Challenges to Equity and Access to Medicines and Vaccines - a Health Systems Approach

Professor Zaheer Babar
Professor In Medicines and Healthcare, Director, Centre for Pharmaceutical Policy and Practice Research
University of Huddersfield UK, z.babar@hud.ac.uk / @SUDBabar

Equitable and appropriate access to quality medicines and vaccines in the Commonwealth
Commonwealth Civil Society Policy Forum I Tuesday 18 May 2021
Growth in Global Medicine Spending: 2007-2021

- Global medicine spending
  - $370 billion, 2016
  - $1.5 trillion in 2021
- The total volume of medicines consumed globally will increase by about 3% annually.
- 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

<table>
<thead>
<tr>
<th>Country</th>
<th>US$</th>
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<tbody>
<tr>
<td>USA</td>
<td>1,955</td>
</tr>
<tr>
<td>Canada</td>
<td>776</td>
</tr>
<tr>
<td>Japan</td>
<td>739</td>
</tr>
<tr>
<td>Europe</td>
<td>577</td>
</tr>
<tr>
<td>Australia</td>
<td>513</td>
</tr>
<tr>
<td>South Korea</td>
<td>295</td>
</tr>
<tr>
<td>Pakistan, India, Bangladesh</td>
<td>20-30</td>
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Major challenges with regards to access 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 expenditures are rising faster than other healthcare costs
  • New high-priced drugs
  • Aging population
  • Increased demand for speciality treatment/products by patients
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 have significant impact on health system budgets.

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

Access to Affordable Medicines

• 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.

https://www.thelancet.com/commissions/essential-medicines
Reduction in Cardiovascular Disease

- The cardiovascular disease, (disability-adjusted life-years per 100,000 people) fell by 30% in rich countries (1990 - 2017)
- It declined by only 9% in poor countries
- The role and contribution of medicines


Factors impacting Access and Equity to Medicines

• No governmental control on drug prices
• Excessive use of innovator brands
• Patents
• Development of specialty drugs, cancer and orphan medicines in the recent years
Access to Innovative medicines for Metastatic Melanoma in 34 countries

• Great discrepancy exists in metastatic melanoma treatment globally.
• Access depends on economic as well as on healthcare system performance parameters.
• Price negotiations and managed entry agreements (MEAs) are needed

Prices of Older Drugs

• Growth in off-patent pharmaceutical prices
• 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


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.

Additional references:

## Prices of new Cancer Treatments and Multiple Sclerosis

<table>
<thead>
<tr>
<th></th>
<th>Mid-1990s</th>
<th>2015</th>
</tr>
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<tbody>
<tr>
<td>Multiple sclerosis</td>
<td>$8000 - $11 000/ year</td>
<td>$60 000 / year</td>
</tr>
<tr>
<td>New cancer treatments</td>
<td>1960s</td>
<td>Recent years.</td>
</tr>
<tr>
<td></td>
<td>$100</td>
<td>Over $10 000</td>
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This trend in cancer prices has not been accompanied by evidence of improvements in treatment outcomes.

Revenues versus fairness of returns on R &D costs

• It has been argued that excessive pharmaceutical prices and revenues are fair 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 on lower development costs.

The role of Public and non-profit Financing of Research and Development

- 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.


- 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 effort is to be foreseen. *Orphanet J Rare Dis* 2017;12:64. doi:10.1186/s13023-017-0617-1
These are the problems, so what are the solutions?
The Concept of Fair Pricing for Medicines
Moon et al, 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
Ways to improve access and affordability of medicines and vaccines

- 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)
      - Agencies have been set up to decide which drugs are value for money (Pharmacoeconomics)
Examples from Commonwealth Countries
Bangladesh Medicines Pricing Study 2017

- WHO/HAI Methodology (developed at Harvard, tested in over 70 countries)
- To gauge the scale of the problem
- To develop pricing interventions
- The country exercises a price control

Pakistan Pricing Study 2019

• The country exercises a price control

• Majority drugs are reasonably priced
Median Prices at Private Retail Pharmacies using WHO/HAI methodology

- No medicines price control in Malaysia
- High medicine prices

Impact of PHARMAC on drug expenditure in New Zealand

- Monopsony purchaser
- Reference pricing
- Cost utility analysis
- Generic medicines

New Zealand is making large medicines savings over time

The graph below shows estimated savings on medicines spending, using 2010 subsidies as a baseline. Over the last ten years, PHARMAC has saved $9.3 billion on net medicine costs, with the gap between the two lines highlighting how much money PHARMAC is estimated to have saved through its work.

PHARMAC’s impact on predicted CPB medicines expenditure over time (actual 2010-2020)
Pertinent issues in Access and Pricing

1. Voluntary licenses to promote access
2. Price secrecy and discrimination
3. Reporting of pharmaceutical expenditures and access
4. The three-step framework for monitoring and accountability
5. Patient-centred comprehensive primary care services
6. Affordability and uptake of medicines?
1. Voluntary Licences for Hepatitis C Medicines in 34 countries

- Since 2014, non-exclusive voluntary licences have been issued by Gilead and Bristol-Myers Squibb for key drugs for hepatitis C virus (HCV) infection.
- Voluntary licences were associated with an increase in the annual number of people accessing HCV treatment (95% CI 46·7–91·9; p=0·0060).
- This evidence supports the expansion of licensing strategies to include more countries and more treatments.

2. Price Secrecy and Discrimination

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

- 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.

  
  - Health Action International. Life-saving insulin largely unaffordable—a one day snapshot of the price of insulin across 60 countries. 2010.
  
3. Reporting of Pharmaceutical Expenditures

- Pharmaceutical expenditures in the public and private sector is rarely reported.
- Without systematic data reporting, there is a lack of attention to access to essential medicines in World Health Statistics reports.

4. The three-step Framework for Monitoring and Accountability to Promote Access

- To improve access, a robust monitoring and accountability system is needed
  - The three-step framework involves “appropriate collection of data”, “review” and the “necessary corrective action”.
- Necessary to promote equity and good governance

5. Towards patient-centred comprehensive primary care services

• The focus of accountability should move away from measuring only availability of medicines

• This needs to be focused towards effectiveness, quality, and efficiency of patient-centred comprehensive primary care services, which encompasses equitable access to essential medicines.

6. Affordability and Uptake of Medicines?

• Novartis Access, medicines for cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer, at a wholesale price of $1 per treatment per month.

• Significantly increased availability of two medicines (amlodipine and metformin), however it did not affect availability of portfolio medicines overall (p=0.096)

• The results highlight the poor uptake of affordably priced medications

• Deriving impact from enhancing availability of medicines is much more complicated than just having the products on shelves.

• Collaboration is needed within all layers of the health-care system

Conceptual Framework of Factors Impacting Access to Medicines

Babar, ZUD. May 2021
Policy Recommendations

• Similar issues in low, middle and high income countries regarding access, the scale of the problem may differ
• Traditional pricing and reimbursement policies have proved insufficient to ensure access
• Extending intellectual property rights is a barrier to access
• WHO Roadmap for Access 2019–2023 outlines ten priority areas, including fair pricing, management of intellectual property, and procurement and supply chain management.

Policy Recommendations

• Transparency is needed for R&D costs, and for prices and discounts
• Increased cross-country cooperation of purchasers and public payers to improve purchasing power.
• To support generic medicines policies
• Regulating retail mark-ups in the supply chain in LMICs


Vaccines

About 80% of the vaccines are produced by five big manufacturers including Glaxo Smith Kline, Merck, Novartis, Pfizer and Sanofi Pasteur
Global Procurement of Vaccines

Can be divided into the following:

1. Countries procuring through UNICEF, eligible for GAVI support
2. Middle-income countries procuring through UNICEF but not eligible for GAVI support
3. Countries procuring through Pan American Health Organization Revolving Fund (PAHO-RF)
4. Middle-income countries self-procuring all or most of the vaccines
5. Self-procuring high-income countries
Vaccine Prices

• In LMICs, most vaccines are heavily subsidized to keep prices manageable
• In high-income countries, the maximum price for a vaccine is almost 30 times higher.
• Hepatitis B (HepB) vaccine was initially unaffordable for many lower-income countries at a price of USD 30 per dose
• Recently introduced vaccines were expensive due to the use of newer technologies
• Affordable vaccine prices can be achieved through WHO, GAVI, UNICEF, PAHO-RF

Are Published Vaccine Prices Real?

• Recently manufacturers have started to publicize the criteria used in the pricing process
• Are published prices real?
• Confidential rebates
• Non-disclosure agreements with the buyers, and governments
• Tiered pricing for countries

https://www.mdpi.com/2076-393X/7/3/97/htm
# COVID19 Vaccine Prices

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<thead>
<tr>
<th>No</th>
<th>Manufacturer</th>
<th>Prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Oxford/AstraZeneca</td>
<td>€1.78</td>
</tr>
<tr>
<td>2</td>
<td>Johnson &amp; Johnson</td>
<td>$8.50</td>
</tr>
<tr>
<td>3</td>
<td>Sanofi/GSK</td>
<td>€7.56</td>
</tr>
<tr>
<td>4</td>
<td>Moderna</td>
<td>$18</td>
</tr>
<tr>
<td>5</td>
<td>BioNTech/Pfizer</td>
<td>€12</td>
</tr>
<tr>
<td>6</td>
<td>BioNTech/Pfizer</td>
<td>€15.50 (18.90 USD) (Europe) 19.50 USD (USA)</td>
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Vaccine makers are charging different prices
Price per dose ($USD)

Note: all prices are subject to trade agreements
Source: Unicef, US Government contracts, WHO

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Global Access to COVID 19 Vaccines

- Situation is dynamic and transforming with regards to access
- COVAX - a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines.
  - COVAX has so far sent over 54 million COVID-19 vaccines to 121 participants
- USTR is supporting the COVID-19 TRIPS Waiver

FOR IMMEDIATE RELEASE:
May 5, 2021

CONTACT: media@ustr.gov

STATEMENT FROM AMBASSADOR KATHERINE TAI ON THE COVID-19 TRIPS WAIVER

WASHINGTON – United States Trade Representative Katherine Tai today released a statement announcing the Biden-Harris Administration's support for waiving intellectual property protections for COVID-19 vaccines.

"This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved.

"The Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible. As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution. It will also work to increase the raw materials needed to produce those vaccines."

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Conclusion

• Published prices may not be the real prices
• Differential pricing (depending on the countries’ ability to pay)
• Countries current policies on access may have little impact on procurement and pricing (in the current pandemic situation)
• Transparency is needed in pricing data for COVID19 vaccines so that countries can make informed decisions
Thank you

Professor Zaheer Babar
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Director, Centre for Pharmaceutical Policy and Practice Research, University of Huddersfield UK