EL DESAFÍO DE LOS PRECIOS EXCESIVOS Y EL ACCESO A LOS MEDICAMENTOS EN LA UNIÓN EUROPEA

Costes, precios, patentes y licencias obligatorias

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Introduction

Wide and growing concern with prices of new pharmaceutical products – some estimates for the US state 7-10% yearly growth rate in list prices (down from a mean above 10%/year in 2011-2016), 2-5% yearly growth rate on net prices of branded drugs (source: QuintilesIMS)

More products will arrive in the market until 2021

EU health ministers have expressed concern about “affordability”

EU MPs have contributed to this debate, as it is well known

Companies have reacted, looking for “new pricing models, such as outcomes-based, or value-based contracts”
Will these efforts succeed?

Most likely, NO!

A question we should ask is whether, or not, proposed “solutions” are addressing the true problem.
A quick review of the past

Market economies and decentralized system to promote and to reward innovation have patents has a key feature.

Patents manage a trade-off between monopoly power and incentives for R&D (profits to reward innovation).

Patents allow for competition for the market (obtaining new products/new processes).

Patents have limits on market power coming from sensitiveness of consumers to prices.

Patents do not require the ex-ante definition of what is the innovation to be obtained and its value for consumers.
What do health systems bring to change this?

- Health and health protection systems – universal healthcare coverage as a goal – patients will pay a small fraction of the price, or even zero price
- Agency relationships – doctors acting on behalf of patients are not naturally sensitive to prices
- Health “targets” from neglected areas have been identified
- Institutional design – health technology assessment and economic evaluation to screen products
Lead to “threshold approaches” – it is worthwhile to have a new product if Cost/Benefit < K (K=threshold) (or a variant, such as ICER)

Critical issues: cost for payer/health system is price paid, benefit measured in Quality-Adjusted Life Years and K is value per life year.

For companies:

A price that still keeps cost to payer below the threshold does not affect demand – optimal price: the one that meets the threshold and call it value-based price

Increasing measured benefits is a way to implicitly or explicitly increase prices – invest resources in enlarging the scope of benefits to be included

This approach hides margins (split of value between who pays and who produces)

It avoids the need to know R&D costs (which can be claimed to be driving prices as well)
The main problem is with the institutional design, not with firms that operate under that design.

What is being “explored” as solution?

Health care payers obtain “secret” price discounts by direct negotiation (breaking the international reference pricing policies).

Claim for differential (tier) pricing – price discrimination that can increase efficiency of market allocations, but only under certain conditions (and these do not include free exercise of market power).

Better measurement of value of new products.

Joint procurement by purchasers, in an attempt to gain bargaining power by increasing volume of acquisition.

None of this addresses the key issue - division of value, and “abuse of market power” through use of existing institutional design.
“Abuse of market power” concerns are now making its way to policy


2015 – Pfizer fined by UK’s Competition and Markets Authority – excessive price and abuse of market power

May 2017 – European Commission opens case against Aspen

2017 – Maryland law on pharmaceutical price gouging

A trend is emerging...
End objective?

- Obtain innovation at “affordable” prices (?)
- Innovation in identified neglected areas – think about procurement for innovation, without necessarily giving market power through patents
- Innovation driven by companies choices – keep incentives by providing better rewards to better innovations (value-based health care measurements are useful here), without paying for costs only (it will drive costs up to justify prices)
What else can be done?

• Achieve a better balance in value division, by making clear the value created for society – difference between value of drug to payer/society and cost of R&D, production and commercialization (which need to be truthfully disclosed by companies to authorities)

• Assuming that negotiation of prices will remain,
  • Strengthen bargaining power of purchasers by using available instruments, including mandatory licensing due to public health motives
  • Assess which rules actually facilitate high price demands by companies

• Look for different ways to procure targeted innovation

• Recognize the relevance of international coordination in rewarding innovation (balance of “power” and interests across countries matters)
What’s next?

No single and simple solution is likely to emerge

A variety of options should be considered from the available menu

Both targeted and “organic” innovation are relevant – their different characteristics will demand different instruments

Country / health systems coordination is quite important

Health care payers need to assess their options to gain bargaining power without hurting innovation incentives

Changes in institutional frameworks and practice need to account for all reactions by all economic agents involved, and needs to go beyond “value-based pricing”, “risk sharing” agreements, etc.
Take home message

- The problem lies with the institutional design and rules we have
- Twin objectives of promoting R&D and affordable prices require trade-offs
- More options have to be explored:
  - Procurement of innovations vs patents as centralized vs decentralized innovation
  - Use instruments that provide bargaining power to countries/health systems
  - Approach abuse of market power directly (with new instruments if necessary)