UNPACKING THE CONCEPT OF FAIR PRICING AND PUTTING IT INTO PRACTICE

PLENARY SESSION: FAIR PRICING IN PRACTICE
2ND GLOBAL FORUM ON FAIR PRICING
WORLD HEALTH ORGANIZATION

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LENALIDOMIDE

R 828,000 PER YEAR

IS NOT A FAIR PRICE

$59,000
WHAT IS A FAIR PRICE FOR A MEDICINE?
FAIRNESS TO SELLERS AND BUYERS
A SIMPLIFIED MODEL

Sellers:
Small and large developers, manufacturers, distributors

- Cost of R&D
- Cost of manufacturing and distribution
- Other related costs (e.g. registration, administration, pharmacovigilance)
- Fair profit

Buyers:
Payers, insurers, households, patients

- Present and future affordability (binding constraint)
- Value to the individual and health system
- Security of supply

A ZONE OF FAIR PRICING: EQUALLY DISTRIBUTED R&D COSTS

Fig 1. Price ceilings and floors across 3 thresholds

A ZONE OF FAIR PRICING: PROGRESSIVELY DISTRIBUTED R&D COSTS

Fig 2. Price ceilings and progressive price floors across 3 affordability thresholds

A ZONE OF FAIR PRICING

GENERIC MEDICINE

Fig 2. Price ceilings and progressive price floors across 3 affordability thresholds

Excessive pricing zone

Fair pricing zone

High affordability threshold  Medium affordability threshold  Low affordability threshold
ILLUSTRATIVE EXAMPLE

SOFOSBUVIR (HEPATITIS C)

- R&D costs:
  - Pharmasset ($62 M) + Gilead ($880 M) = $943 M
- Gilead acquires Pharmasset: $11,000 M
- Gilead outlay: $11,880 M (R&D + acquisition cost)
- Recouped over 10 years (minimum) patent term
- Cost of production: $47 per treatment course
- Administration, distribution, registration: 10%
- Profit: 14%

<table>
<thead>
<tr>
<th>Capacity to pay</th>
<th>Country</th>
<th>% of global economy</th>
<th>GNI per capita</th>
<th># patients treated/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Australia</td>
<td>1.65</td>
<td>51,360</td>
<td>15,000</td>
</tr>
<tr>
<td>Medium</td>
<td>Brazil</td>
<td>2.35</td>
<td>8600</td>
<td>40,000</td>
</tr>
<tr>
<td>Low</td>
<td>Morocco</td>
<td>0.14</td>
<td>2860</td>
<td>6500</td>
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</tbody>
</table>

A ZONE OF FAIR PRICING

SIMPLIFIED EXAMPLE: SOFOSBUVIR FOR HEP C

Excessive pricing zone

Fair pricing zone

Simplified example: Sofosbuvir for Hepatitis C

Profit margins
Adm/Dist/Reg
R&D costs
Cost of production
Price ceiling

IS:
- Conceptual
- Judgment tool

IS NOT:
- Fixing a price
- International agreement
HOW DO WE THINK ABOUT MEDICINES PRICES?

Old
• How much do we pay, compared to others (like us)?
• How does it compare to prices of competing products?
• At that price, how many people can we afford to treat?
• How to achieve fairness in my country?
• What is the price per patient?

New
• What price is affordable & allows for universal access?
• How much did it cost? (to develop, produce and distribute)
• How much profit has been earned? What’s a fair profit?
• How to achieve fairness in my country, in a global context?
• How to pay for innovation, delinked from setting a price per person treated?

Need some combination of old and new, but probably more new
Negotiation

Pooled procurement

Mandate Information Disclosure

“Netflix” model

Health Technology Assessment

Address regulatory barriers to competition

Import for Personal Use

Medical Tourism

Pharmacist compounding

Reference Pricing

Licensing - compulsory or voluntary

Patentability criteria

Competition Law

Alternate R&D models

Conditions on public R&D funding & incentives

Publicly-mandated production
AUSTRALIA’S “NETFLIX” MODEL
HEPATITIS C

• 2015: estimated 230,000 with HepC but high drug prices
• Fixed lump-sum fee – or “prize” of ~AU$ 1 billion ($766m)
• 5 years of unlimited supply = universal access offered

• Our estimate 2016-21: 104,000 patients
  • Effective per-patient price: AU$ 9600 ($7352) vs ~$54,000
• Savings: AU$ 6.4 billion or 93,000 patients
• Australia: 1.65% global GDP vs 1.32% global DAA market

• Public benefit: budget certainty; each person = no marginal cost; incentive to treat early
• Seller benefits: sizeable reward; revenue certainty; production cost ~1% revenue

Source: Moon and Erickson (2019)
3 CONCLUSIONS

1. A clear idea of “fairness” can help
   → To achieve it in practice
   → To justify it to publicly

2. More information transparency needed to assess fairness more objectively

3. Many tools available to make prices fair(er) in practice
   → Key question: political willingness to use these tools

Thank you, Ke a leboha
Comments to: Suerie.moon@graduateinstitute.ch
Exhibit 8: Developed Market Brand Invoice and Net Spending 2007-2022

**PRICE TRENDS**

Exhibit 10: Brand Spending Growth of Specialty and Traditional Drugs 2013-2022 in the Developed Markets


- Specialty: ~40% total spending (2018) → ~50% by 2022
- Includes cancer, HIV, Hepatitis C, autoimmune, others
STICKER SHOCK

€ 48,000 (2014)

€ 133,000 (2015)

€ 320,000 (2018)

$850,000 (2018)

TRANSPARENCY

REMOVING THE BLINDFOLD ON MEDICINES PRICING

Information needed on:
- Prices
- R&D costs
- Public R&D funds
- Tax breaks
- Patent status
- Data on safety, efficacy, health system effects

Source: Moon S. (2018) Removing the blindfold on medicines pricing. BMJ; 360 doi: https://doi.org/10.1136/bmj.k840
PUBLIC RETURN ON PUBLIC INVESTMENT: CASE STUDY DAA FOR HEPATITIS C

- 1974: Non-A, Non-B Hepatitis identified by US NIH scientists
- 1989: Hepatitis C virus identified (US CDC, US NIH, Chiron)
- 1999: Replicon isolated by R. Bartenschlager (Heidelberg University, funded by German Ministry for Research & Technology, German Society for Research)
- 2002: Replicon improved by C. Rice (Rockefeller University, funded by US NIH)
- 1999-2008: Apath (SME) distributes replicon to drug developers (funded by US Small Business Innovation Research program)
- 2001-11: Pharmasset (SME) develops sofosbuvir
  - 2004-8: PS-6130 adapted with McGuigan method (UK Medical Research Council, European Commission, Belgium)
- 2011: Gilead acquires Pharmasset for $11 billion
- 2012-5: Merck, Bristol Myers Squibb, J&J acquire Hep C SMEs
- 2013: US FDA approves Gilead’s sofosbuvir
- 2013-7: Gilead HepC revenues >$50 billion

PUBLIC RETURN ON PUBLIC INVESTMENT

• Sampat & Lichtenberg (2011):
  • Patents on 478 FDA-approved medicines 1988-2005
  • About ½ approved medicines benefits from publicly-financed research
  • 2/3 for priority review medicines

• Cleary et al (2018):
  • Publications relating to 210 new molecular entities FDA-approved (2010-6)
  • 100% benefited from US NIH funding

• Areas of market failure:
  • Neglected disease: 84% public (64%) & philanthropic (21%)
  • Antibiotics, Outbreak-prone pathogens?

OUTSIDE THE BOX R&D:
DNDI’S HEPATITIS C STRATEGY

Traditional pharmaceutical business model

New pharmaceutical business model?

Innovation “balanced” against affordability

Innovation with affordability
DNDI’S HEPATITIS C STRATEGY

• Hep C DAA race: Gilead, Merck BMS, J&J, AbbVie
• Slower: Presidio Pharmaceuticals (SME): ravidasvir
• Multiple firms, parallel DAA R&D on public knowledge base

• Drugs for Neglected Diseases initiative (DNDi)
  • 2016 launches ravidasvir+sofosbuvir development
  • Especially relevant for middle-income countries
  • Medicines Patent Pool license: 4% LIC royalty, 7% MICs
  • High-income countries: why not?
OUTSIDE THE BOX R&D: DNDI’S HEPATITIS C STRATEGY

HEALTH • DRUG PRICES

Hepatitis C Drugs Can Cost $84,000. This New One May Be Just As Good—but Cost $300

Donald Trump Says Pharma Companies ‘Get Away with Murder’
And the comments took a toll on their stocks

By SY MUKHERJEE  April 12, 2018

Striking advances in hepatitis C drug development over the past five years have made the infectious, liver-wasting viral disease a curable one—if you can afford the drugs.