

Pharmaceutical policies in Australia and New Zealand

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Zaheer-UD-Din Babar, PhD
Head of Pharmacy Practice
School of Pharmacy, University of Auckland
z.babar@auckland.ac.nz

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

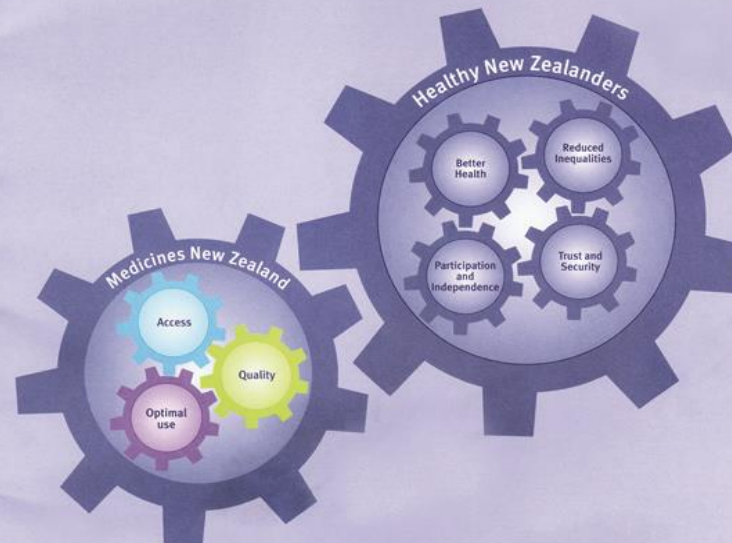
Jurisdiction	Subsidized patient access system	Coverage	Patient co-payment
Australia	Pharmaceutical Benefit Scheme	Universal coverage of subsidised medicines for Australian residents	AU\$ 37.70 (adult) AU\$ 6.10 (concession)
New Zealand	PHARMAC	Universal coverage of subsidised medicines for NZ residents	NZ\$5 Free for children

Cook G, Kim H. From Regulatory Approval to Subsidized Patient Access in the Asia-Pacific Region: A Comparison of Systems Across Australia, China, Japan, Korea, New Zealand, Taiwan, and Thailand
. Value in Health Regional Issues 6C (2015) 40–45

Medicines New Zealand

Medicines New Zealand

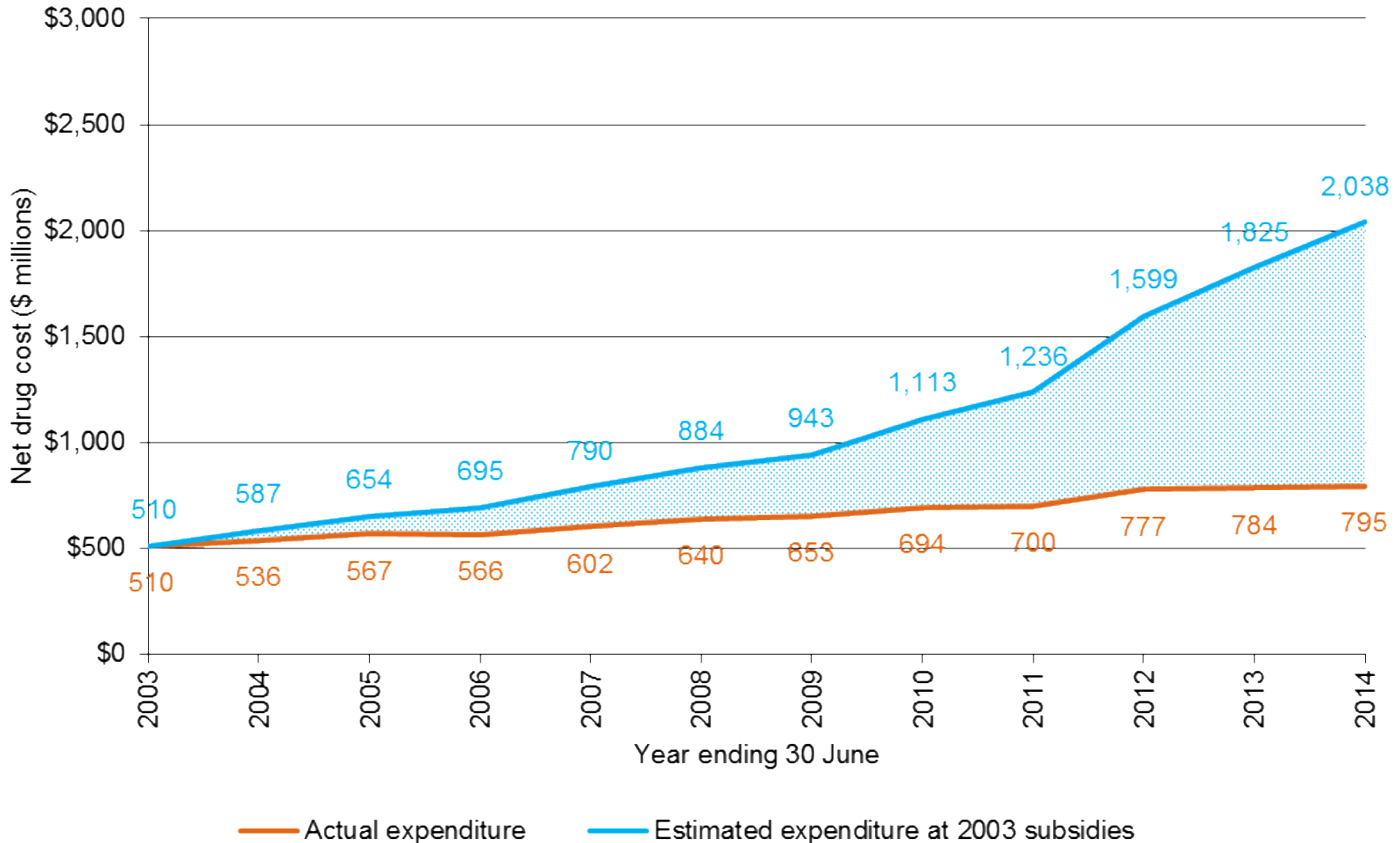
Contributing to good health outcomes
for all New Zealanders



Pharmaceutical Management Agency of New Zealand (PHARMAC)

- Established in 1993 by Governemnt
- 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



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?

Source: Babar, Z. -U. -D., Susan, F. Identifying priority medicines policy issues for New Zealand. *BMJ Open* 2014; 4(5):e004415

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.

Source: Vitry A, Thai RE. Pharmaceutical pricing Policies in Australia. In: Bazar, ZU, editor. Pharmaceutical Prices in the 21st Century. Springer Publishing. 2015; DOI: 10.1007/978-3-319-12169-7_1.

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

Sarah J. Mansfield. Generic drug prices and policy in Australia: room for improvement? A comparative analysis with England. *Australian Health Review*, 2014, 38, 6–15. <http://dx.doi.org/10.1071/AH12009>)

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.

Vogler S, Kilpatrick K, Babar ZU Analysis of Medicine Prices in New Zealand and 16 European Countries. *Value in Health* 2015 ; 18(4):484-492

Price Comparison between NZ and European Countries

- New Zealand's prices ranked lowest in four cases
 - abacavir,
 - escitalopram generic version,
 - mycophenolate mofetil originator 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

No	NZ Lowest	NZ highest
1	abacavir	darunavir
2	escitalopram generic version,	ethanolate
3	mycophenolate mofetil orginator version	indinavir
4	pioglitazone generic version	insulin lipro
5		sunitinib, and venlafaxine

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)

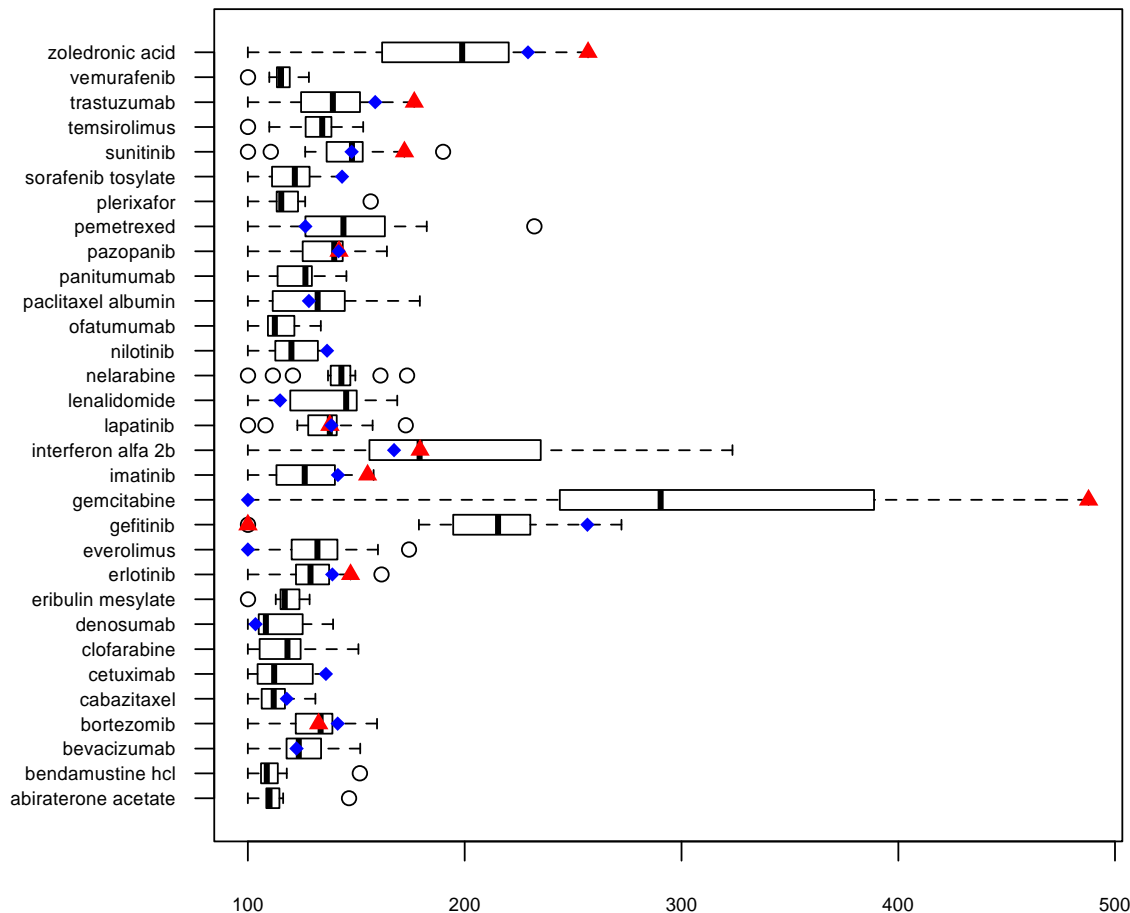
- Data availability was higher in the European countries compared with Australia and particularly New Zealand.
- Oncology medicines are highly priced.
 - None of the medicines surveyed had a unit price below €10 in the 18 surveyed countries.
 - Five medicines had an average unit ex-factory price between €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

Countries	Evidence exist/what has worked	Challenges and Gaps in Evidence
NZ	<p>Low prices in government sector</p> <p>Pharmac is monoposny purchaser</p>	<ul style="list-style-type: none"> • Research regarding prices of drugs not covered by Pharmac • Impact of TPPA on prices
Australia	<p>Generic medicine price reforms have included mandatory price reductions and price disclosure cycles</p>	<ul style="list-style-type: none"> • High prices of generics • Price agreement for new medicines

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).

Wonder M, Milne R. Access to new medicines in New Zealand and Australia. N Z Med J. 2011;124(1346).

<http://journal.nzma.org.nz/journal/124-1346/4966>

- 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

Do pharmaceutical score cards give us the answers we seek? NZMJ, Vol 124 No 1346, 2011. <http://journal.nzma.org.nz/journal/124-1346/4976/>

- **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

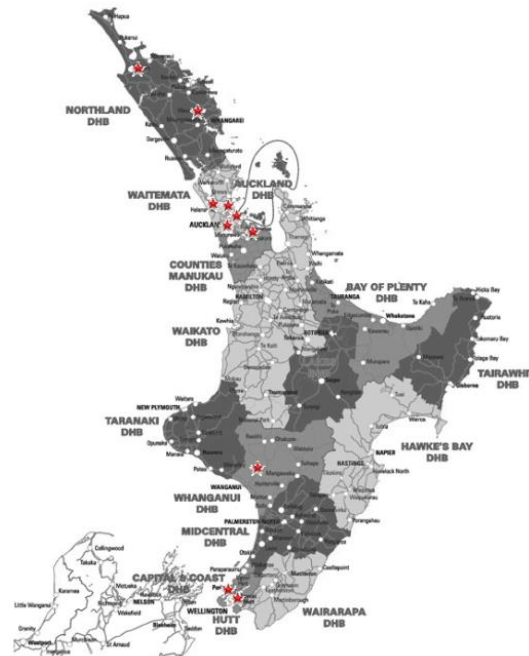
- The research concluded that although there were some issues with the availability of certain drugs, most GPs were satisfied with the broader access to medicines situation in New Zealand.
- The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding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

Babar ZU, Grover P, Rachael P, Bye L, Sheridan J. A qualitative evaluation of general practitioners' perceptions regarding access to medicines in New Zealand. *BMJ Open* 2012;2:e000518, March 28, 2012

<http://bmjopen.bmj.com/content/2/2/e000518.full>

General practitioners' opinions on access to medicines in NZ

- Questionnaire, via PHO's, North Island



Babar, Z.-U.-D., Lessing, C., Stewart, J., & Sheridan, J. (2015). Evaluating general practitioners' opinions on issues concerning access to medicines in New Zealand. *Journal of Pharmaceutical Health Services Research* 6;3:145-155

Babar, Z.-U.-D., Lessing, C., Stewart, J., & Sheridan, J. (2015). Evaluating general practitioners' opinions on issues concerning access to medicines in New Zealand. *Journal of Pharmaceutical Health Services Research* 6;3:145-155

Statements	agree	neutral	disagree
The range of medicines available in NZ is adequate to treat all the health conditions I see in my daily practice.	53%	23%	24%
Whether NZ takes too long to subsidise newer medicines available in other OECD countries such as Australia.	73%	19%	8%

Babar, Z.-U.-D., Lessing, C., Stewart, J., & Sheridan, J. (2015). Evaluating general practitioners' opinions on issues concerning access to medicines in New Zealand. *Journal of Pharmaceutical Health Services Research* 6;3:145-155

Statements	agree	neutral	disagree
PHARMAC sole supply policy (only <u>one brand</u> of a medicine is funded) negatively impacts on my clinical decisions	53%	23%	24%
PHARMAC is effective in managing the budget for community medicines and achieves the widest possible range of medicines from the available funds.	56%	32%	12%

Jatrana S, Crampton P, Norris P. Ethnic differences in access to prescription medication because of cost in New Zealand. J Epidemiol Community Health 2011;65:454–60.

http://jech.bmj.com/content/65/5/454.abstract?ijkey=2e30b5910d6eb1743f5278d10106af799b19265f&keytype2=tf_ipsecsha

- 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.

- Babar, Z. -U. -D., Susan, F. Identifying priority medicines policy issues for New Zealand. *BMJ Open* 2014; 4(5):e004415

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.
- *Andrew Searles, Evan Doran, Thomas A Faunce, David Henry. The affordability of prescription medicines in Australia: are copayments and safety net thresholds too high? Australian Health Review, 2013, 37, 32–40. <http://dx.doi.org/10.1071/AH11153>*

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.

Agnes Vitry, Elizabeth Roughead. Managed entry agreements for pharmaceuticals in Australia. Health Policy 117 (2014) 345–352.

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.

Agnes Vitry, Elizabeth Roughead. Managed entry agreements for pharmaceuticals in Australia. *Health Policy* 117 (2014) 345–352.

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.

Wendy Lipworth, Evan Doran, Ian Kerridge, Richard Day. Challenges to pharmaceutical policymaking: lessons from Australia's national medicines policy. *Australian Health Review*, 2014, 38, 160–168. <http://dx.doi.org/10.1071/AH13240>

Challenges for National Medicines Policy of Australia

Challenges	Relevant NMP domains and how they are affected		
	Ensuring safe and effective medicines	Ensuring access to affordable medicines	Promoting a viable medicines industry
Competing Commercial & public health interest	<ul style="list-style-type: none"> Lack of industry commitment to pharmacovigilance and post-marketing research 	<ul style="list-style-type: none"> Industry overpricing medicines 	<ul style="list-style-type: none"> Excessive regulatory caution Unrealistic demands for clinical data from payers & regulators Drug pricing reforms making investment unappealing
Lack of government funding	<ul style="list-style-type: none"> Reliance of TGA on industry funding Lack of funding for post-marketing research 	<ul style="list-style-type: none"> Inadequate funding of medicines through the PBS 	<ul style="list-style-type: none"> Inadequate government support for the pharmaceutical industry Inadequate government support for academic drug development research

Challenges for National Medicines Policy of Australia

Challenges	Relevant NMP domains and how they are affected		
	Ensuring safe and effective medicines	Ensuring access to affordable medicines	Promoting a viable medicines industry
Globalisation of drug development	<ul style="list-style-type: none"> • Questions about generalisability of clinical research data to local populations 	<ul style="list-style-type: none"> • Lack of local clinical knowledge about/early access to innovative medicines 	<ul style="list-style-type: none"> • Loss of investment in local clinical trials
Consumer advocacy	<ul style="list-style-type: none"> • Possible consumer over-reactions to safety concerns 	<ul style="list-style-type: none"> • Consumer advocates demanding access to expensive medicines irrespective of opportunity costs 	
Changing scientific paradigms (e.g. targeted therapies)	<ul style="list-style-type: none"> • Difficulty interpreting safety and effectiveness data from complex clinical trials • Development of 'me too' drugs v. genuine innovation 	<ul style="list-style-type: none"> • Payers being unwilling to fund therapies on the basis of small clinical trials • Population-level opportunity costs due to the expense of targeted therapies and companion diagnostics 	<ul style="list-style-type: none"> • Increased expense of complex clinical trials

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