Policies and incentives for promoting innovation in antibiotic research

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Policies and incentives for promoting innovation in antibiotic research

Elias Mossialos & Chantal Morel

Conference on Innovative Incentives for Effective Antibacterials
Stockholm,17 September 2009
Sponsored by the Swedish Presidency of the Council of the European Union

European Observatory on Health Care Systems

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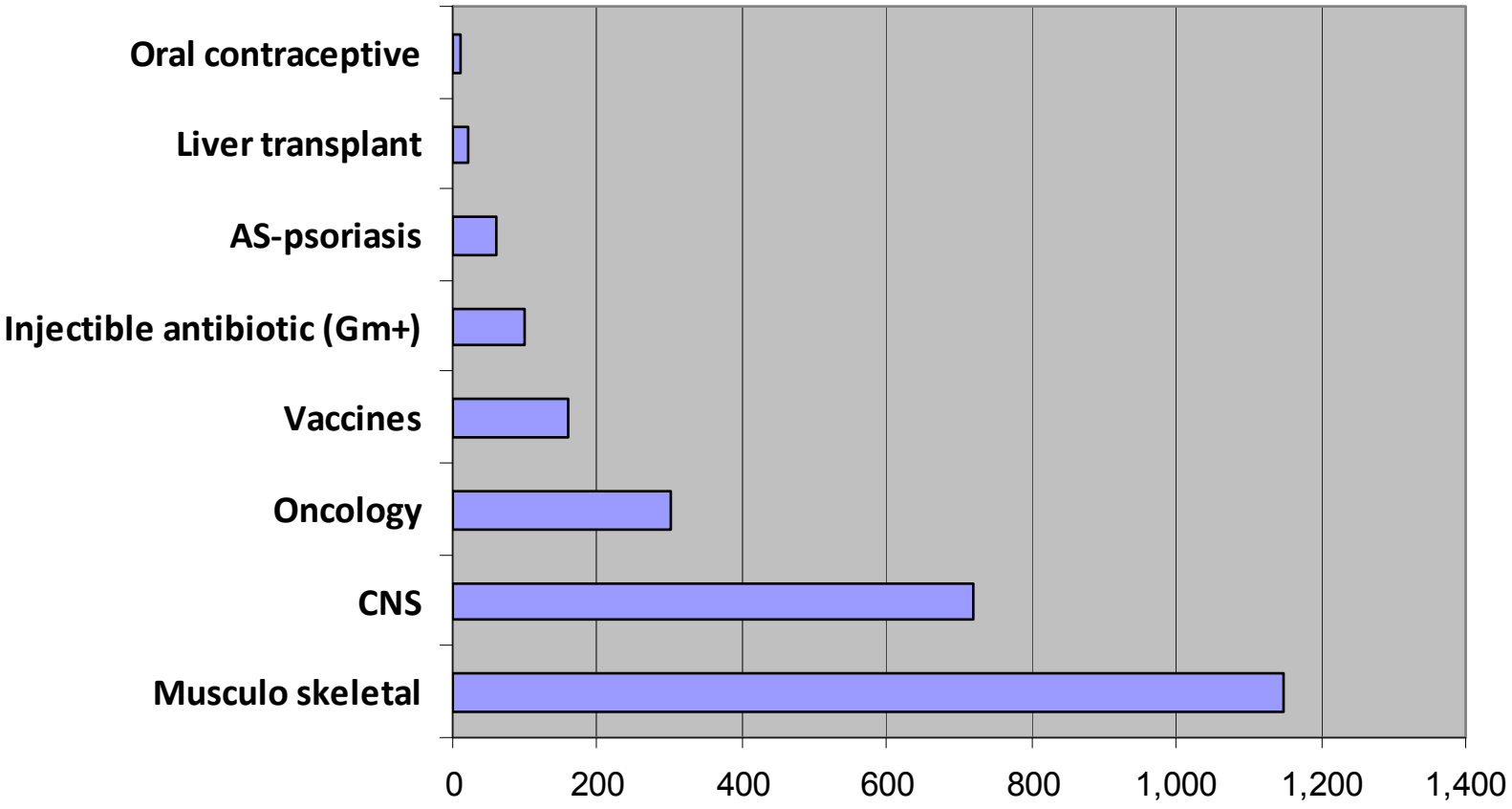
Why are so few new antibiotics being developed?

- Conflict between health policy and industrial policy (Discourage use Vs encourage innovation)
- Pricing and reimbursement
- Perceived low profitability due to short-course regimens and availability of generics
- Incentives

Net present value estimations



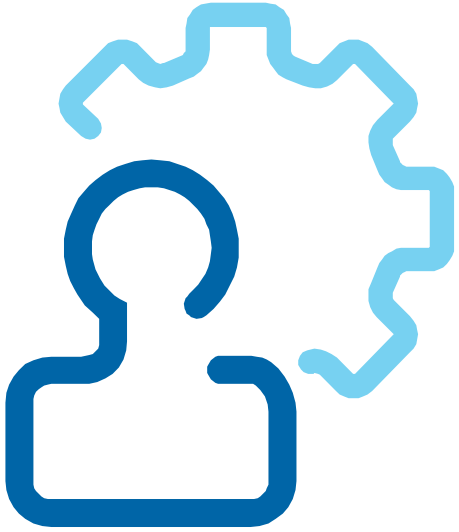
Risk adjusted NPV x $1,000,000, Source Projan 2003

How can we support appropriate health policy?

- Antibiotic surveillance
- Infection control
- Physician training
- **Diagnostic tests (silo budgeting disincentives)**
- **Realignment of health system financing and performance-related incentives**

How can we support policy developments?

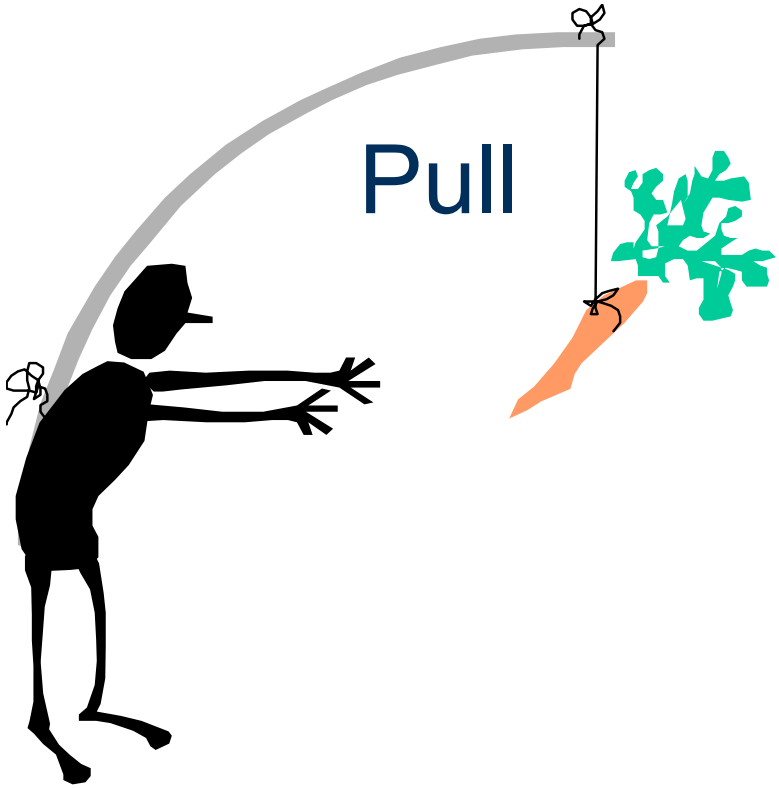
- **EU research framework programmes and DG Sanco (fellowships/training)**
- **Innovative Medicines Initiative (focus on the most socially beneficial areas)**
- **Mandatory free access to outputs from publicly funded research**
- **New incentive mechanisms**



Primary incentive types

Push

Pull



Hybrid

Push and pull mechanisms

- Decrease risk of R&D

- Ensure Return on Capital Invested

Pull and Push mechanisms

Push mechanisms **(early funding)**: grants or research-related tax breaks

- remove barriers to developer entry (by affecting the marginal cost of funds to the developer for investments in R&D)

Pull mechanisms **(output/outcome based funding)**: monetary prizes, intellectual property extensions, or specified advanced market commitments

- financial reward only *after* a technology has been developed

Pull and Push mechanisms

Push mechanisms
(early development funding)

Particularly useful for attracting small and medium enterprises (SMEs) who often operate with less than 6 months cash on hand

Developers paid through push mechanisms may lack the motivation to move into the next, more applied, phases of production

Agency problems: researchers are compelled to show their work in the best light possible

Risk: funders

Pull mechanisms
(reward outcomes)

Better align internal incentives to rectify inefficiencies

Provide researchers with the incentive to self-select the most promising products and thereby bypass many of the agency problems inherent in push mechanisms

Risk: developers

Monetary prizes

FOR

Reward only successful research

Decouple sales from the recouping of R&D costs which can improve socially beneficial market segmentation (e.g. between rich and poor countries) and help reduce over-marketing

AGAINST

Ex ante calculation of prize amount poses numerous challenges

All risk is borne by the developer

Advanced Market Commitments

FOR

Predetermined price/volume reduces risk to developer

Reward only successful research

May increase size of market

AGAINST

Commitment may lead to rewarding the development of a product that is ultimately of lesser quality than another that has been developed in the interim

Risk of over-purchase of product relative to epidemiological needs (stockpiling may be an option but can impose logistical challenges such as formulation requirements on the product)

Licensing arrangements

FOR

Patent buyouts decouple sales from profit, allowing for control over marketing and pricing strategies by the public funding body

Patent pools increase access to existing but abandoned molecules thereby accelerating downstream innovation. Could facilitate the combining of molecules for Fixed Dose Combinations

AGAINST

Patent buyouts might reduce follow-on innovation

Calculation of optimal patent price is challenging

Patent pools may foster incremental innovation rather than novel mechanisms of action

Pricing & Reimbursement

FOR

Pricing & Reimbursement reforms could allow for prices to better reflect the true value of antibiotics

AGAINST

Pricing & Reimbursement reforms would be stronger if made on an EU-wide basis; harmonization would be challenging

Transferable vouchers

FOR

Strong incentive to invest in antibiotics

AGAINST

Competition policy considerations

Intellectual Property extensions

FOR

- **Generally very attractive to large developers**
- **No need to overtly calculate reward**

AGAINST

- **Social cost of extended monopoly pricing could be unjustifiably high**
- **Major risk of setting precedent**
- **Delay generic competition (which could further delay accessibility in poorer countries)**

Wildcard extensions

FOR

- **Attractive to developers, especially if they can be sold on to other developers with more lucrative products to protect (this makes them more appealing to smaller companies)**

AGAINST

- The application of the extension to blockbuster products would result in a potentially unjustifiable social cost

Product Development Partnerships

FOR

Potential for risk-sharing

Potential for positive collaboration between public and private sectors

Can maximize comparative advantages with regards to skill sets (regulatory understanding, treatment needs) and R&D infrastructure

AGAINST

Harmonizing goals of funder (to produce a novel antibiotic in a manner that is socially optimal, cost-effective) with primary goal of private developer (to profit maximize) is challenging

Complicated IP or reward arrangements

Pricing

Funding mechanisms

Market commitment?

Product Development Partnerships

Call options model

In the CO model, a potential purchaser would buy a right (during development) to purchase a specified amount of the drug at a later date, for a specified price.

If the drug never makes it to market, the purchaser only pays a premium equal to the cost of the initial “option” contract.

Call options model combined with Advanced Market Commitments

While pull mechanisms seek to increase future payouts, and push mechanisms help to lower current costs, our strategy does both.

Call options model combined with Advanced Market Commitments

Pricing: a) depends on investment size and timing b) European price and tier pricing for Member States and other participating countries) c) marginal cost pricing for developing countries d) quality adjustments e) higher prices for partnerships f) price-volume trade-offs if consumption exceeds predefined market commit

Characteristics of an ideal incentive mechanism

- Rewards only true innovation
- Based on uncomplicated partnerships
- Discourages over-marketing or over-consumption
- Risk-sharing hybrid push-pull design
- Allows for some control over prices such that richer and poorer markets can be segmented

Policy recommendations

Some key recommendations

- Preserving the Effective Life of Existing and New Antibiotics
- Mandatory free access to outputs from publicly funded research
- IMI: focus on the most socially beneficial areas of therapeutic need such as the area of antibiotics.
- Fellowships and grants for new and experienced researchers
- Investment and prioritization of diagnostics within health systems
- Clarity and consistency in regulatory requirements
- Reassessment of antibiotics within the pricing & reimbursement systems at Member State level
- Encourage hybrid push-pull risk-sharing mechanisms at the EU level