Algunos aspectos de los sistemas de precios: diferenciación internacional de precios y precios basados en el valor

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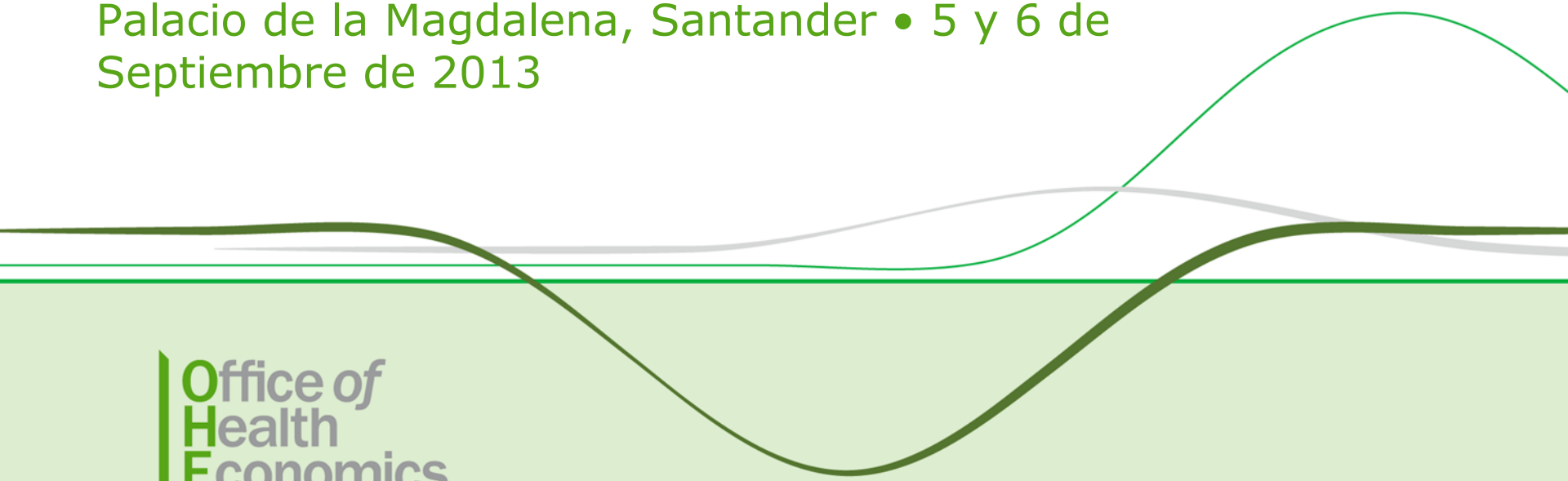

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Agenda

1. Background: static and dynamic efficiency
2. Value-Based Differential Pricing (VBDP)
    1. Application to universal payers
    2. Practical issues
    3. VBDP between countries
3. Relation between VBDP and Ramsey pricing
4. Self-pay markets
5. Some examples of differential pricing
6. Conclusions

Background

- Achieving efficient pricing of pharmaceuticals between and within countries is a complex conceptual and policy problem
- The optimal price that maximises the social welfare must consider two objectives:
  - Static efficiency, i.e. optimal use of existing products
  - Dynamic efficiency, i.e. optimal investment in R&D

Achieving static and dynamic efficiency

- Reconciling these two objectives for pharmaceuticals is problematic:
  - Marginal cost pricing to achieve first best static efficiency would fail to cover total R&D costs
    - Patents enable pricing above the marginal cost to recover R&D investments ("second best" pricing if it reduces utilisation)
  - The effect of patents is distorted by insurance coverage
    - In most industrialised countries, insurance makes demand highly price-inelastic, creating the incentives for pricing above the "second best"
    - In middle and lower income countries (MLIC) – self-pay markets - the lack of insurance avoids price distortions. However, other factors (e.g. skewed income distributions) contribute to prices exceeding the "second best"
  - R&D is a global joint cost benefiting consumers worldwide - Efficient global pricing requires appropriate contributions from different countries to this joint cost
    - Price discrimination and Ramsey pricing theory provide criteria for an efficient structure of *relative* prices but *do not address absolute price levels*
- We outline an approach to achieve static and dynamic efficiency within and between countries

NBER WORKING PAPER SERIES

VALUE-BASED DIFFERENTIAL PRICING: EFFICIENT PRICES FOR DRUGS IN A GLOBAL CONTEXT

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Working Paper 18593
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Value-Based Differential Pricing

- As starting point we consider the problem of optimal pricing and utilisation in a single country, treating the availability and price of medical technologies as exogenous

- It can be shown (see Garber and Phelps, 1997) that optimal utilisation requires equating the technology's incremental cost-effectiveness ratio (ICER) to the consumer's willingness to pay (WTP) for medical care

VBDP: application to a universal payer

- We assume that each country operates a universal insurance system
  - Prices charged by manufacturers and technology availability are endogenous and influenced by insurance design and payer strategies
- The payer can indirectly control prices by setting an ICER threshold that reflects its citizens' willingness to pay
  - Given the manufacturer's choice of price, the payer can achieve appropriate use by limiting coverage to those patients for whom the product is cost-effective at this price and ICER threshold
    - If a firm chooses a high price, the payer would restrict use to patients whose condition implies an expected health benefit sufficient to meet the ICER threshold
    - If a firm chooses a low price, the payer would encourage use by patients subgroups with lower expected benefit
- The manufacturer selects the profit maximising price, given the use that the payer would permit at that price
  - Static and dynamic ("second best") efficiency could be enhanced
  - If the manufacturer could vary prices by indication/subgroup, first best efficiency could be achieved at the limit
  - Such differential pricing within product may become increasingly feasible as drugs becomes more "personalised" based on patient biomarkers and data systems are improved

VBDP: application to a universal payer. Some remarks

- Our approach is grounded in overall utility maximization, so the payer's ICER threshold reflects consumers' willingness-to-pay for health gain, with the health care system
- Our approach permits prices that transfer all surplus to manufacturers for the duration of the patent, to achieve optimal R&D incentives

Practical issues in defining the optimal ICER threshold

- If a payer applies a single threshold ICER across all individuals, this ICER may differ from the willingness to pay for medical care of some individuals (patient heterogeneity)
  - In such a context, setting payer rules to reflect consumer preferences is likely to be superior to ignoring them
    - How best to elicit such preferences is an important issue for future research
  - In a pluralist system of competing insurers (e.g. the USA) different health plans could choose different ICER thresholds, implying different levels of patient access and different drug prices
  - In single payer or competing payer systems, payers could also vary ICERs by health conditions to address social preferences across conditions
    - An illustrative example is the UK NICE "end of life" ICER threshold reflecting perceptions that society's willingness to pay for health increases with disease severity

VBDP across countries

- The VBDP framework can be applied to determine optimal prices in each country with universal insurance coverage and optimal differentials across such countries
- If each public and private payer defines its ICER threshold unilaterally, based on its citizens' willingness to pay, the resulting prices and utilisation should be consistent with (second best) static and dynamic efficiency within each country and across countries
- If two countries differ in per capita income but are otherwise similar, our model suggests willingness to pay and the *resulting ICER threshold and price levels will likely be higher in the higher income country*
    - But the precise relationship to income cannot be predicted *a priori*

Incentives to free ride

- A country that accounts for a small share of global drug sales might recognize that setting its ICER threshold below its true willingness-to-pay reduces the prices that it pays for drugs with at most modest effect on its access to existing drugs or on global incentives for R&D to develop new drugs

- Such free riding incentives exist in any price regulation scheme and are not unique to VBDP

- Free riding tends to undermine appropriate price differentials between countries and would likely lead to suboptimal R&D

Relation between VBDP and Ramsey pricing

- Ramsey optimal pricing (ROP) has been proposed as an alternative framework for determining optimal pharmaceutical price differentials between countries
- How does ROP and VBDP relate?
- ROP is designed to determine welfare-maximising price differentials across consumer groups, given an exogenous joint investment and a normal return-on-investment (ROI) constraint
- Formally, ROP prices are designed to minimize the single-period welfare loss from consumption below first-best levels, subject to the ROI constraint, but ignoring future utility, incentives for R&D and any consumer budget constraint
- The *resulting ROP vary across countries inversely with price elasticity of demand*, assuming uniform marginal cost and one price per country
    - Absolute price levels are indeterminate without knowing cost and demand parameters and the ROI constraint

Relation between VBDP and Ramsey pricing

- VBDP is designed to address both dynamic and static efficiency; it incorporates consumers' lifetime utility and budget constraints, and sets prices to transfer all surplus to the innovator firm, to incentivise future R&D
- Both VBDP and ROP are designed to achieve second best static efficiency, but subject to different constraints and with VBDP also designed to achieve dynamic efficiency
- Only VBDP offers a practical approach to determine absolute prices, as well as relative prices
- Both the ROP and VBDP approaches suggest that *optimal prices will plausibly increase with income*

Conditions for differential pricing

1. The manufacturer must have market power – granted by patents
    - The manufacturer will no longer be able to exert its market power once the patent has expired
2. The manufacturer must be able to prevent arbitrage
    - Parallel trade limits this
3. Different buyers must attribute different values to the product, and the manufacturer must be able to separate these buyers into groups - *manufacturer must be able to segment the market*
    - International reference pricing limits this

Benefits of differential pricing

- Price discrimination *between* markets is likely to be welfare enhancing (as compared to uniform pricing) if:
  - Demand dispersion between markets is large
  - Aggregate consumption increases
  - No markets drop out as a consequence
- Also likely to increase profits and R&D incentives

Self-pay markets

- Countries without universal insurance coverage lack its distorting effect on prices
  - Patients' self-pay demand should therefore reflect their willingness-to-pay for expected incremental QALY benefits, given good information on product quality and effectiveness
  - Since profit maximizing price discrimination leads to the same *relative* prices (inversely related to demand elasticities) as ROP prices, market incentives should lead unregulated price discriminating firms to set optimal price relativities across markets, provided they can segment markets between and within countries
  - Absolute price levels might be constrained to yield only a normal return by competitive entry

Self-pay markets

- Whether actual cross-national price differentials in self-pay MLIC markets approximate ROP differentials cannot be determined because true demand elasticities and marginal costs are not observable
- However, empirical evidence across a sample of self-pay MLICs shows that actual prices are inconsistent with optimal differentials under either ROP or VBDP prices (Danzon et al., 2011)
  - Highly skewed income distributions create incentives for single-price originators to charge prices that are high relative to average per capita income (Flynn et al., 2009), and
  - price-discrimination between income groups within countries is generally not feasible
  - Quality of generic "copies" is uncertain in most MLICs because such generics are not required to meet regulatory standards of bioequivalence to the originator. This leads to competition focused on brand rather than price

Self-pay markets

- Thus achieving prices closer to VBDP optimal prices in these self-pay markets requires regulatory requirements to assure product quality and purchasing mechanisms that facilitate differential pricing between market sectors based on income
- Procurement mechanisms for HIV, TB and malaria drugs provide an interesting prototype, at least for these drugs

An example of global differential pricing: the Global Alliance for Vaccines and Immunization (GAVI)

- The GAVI Alliance is a public-private partnership bringing together developing countries, (public and private) donors and the vaccine industry to provide vaccines in eligible developing countries
  - Most vaccines now have a three-tiered pricing structure with full prices in rich countries, low prices in GAVI countries, and intermediate prices in other middle/low-income countries (Yadav, 2010)
  - In 2011, UNICEF procured 2.5 billion vaccine doses worth over US$ 1 billion on behalf of developing countries, with GAVI-funded vaccines representing nearly two thirds of this amount (GAVI, 2011)

Vaccines

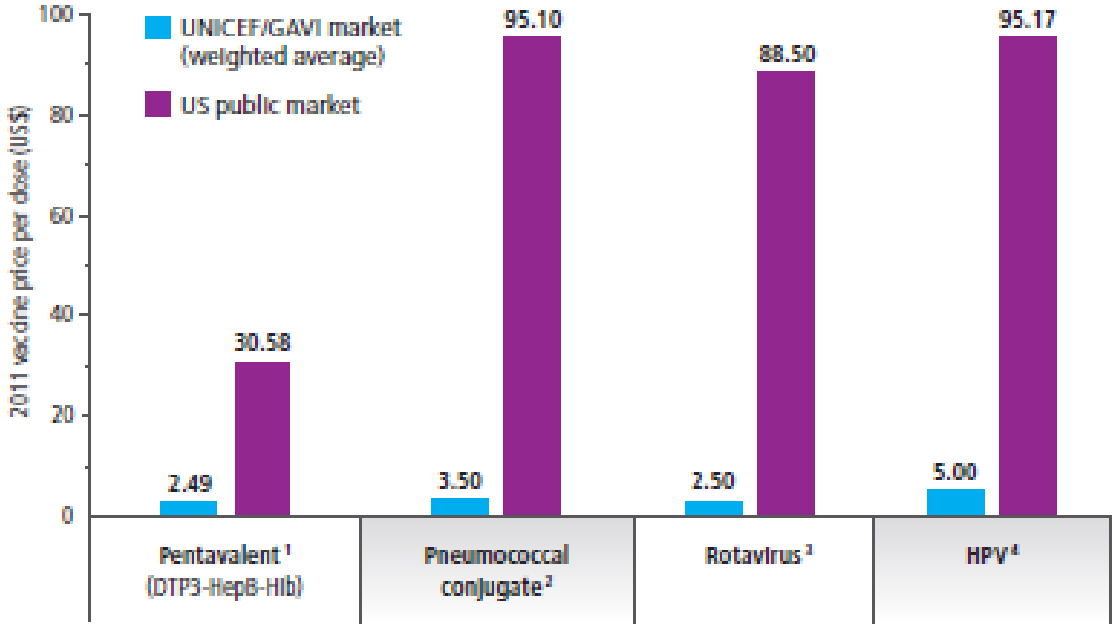
- The application of differential pricing for vaccines sold in both high- and low-income countries is facilitated by some conditions that act to prevent arbitrage:
  - *"vaccine supply systems are largely publicly owned and vaccines are typically administered through injection so they cannot be sold freely like drugs"*, and
  - *"vaccines require a cold chain from the start till the end of distribution cycle implying a better monitor capability"* (Yadav, 2010)
- Empirical evidence also shows that arbitrage from low-income to high-income countries is limited (Outterson, 2005)

Vaccines

- More importantly, differential pricing for vaccines for global diseases has received *widespread support* from policymakers in both high- and low-income countries in addition to the manufacturers' support, a condition that helped in implementing tiered pricing of vaccines
- Low-income markets would gain access to essential vaccines that would otherwise be unaffordable if priced at a uniform price. It has been estimated that high-income countries provide 82% of the revenue of vaccines industry, but represent only 12% of volume (Plahte, 2005; Outterson, 2006). This means that the remaining 88% of volume is represented by people in middle- and low-income countries who have access to vaccines mainly because of differential pricing
- Manufacturers can increase their total revenues by expanding sales to middle- and low-income markets

Vaccine prices - examples

Figure 22: Tiered pricing: vaccine prices in different markets



[1] The combination procured by UNICEF is not provided in the US markets; US prices refer to the sum of a DTaP (diphtheria-tetanus-acellular pertussis) vaccine, a HepB monovalent vaccine and a Hib vaccine.

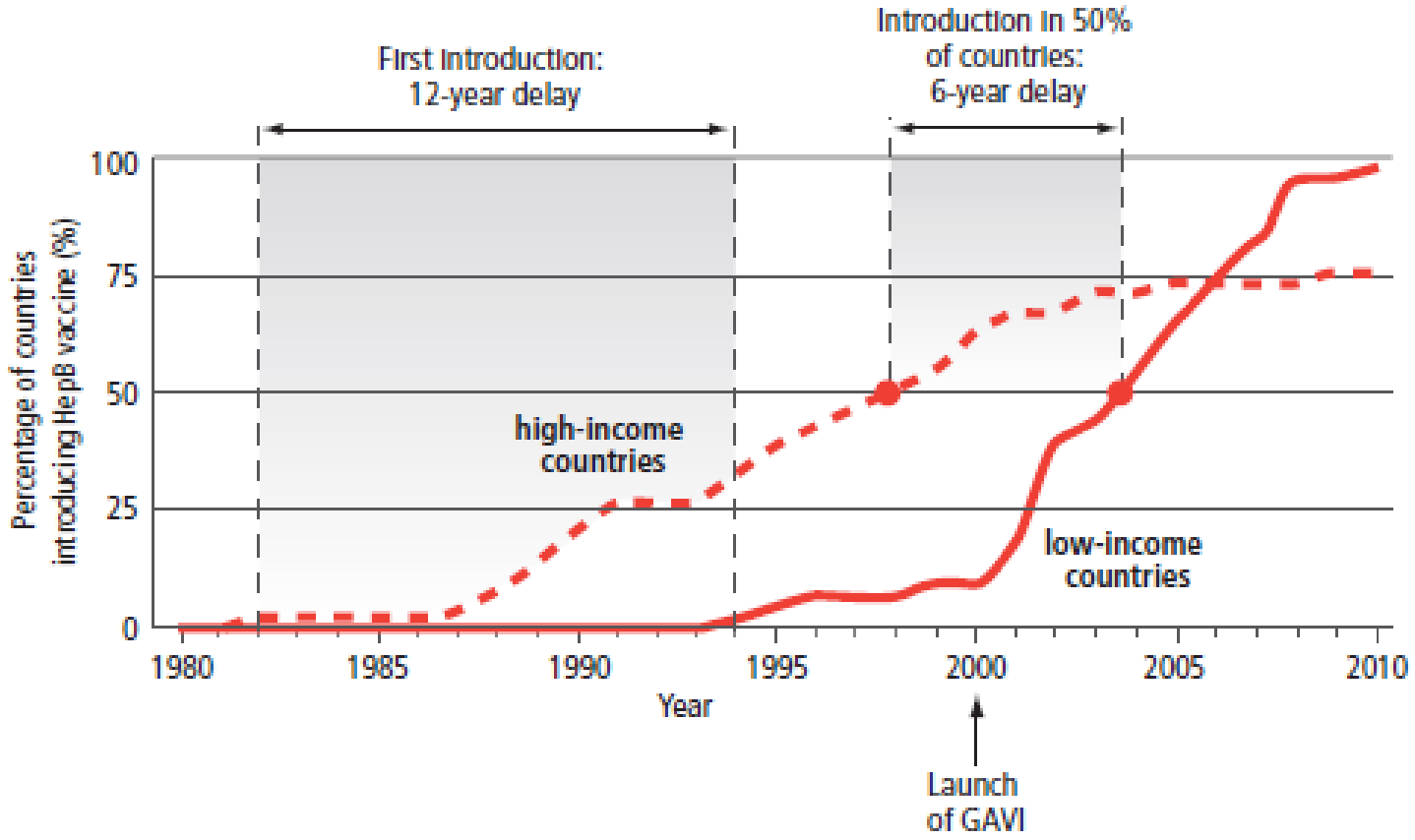
[2] 13-valent vaccine (US markets) and tail price cap under the AMC agreement (UNICEF/GAVI market).

[3] Refers to GlaxoSmithKline product procured by GAVI as of 2012.

[4] Refers to price offer to GAVI in 2011.

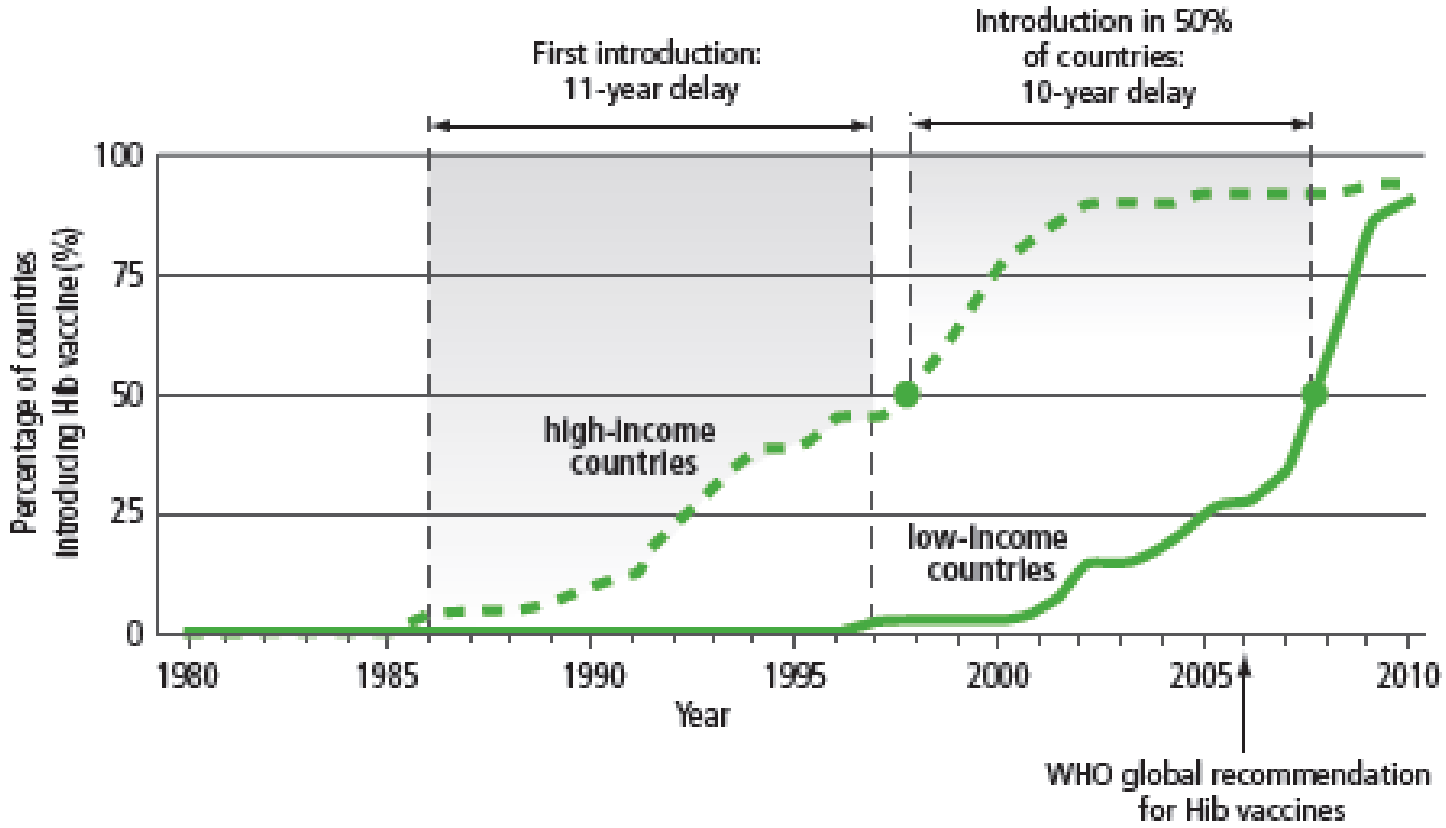
Source: GAVI (2011)

GAVI – Hepatitis B (HepB) vaccine



Source: GAVI (2011)

GAVI – Haemophilus influenzae type b (Hib) vaccine



Source: GAVI (2011)

Current state of differential pricing

Table 4. Summary of Current State of Differential Pricing for Different Categories

Essential medicines	• Few clear examples of positive differential pricing on a large scale • No significant volume or income effects on prices found in empirical studies • Many manufacturers have started large scale differential pricing programs only recently • Drug donation programs with $p = 0$ commonly used
HIV/AIDS Drugs	• Multiple examples of tiered-pricing • Political pressures from low and middle income countries to reduce prices • High risk of informational arbitrage to erode margins in high income markets • With new entrants, supply market dynamics working in favor of using price differentials
Contraceptives	• Price of contraceptives in low income countries is lower by a factor of 10-100 • Careful product versioning and differential branding • Social marketing and social franchising often used as the sales channel
Vaccines	• Price of vaccines is much lower in developing countries • Vaccines are purchased by UNICEF, PAHO and vaccination programs are run by state and NGO actors • Higher opportunities for differentiation due to multi-valency • Little risk of leakage and good supply chain traceability • Buy side market structure creates challenges for differential pricing
Malaria Drugs	• Intra country price differential between public and private sector • Plans to further differentiate the prices within the private sector channel to better reflect ability-to-pay of each segment

Source: Yadav (2010)

In-country differential pricing

- The same theoretical and practical benefits from the optimal allocation of R&D costs when applying differential pricing between countries arise when considering differential pricing *within* a country
  - Differential pricing reflects more clearly the redistribution of the financial burden of the development costs of a medicine from the poor to the rich

In-country differential pricing

- "A key prerequisite for in-country differential pricing is the existence of two distinct markets: one with higher income and affordability and another with lower income and affordability" (Yadav, 2010)
- It might be most appropriate for the so-called middle-income or emerging markets, where there are substantial differences in income levels between the wealthy (very small proportion of population) and the poor
- If uniform prices are applied in these countries, it is most probable that the poorer segment would not be able to afford them

In-country differential pricing

- Factors affecting implementation:
  - Lack of universal health insurance coverage associated with significant patient out-of-pocket expenditure
  - Urban-rural income divide, and
  - Confidentiality of rebates and discount agreements
- Brazil, China, India, and Thailand can be considered a favourable ground for implementing in-country differential pricing (Daems et al., 2011)
  - Benefits: *"can lead up to 90% of the population having access to the drug and increases the manufacturer's overall revenue from the market"* (Yadav, 2010)

In-country differential pricing

Examples

- Hepatitis B vaccine offered by GSK
  - India: US$2/dose in the private market, and around $1.00/dose in the public and NGOs Indian market.
  - Brazil: price varied from $5/dose to the private sector to $0.58/dose in the public sector (Yadav, 2010)
- AMF (2012): "Since 2010, seven additional companies have started to implement intra-country tiered pricing, bringing the total with intra-country schemes to 12"
  - Leaders: Novartis, GSK and Sanofi

Source: Access to Medicine Foundation (2012). Access to Medicine Index: 2012. Available online: http://www.accesstomedicineindex.org/index-publications

Issues for the future?

- **Collaborative international agreement:** "Public" two-tier pricing for vaccines and "key" diseases across countries works well. However, there is resistance to a "middle tier" from MICs. HICs continue to use reference pricing
- **Confidentiality and negotiation:** Within country segmentation requires either a protected procurement channels or ability to target (e.g. to assess income, use of a discount card). Public hospitals, targeted insurance programs or other mechanisms might serve as such a protected channel
- Finding better mechanisms to promote price competition and enable differential pricing between and within low and middle income countries remains an important challenge for companies and policymakers

Conclusions

- Optimal pharmaceutical pricing is complicated by high R&D and patents, and by extensive insurance in industrialised countries
- For countries with universal insurance, if each country/payer unilaterally and non-strategically sets an ICER threshold based on its citizens' willingness to payer for health gain, the resulting prices and utilisation would be "value-based" and yield (second best) static and dynamic efficiency within and across countries
    - Such value-based prices are likely to vary cross-nationally with per capita income
- In self-pay MLICs, unregulated price discrimination could lead to optimal prices, provided that consumers are well-informed about product quality and firms can price-discriminate within as well as between countries

To enquire about additional information and analyses, please contact Dr. Jorge Mestre-Ferrandiz at jmestre-ferrandiz@ohe.org

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