Access to medicines, Pharmaceutical Policy, and Patient Health-Outcomes: What's the future like?

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Presentation Outline

- Pharmaceutical Policy
- Access to medicines and pharmaceutical policy
  - Examples from countries (Pakistan, Malaysia, Bangladesh, New Zealand, the UK and Global)

Why interested in Medicines?

A major intervention to improve health and well being

Growth in Global Medicine Spending : 2007-2021

- Global medicine spending
  - $370 billion, 2016
  - $1.5 trillion by 2021
- The total volume of medicines consumed globally will increase by about 3% annually through 2021.
- Biologics to contribute 52% of the Top 100 product sales by 2022

Source: IMS Market Prognosis, Sept 2016; QuintilesIMS Institute, Oct 2016

Global Per Capita Medicine Spending, 2007-2021

Country	US$
USA	1,955
Canada	776
Japan	739
Europe	577
Australia	513
South Korea	295
Pakistan, India, Bangladesh	20-30

Major challenges with regards to medicines!

- Half of medicine spending is in the U.S. and EU followed by Europe, Japan and emerging economies
- Specialty medicines growth such as Cancer, diabetes, autoimmune disorders etc
- Drug expenditure has risen faster than other healthcare costs in many countries.
  - New high-priced drugs
  - Aging population
  - Increased more demand for speciality treatment/products by patients

Access to medicines and National Medicines Policy

Pharmaceutical policy deals with the development, provision, and use of drugs within a healthcare system.

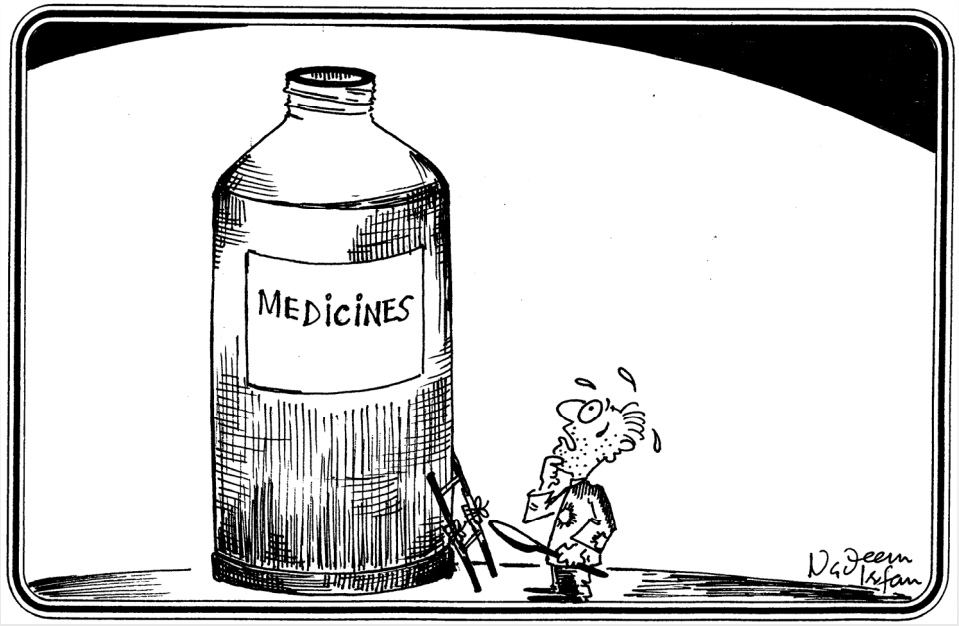
- Safety
- Effectiveness
- Quality
- Medicines Use
- Medicines Access (affordability)

Access to Essential Medicines

- UN Sustainable Development Goal 3.8 specifically mentions the importance of “access to safe, effective, quality and affordable essential medicines for all”

Access to affordable medicines-a fundamental human right

- 400 million people lack health care, including access to medicines
  - 300 million live in middle-income countries.
- Major issue in 2016 US elections
  - $1,000-per-pill hepatitis C treatments,
- In Europe, serious concern that yearly price increases will break health system budgets.



The United Nations Secretary-General's High-Level Panel on Access to Medicines Report, September 14, 2016

Suerie Moon, Powerful Ideas for Global Access to Medicines. N Engl J Med 2017; 376:505-507 2017 DOI: 10.1056/NEJMp1613861

Lancet Commission on Essential medicines Report

- The Lancet Commission estimated that between US$77·4 and $151·9 billion (or $13 to $25 per capita) is required to finance a basic package of 201 essential medicines in all LMICs.
- In 2010, many LMICs spent less than $13 per capita on pharmaceuticals.
- **Total expenditures on medicines**
  - **Poor Countries: 9.5 %**
  - **High income countries: 3.5%**

Affordability of key asthma medicines, a case study example in 52 low and middle income countries !

ISAAC team help to drive and publish world first Global Asthma Report 2011

International Union Against Tuberculosis and Lung Disease
Health solutions for the poor

ISAAC
The International Study of Asthma and Allergies in Childhood

Essential Medicines: Pricing, Availability and Affordability

Zaheer-Ud-Din Babar, Charon Lessing, Karen Bissell, Cécile Macé

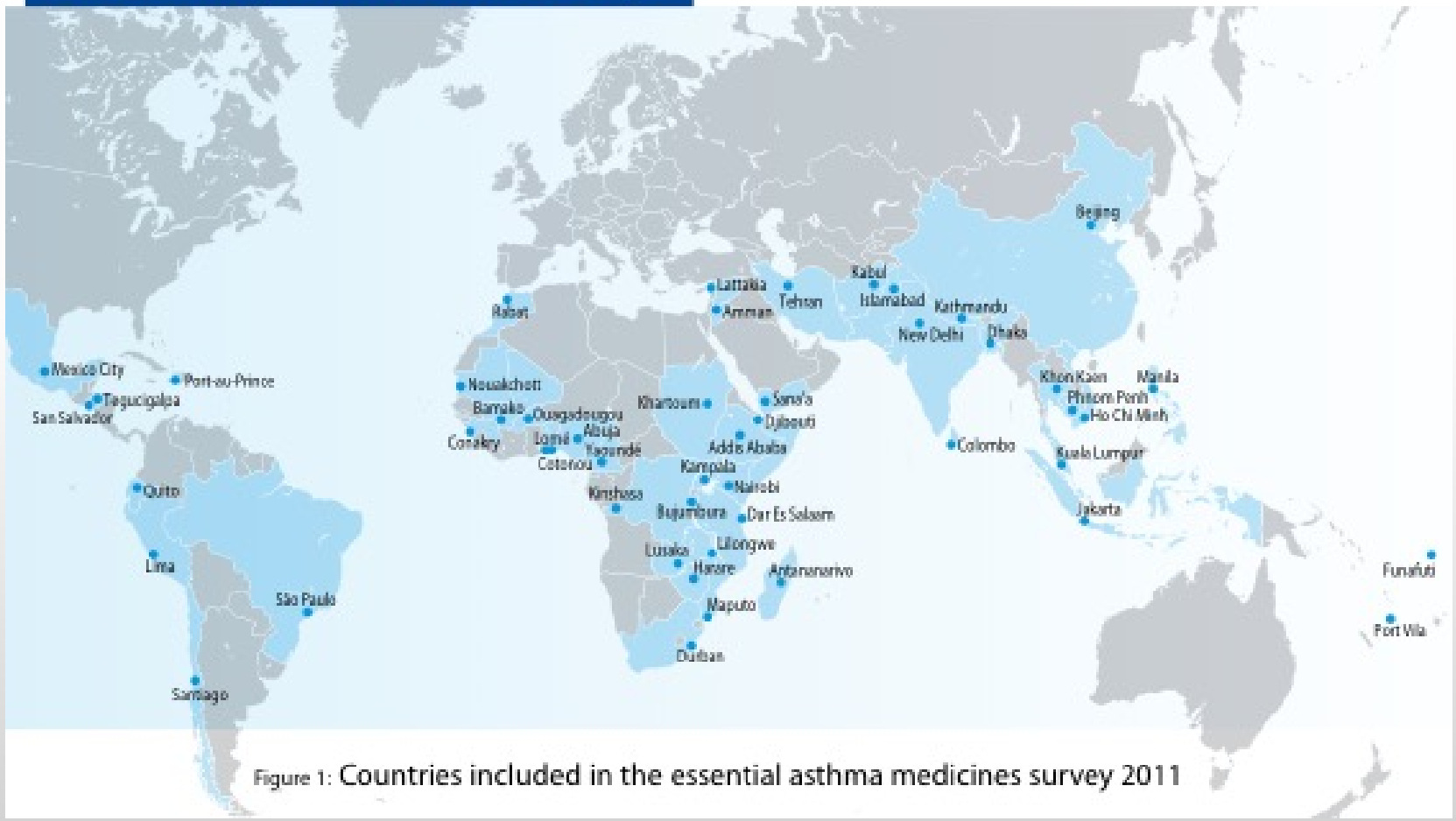
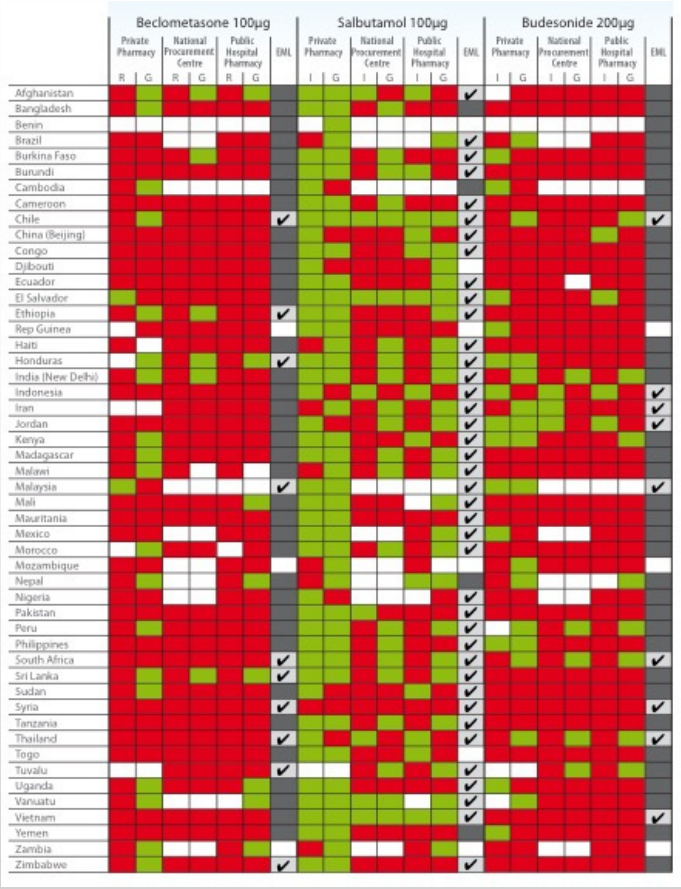
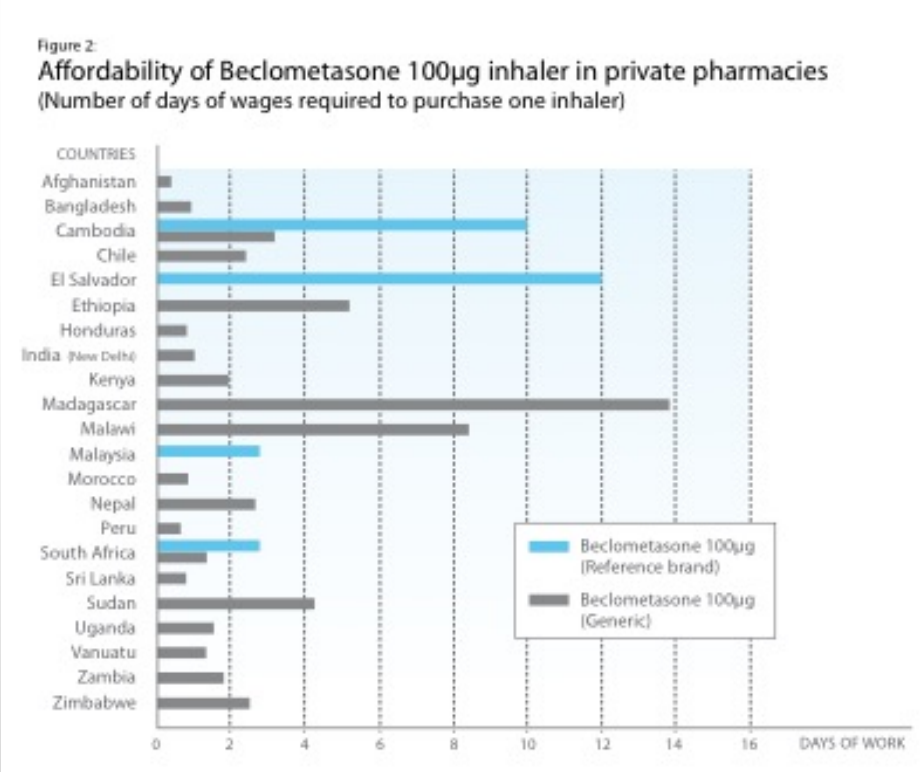


Figure 1: Countries included in the essential asthma medicines survey 2011

Asthma drugs availability in 52 countries



Affordability of beclometasone inhaler at private pharmacies in 52 countries



Factors impacting on Access to medicines!

- Pricing
- Development of specialty drugs, cancer and orphan medicines in the recent years
- Generic medicines
- R&D costs
- Future medicines policy issues

Pricing

- Pharmaceutical pricing is a growing challenge for all countries
  - Rising prices are a primary concern for health system managers

- **Prices of older drugs**
  - Growth in off-patent pharmaceutical prices

Prices of older drugs

- WHO essential generic medicines sold in the UK and South Africa are priced at more than 100 times their estimated cost of production.
- Daraprim (pyrimethamine), to prevent or treat toxoplasmosis in immunocompromised patients. It has been available for about 60 years and went off patent in the 1970s.
- Turing Pharmaceuticals increased the price of a tablet from $13.50 to $750, a 5500% increase.

- Hill AM, Barber MJ, Gotham D. Estimated costs of production and potential prices for the WHO Essential Medicines List. *BMJ Glob Health* 2018;3:e000571. doi:10.1136/ bmjgh-2017-000571
- 29 Tallapragada NP. O -patent drugs at brand- name prices: a puzzle for policymakers. *J Law Biosci* 2016;3:238-47. doi:10.1093/jlb/lsw008

Specialty drugs and cancer treatments, orphan drugs

Development of specialty drugs in recent years

- Over the past decade, US FDA approvals of new oncology drugs increased 204% and orphan drug approvals increased by 175%.
- In 2015, 65% of new active substances approved by the FDA, the European Medicines Agency, and Health Canada were specialty drugs.

- CenterWatch. FDA approved drugs for oncology. 2018. https://www.centerwatch.com/drug- information/fda-approved-drugs/therapeutic- area/12/oncology.
- 4 EvaluatePharma. *Orphan drug report 2017.* 4th ed. 2017. http://info.evaluategroup.com/rs/607- YGS-364/images/EPOD17.pdf
- 5 PMPRB. Meds entry watch, 2016. Ottawa: Patented Medicine Prices Review Board, 2018. http://www. pmprb-cepmb.gc.ca/view.asp?ccid=1374&lang=en

Prices of new cancer treatments and multiple sclerosis

	Mid-1990s	2015
Multiple sclerosis	$8000 - $11 000/ year	$60 000 / year
New cancer treatments	**1960s**	**Recent years.**
	$100	Over $10 000

This trend in cancer prices has not been accompanied by evidence of improvements in treatment outcomes.

Hartung DM, Bourdette DN, Ahmed SM, Whitham RH. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: too big to fail? *Neurology* 2015;84:2185-92. doi:10.1212/ WNL.0000000000001608

Bach PB. *Price & value of cancer drug.* Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center, 2019. https://www.mskcc. org/research-programs/health-policy-outcomes/ cost-drugs

Cressman S, Browman GP, Hoch JS, Kovacic L, Peacock SJ. A time-trend economic analysis of cancer drug trials. *Oncologist* 2015;20:729-36. doi:10.1634/theoncologist.2014-0437

Treatment of Rare diseases

- In the US in 2016, the median annual price for each patient a year treated with top selling orphan drugs was $83, 883.
- This is 5.5 times the median annual cost for top selling non-orphan drugs.
- An example of this is ivacaftor, a treatment for cystic fibrosis.
  - In US at about $300000 per patient per year
  - Global revenues of $3.65bn from 2014 through 2018

- EvaluatePharma. *Orphan drug report 2017.* 4th ed. 2017. http://info.evaluategroup.com/rs/607- YGS-364/images/EPOD17.pdf
- Cohen D, Ra ery J. Paying twice: questions over high cost of cystic brosis drug developed with charitable funding. *BMJ* 2014;348:g1445. doi:10.1136/bmj. g1445
- Business Wire. *Vertex reports full-year and fourth- quarter nancial results.* Vertex Pharmaceuticals Incorporated, 2019. https://www.businesswire.com/news/home/20190205005917/en/Vertex-Reports- Full-Year-Fourth-Quarter-2018-Financial-Results

- Extraordinary revenues and treating a single disease raise questions about affordability for health systems and the fairness of returns on research and development costs.

- Research and development costs

Research and development costs

- It has been argued that excessive pharmaceutical prices and revenues are fair today because development costs are higher.
- Manufacturers do not disclose their research and development costs
- Many Orphan drugs are being approved based on smaller trials and, consequently, lower development costs.

- Morgan S, Grootendorst P, Lexchin J, Cunningham C, Greyson D. The cost of drug development: a systematic review. *Health Policy* 2011;100:4-17. doi:10.1016/j.healthpol.2010.12.002
- Avorn J. The $2.6 billion pill—methodologic and policy considerations. *N Engl J Med* 2015;372:1877- 9. doi:10.1056/NEJMp1500848
- Jayasundara K, Hollis A, Krahn M, Mamdani M, Hoch JS, Grootendorst P. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. *Orphanet J Rare Dis* 2019;14:12. doi:10.1186/ s13023-018-0990-4

The role of public and non-profit financing of research and development.

- A recent study found that the US National Institutes of Health contributed an average of $839m for research for each of the 210 first-in-class drugs approved in the US between 2010 and 2016.
- Governments also gave tax deductions and tax credits.
- These contribute significantly lower manufacturer-borne development costs, particularly for orphan drugs.

- Galkina Cleary E, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. Contribution of NIH funding to new drug approvals 2010-2016. *Proc Natl Acad Sci USA* 2018;115:2329-34. doi:10.1073/ pnas.1715368115
- Giannuzzi V, Conte R, Landi A, et al. Orphan medicinal products in Europe and United States to cover needs of patients with rare diseases: an increased common e ort is to be foreseen. *Orphanet J Rare Dis* 2017;12:64. doi:10.1186/s13023-017-0617-1

These are the problems, what are the solutions?

Moon et al, The concept of fair pricing for medicines BMJ 2020;368

- Mechanisms to delink drug development costs from final pricing are required.
- Building a model for the fair pricing of medicines

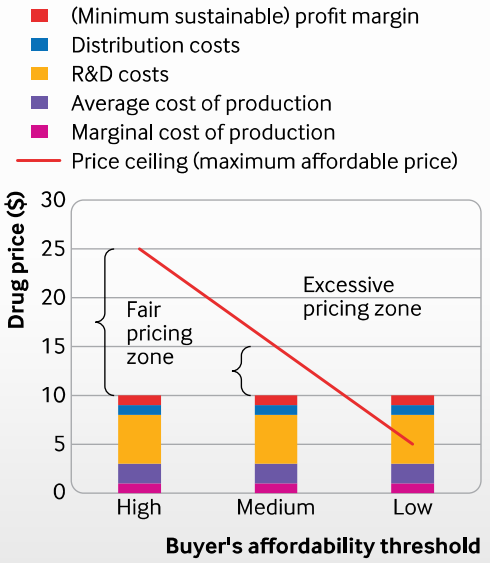


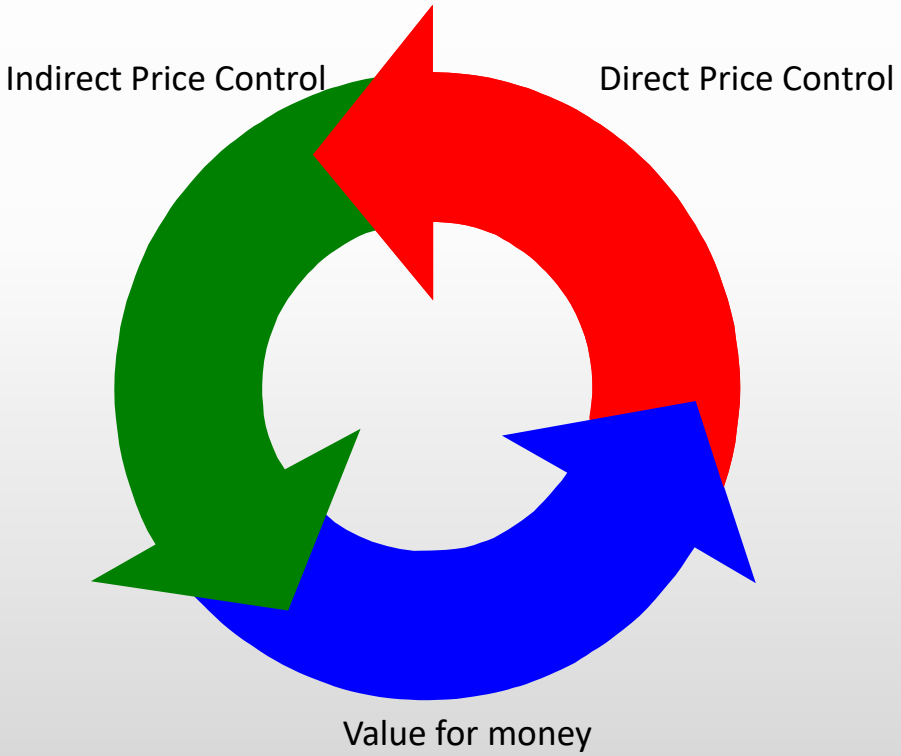
Fig 1 | Hypothetical price ceilings (ie, the maximum that is affordable to the buyer) and fair prices for countries with different affordability thresholds

- Røttingen J-A, Chamas C. A new deal for global health R&D? The recommendations of the Consultative Expert Working Group on Research and Development (CEWG). *PLoS Med* 2012;9:e1001219.

Improve affordability and to regulate medicine prices!

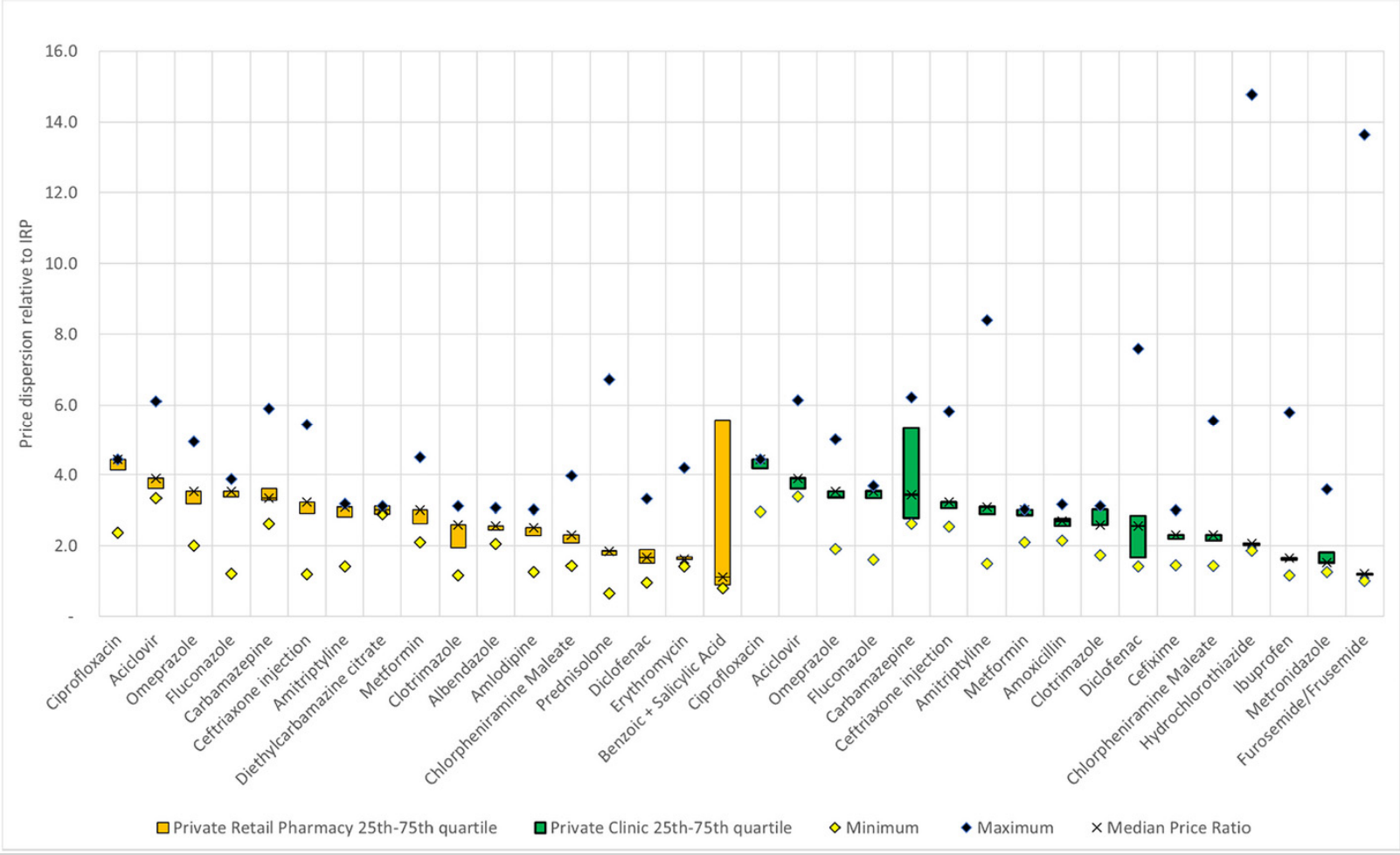
Ways to improve access and affordability of medicines

- Regulate markets (Control Prices)
  - Most countries in the world except USA and few others
  - Different methods to control prices
    - Direct Control (India, Pakistan Bangladesh etc)
    - Indirect Control (Governments Negotiation)
      - Compulsory Health Insurance (UK, Australia, NZ)
      - Korea (Reference Pricing)
      - Agencies have been set up to decide which drugs are value for money (Pharmacoeconomics)

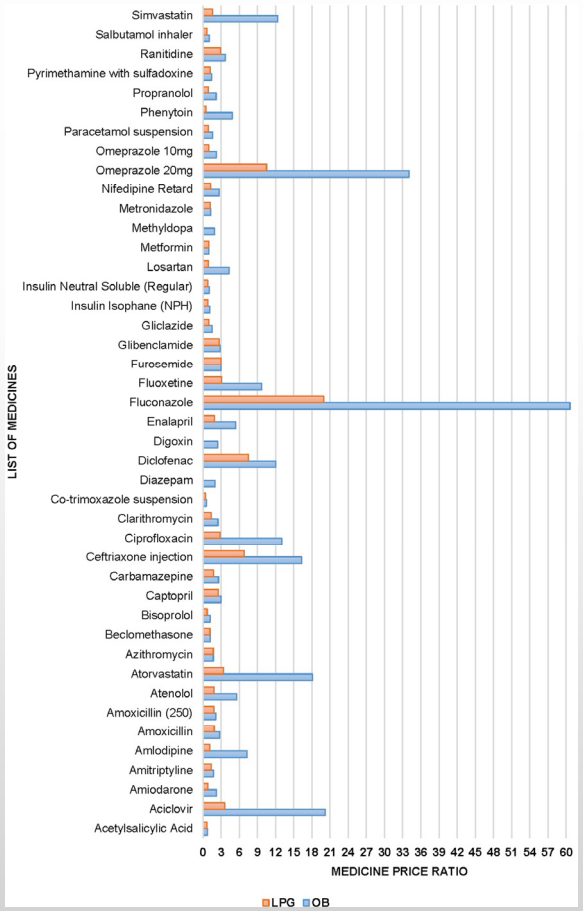


- Examples from low and middle income countries
  - Malaysia, Bangladesh, Pakistan (WHO/HAI pricing studies)
  - NZ and the UK

Bangladesh Medicines Pricing Study 2017



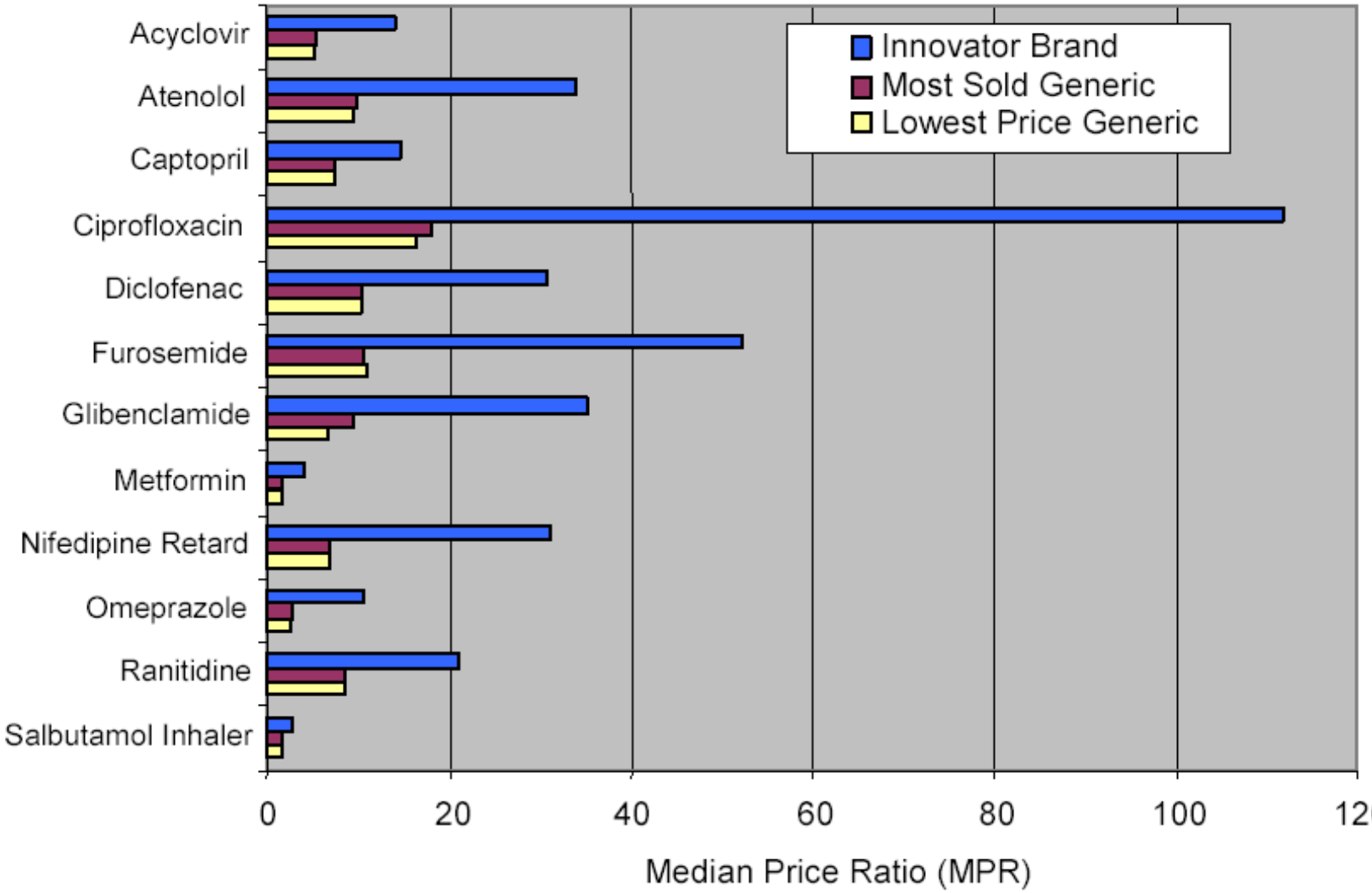
Pakistan Pricing 2016/2017



Access to medicines in Malaysia

- Free market economy

Median Prices at Private Retail Pharmacies



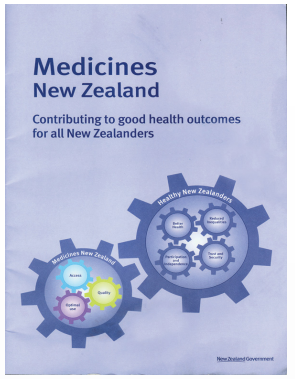
Access to medicines and Medicines Pricing in New Zealand

Medicine Use in New Zealand

- $870 million – yearly community pharmaceutical expenditure (on budget)
- 45.8 million – number of funded prescription items filled
- 3.68 million – number of New Zealanders receiving funded medicines (2.2 percent increase)

Source: PHARMAC Annual Report 2018

PHARMAC



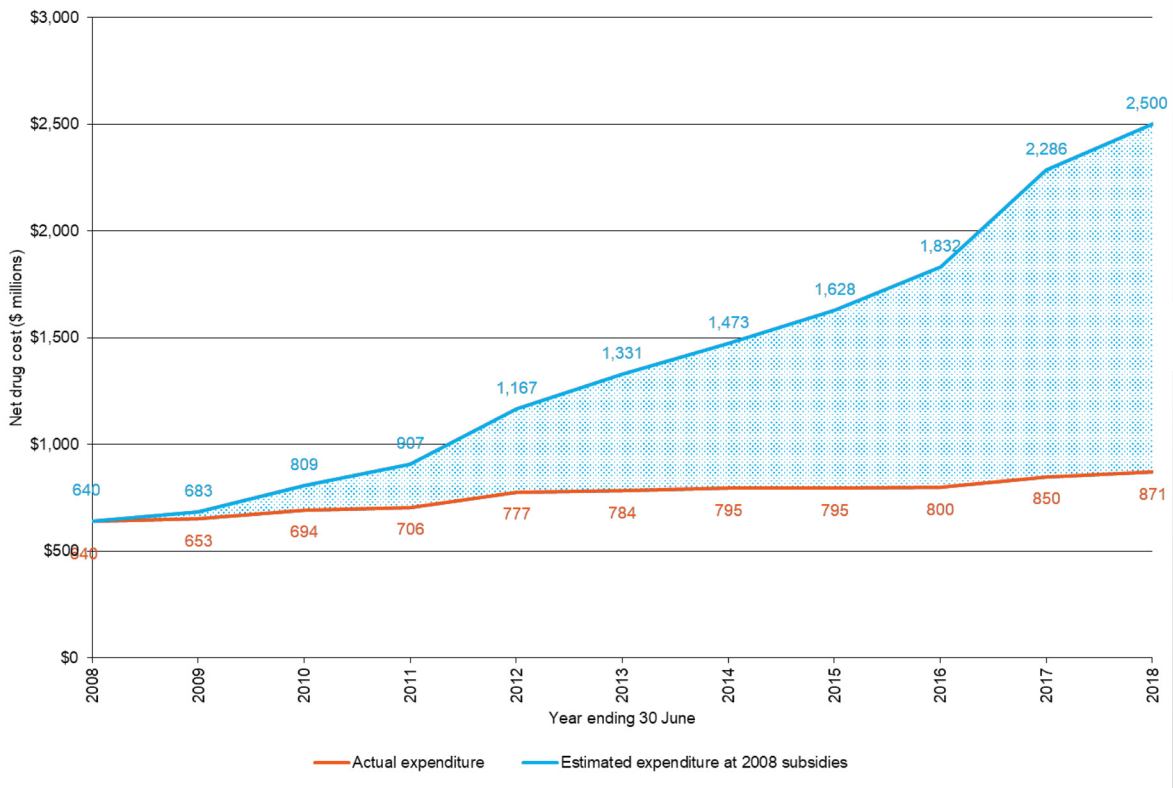
- Pharmaceutical Management Agency of New Zealand (PHARMAC)
  - Single purchaser of pharmaceuticals
  - PHARMAC's key role is to decide whether a medicine will be subsidised or not

- Established in 1993, the Pharmaceutical Management Agency of New Zealand (PHARMAC) works within a fixed budget for public spending on medicines in New Zealand.

Source: Morgan & Boothe (2009) Prescription drug coverage in Australia and New Zealand: a view from afar- Australian Prescriber

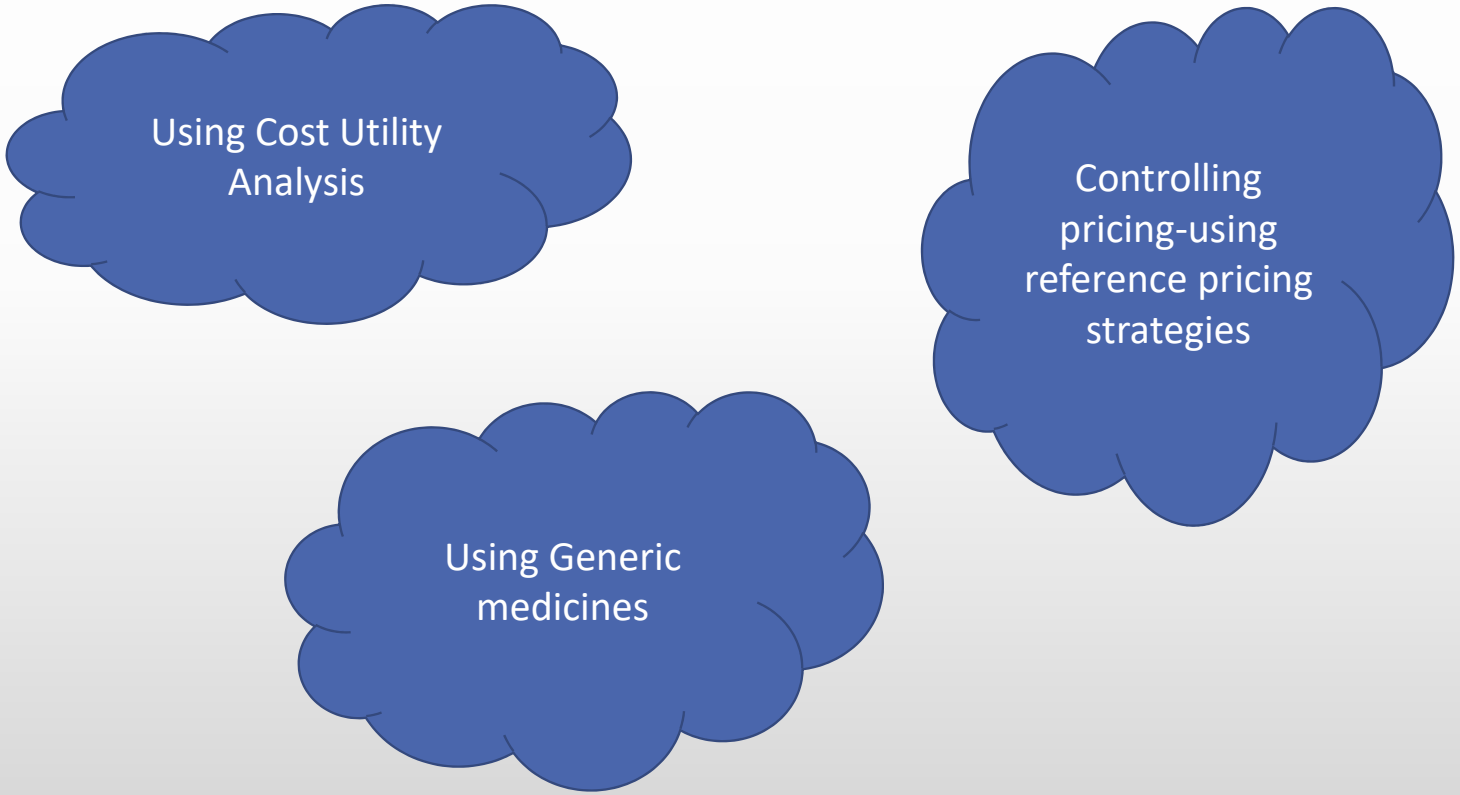
http://www.australianprescriber.com/magazine/33/1/2/4

Impact of PHARMAC on drug expenditure



Source: PHARMAC

PHARMAC Strategies to improve medicines cost effectiveness

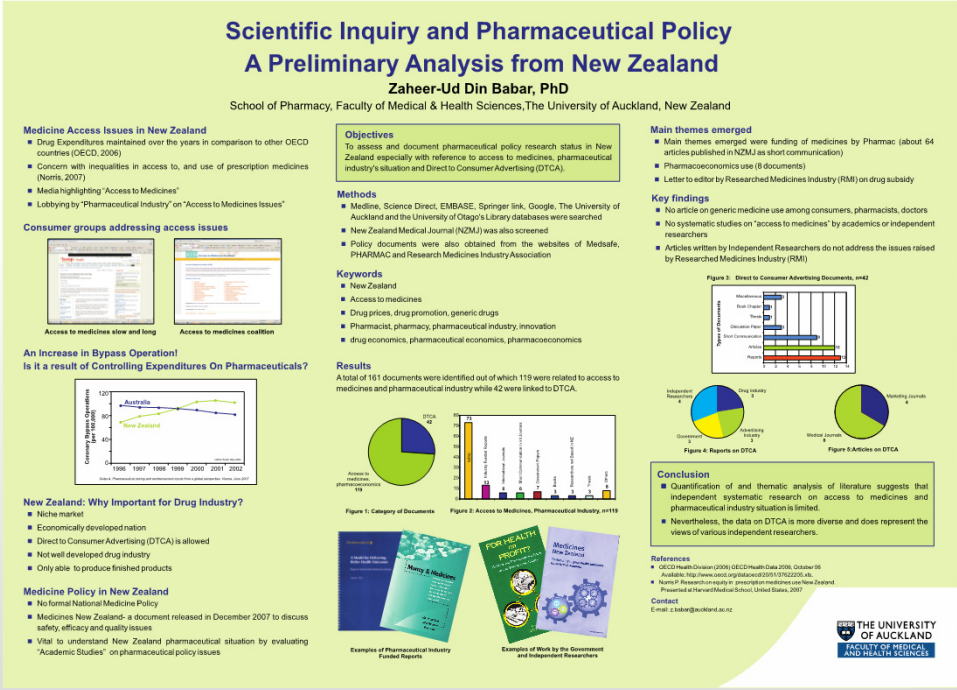


Controlling Drug Expenditures and Improving Access

- What PHARMAC is doing, is it right?
- Evaluating the impact?

Access to medicines criticism in New Zealand

- General appreciation towards PHARMAC
- However, access to medicines is not adequate in NZ?
- Key stakeholders including GPs' opinion not known about the issue.



Scientific Inquiry and Pharmaceutical Policy
A Preliminary Analysis from New Zealand

Zaheer-Ud Din Babar, PhD
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Medicine Access Issues in New Zealand
- Drug Expenditures maintained over the years in comparison to other OECD countries (OECD, 2006)
- Concern with inequalities in access to, and use of prescription medicines (Norris, 2007)
- Media highlighting "Access to Medicines"
- Lobbying by "Pharmaceutical Industry" on "Access to Medicines Issues"

Consumer groups addressing access issues

Access to medicines slow and long — Access to medicines coalition

An Increase in Bypass Operation! Is it a result of Controlling Expenditures On Pharmaceuticals?

New Zealand: Why Important for Drug Industry?
- Niche market
- Economically developed nation
- Direct to Consumer Advertising (DTCA) is allowed
- Not well developed drug industry
- Only able to produce finished products

Medicine Policy in New Zealand
- No formal National Medicine Policy
- Medicines New Zealand- a document released in December 2007 to discuss safety, efficacy and quality issues
- Vital to understand New Zealand pharmaceutical situation by evaluating "Academic Studies" on pharmaceutical policy issues

Objectives
To assess and document pharmaceutical policy research status in New Zealand especially with reference to access to medicines, pharmaceutical industry's situation and Direct to Consumer Advertising (DTCA).

Methods
- Medline, Science Direct, EMBASE, Springer link, Google, The University of Auckland and the University of Otago's Library databases were searched
- New Zealand Medical Journal (NZMJ) was also screened
- Policy documents were also obtained from the websites of Medsafe, PHARMAC and Research Medicines Industry Association

Keywords
- New Zealand
- Access to medicines
- Drug prices, drug promotion, generic drugs
- Pharmacist, pharmacy, pharmaceutical industry, innovation
- drug economics, pharmaceutical economics, pharmacoeconomics

Results
A total of 161 documents were identified out of which 119 were related to access to medicines and pharmaceutical industry while 42 were linked to DTCA.

Figure 1: Category of Documents — Figure 2: Access to Medicines, Pharmaceutical Industry, n=119

Examples of Pharmaceutical Industry Funded Reports — Examples of Work by the Government and Independent Researchers

Main themes emerged
- Main themes emerged were funding of medicines by Pharmac (about 64 articles published in NZMJ as short communication)
- Pharmacoeconomics use (8 documents)
- Letter to editor by Researched Medicines Industry (RMI) on drug subsidy

Key findings
- No article on generic medicine use among consumers, pharmacists, doctors
- No systematic studies on "access to medicines" by academics or independent researchers
- Articles written by Independent Researchers do not address the issues raised by Researched Medicines Industry (RMI)

Figure 3: Direct to Consumer Advertising Documents, n=42

Figure 4: Reports on DTCA — Figure 5:Articles on DTCA

Conclusion
- Quantification of and thematic analysis of literature suggests that independent systematic research on access to medicines and pharmaceutical industry situation is limited.
- Nevertheless, the data on DTCA is more diverse and does represent the views of various independent researchers.

References
- OECD Health Division (2006) OECD Health Data 2006, October 06 Available: http://www.oecd.org/dataoecd/23/51/37622295.xls.
- Norris P. Research on equity in prescription medicines use New Zealand. Presented at Harvard Medical School, United States, 2007

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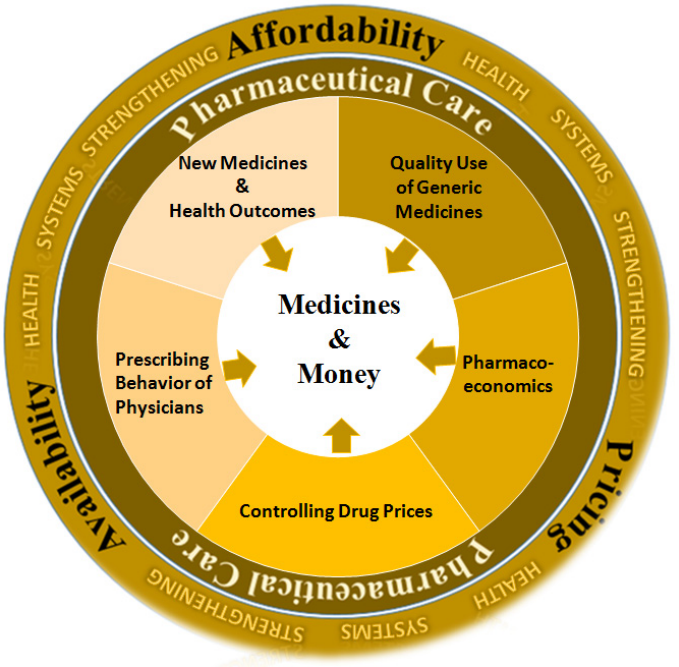
Conceptual Framework of research in New Zealand

- Medicine pricing
- GPs and Access to Medicines
- Generic Medicines



GPs and access to medicines

- Most GPs were satisfied with the The range of medicines available in NZ and there was ggeneral support for the PHARMAC work
- However, the following issues were identified:
  - availability of certain drugs
  - Sole supply
  - the use of generic medicines

Open Access Research

BMJ open

A qualitative evaluation of general practitioners' perceptions regarding access to medicines in New Zealand

Zaheer-Ud-Din Babar,[1] Piyush Grover,[2] Rachael Butler,[3] Lynne Bye,[1] Janie Sheridan[1]

JPHSR Journal of Pharmaceutical Health Services Research

ROYAL PHARMACEUTICAL SOCIETY

Research Paper

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Evaluating general practitioners' opinions on issues concerning access to medicines in New Zealand

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Australia and NZ medicines availability and funding

- Australia is funding more medicines as compared to NZ

Australian Prescriber
VOLUME 37 : NUMBER 5 : OCTOBER 2014

EDITORIAL

Differences in Australian and New Zealand medicines funding policies

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Australia and New Zealand are well known internationally for having implemented national medicines policies that aim for equitable access to cost-effective and safe medicines. However, each country adopted a different approach.

In 2011, Australia spent more than double what New Zealand spent on pharmaceuticals per capita. Australia spent US$587 (around 22% more than the Organisation for Economic Co-operation and Development (OECD) average) while New Zealand spent US$288 (around 40% less than the OECD average).[1] A 2011–12 analysis of the 73 individual drug–dose combinations that are prescribed the most

drugs compared with current standard of care, but has no capped budget. The decision to subsidise an item has to be determined by the Minister for Health if the net cost to the PBS is greater than $20 million per year.

Australia has introduced new pricing policies that involve price disclosure by manufacturers to the government, including incentives and discounts to pharmacies. Australian consumers support accelerating these price cuts, but there are concerns that they will affect the profitability of pharmacies.[6,7]

Only a minority of new drugs provide a definite

Uptake of new medicines: the Pharmaceutical Management Agency of New Zealand (PHARMAC) in the international context

Rajan Ragupathy, Zaheer-Ud-Din Babar

CSIRO PUBLISHING
Australian Health Review
http://dx.doi.org/10.1071/AH15070

Comparing the reimbursement of new medicines between Australia and New Zealand

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Lancet cancer pricing article

- More medicines were available in Austria, Denmark, Finland, Germany, Italy, Norway, Sweden, and the UK, as compared to New Zealand and Portugal
- The difference of a drug price between the highest priced country and the lowest priced country varied between **28% and 388%.**
- Overall, Greek and UK prices ranked at a low level, whereas Sweden, Switzerland, and Germany showed price data in high ranges.

Cancer drugs in 16 European countries, Australia, and New Zealand: a cross-country price comparison study

Sabine Vogler, Agnes Vitry, Zaheer-Ud-Din Babar

Summary

Background Cancer drugs challenge health-care systems because of their high prices. No cross-country price comparison of cancer drugs for a large number of countries has been published. We aimed to survey the prices of cancer drugs in high-income countries (Europe, Australia, and New Zealand).

Lancet Oncol 2016; 17: 39–47
Published Online
December 3, 2015
http://dx.doi.org/10.1016/S1470-2045(15)00449-0

Price secrecy and discrimination

- Confidential price discounts allow manufacturers to charge different payers different prices.

Price secrecy and discrimination

- Although they reduce final prices, the widespread use of confidential discounts is still a concern for health systems.
- list prices of some medications are higher as percentage of average income in low and middle income countries than in high income countries

- Morgan SG, Vogler S, Wagner AK. Payers' experiences with con dential pharmaceutical price discounts:a survey of public and statutory health systems
  in North America, Europe, and Australasia. *Health Policy* 2017;121:354-62.
- Health Action International. Life-saving insulin largely una ordable—a one day snapshot of the price of insulin across 60 countries. 2010.
- Goldstein DA, Clark J, Tu Y, et al. A global comparison of the cost of patented cancer drugs in relation to global di erences in wealth. *Oncotarget* 2017;8:71548-55. . doi:10.18632/ oncotarget.17742

Generic Medicines

Access to safe, effective, quality assured, and affordable essential medicines and vaccines for all has been identified as key to achieving universal health coverage

Promoting quality use of generic medicines

Studies have shown that the consumers' attitudes, beliefs and compliance regarding the use of generic medicines is determined largely by ..

- Physicians
- Pharmacists

What NZ consumers think about generic medicines ? (Babar et al, 2010)

- Many consumers have misconceptions regarding generic medicines.
- Participants were more prepared to change to a generic for a minor illness (79%) than for a major illness (58.7%).Those who had better knowledge were more likely to use a generic in major illness
- Attitude of participants toward the use of generic medicines was determined by their knowledge of generics, whether it was recommended by a pharmacist and their type of illness.

- Previous positive experiences with generics also determined consumers' willingness to use generics.
- Having knowledge about generics and the advice by doctors and pharmacists are key indicators to improve the quality use of generic medicines.

What NZ doctors think about generic medicines ?

- GPs frequently use the generic name in both prescriptions and in conversation with patients
- Generally unable to distinguish between names of innovator brands and generic equivalents.
- The concept of generic medicine and originator brand is unclear
  - Only 7% of GPs could identify $\geq$7 out of 8 generics
  - Half the GPs could only identify $\leq$3 out of 8 generics
    - 42% of GPs identified at least one original/patented medicine as a generic

Babar ZU, Lessing C, Sheridan J. A quantitative study to evaluate perceptions, knowledge and attitudes of General Practitioners regarding generic medicines and access to medicine issues in New Zealand. FRDF Report Submitted to University of Auckland , 2011.

What NZ Pharmacists think about generic medicines (Babar et al, 2011)

- About one-third of pharmacists correctly defined the term “generic medicines”
- Concerns were raised regarding: quality, safety, and effectiveness; however, most pharmacists acknowledged the economic benefits to the health care system.
- However, 65% stated that original brand medicines were of higher quality than their generic counterparts,
- Half of the respondents stated that the generic medicines and original brand medicines are equally effective.

BABAR, Z; GROVER, P; STEWART, J; HOGG, M; SHORT, L; SEO, H.G; REW, A. 'Evaluating pharmacists' views, knowledge, and perception regarding generic medicines in New Zealand', *Research in Social and Administrative Pharmacy,* 7, (3), p294-305, 2011.

Where we see the future !

Priority Medicines Policy Issues for New Zealand

- Affordability/Access
  - Low socioeconomic patients were considered to have a higher burden of disease.
- Higher burden of disease in Maori & Pacifica population
- An increasing demand for medicines including High cost medicines
- PHARMAC
  - Delays in the submission process of up to eight years and described as a *"medicines waiting list"* was of concern.
  - Economic evaluations becoming more complex
  - Access to niche market medicines
    (genomic & patient subgroup profiling)

What about the UK!

Are issues the same or different?

Access to medicines in the UK!

- Variability in access to medicines across all countries in United Kingdom & EU and across different categories of medicines.
- Variability in access is due to:
  - differences in reimbursement and pricing process,
  - mandates of agencies
  - stakeholder's/ societal preferences
  - differences in evidence requirements to support reimbursement
  - interpretation of submitted evidence
  - and the lack of adherence with reimbursement recommendations.

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Access to medicines - a systematic review of the literature

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What is required to improve the situation?

Key Messages

- New models to look at pricing and affordability
- Governments can intervene to promote access and prevent unfair pricing
- Governments need to develop their capacities
- Policies that extend intellectual property rights and limit price controls are barriers to universal health and access to medicines

Key challenges

- Methodological rigour in studies
- Systematic reviews and meta analysis
- Understanding health systems!
- *Applicability and Transferability - What are the challenges in applying knowledge from high income countries to LMICs?*
- Similar issues in low, middle and high income countries as well as availability, affordability of medicines are concerned, the scale of the problem may differ