Accessing Innovation in CEE

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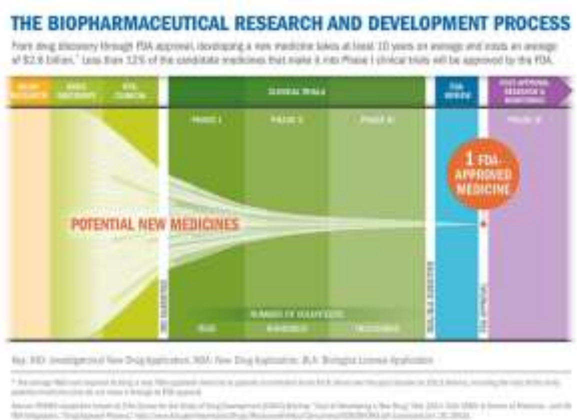
Why do we need innovation?

- Recent examples: Hepatitis C, CAR-T, Multiple myeloma, Melanoma
- There is still unmet need!
  - Rett syndrome
  - Huntington's disease
  - Alzheimer's disease
- We need to ensure the future of innovation
- We need a sustainable business model for pharmaceutical companies

Finding the right molecule



https://www.skepticalraptor.com/skepticalraptorblog.php/pharmaceutical-drug-development-vaccines/

How much does it cost?

- When capitalizing out-of-pocket costs and post-approval R&D costs, the total pre-approval cost estimate is **2.2 Billion EUR**
- For those companies that have launched more than four drugs, the median cost per new drug is **4.5 Billion EUR**
- Total capitalized costs were shown to have increased at an annual rate of **8.5% above general price inflation**.

DiMasi, J. A., et al. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of health economics*, *47*, 20-33.
Herper M. How Much Does Pharmaceutical Innovation Cost? A Look At 100 Companies. *Forbes*, Aug 11, 2013

How do we pay for it?

- Every single country has limited resources available!
- The budgets are tight and strictly controlled – need to be sustainable!
- Are the patients and payers willing to pay for innovation costs?
- Manufacturers need incentives to further continue innovation

Life expectancy

WHO data from 2012
https://jakubmarian.com/map-of-life-expectancy-in-europe/

GDP per capita

Source: https://hu.pinterest.com/vividmaps/

Common problem in middle income countries

- New drug in a disease area with huge public health priority
- However…
  - drug is not good value for money
  - with significant budget impact
  - uncertainty in the number of patients
  - uncertainty in health benefits for local patients

Implementation of Value Based Pricing across Europe

- Ex-factory pharmaceutical prices are usually **established for high income countries**
- What is fair (i.e. value based) price in a high income country, **may not be a fair price** in a lower income country
- Implementation of value based pricing of new health technologies necessitates **differential pricing** across countries

Potential scenarios

- Negotiate about the price reduction to improve value for money and affordability
- If the manufacturer cannot reduce the price:
  1. Purchase the medicine at a price which is above its value and affordability
  2. Not purchasing the breakthrough medication
- **Other option: managed entry agreement**

Solutions to facilitate differential pricing

- **Ramsey (differential) pricing** – adjustment of ex-factory prices to local purchasing power – the old method. May not be realistic expectation…
- **EU restrictions** on international price referencing (e.g. referencing according to the GDP) and parallel trade – against the EU framework

Kaló Z, Annemans L, Garrison LP.
Differential pricing of new pharmaceuticals in lower income European countries.
Expert Review of Pharmacoeconomics & Outcomes Research, 2013. 13. 6. 735-41.

Solutions to facilitate differential pricing

- **confidential rebate mechanism**
  successful approach only if
  - confidentiality remains
  - confidential rebate is not implemented in high income countries
- **risk-sharing** (i.e. patient access schemes)
  - financial risk sharing: easy to implement even is small lower income countries
  - outcome based risk-sharing: experience mainly in higher income countries, but already started in some CEE countries

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Managed entry agreement

- Managed entry agreements =
  - risk-sharing: to reduce uncertainty of payers
  - confidentiality: to facilitate differential pricing in order to increase patient access

"Risk sharing agreement forces clinicians to focus on patient outcomes"

Sergio Pecorelli
Italian Medicines Agency (AIFA)

ISPOR Milan, 2015

Necessities of managed entry agreements

1. Knowledge: ability to judge the value of new technologies (e.g. HTA agency)
2. Target: e.g. benchmark
3. Legal process: willingness and opportunity to negotiate about the price
4. Real world data (claims database or patient registry): for the implementation of discount, rebate, or payback

Thank you for your kind attention!