



# WORLD HEALTH ORGANIZATION

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## **WHO Commission on Intellectual Property Rights, Innovation and Public Health**

### **Report by the Secretariat**

#### **INTRODUCTION**

1. In response to resolution WHA56.27, the Director-General established the Commission on Intellectual Property Rights, Innovation and Public Health in February 2004 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 ...”. Its final report was to be submitted to the Executive Board at its 115th session.
2. In view of the wide-ranging, complex issues that the Commission needed to study in depth, the Fifty-seventh World Health Assembly agreed to extend the deadline for submission of the report to the 117th session of the Board.<sup>1</sup>
3. The Commission agreed that all its work would be as transparent and accessible as possible. To that end, its web site provides full information on the activities of the Commission.<sup>2</sup>

#### **ACTIVITIES OF THE COMMISSION**

4. The Commission held its first meeting in Geneva in April 2004. Subsequent meetings were held in Washington DC, (October 2004); Rio de Janeiro/Brasilia, (February 2005) and Brussels, (March 2005). These meetings provided an occasion for members of the Commission to have contact with a diverse group of stakeholders from different sectors, and to hear their views on issues relating to the Commission’s work. Future meetings are planned for June and September 2005 in Geneva, when members can have focused discussions on substantive issues, and build their final report.

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<sup>1</sup> Decision WHA57(9).

<sup>2</sup> [www.who.int/intellectualproperty](http://www.who.int/intellectualproperty).

5. At the same time, the Commission held extensive discussions with government departments (or equivalents) and other interested parties in the countries visited, and in Ottawa, (October 2004) and New Delhi, (November 2004). In addition, several members attended the Ministerial Summit on Health Research (Mexico, November 2004) and presented the Commission's work. The Chair of the Commission also participated in a dialogue with leaders of the pharmaceutical industry at the World Economic Forum (Davos, Switzerland, January 2005).<sup>1</sup> It is expected that members of the Commission will visit Africa in May 2005.

6. The Commission has been gathering evidence, and stimulating constructive debate in stakeholder communities. Details of these activities are recorded in a regular newsletter in English, French and Spanish which now has well over 1100 recipients worldwide.<sup>2</sup>

7. Over 20 studies have been commissioned to examine different aspects of the subject, to consolidate existing knowledge and proposals, and in certain areas to provide new evidence. They should be accessible on the Commission's web site by the time of the Fifty-eighth World Health Assembly.<sup>3</sup>

8. The Commission's web site, and the associated electronic discussion forum launched in July 2004, has also proved a useful means of stimulating constructive debate.<sup>4</sup> The web site is constantly updated with recent news relevant to the Commission's agenda, submissions from interested parties, and other key documentation. In November and December 2004, there was an active debate on the forum on the use of advance purchase contracts as a means of stimulating research and development on diseases that mainly affect developing countries. Many other topics have been covered, including the issue of incremental innovation and the implications of the new patent law in India.

9. To date, the Commission has received over two dozen submissions from individuals and institutions.<sup>5</sup> Many of these proposed new and innovative solutions to the issues being addressed by the Commission. The Commission is considering these proposals along with many others. Consultations have also been held throughout WHO and with pertinent organizations.

10. The Commission's period of consultation will culminate with a two-day workshop on 30 and 31 May 2005 and a one-day public consultation on 1 June 2005, both in Geneva. The workshop will gather a select group of experts from across sectors and disciplines to discuss specific issues of interest to the Commission, on the basis of the studies commissioned. This input, as well as that generated at the public consultation, will feed into the deliberations of the Commission, which will then complete and submit its report.

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<sup>1</sup> [http://www.who.int/intellectualproperty/events/meetings\\_visits](http://www.who.int/intellectualproperty/events/meetings_visits).

<sup>2</sup> Accessible at <http://www.who.int/intellectualproperty/documents/newsletter3>.

<sup>3</sup> <http://www.who.int/intellectualproperty/studies>.

<sup>4</sup> <http://www.who.int/intellectualproperty/forum>.

<sup>5</sup> See <http://www.who.int/intellectualproperty/submissions>.

## Key issues

11. The Commission produced a framework paper in 2004 that set out the key issues.<sup>1</sup> The paragraphs below provide an indication of the focus of discussions, although conclusions to be drawn are continually evolving.

### Current incentive mechanisms

Various factors affect the incentives for devoting resources to research and innovation in the field of diseases that disproportionately affect developing countries.

The questions below require consideration.

- Does the patent system affect the volume, distribution and quality of research undertaken to address public-health needs in developing countries? If so, how?
- Do patenting and licensing practices, particularly in the biotechnology sector, affect research on diseases particularly prevalent in developing countries? If so, how?
- How effective is public sector patenting in promoting relevant innovation?
- How effective have exclusivity-based systems (such as those relating to orphan drugs, paediatric extensions or data-confidentiality rules) been in stimulating research where market incentives are otherwise weak?
- How should the patent system, consistent with international obligations, be designed so that it enables developing countries to have access to new medicines and other products?
- Will full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (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? How important would be this impact in relation to other factors affecting pricing and access?
- How has the evolution of 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?
- Are the public-private partnerships for product development effective?

### Improvements to incentive regimes and new medicines

Drawing on an analysis of current incentive systems, there is a need to consider whether any alternative proposals are viable and whether other new ideas or mechanisms might be effective. Such proposals could include measures operating on the demand side, by boosting

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<sup>1</sup> [http://www.who.int/intellectualproperty/documents/framework\\_paper](http://www.who.int/intellectualproperty/documents/framework_paper).

rewards for new products, or on the supply side, by reducing costs. Alternatively, new institutions or mechanisms for pursuing research and development could be considered (of which public-private partnerships are an 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 or patent buyouts and similar approaches
- tax credits
- strengthening and adaptation of 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
- consideration of the role of traditional medicines and whether further incentives would strengthen development of effective treatments
- reduction of the cost of innovation, for instance by encouraging more research and development 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 geared to diseases prevalent in developing countries.

12. The first analytical chapters of the Commission's report, currently being drafted, will include an overview of the issues and definition of the Commission's task; an analysis of intellectual property rights, innovation and public health; a review of the research and development process in the public and private sectors; a review of the broader policy environment affecting innovation; and factors affecting access to health-care products. The second part of the report will be devoted to consideration of concrete proposals, including the possibility of new incentives; priorities for governments in terms of policies and funding; and policies to strengthen innovative capabilities in developing countries.

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