand

• The research concluded that although there were some issues with the availability of certain drugs, most GPs were satisfied with the broader access to medicines situation in New Zealand.
• The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding of medicines could be improved with better systems.


http://bmjopen.bmj.com/content/2/2/e000518.full
General practitioners' opinions on access to medicines in NZ

- Questionnaire, via PHO’s, North Island


<table>
<thead>
<tr>
<th>Statements</th>
<th>agree</th>
<th>neutral</th>
<th>disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <strong>range of medicines</strong> available in NZ is <strong>adequate</strong> to treat all the health conditions I see in my daily practice.</td>
<td>53%</td>
<td>23%</td>
<td>24%</td>
</tr>
<tr>
<td>Whether NZ takes <strong>too long to subsidise</strong> newer medicines available in other OECD countries such as Australia.</td>
<td>73%</td>
<td>19%</td>
<td>8%</td>
</tr>
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<th>Statements</th>
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<th>neutral</th>
<th>disagree</th>
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<tr>
<td>PHARMAC sole supply policy (only <em>one brand</em> of a medicine is funded) <em>negatively</em> impacts on my clinical decisions</td>
<td>53%</td>
<td>23%</td>
<td>24%</td>
</tr>
<tr>
<td>PHARMAC is <em>effective</em> in managing the budget for community medicines and achieves the widest possible range of medicines from the available funds.</td>
<td>56%</td>
<td>32%</td>
<td>12%</td>
</tr>
</tbody>
</table>

- Out of a total of 18 320 respondents, 6.4% reported that they had deferred collecting a prescription at least once during the preceding 12 months because they could not afford the cost of collecting the prescription.

- Younger adults aged 15–24 years, females, smokers, Māori and Pacific patients, and those with the lowest income status were more likely not to obtain or buy prescription drugs because of cost barriers.

- Policy measures to further reduce financial barriers to buying medication may improve access to care.
Identifying priority medicines policy issues for New Zealand.

Broad themes identified

- General Medicines Policy issues
- Ethnicity
- High cost medicines
- Transpacific partnership agreement
- Pharmac
Broad themes identified

General Medicines Policy issues
- Low socioeconomic patients were considered to have a higher burden of disease.
- Affordability - 2013 raise in prescription co-payment from NZ$3 to NZ$5.
- Abuse of community services cards
- Sole supply provision raised issues in terms of: supply outages when switching supplier

Ethnicity
- Higher burden of disease in Maori & Pacifica population
- Inequity lens required when GPs are prescribing for Maori & Pacifica population
- Health literacy for consumers
- English as second language for consumers
- Usage of traditional and alternative treatments
  - Safety & negating effects (M)
PHARMAC

• There was general appreciation shown towards PHARMAC’s strategy of creating competition in order to achieve a lower purchasing price.
• Delays in the submission process of up to eight years and described as a “medicines waiting list,” were of concern
• Economic evaluations more complex
• Niche market medicines
  – (genomic & patient subgroup profiling)
Transpacific Partnership Agreement

- Patent extension, delaying generic entry to market, thereby prolonging a higher cost of provision
- Secrecy in the trade talks
- Quicker access to new medicines
- Industry transparency
- Increased appeals/litigation
- Impact upon healthcare
New Zealand’s medicines policy

Conclusion

• There was reasonable satisfaction with the New Zealand’s medicines policy and its principles.

• Some patient groups still experiencing difficulties in access.

• Such groups being rare disorders and the low socio economic (encompassing rural, Māori and Pacifica populations).

Future issues to deal

• The pharmaceutical industry’s pricing of new medicines

• Manufacturer and registration requirements

• Increasing demand for medicines and the resultant financial impact

• Budgetary constraints

• Cultural and health literacy

• Patient affordability and access to prescribers;
Australia
Australia

- Impact of cost sharing and medicines affordability
- Managed entry agreements for pharmaceuticals in Australia
- Challenges to Australia’s national medicines policy
Affordability of prescription medicines in Australia

• A 3 month cross-sectional study was conducted and patients were interviewed by telephone to report financial burden of obtaining prescription medicines in Australia.

• Extreme and heavy financial burdens were reported by 2.1% and 6.8% of participants, respectively.

• A moderate level of burden was experienced by a further 19.5%.

• The research suggests that the copayment and safety net threshold are not protecting nearly one third of Australian patients from financial burden.

Impact of cost sharing and medicines affordability

• The evidence consistently shows that costs sharing does not always act selectively
  – It could reduce the use of essential medicines as well as less important therapies, particularly among lower income groups.

• Decrease in use is associated with the uptake of more intensive and expensive health services.

• There is considerable evidence that ever-increasing co-payments applied to all is hurting australians

• Doran E, Robertson J. Australia’s pharmaceutical cost sharing policy: reducing waste or affordability. Australian Health Review May 2009 Vol 33 No 2
Managed entry agreements for pharmaceuticals in Australia

• In Australia, a number of managed entry agreements have been developed to enable national coverage of new medicines.
• However most of these agreements are non-outcome based agreements.
  – Non-outcome based agreement are usually pricing arrangement that involve price or volume rebate agreements.
  – The confidential nature of these agreements limits the evaluation of their benefits with regards to coverage and pricing of new medicines compared with other countries.

Managed entry agreements for pharmaceuticals in Australia

- In February 2013, there were at least 71 special pricing arrangements in place, including 26 for medicines restricted to use in hospitals.

- At the individual level, there were 28 medicines funded subject to continuation rules involving documentation of adequate benefit within the individual; some of these medicines also had price agreements in place.

- At the population level, only one outcome-based agreement has been implemented so far, for bosentan, a medicine marketed for pulmonary hypertension.

Challenges to pharmaceutical policy making: lessons from Australia’s national medicines policy

• National medicines policies (NMP) provide a means for governments to achieve their objectives in relation to pharmaceuticals

• Lipworth et al. conducted a qualitative study aimed to explore drug development, clinical research and the regulation and funding of medicines from the perspective of all key stakeholders.

### Challenges for National Medicines Policy of Australia

<table>
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<tr>
<th>Challenges</th>
<th>Relevant NMP domains and how they are affected</th>
</tr>
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<tbody>
<tr>
<td><strong>Ensuring safe and effective medicines</strong></td>
<td><strong>Ensuring access to affordable medicines</strong></td>
</tr>
<tr>
<td>Competing Commercial &amp; public health interest</td>
<td>• Lack of industry commitment to pharmacovigilance and post-marketing research</td>
</tr>
<tr>
<td></td>
<td>• Industry overpricing medicines</td>
</tr>
<tr>
<td></td>
<td>• Excessive regulatory caution</td>
</tr>
<tr>
<td></td>
<td>• Unrealistic demands for clinical data from payers &amp; regulators</td>
</tr>
<tr>
<td></td>
<td>• Drug pricing reforms making investment unappealing</td>
</tr>
<tr>
<td>Lack of government funding</td>
<td>• Reliance of TGA on industry funding</td>
</tr>
<tr>
<td></td>
<td>• Lack of funding for post-marketing research</td>
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<tr>
<td></td>
<td>• Inadequate funding of medicines through the PBS</td>
</tr>
<tr>
<td></td>
<td>• Inadequate government support for the pharmaceutical industry</td>
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<td>• Inadequate government support for academic drug development research</td>
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<td></td>
<td>Promoting a viable medicines industry</td>
</tr>
<tr>
<td>Globalisation of drug development</td>
<td>• Questions about generalisability of clinical research data to local populations</td>
</tr>
<tr>
<td></td>
<td>• Lack of local clinical knowledge about/early access to innovative medicines</td>
</tr>
<tr>
<td>Consumer advocacy</td>
<td>• Possible consumer over-reactions to safety concerns</td>
</tr>
<tr>
<td>Changing scientific paradigms (e.g. targeted therapies)</td>
<td>• Difficulty interpreting safety and effectiveness data from complex clinical trials</td>
</tr>
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<td></td>
<td>• Development of <code>me too</code> drugs v. genuine innovation</td>
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<td></td>
<td>• Increased expense of complex clinical trials</td>
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</table>
Conclusion
Similarities and differences between medicines policies of Australia and NZ

**Similarities**
- Patient co-payments and affordability
- Expensive new targeted therapies
- High cost medicines
- Managed Entry agreements
- Pharmaceutical industry pricing of new medicines

**Differences**
- Lack of support of pharmaceutical industry
- Lower uptake of generic medicines as compared to NZ
- Access to medicines