Delinking incentives for investments in R&D for new medical therapies and diagnostics, including for the treatment of cancer

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How do we financing biomedical R&D?

Primarily via three avenues, all of which are important.

1. Direct funding of research
2. Subsidies for research, as as public investments in infrastructure and tax credits
3. Incentives, fashioned as rewards for successful development that induces private investments, including the grant of exclusive rights on patented inventions and a variety of regulatory exclusivities such as those relating to test data, rare diseases, pediatric testing, antibiotic drug development and the supplementary protection certificates (SPC).

Costs of exclusive rights

The social cost of the incentives is excessive, relative to the (risk adjusted) costs of the investments induced.

Patients face restrictions on access to effective treatments that are inexpensive to manufacture/supply.

Access is unequal, by geography and by income

Inefficiencies relating to exclusive rights

There are a number of well known inefficiencies associated with the grant to exclusive rights, including most important:

1. Incentives to invest in products/services that only match rather than improve outcomes, leading to excessive investments in products that do not improve patient outcomes.
2. Exclusive rights are not an effective incentive for research that advances science and technology but for which are pre-commercial or difficult or impossible to appropriate.
3. Exclusive rights do not provide sufficient incentives to share knowledge, data, etc.
4. Overly broad exclusive rights can impose high costs or absolute barriers to entry for new research.
5. Special problems relating to diseases for low income populations, antibiotic drugs, rare diseases.

Policy Incoherence

Lower prices increase affordability and access, reduce inequality, and remedy excessive costs of incentives

Lower prices also decrease incentives for R&D

Overcoming policy incoherence

Progressively delink R&D incentives from the prices of biomedical treatments and diagnostics

Embrace mechanisms to finance R&D that do not rely upon high prices, such as by increasing (1) direct funding, (2) subsidies and (3) monetary rewards not linked to prices.

Create new global for funding R&D that recognize the value of direct funding, subsidies and monetary rewards for biomedical R&D, and create more flexibility for intellectual property rights policies.

Delinking R&D incentives

Exclusive rights are a means to an end. That end is the monetary reward from the monopoly, achieved by charging high prices on products/services that are inexpensive to manufacture/provide but have high value to patients.

The incentive from monopolies/exclusive rights can be reduced or eliminated, but only if there is a replacement.

Firms will respond to monetary rewards that are unrelated to monopolies and high prices.

If monetary rewards are large enough, and well designed, they will be more effective, but still cheaper, than the monopoly, in inducing useful R&D investments.

Design on market entry rewards

A **market entry reward** or **innovation inducement prize fund** can be designed to work in many different ways. There are many degrees of freedom in designing prize funds that do not exist when rewards are linked to prices.

Current thinking is to create a right to 7 to 10 annual evaluations of the efficacy and use of products, and to divide prize fund rewards among competitors, according to relevant merits of products and utilization, benchmarked against alternative treatments, with nuances and modifications to optimize innovation given objectives as regards follow-on innovation, redundancy of treatments and products to treat diseases with fewer or greater numbers patients, or to conserve antibiotic resources.

All of this using data now used in typical health technology assessments.

The incentives mechanism for end products

Sometimes called “market entry rewards” (MERs), or innovation inducement prizes.

Common mistake is to imagine the incentive as a cash payment per quality-adjusted life year (QALY) benefit.

The structure of incentives can be more nuanced, to ensure innovation objectives are addressed, and the money spent on incentives is efficient.

Rewards should induce investments in products with large and small client populations.

A strict reward per QALY provides excessive rewards for some products, and inadequate rewards for others.

Having accurate, relevant and regularly updated data on R&D costs and risks by phase will be useful, to simulate rewards parameters, in order to optimize the efficiency of the incentive.

Shift to delinkage mechanisms emphasizing competition and decentralization

Older approaches

Pull

Offer a prize of X, to achieve Z

Push

Centralized management of grants

Newer approaches

Pull

Create a prize fund of X value, and create a competitive mechanism to compete for shares of the prize fund, based upon evidence of efficacy, relative to competing products and benchmarked against existing options.

Open source dividend

Push

Competitive intermediaries to manage direct funding

Open source dividend

First proposed in 2007, in connection with prizes for TB diagnostic tests, the open source dividend (OSD) is a mechanism to reward persons, groups and communities that openly and without discrimination share (royalty-free access) to knowledge, inventions, data, materials and technologies.

The OSD is an economic incentive to make science open, rather than closed, correcting the current asymmetry between open and closed. Drug developers benefit from the OSD because they don’t have to license the open sourced R&D inputs.

Competitive intermediaries

Competitive intermediaries

- Obligations of plans to fund and/or reward research
- Competition among intermediaries to manage the resources

Cancer Innovation Fund

Cancer Research Fund: Basic structure

1. De-monopolize cancer drugs
2. Require percent of treatment budgets or GDP into an innovation fund.
3. Option 1: Mandate allocation of cancer innovation fund money. For example:
    - 45 percent grants/direct funding
    - 40 percent end prizes
    - 10 percent interim prizes
    - 5 percent open source dividend
4. Option 2: countries choose which mechanism to fund.
5. Option 3: Some combination of option 1 and 2.

CRF: Challenges in administration

Will resources be pooled, and if so, how will they be governed? Governance is not intrinsically difficult, but it's something that needs to be resolved.

Are grants available to non-residents?

Overcoming trade norms on IPR (for example, via Article 30 or Article 44.2 of the TRIPS).

Can consensus be reached on levels of funding and allocations between grants and various prize types?

CRF - Coalition of willing

Scenarios for CRF for a coalition of the willing area feasible if the collective market is large enough to induce generic entry.

Benefits of expanded access to products, and CRF grants, are very large, and even a relatively small coalition could transform the world very quickly.

Initially base contributions on cancer treatment outlays.

Graduated and progressive obligations may facilitate greater participation by countries with lower incomes.

Next steps

Studies, examining the following issues.

1. Current and projected future (through 2030 at least) spending on and access to cancer drugs (and vaccines, diagnostic tests), in scenarios where
    a. the primary incentive for funding R&D are the grant to monopolies with weak exceptions, with bargaining over prices limited to decisions to withhold reimbursements or purchases of products.
    b. Drug monopolies are eliminated and R&D costs are financed using delinkage mechanisms.
2. Assessment of the minimum size of markets needed to induce efficient entry by competitive generic suppliers.
3. Costs of clinical research needed to establish safety and efficacy of new cancer drugs

Next steps

Studies, con't

4. What level of global funding in R&D for new cancer drugs is appropriate?
    a. What is the relationship between end-product incentives and various upstream R&D funding, and open source incentives? For example, if trial costs are subsidized to a larger extent, how large are the incentives needed to stimulate investments in clinical evidence of safety and efficacy?
    b. How elastic is the supply of new products to the size of the end product incentive (as compared to expanded funding of upstream research and openness incentives)?
5. Which mechanisms are best for funding or rewarding testing of drugs for new indications and comparison with other drugs?
6. What changes are needed in regulatory policies, trade secret and data protection rules to enable competitive supplies of affordable biologic products?

Benefits of delinkage

Studies

How will marginal cost pricing of drugs and other products change treatment, access and outcomes

Next Steps

Meetings to discuss the harsh, expensive and appalling future if we do not change the business model for financing R&D, and the plan a way forward

For more information

https://delinkage.org

https://keionline.org