Challenges on access to medicines in Europe and policy solutions

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Health Action International (HAI)

• Non-profit organisation
• Vision: Access to safe, effective, affordable and quality-assured medicines for everyone, everywhere
• Advocacy, policy, research
• Global network – HAI Europe Association
• Funding from governments and foundations
• No funding from the pharmaceutical industry

http://haiweb.org/
HAI’s European projects

Goal
• Advance policies for improved access to medicines and rational medicines use in the European Union

Challenge
• High prices of newly marketed medicines increasingly threaten:
  ➢ Affordability
  ➢ Sustainability of healthcare systems
The case of Lutetium-octreotaat:

- Cancer drug developed by researchers from the Erasmus Medical Center Rotterdam
- Produced at the hospital pharmacy
- Novartis starts marketing it as an orphan drug
- Five-fold price increase

The CDCA case (chenodeoxycholic acid):

- Available for long time at a low cost to treat gallstones
- In 2017 Leadiant gets approval to market it as an orphan drug for CTX
- 500-fold price hike
- Pharmaceutical Accountability Foundation files a complaint
Sovaldi: “The $1.000 Pill”

Official prices of a 12 week treatment

Unaffordable prices

High prices for new cancer treatments

“\The launch prices of drugs for cancer and rare diseases are rising, sometimes without a commensurate increase in health benefits for patients.\”


- What relation between R&D costs and prices?
- Innovation in the benefit of patients?
R&D spending, how much?

Independent estimates on R&D spending on ten cancer drugs:

• Median cost of drug development was $648 million ($757.4 million for a 7% opportunity costs)

• While the median revenue since approval was $1658.4 million (range, 204.1 $million to $22 275 million)

• With a median of 4 years since approval, the total revenue from sales was $67 billion...

  ... compared with total R&D spending of $7.2 billion ($9.1 billion, including 7% opportunity costs)

Evidence of benefit (or lack of)

- Published study at BMJ on cancer indications approved by EMA 2009-2013
- Research supported by HAI
- Results: Of the 68 cancer indications with EMA approval, and with a median of 5.4 years’ follow-up, only 35 (51%) had shown improvement in survival or quality of life, while 33 (49%) remained uncertain
- Survival gains over existing treatment options or placebo were often marginal
Measures to improve affordability & sustainability of health systems

• Health technology assessment
• Joint price negotiation
• Transparency of R&D costs and medicines prices
• Pro-public health innovation framework
• ‘Sunshine act’ legislation
Health Technology Assessment

• What added value of a new health technology compared to existing ones?

Based on EUnetHTA Core Model

- HTA Domains
  1. Health problem and use of current technology
  2. Description and technical characteristics
  3. Relative safety
  4. Relative clinical effectiveness
  5. Cost and economic evaluation
  6. Ethical analysis
  7. Organisational aspects
  8. Social aspects
  9. Legal aspects

• Informs price and reimbursement decisions

EUnetHTA

• Network of 80+ organisations in 30 European countries
• Joint Action 3 (2016-2020)
• Joint assessments, early dialogues, horizon scanning

• HTA Network
• HTA Network Stakeholder Pool (HAI, EFA)

Challenges:
Low uptake joint outputs
Sustainability issues
EU Regulation on HTA

• 2018 Commission proposal for a Regulation on HTA
  ➢ Mandatory joint clinical assessments
  ➢ Joint scientific consultations
  ➢ Horizon scanning
  ➢ Voluntary cooperation in non-clinical HTA domains

• Important principles for HAI:
  ➢ High quality assessments
  ➢ Flexibility
  ➢ Transparency
  ➢ Independence
Joint price negotiation

• Increased bargaining power

• Beneluxa initiative: Belgium, The Netherlands, Luxembourg, Austria, Ireland
  - Orkambi
  - Spinraza

• Other less advanced initiatives (e.g. Valletta Declaration, Visegrad group)
Transparency
R&D costs and medicines prices

Tell us the truth:
How the industry hides the true cost of developing new medicines

Pharmaceutical companies say that prices for new medicines are so high because it costs them so much to research and develop them.

But if that's true, why won't they tell us how much developing new medicines actually costs?

They've tried to tell us that, on average, it costs US$ 1.2 BILLION

But even the CEO of one of the biggest pharmaceutical companies admitted that that was "one of the greatest myths of the industry."

- Andrew Witty, CEO, GlaxoSmithKline

In fact, a not-for-profit research and development (R&D) organisation says that it only costs them €100-150 million to develop a new medicine.² Meanwhile, pharmaceutical companies actually spend far more on marketing than they do on research.³

If the industry can't be open about their costs, why should we accept their prices?

Let's demand transparency!
Join the fight for fair medicine prices.
www.ourmedicinesourright.eu

https://www.ourmedicinesourright.eu/take_action
Pro-public health innovation framework

• Public health sensitive IP rules
• Full use of TRIPS flexibilities
• Conditionalities to publicly funded R&D (Horizon 2020 & FP9)

http://accesstomedicines.org/
‘Sunshine act’ legislation

• Industry payments to physicians associated with higher rates of brand-name drug prescription and prescription costs (1, 2)

• Transparency of financial relationships can contribute to:
  ➢ Better informed decisions about HCPs and treatment
  ➢ Lower healthcare costs

• EU countries with legislated transparency: Belgium, Denmark, Greece, France, Latvia, Portugal, Romania, Slovakia


Thank you!

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