SOUTH CENTRE

POLICY BRIEF 8

No. 8 | 7 April 2012

Rethinking The R&D Model for Pharmaceutical Products: A Binding Global Convention

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Summary

- "Research and development (R&D) for pharmaceutical products has failed to deliver medicines for a large number of people, particularly those living in developing countries"[1]. Several reports and studies, including the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) adopted by WHO Member States (2003-2008); acknowledged this problem.

- There is a need for new mechanisms that simultaneously and effectively promote innovation and access to medicines, particularly for diseases that disproportionately affect developing countries. After the failure of the World Health Organization (WHO) Expert Working Group (EWG) on "Research and Development Coordination and Financing" in 2010,[2] a new report of the WHO Consultative Expert Working Group -CEWG– of 5 April, 2012 recommends to start negotiations for a binding international instrument on pharmaceutical R&D (under article 19 of the Constitution of the WHO).

The failure of the current incentive model to provide needed medicines, especially in Southern countries, calls for urgent action. Today, in the twenty-first century, communicable diseases still kill more than 10 million people every year, 90 per cent of whom live in developing countries. One-third of the global population does not have ordinary access to needed medicines. This situation is worsened in Least Developed Countries (LDCs) where up to 50 per cent of the population does not have access to necessary medicines.[3]

The current model of pharmaceutical research and development (R&D) does not make medicines available to a large number of people, especially those that live in developing countries. On one hand, there is little investment in R&D in relation to diseases that

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are prevalent in developing countries, since major pharmaceutical companies concentrate on the development of products to satisfy the demand of wealthy markets. On the other hand, products that are subject to patents and other forms of exclusive rights are normally sold at prices that are out of reach for large sectors of the population.

The report of the Commission on Intellectual Property Rights, Innovation and Public Health (known as the CIPIH Report) of 2006 recognised that intellectual property rights incentives were not meeting the needs for the development of new products to fight diseases in countries where "the potential paying market is small or uncertain". The CIPIH Report also recognised "the need for an international mechanism to increase global coordination and financing of R&D medications", and recommended that work toward the adoption of an R&D treaty should continue "in order to develop these ideas, in a way that governments and other people in charge of the formulation of policies can make a decision based on it".

At the same time, the context for tackling the problem of access to pharmaceutical products is changing. Developing countries –including India, the largest provider of generic medicines– have applied the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) with respect to the patentability of pharmaceutical products. As a result, the proportion of drugs that is being protected by patents is on the increase and it is expected that this will mean higher prices.[4]

I. Changing the Research and Development Model

The problems that are faced in this field cannot be resolved only by means of improvements on or adaptations to the existing incentive-based model. Intellectual property (IP) does not produce the innovation necessary to address the public health needs of developing countries, and the CIPIH Report recognised that this problem can, in fact, affect developed countries:

> "This is an important issue, because even in developed countries, the rapidly rising cost of health care, including drug delivery, is of great public concern. In developing countries, and even in some developed countries, the cost of drugs, which often cannot be acquired through the public health care systems, can be a matter of life or death."[5]

New mechanisms are needed in order to simultaneously and effectively promote innovation **and** access to medicines, particularly for diseases that mainly affect developing countries. A binding international instrument or international treaty on R&D, to be negotiated under the auspices of the WHO, can provide the adequate framework to define priorities and ensure the coordination and sustainable financing of R&D on drugs that could be made available at affordable prices in developing countries.[6]

II. A Mandatory Global Convention

Created in 1948 as the first specialized United Nations agency, the World Health Organization (WHO) has constitutional powers that may be used to generate a necessary change of the research and development model for pharmaceutical products. Article 19 of the WTO Constitution establishes that: **"The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the**

Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes."[7]

There is only one precedent in WHO history of the use of article 19: the WHO Framework Convention on Tobacco Control, which has proven to be an important instrument to reduce the public health impact of tobacco consumption[8] .

II.1 Objectives

A mandatory global instrument on research and development of pharmaceutical products negotiated at the WHO could have the following objectives:

- to promote R&D for all diseases, conditions and problems (including non-transmissible diseases) which are relevant in developing countries;
- to develop sustainable financing mechanisms;
- to prioritize R&D on the basis of health needs;
- to coordinate public R&D; and
- to promote the research capacity of developing countries.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) adopted by the Member States of the WHO in May 2008 (WHA Resolution 61.21)[9] had recognised the structural problems of the present R&D model based on the IP model:

- The Strategy recognised that the current initiatives to increase access to pharmaceuticals were insufficient.
- The Strategy also recognised that the incentive mechanisms of intellectual property rights were not offering results for people who live in "small or uncertain" paying markets.
- The GSPA-PHI recognised that the current system of incentive-based innovation has failed to stimulate the development of drugs for diseases that disproportionately affect the majority of the world's population living in developing countries.
- One of the main objectives of the Global Strategy was to promote new ideas about innovation and access to medicines.
- In this regard, paragraph 2.3(c) of the GSPA-PHI referred to a possible international treaty on research and development of new pharmaceutical products.

Therefore, the negotiation and adoption of an international instrument on pharmaceutical R&D should be a key element for the implementation of the GSPA-PHI. And, if successful, this could be the most important achievement of WHO in the area of medicines since its creation.

In May 2010, the World Health Assembly rejected the report presented by the WHO Expert Working Group (EWG) which was established by the WHO to examine the issues of coordination and financing of pharmaceutical R&D. In 2011, a new group was established by the World Health Assembly (Resolution WHA 63.23): the Consultative Expert Working Group (CEWG), in order to deepen the analysis and cover issues which were not addressed or inadequately addressed by the EWG. The CEWG report, issued on 5 April 2012, recommends WHO member states to start negotiations

on a binding international instrument on health R&D under article 19 of the WHO Constitution, as the best way to create an appropriate framework to ensure priority setting, coordination, and sustainable financing of affordable medicines for developing countries.

II.2 Possible Components of a Treaty on R&D

- Creation of a common public fund to finance R&D of pharmaceutical products. In order to assure sustainable financing for R&D, the global convention (or treaty) should provide for mandatory contributions to a common fund by those countries that ratify the treaty. The contributions should be fixed according to the GDP of each country. This financial contribution should be in the context of the States' obligation to guarantee the right of access to health and medicine of all citizens. The results of the research conducted under this new model should be considered a public good and should therefore remain in the public domain. The cost of research funded by this public fund should be transparent. Expectedly, this model will prove to be more efficient and less burdensome than the current one based on exclusivity and monopoly through patents.

- Overall coordination of the work of R&D with public funds. The right to health should take precedence over commercial interests; the new model should therefore seek health coverage rather than commercial competition for profit.

- A fundamental feature of such coordination should be the prioritization of R&D based on real health needs.

- As a way to ensure that access remains a fundamental objective of the new model, mechanisms should be defined to de-link the cost of R&D from the price of medicines. The final price should be fixed so that medicines are accessible to all who need them.

The proposed components are not exhaustive; other elements are likely to be identified during the negotiations (as was the case, for example, during the negotiation of the Tobacco Convention). It is possible that the negotiation may have to face issues such as:

- The ethical criteria and financial mechanisms for conducting clinical trials with full disclosure of test data.

- Mechanisms to build and strengthen local research capacity in developing countries.

- Mechanisms to ensure that the results of R&D will remain in the public domain or will be otherwise accessible in developing countries.

VI. Conclusions

- There is a need for a paradigm shift to promote R&D in order to meet the needs of public health in the long and medium term, especially in developing countries.

- The negotiation of "a binding global instrument for R&D and innovation for health", as recommended by the report of the CEWG is a promising step that may even be useful for the health systems of industrialized countries that are suffering from the financial crisis.

- The adoption of a binding instrument

by WHO, as permitted by Article 19 of its Constitution, could help WHO to regain its leadership in this area and redefine global health governance.

Endnotes

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