Pricing medicines

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Content

- Basic concepts
- Drug markets and pricing strategies
- Types of price regulation
- Conclusions and recommendations

Skyrocketing drug prices

Source: Liz Szabo USA TODAY 8:04 a.m. EDT June 15, 2015
http://www.usatoday.com/story/news/2015/06/14/rising-drug-prices/71077100/

New cancer drugs routinely priced over $100,000 a year

A drug for a subset of people of cystic fibrosis, a lung disease that kills most patients by their early 40s, costs more than $300,000 a year.

Drugs for multiple sclerosis, which cost $8,000 to $11,000 a year in the 1990s, now sell for about $60,000 a year.

Sovaldi, approved in 2013 to treat chronic hepatitis C infections and cures 90% of patients in 12 weeks. But some people with hepatitis C will never have a chance to try it at $1,000 a pill ($84,000 per course of treatment.)

Gleevec, which transformed chronic myeloid leukemia from a death sentence into a chronic disease, cost $31,488 when it was approved in 2001. Its cost has since tripled — to more than $110,000 — even though it now competes with two similar drugs.

What is a price?

- The amount of money that you pay for something (monetary price).
- Transaction price vs. catalogue, list or official (maximum) price.
- Discounts, rebates and in kind payments should be deducted when quantifying the price.
- A price can be defined at a single transaction or as a representative value (e.g. average) of the transactions that occurred over a certain period of time in a given market.

What kind of medicine prices do we want?

- Efficient prices?
- Competitive prices?
- Optimal prices?
- Affordable prices?
- Fair prices?

Assumptions of perfect competition

1. Large Number of Sellers and Buyers.
2. Homogeneous Product: The technical characteristics of the product, as well as the services associated with its sale and delivery are identical. There are no imagined differences in the minds of different buyers for the products made available by various sellers.
3. Free Entry and Exit: No entry and exit barriers; firms are free to enter or leave the industry.
4. Absence of Government Regulation.
5. Perfect Mobility of Factors of Production.
6. Perfect Knowledge: The information regarding the availability, cost, price, quantity, nature of the factor or product, etc. is assumed to be available free of cost. Uncertainty of any kind does not exist.
7. Absence of Transportation and Selling Costs

Outcomes of perfect competition

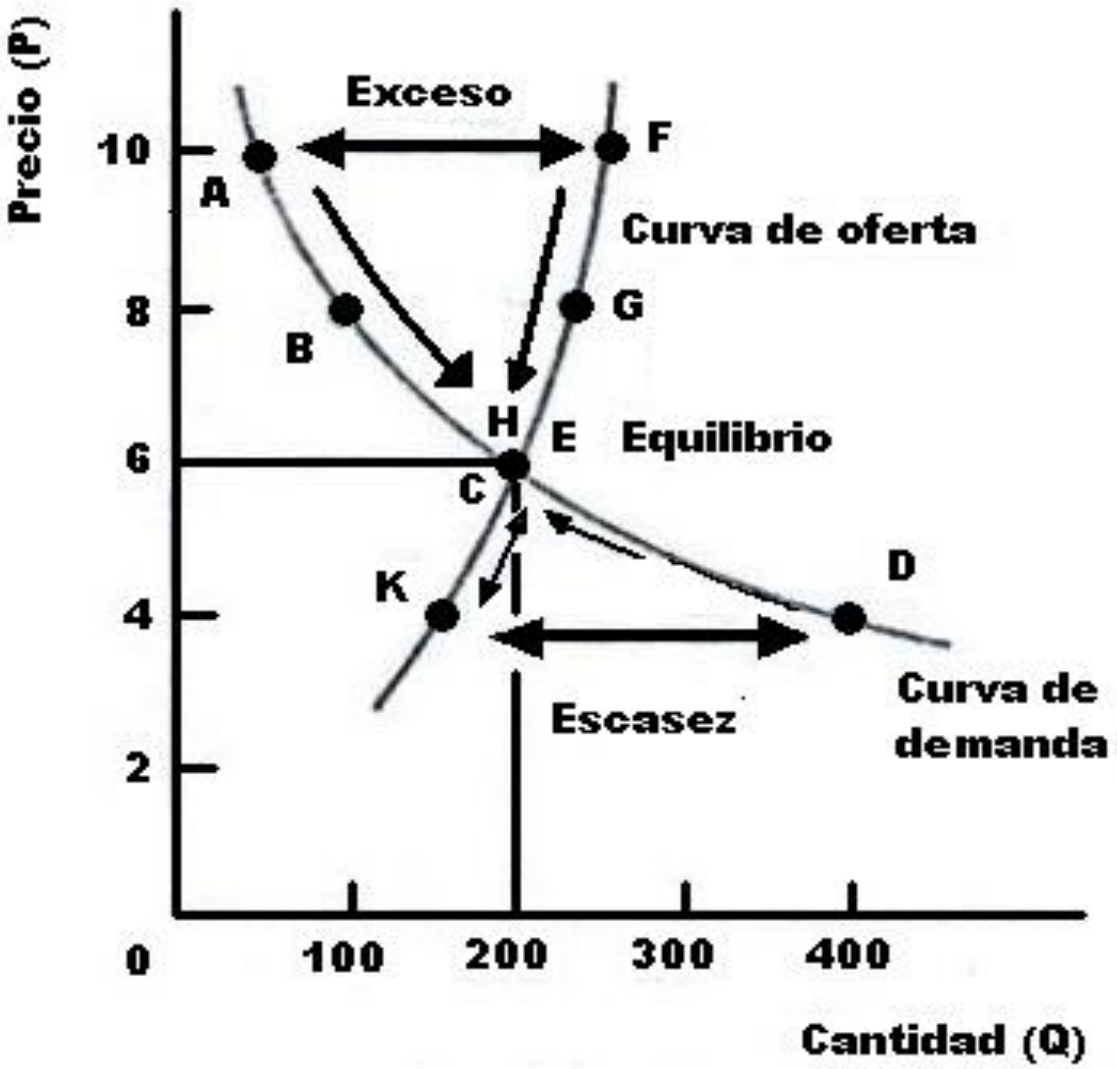
- A single price will prevail, because:
- No individual seller would change its price from the market price level. If it attempts to raise the price above this level, he will lose all its buyers, who will shift to products supplied by some other seller.
- Similarly, no seller would like to lower its price below the market level, as it can sell «any» quantity at the said price.

The role of prices

- In a market economy prices send signals and provide incentives for buyers and sellers.

- Higher prices send a signal to buyers to reduce their consumption and a signal to sellers to increase their production. Both buyers and sellers have an economic incentive to do so. These market reactions ensure that shortages either do not occur or are short lived.

The invisible hand at work

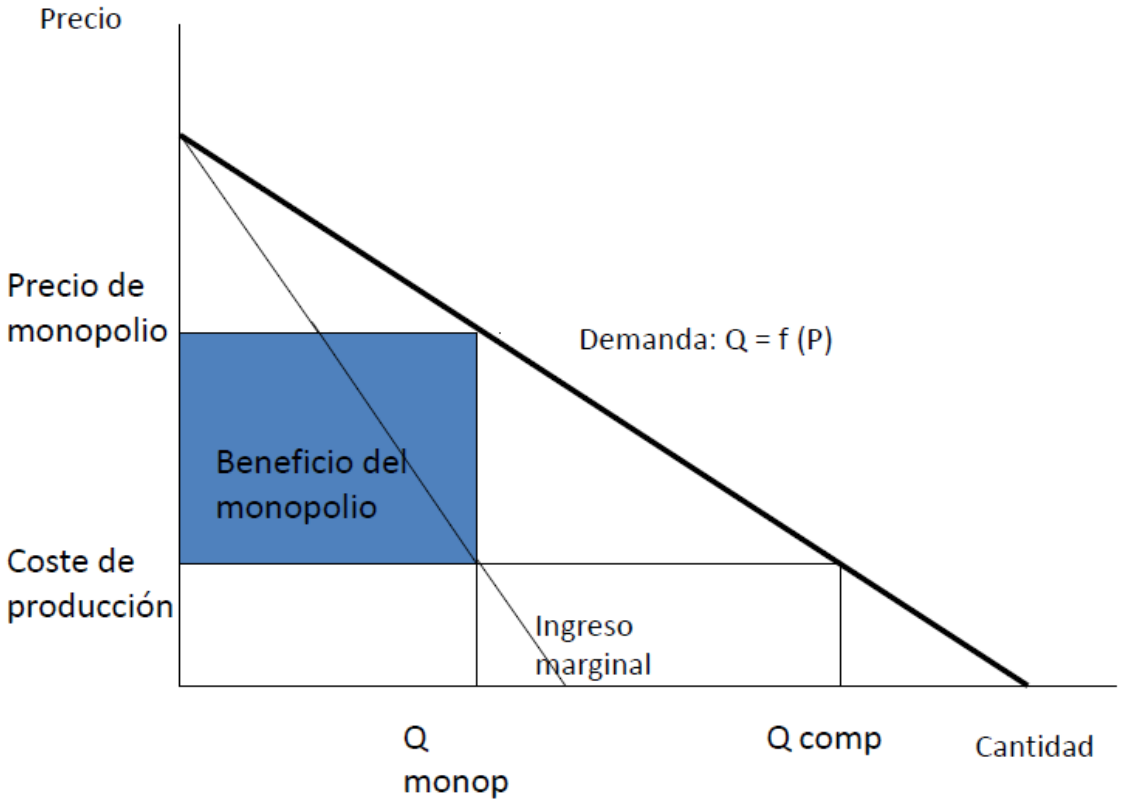


Perfect competition vs. monopoly

- In a market under perfect competition prices tend to be set at the cost of the last unit of good produced (including a normal profit). The firm is a price taker and output adjuster.
- In a monopolistic market the firm sets either the price or the output; a profit maximising monopolist sets the price at the level that it obtains the largest total profit (units of product x price – total costs).

The monopoly

Figura 1: El mercado en monopolio



How do medicines markets work?

- Markets of single-source medicines (on-patent or protected by other exclusivity rights) with no equivalent medicines (with similar effects), work basically as the monopoly model predicts.
- Markets of multisource, INN medicines work basically as the perfect competition market model predicts.
- Other market modalities: monopsony, oligopoly, product differentiation (monopolistic competition, with brand loyalty) and combinations.

The assumptions of perfect competition in medicines markets

1. One, few or many sellers and buyers
2. Products can be considered technically homogeneous if the DRA enforces strict quality standards; still, brands and advertising lead to product differentiation
3. Patents and exclusivity rights, know-how, size and brand loyalty set barriers to entry
4. The industry is highly regulated
5. Information asymmetries

The assumptions of perfect competition in medicines markets

6. Supply and demand are often not “at arms length” (perverse incentives can induce (increase) demand beyond clinical/rational reasons.

7. Insurance and public financing remove the budget constraints of the users and its sensitivity to price (increased demand due to moral hazard)

The imperfections and market failures of medicines markets can justify market intervention by authorities to attain accessibility, innovation and sustainability.

Strategies to attain access, innovation and sustainability

- Financing/reimbursement policies

  The primary aim is to ensure equitable access and affordability. They can also reduce prices.

- Competition policies

  They are aimed at removing/reducing market failures and improving competitive forces.

- Price regulation

  Aimed at substituting market forces by administrative decisions in determining prices

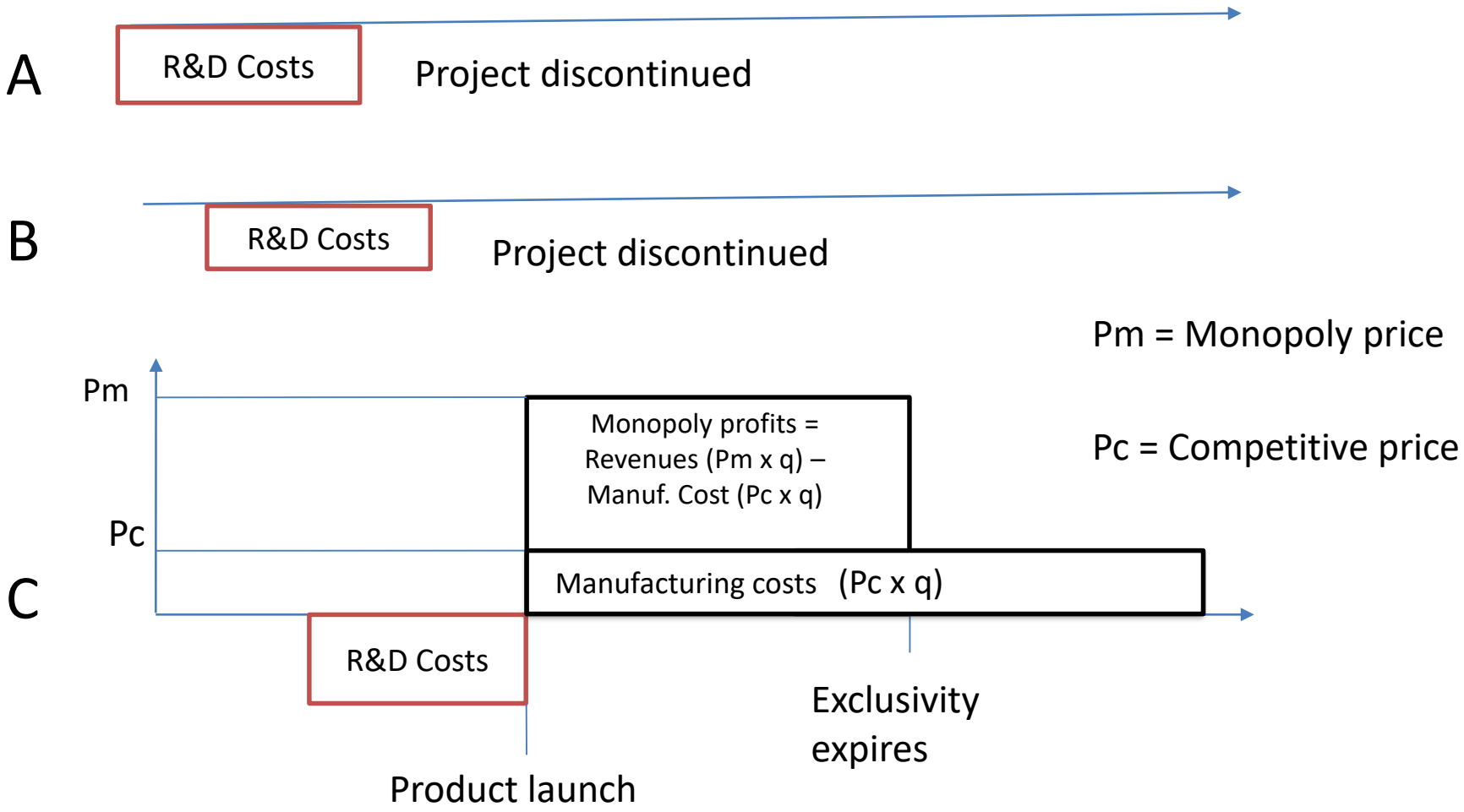
Financing/reimbursement policies (Selective financing)

- Positive and negative lists (essential medicines, cost-effective medicines)
- Subsidies/co-payments levels related to therapeutic value or to cost-effectiveness
- Internal reference prices (public financing up to the level of the lowest priced equivalent medicines)

Competition policies

- Providing prescribers and users unbiased information on characteristics and prices of medicines
- Providing incentives to prescribers for rational and efficient prescribing: monetary incentives, advice, supervision,…
- Enforcing or promoting INN prescribing and generic substitution by pharmacists
- IP management: fighting patent abuses, granting compulsory licenses, promoting non-monopolistic R&D mechanisms.

Present innovation model based on patents and exclusive marketing rights



Modalities of price regulation for medicines under exclusivity

- Cost of production criterion (cost-plus)
- *Profit control*
- Value-based pricing
- *Price of similar treatments for the same indication*
- External reference pricing
- Differential (equity, tiered) pricing

Cost of production approach

- Traditionally applied in regulating monopolies of public utilities (water, energy, roads,…)
- First approach used in regulating drug prices, but progressively abandoned.
- It does not consider the (therapeutic) benefits of a drug and hence it does not promote efficiency.
- Difficult to apply to originator firms due to the size of sunk R&D costs and the uncertainty of the results of the R&D processes.

Profit control

- The only interesting example is the UK PPRS (Pharmaceutical Pricing and Reimbursement Scheme)
- Applied only to large originator companies.
- A maximum profit rate is allowed on NHS sales. The size of the profit rate relates to the innovative nature of the firm.
- If profit rate is exceeded the company must return the extra profits.
- Independent audits of the firms' costs and sales, including the headquarters of foreign firms.
- PPRS pricing is often followed by NICE's Value Based Financing (cost-effectiveness threshold)
- Plans to merge PPRS and NICE VBF are under discussion.

VALUE BASED PRICING (VBP)

- Economic evaluation of new drugs and technologies provide an incremental cost-effectiveness ratio (ICER), e.g., cost per QALY.
- Ideally, a cost-effectiveness threshold must be set to decide whether:
  1. The price requested by the firm is accepted, or
  2. The drug is reimbursed at the price requested
- The decision procedure can be modified in order to account for factors and values not captured by economic evaluation (rare diseases, end-of-life conditions, etc.). For instance, by setting higher thresholds for specific diseases or conditions.

Pricing according to the costs of existing equivalent treatments

- A simple form of VBP that can be applied when a new drug/technology is equivalent (does not make a therapeutic contribution) to the existing treatments for a given indication, i.e. it has the same value.
- The maximum price allowed for the new drug is set at the level that makes the total cost of the new treatment equal to the total cost of the most effective existing treatment.
- The decision is based on a cost-minimisation analysis
- It has a limited applicability, as perfect therapeutic equivalence is seldom the case. Many new drugs (me-toos/follow-ons) might have small therapeutic advantages, at least for some patients.

Risk sharing agreements (1)

RSA includes a set of mechanisms whereby the buyer does not committed itself to pay the units of product used at a fixed price, but:

1. Price volume agreements
   - If sales exceed the initially estimated/agreed level, the unit price is progressively reduced
2. Payment related to outcomes
   - The buyer pays as far as there is a positive outcome at individual or community treatment level

Risk sharing agreements (2)

- Imply a certain discount on the list price of the drug, i.e. a lower transaction price.
- Discourage potential pressures for unexpected, unjustified prescribing.
- Imply paying for health gains, not for health goods/services.
- But they are expensive to design and implement.
- Companies often impose the confidentiality of the terms of the agreement in order to hide the real price and prevent spillovers (other buyers asking for the same low price or using it in its external reference pricing formula)

Mapping External Reference Pricing Practices for Medicines

September 2014

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Results (1)

- 55 countries are using ERP
- 45 countries are not, but
  - 14 are planning to use ERP.

- Most countries using ERP are in the European region, and classified by the World Bank (2014) as high-income countries.
- Only five low-income countries are using ERP.
- The majority of countries (9 of 14) planning to use ERP are middle-income countries.

Table 10. Countries that reference countries with a lower GDPpc

Referencing country	GDPpc in US$	Total number of referenced countries	Number of referenced countries with a lower GDPpc	Average difference in GDPpc as a %	Referenced country with the largest GDPpc difference as a % in relation to the referencing country
Hungary	19,637	30	4	-19.6	Romania: -34,8;
Latvia	18,254	7	1	-29.8	Romania: -29.8
Poland	20,591	8	3	-9.8	Croatia: -13.5;
Slovakia	24,249	27	9	-22,0	Romania: -47.2;
Czech Republic	27,191	27	13	-22,8	Romania: -52.9
Austria	42,409	27	26	-32,1	Romania: -69.8
Belgium	37,883	27	21	-32,7	Romania: - 66.2
Spain	30,557	27	16	-26,7	Romania: -58,1
Ukraine	7,374	8	1	-53.7	Moldova: -53.7
Malaysia	16,992	11	6	-22,7	South Africa: - 32.8
Pakistan	2,880	2	1	-29,9	Bangladesh: -29.9
Colombia	10,792	17	2	-3,7	Ecuador: -6,8

Conclusions (1)

- Based on information from 100 countries, we found no examples of high-income countries referencing low-income countries as defined by the World Bank.
- On the basis of this finding, low prices offered by pharmaceutical companies to low-income countries would not result in reduced prices in high-income countries as a consequence of current, formal ERP practices.

Conclusions and comments (5)

Two basic principles for a fair system to finance medical R&D:

- Biomedical innovation is a global public good.
- The cost of innovation should be shared by beneficiaries/users countries and consumers in a fair/equitable way, i.e. in relation to purchasing capacity/income and maybe other factors (e.g. burden of disease)
- The rational option: an International Treaty for Financing Biomedical Research

A final recommendation (1)

- In the absence of an international consensus, countries could unilaterally apply a fair, equitable, value-based and income-adjusted external reference pricing approach, based on the following criteria:
- Use a basket of countries with transparent value-based pricing procedures (e.g., UK-NICE, Canada, The Netherlands, Australia, etc.)
- Request affidavits from the firms on the actual transaction prices and discounts in the reference countries. Cross-check whenever possible.
- Adjust the average or median price of the basket for PPP or relative income per capita.

A final recommendation (2)

- Consider more sophisticated approaches (assess or estimate manufacturing costs, R&D costs and other necessary costs in order to fine-tune the procedure)
- Use Value Based Pricing as a second line approach
- Prepare a Plan B in case companies stop launching important products in the country: issuing compulsory licenses, finding appropriate providers or promoting local production, etc.

Thank you for your attention

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