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Essential Innovation and Access to Medicines: towards new models of research and development

Health Action International (HAI) Europe

EMA PCWP, 13 September 2011

Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

What is HAI Europe?

- Established as a consumer network in 1981
- Members include consumers, public interest organisations, health care providers, academics, media and individuals
- Independent of pharmaceutical industry funding
- Goals: to promote access to essential medicines and their rational use

Declaration of interests

This workshop arises from the
HAI Europe Operating Grant Award for 2011, which has received funding from the European Union
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The opinions expressed herein are those of the author. The Executive Agency for Health and Consumers is not responsible for the information presented here.

Executive Agency for Health and Consumers

Overview

- The Facts
- The current model of medical innovation
  - Framework
  - Myths
  - Negative Effects
- From theory to practice:
  - Policy commitments
  - New approaches to Research and Development of medicines

Nearly two billion people (1/3 of world population) are not regularly receiving all the medicines they need.

Over one billion people – one sixth of the world's population – suffer from one or more neglected tropical disease.

WHO, 'Equitable access to essential medicines', 2004

WHO Neglected Diseases. Geneva, 2010

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State of Affairs

- Non-communicable diseases have unleashed a new epidemic of suffering across developed and developing world
- Access to medicines is a critical challenge:
  - Prices are high: unaffordable
  - New medicines and vaccines are lacking: unavailable or inaccessible
  - Dosage form does not meet needs: inadequate

Current R&D model

- Patent system is the stepping stone
- Link between cost of innovation and product price
- New medicines are developed for a market that can pay
- Those who could benefit from medicines but have little resources or represent a small market are excluded
- Lack of innovation in certain areas: unmet needs
- Health needs of the poorest remain unattended: Neglected diseases remain neglected

Only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden, the so-called 10/90 Gap.

(The Global Forum for Health Research)

Unfolding the myths: Costs (1)

- Lack of transparency about real costs of R&D
  - Industry estimates in 2000: 802 million USD per new drug
  - Independent estimates in 2011
    - [13 million USD – 204 million USD]
    - Median per new drug: 59.4 million USD

(Light & Warburton, 2011)

- There is a significant public contribution to innovation:
  - Worldwide on average public funding makes up for about 45 % of spending on R&D.

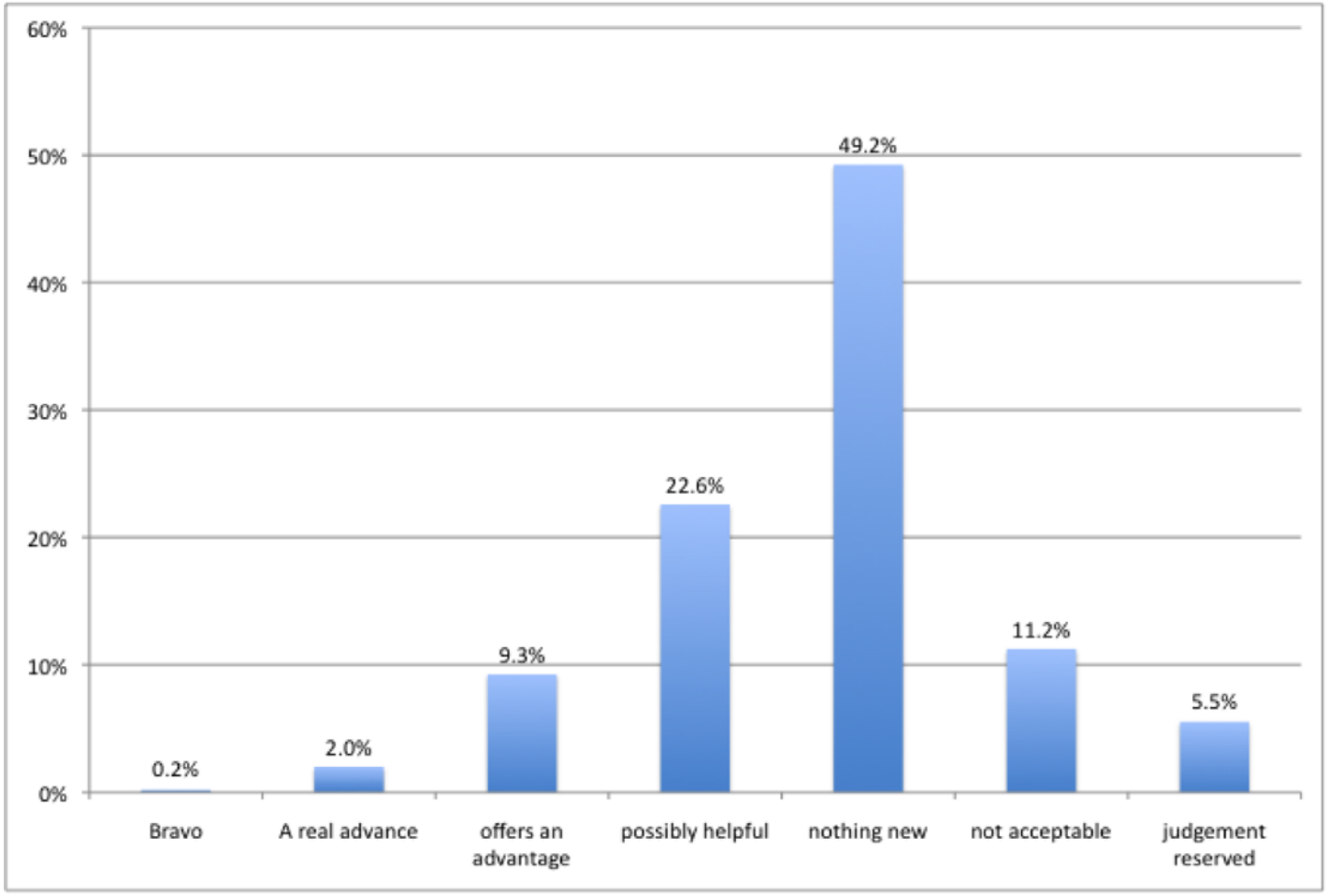
(WHO, 2004)

  - During the last 40 years, 153 new FDA-approved drugs, vaccines, or new indications were discovered through research carried out in public-sector research institutions.

(Stevens et al, 2011)

Innovation or more of the same? (2)

Figure 1.1: Evaluation of new medicines and indications in France, 1999-2008, la Revue Prescrire (n=961)



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

(European Commission, 2009)

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 and for discussion:

- 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
- We need to think outside the box
- What role can patients and consumer groups play in this scenario?