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

Grupo de la Alianza Progresista de los Socialistas & Demócratas en el Parlamento Europeo
Delegación Española

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
  - 2014: case of Southeastern Pennsylvania Transportation Authority vs Gilead on pricing – dismissed in 2015. Dec 2015 – US Senate Hatch-Wyden report on pricing
  - 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)