

# Negative effects of the current model

- Biased model: Biased results » Incremental innovation
- Threatens the sustainability of health systems (governments)
- Innovation is difficult and costly
- Current model has perverse incentives and does not provide for health-driven equitable innovation
- A great part of the benefits from the monopoly system are not reinvested in more R&D.
  - Originator pharmaceutical companies spend 23% of turnover on marketing, while only 17% is allocated to research and development.
  - Considerable efforts have been shifted towards aggressive litigation and ever greening

# Towards new models: Global Strategy (1)

- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. (WHA Resolution 61.21, 2008)
  - Promotes measures to increase access to medicines
  - Encourages Member States to develop new models of biomedical innovation in order to ensure both Access and Innovation.
  - Calls on stakeholders to “explore and promote a range of incentive schemes for research and development including addressing the de-linking of the cost of R&D and the price of health products.”

## Towards new models: EU Strategy (2)

- EU Communication & Council Conclusions on Global Health - May 2010
  - *“working towards a **global framework for research and development that addresses the priority health needs** of developing countries and prioritises pertinent research actions to tackle global health challenges”*
  - *“...exploring models that **dissociate the cost of Research and Development and the prices of medicines** in relation to the Global Strategy Plan of Action, including the opportunities for **EU technology transfer to developing countries**”*
  - *“...ensuring that **EU public investments** in health research secure access to the knowledge and tools **generated as a global public good** and help generate socially essential medical products at **affordable prices**, to be used through rational use.”*
- Innovation Union Communication: Flagship 2020
  - EU innovation should be needs-driven, more efficient, cooperative
  - Calls for the creation of platforms for open innovation and citizen engagement

# Open or equitable licensing

- To create the highest possible social benefit for publicly funded research.
- If the results are licensed to a private company, the contract includes a set of conditions with the aim of achieving a low product price and a high accessibility.
- In 2001, Yale University renegotiated its license with Bristol-Myers Squibb for the ARV Stavudine.
- Matured into institutionalized programs, it is now in use in by several universities in the US and by the US National Institutes of Health.
- The model is accepted by pharmaceutical companies at least in the area of infectious diseases.
- Should be a precondition for biomedical grants in EU FP8

# Biomedical R&D treaty

- Proposal
- Under WHO auspices, to be ratified by Member States: compulsory
- R&D priorities based on health needs
- Created with contributions according to R&D capacity and/or number of inhabitants/country.
- Conditions:
  - De-linkage
  - Transparency of clinical trials
  - Providing incentives to implement public R&D in developing countries
  - Ensuring that results remain in the public domain

## Medicines Patent Pool

- Example of a licensing strategy
- Medicines Patent Pool for second-line HIV/AIDS treatment for adults and children
  1. Multiple patents are ‘pooled’ and licensed out by one entity, in order to cut down on transaction costs for all parties involved.
  2. Patent-holders agree to share their intellectual property through the negotiation of licences.
  3. Third parties, generic manufacturers, can make use of the patents against the payment of a royalty.

# Medicines Patent Pool

## Benefits:

- More affordable and more adapted drugs
- At greater speed
- Producer can manufacture the patented medicines and sell them before the expiration of the patent term.
- It serves as a 'one stop shop' for all involved.

## Problems:

- Existing license only allows thus far one producing country: India

# Innovation inducement prizes

- Instead of market exclusivity, a bag of money
- A prize is a financial incentive to reward innovation that:
  - Meets health priorities
  - Improves health outcomes over existing products
  - Is accessible: price and affordability are considered from inception
- “Winner takes all” approach versus proportional system with milestone achievements
- Examples:
  - MSF: Tuberculosis point of care diagnostic test
  - Chagas Prize Proposal (American trypanosomiasis)
  - Donor Prize Proposal for HIV/AIDS
  - Cancer Prize Fund Proposal



## In conclusion:

- Diversity of models at different stages of implementation: from ideas to reality
- It is urgent to call upon governments to abide to previous policy commitments, made at national, regional and intergovernmental level and to demand policy coherence:
  - Equate policy space to real action
  - Provide sustainable funding for ongoing schemes
  - Promote access to public funded research: public funds for public goods
  - Implement pilots and feasibility studies
- Need to think outside the box
- No longer abide to the old model that only benefits a few.



## And finally...

- Any questions?
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