Policy Choices and Access to Medicines

Margaret Kyle, Mines ParisTech (CERNA)

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Broad policy areas

- Science and innovation policy
  - Intellectual property
  - Investment in education, grants, etc.
- Trade policy
  - Regulation of access
  - Exhaustion of IP
- Health policy
  - Public vs. private health insurance
  - Price regulations
  - Investment in health care infrastructure
IP and pharmaceuticals

- In general, the patent system works well as an incentive mechanism in pharmaceuticals
  - Some important exceptions (neglected diseases, orphan drugs)
  - Most of the incentives created by large, rich markets
- Downside: patents give pricing power
  - High prices can be (and often are) a barrier to access
  - But patents can also increase access
    - Innovators are more likely to launch with patents
    - Generic launch doesn't always occur in the absence of patents
Policy choices

- TRIPS requires pharmaceutical product patents and a minimum term of 20 years
- TRIPS also allows some flexibilities
  - Compulsory licensing
  - Price controls
  - Research exceptions
- Other approaches:
  - Patent extensions
  - Data exclusivity
Trade policy and pharmaceuticals

- Most countries regulate pharmaceutical entry
  - Safety, efficacy, manufacturing, etc.
  - Can act as a barrier to trade
    - Clinical trials on local population?
    - Importance of relationships with regulators?
    - Opaque bureaucracy/red tape?
- Some countries limit IP as a trade barrier
  - IP is exhausted when the product is marketed elsewhere
  - Allows arbitrage of price differences through parallel imports
Policy choices

- Harmonization of regulatory standards or mutual recognition of decisions
  - E.g., European model
- Exhaustion of IP
  - Tends to benefit the importing country
  - But potentially harms the exporters
    - Risk that the exporting country will face shortages, higher prices, or reduced access
Health policy and pharmaceuticals

- Health insurance
  - Insurance should provide access, even if the prices of treatments are high

- Price regulations
  - Limit the prices faced by uninsured consumers, or by insurers
Policy choices

- Public vs. private insurance
  - It’s complicated, and/or expensive

- Criteria in regulating prices
  - Value-based pricing/cost-effectiveness
    - (How to evaluate?)
    - Associate profits with social value in order to promote the “right” innovation
  - External reference pricing
    - Risk that the referenced country will face higher prices or reduced access (or hide the price)

- General findings:
  - Insurance -> greater access: faster launch, higher consumption
  - Price controls can deter launch, especially in referenced countries
Resolving the access problem

- Encourage differential pricing by patentholders
  - Primarily the responsibility of richer countries
  - Undermined by parallel imports and reference pricing
- TRIPS flexibilities
  - Recognize different needs of developing countries
- Monopoly power should be temporary: are other policies promoting generic approval and competition effective?
- Coordinated health, science and trade policies