

COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH

FRAMEWORK PAPER

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Introduction

1. The Commission's terms of reference ask the following:

“...to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries...”

2. As elaborated at the level of tasks they are to:

- *Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;*
- *Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;*
- *Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;*
- *Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them;*
- *Produce concrete proposals for action by national and international stakeholders.*

The Central Issue

3. An organizing principle for the work of the Commission is that it should review the systems of incentives that determine the allocation of resources to R&D globally with the objective of determining whether these incentives are relevant to the treatment, cure or prevention of diseases that disproportionately affect developing countries, in particular poor people. It should consider whether these incentives could be used better to increase the amount of such R&D, and/or its effectiveness (e.g. in terms of speed and cost of translation into products). Apart from intellectual property rights, there are other factors which may affect incentives for research and development of new products. These include market-based incentives and those arising from national and international policies to promote scientific research and technology transfer. For instance:

- Market incentives, notably the potential revenue flow from a new medicine or technology as modified by risk and uncertainty
- Signals sent by the product approval system e.g. the cost of meeting regulatory requirements, particularly the extent of clinical trials
- National price setting arrangements (e.g. price controls or negotiated prices)
- Specific incentives designed to meet particular goals (e.g. data protection, tax credits, orphan drug laws)
- Incentives provided by the size and manner of distribution of public funding, including funding by international institutions (e.g. World Bank) to support developing world health care systems
- Incentives for governments to invest in R&D.

4. The task of the Commission will be to consider which of these are relevant to diseases that disproportionately affect the developing world and whether improvements might be both necessary and feasible in order to promote the creation of new medicines and other products for those diseases, bearing in mind in particular the need to make such medicines affordable. New instruments and mechanisms may also need to be considered. In undertaking this task, the Commission will need to consider the public good aspects of medical knowledge, and the extent to which insufficient purchasing power, the absence of competition or deficiencies in national and international public policies, results in outcomes that are suboptimal in relation to the public health needs of developing countries.

Prevalence of Diseases

5. An important issue is to identify the major causes of morbidity and mortality in developing countries, and their human, social and economic costs. The Commission will need to define criteria to assess the extent to which the distribution of current R&D efforts reflects appropriately the distribution of social and economic costs caused by disease. Account needs to be taken of the rising burden of non-communicable disease in developing countries (e.g. diabetes) and of the possible contribution of both medicines and non-medicines research in reducing risk factors which are major underlying causes of both communicable and non-communicable disease. There is also a judgement to be made, for particular diseases, as to the relative weight to be given to preventative measures and treatment which raises a number of complex and difficult issues, with implications for R&D.

6. In relation to the Commission's terms of reference, there is the further question of whether currently available medicines for particular diseases are in fact adequate for their intended purpose. If so, devoting more resources to health care services and treatment, including appropriate R&D to increase their impact in developing country settings, might be the appropriate response. In other cases, where current medicines are not adequate, it is necessary to identify priorities for R&D for the discovery and development of new medicines, vaccines and other products.

Research and Development

7. A concern in both the developed and developing world is the apparently escalating cost of drug discovery and development. This is particularly a concern in developing countries since it could exacerbate the gap between the cost of treatments, including their development costs, and what governments and people in developing countries are able to pay for treatments. An important part of the Commission's work will be to consider the reasons for this escalation, whether there are ways of reducing the cost and whether the allocation and utilization of R&D resources, could be enhanced through an improved incentive structure or new instruments and mechanisms. For instance, are there possibilities to increase the contribution of relatively low cost scientific resources in the more technologically advanced developing countries and use them more effectively in the course of research and clinical trials? Is the correct balance being struck between pharmaceutical research on the one hand, and other forms of health research on the other?

8. The Commission needs to develop a view on whether the current global deployment of resources for R&D and innovation takes adequate account of public health needs in developing countries. The private sector, stimulated by the patent system and market forces, mobilizes considerable resources to develop treatments for diseases where significant markets exist. But it is less motivated in developing treatments where the potential market is too small. Similar, and other special considerations, may apply to vaccines and diagnostics and "other products", such as contraceptives or microbicides.

9. It also needs to be remembered that about half of global health R&D is undertaken by the public sector. The allocation of this money is determined principally by governments, but is also influenced increasingly, in the case of biomedical research, by the use of the patent system in public sector research organizations. How this public money is used, in both developed and developing nations, is thus of comparable importance in relation to stimulating appropriate R&D of relevance to health in developing countries. In addition, particularly in relation to funding research on diseases that disproportionately affect developing countries, the philanthropic sector has played an increasing role in recent years.

10. The Commission may need to consider other areas of research of public health importance which current incentive systems fail to stimulate in both the public and private sectors. This might, for instance, include research into methods to treat, cure or prevent illnesses that do not necessarily depend on biomedical research, and may not be adequately supported by the public sector. For instance, there may be a need for research to reduce risk factors arising from diet, or from indoor air pollution. There may be a need for more research related to health promotion or health delivery in the specific context of developing countries: for instance, research to deliver better health to families and communities, including health research for improved child and maternal health and for a sustainable environment. There may also be areas of biomedical research (for example in relation to the off-label use of patented drugs, or new uses of off-patent drugs) that are under-stimulated by current incentive systems. Different incentive considerations may

apply to different sets of products (e.g. drugs, vaccines, medical devices and diagnostic tests).

Current Incentive Regimes

11. As noted above, there are various factors which affect the incentives for devoting resources to research and innovation in the field of diseases that disproportionately affect developing countries. There are a series of relevant questions that require consideration:

- Whether the patent system affects the volume, distribution and quality of research to address public health needs in developing countries? If so, how?
- Whether patenting and licensing practices, particularly in the biotechnology sector, might affect research on diseases particularly prevalent in developing countries? If so, how?
- How effective public sector patenting is in promoting relevant innovation?
- How effective have exclusivity-based system (such as orphan drugs, paediatric extensions or data confidentiality rules) been in stimulating research where market incentives are otherwise weak?
- How should the patent system be designed, consistent with international obligations, in a way that enables access to new medicines and other products in developing countries?
- Will the full implementation of TRIPS (except in least developed countries) affect the pattern and distribution of pharmaceutical research? If so, how? Will there be an impact on the conditions for access to new medicines after 2005? If so, how? And how important is this in relation to other factors affecting pricing and access?
- How has the evolution in regulatory systems affected incentives for research and innovation, and the costs of innovation?
- Is public and non-profit funding effectively distributed, taking account of the needs of developing countries?
- Is the public-private partnership approach to product development effective?

Improvements to Incentive Regimes and New Mechanisms

12. Drawing on an analysis of current incentive systems, there is a need to consider whether any alternative proposals are viable and whether there are other new ideas or mechanisms that might be viable. Such proposals could include measures operating on the demand side (by boosting rewards for new products) or on the supply side by reducing costs. Alternatively, new institutions or mechanisms for pursuing R&D could be considered (of which public-private partnerships are a good example). These proposals might, for example, include:

- Modifications and alternatives to patent and other exclusivity-based systems (including drawing on orphan drug and similar legislation) that might help promote more research and innovation for new medicines and other products
- Advance purchase commitments/patent buyouts and similar approaches
- Tax credits

- Strengthening and adapting the regulatory systems in developing and developed countries to respond better to developing country needs
- More effective ways to spend public and non-profit money to promote relevant research and innovation
- Alternative models of innovation that might generate affordable medicines for the poor
- The role of traditional medicines and whether further incentives would strengthen the development of effective treatments
- Reducing the cost of innovation, for instance by encouraging more R&D in lower cost locations
- Proposals to build capacity in the public and private sectors in developing countries
- New international instruments and mechanisms to promote research to address diseases prevalent in developing countries.