

# ***South Views***

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## **A resolution by the World Health Assembly: Will there finally be a cure for diseases that affect the poor?**

**By Carlos Correa**

On 26 May 2012 the World Health Assembly adopted a resolution that could mark the first step toward a change in the current pharmaceutical research model. The members of the World Health Organization (WHO) decided to undertake an in-depth examination, at the governmental level, of a report produced in April 2012 by an international group of experts that recommended the adoption of a binding convention on research and development (R&D) that, if approved and implemented, could generate the medicines needed, particularly in developing countries, to address communicable and non-communicable diseases.

The recent decision of the WHO – substantially based on a compromise text proposed by UNASUR - is a first response to the crisis of the current pharmaceutical research model that relies on market incentives and the patent system. Innovation in the pharmaceutical industry has declined drastically in the last ten years despite the high profitability of the so called 'research-based' industry, and the availability of better and more powerful science and technological tools. Not only has productivity in terms of research fallen, but the vast majority of new molecules introduced to the market do not provide new therapeutic solutions since other treatments already exist, normally at a lower cost.

Funding for research is focused on areas with the greatest potential for profit. Those areas that would actually have the biggest impact on public health remain largely ignored. A clear indicator is the lack of investment in fighting diseases that are prevalent in developing countries such as Chagas, tuberculosis and malaria. The problem is that although millions of people would benefit from this type of investment, the majority of them are poor who do not create an attractive market for big companies. Moreover, they cannot benefit either from treatments for non-communicable diseases, such as cardiovascular insufficiencies and cancer: even where treatments are available, the high prices of patented products make them inaccessible.

As a result, in the 21<sup>st</sup> century, communicable diseases cause more than 10 million deaths per year, of which 90% take place in developing countries; a third of the global population does not have regular access to the medicines that they need. The situation is worse in least developed countries in which up to 50% of the population does not have access to medicinal treatment.

From both a moral point of view as well as a human rights perspective – the right to health is recognized in international conventions and in numerous national constitutions – this situation calls for greater responsibility by governments and a new research paradigm centered on public health interests, especially in order to meet the needs of developing countries. This is the directional focus that the conclusions and recommendations of the Expert Group Report aimed at targeting.

**Some conclusions and recommendations of the Report**

Some of the conclusions and recommendations of the report were the following:

- The present incentive systems, in particular intellectual property rights, fail to generate enough R&D in either the public or private sector in order to meet the health needs of developing countries.
- Recent trends in the pharmaceutical industry show a decline in innovation, as reflected by the small number of approval of new molecules, the majority of which do not represent a therapeutic novelty.
- Based on the evaluation of close to 100 proposals for mechanisms to promote better financing and coordination of research, the report concluded that an open approach to R&D should be promoted, with the results of R&D being treated as “public goods” not subject to the exclusive rights conferred by patents.
- New forms of shared financing, direct subventions, prizes and patent pools (to increase access to health products) should also be promoted, and mechanisms to coordinate research be established at the global level.
- The report recommended that all countries should dedicate at least 0.01% of their GDP to R&D relevant to meet the health needs of developing countries. As regards coordination, it advised the establishment of a global observatory on R&D, advisory services and a network of research institutions.

The main recommendation of the report was, however, more ambitious: to start discussions regarding a possible binding international convention to promote R&D centered on diseases prevalent in developing countries, including non-communicable diseases.

This recommendation caused the biggest controversy between developed and developing countries at the World Health Assembly in May of this year. A possible explanation is that developed countries perceive the suggestion of a new research model as a threat towards the present system based on the appropriation of profits from innovation through the patent system. But the convention, if adopted, would generate more resources and greater efficiency in terms of research by means of better coordination and a fixation of priorities. Although the main beneficiaries would be developing countries, the results of research could also be used by developed countries. Some of these countries face a severe crisis in their public health systems owing to the increase in the cost of treatment and a reduction in budgets.

The idea of adopting a binding convention is not completely new. The report of a commission established in 2003, also by the WHO, recognized that intellectual property rights do not respond to the need to generate **“new products to combat illnesses in countries that do not have the ability to pay”** or **“where the market is small or uncertain”**. This report also recognized **“the need for an international mechanism to increase the global coordination and funding of medical R&D”**, and recommended that work towards the adoption of a treaty on medical R&D should continue **“in order to develop these ideas, in the way that governments and those responsible for the formulation of policies can make a fundamental decision on it”**. Furthermore, the idea of a treaty on medical investigation was taken up in The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and adopted by the member states of the WHO in 2008.

From its creation in 1948 as a specialized organization of the United Nations, the WHO, in exercise of its constitutional powers, has promoted a single binding international treaty, the WHO Framework Convention on Tobacco Control. This Convention has shown itself to be an important instrument for changing the policies on this topic on a global scale. The proposed convention on R&D offers a major opportunity for WHO to make its work relevant for the attainment of the right to health on a global scale.

The magnitude of the problem that must be confronted in order to generate enough R&D for pharmaceutical products needed by developing countries is such that this objective cannot be reached without effective commitment from all countries. Voluntary contributions from foundations or governments do not offer a sustainable, structural solution. In fact, many of the most promising initiatives for developing new pharmaceutical products to address the diseases that affect the poor are extremely vulnerable, as they depend on the continuity of charitable financing.

A suitable answer to the problem of insufficiency of public health-oriented pharmaceutical R&D will not be reached without a concrete commitment by states to increase financing and improve the coordination of R&D activities. At present, the lack of coordination leads to unnecessary duplication of efforts and rivalry rather than cooperation in search of new products and technologies.

The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) report presents some ideas about possible objectives and elements of a binding convention. Different civil society organizations – some of which have pioneered the idea of such a convention – have contributed important suggestions in this respect. So have some developing countries in previous WHO presentations. However, defining the objective, goal and mechanisms of the instrument to be adopted is a task which is exclusively the responsibility and competence of the governments that are participating in the negotiation process.

### **Possible objectives of the Convention**

The following are possible objectives for the convention: to promote R&D for all diseases, conditions and problems (including non-communicable diseases) which are relevant to the needs of developing countries; to develop sustainable financing mechanisms; to prioritize R&D on the basis of health needs; to coordinate public R&D; to promote the research capacity of developing countries, and to delink the cost of R&D from the sale price of pharmaceutical products.

In order to reach these objectives, it would be necessary to create a common fund to finance the R&D of pharmaceutical products based on mandatory contributions by the countries that ratify the treaty, determined according to the level of economic development of each country. The results of the research obtained would be considered a “public good”. A mechanism could also be created to ensure the transparency of research costs, to coordinate on a global scale the R&D performed with public funds, to decide on R&D priorities—in terms of health needs and not of possible commercial benefits. The final price of new developed medicines should be fixed in a manner that makes the products accessible to all who need them.

### **Summary**

In summary, in order to promote development of new products and their access to populations, especially in developing countries, it is necessary to change the current research model. The cost of research should be delinked from the prices of the products generated. The challenge is not only about increasing investment in research or improving the rate of innovation. This will not suffice if the new products are not effectively accessible for those who need them.

It is a responsibility of States to provide effective solutions to the health problems of the majority of the planet’s population. The recent resolution of the World Health Assembly sets off a process that may lead to the possible establishment of a binding convention on R&D for new medicines, vaccines and other pharmaceutical products and technologies. A global binding agreement, negotiated in the WHO, could be an important part of the solution. Naturally, reaching consensus for its adoption will not be a simple task, neither can it be expected to be instantaneous. It would probably require some years of intense negotiation. However, it will be worth the effort if it can avoid the early death or improve the quality of life of millions of people by creating, on a solid foundation, a new paradigm for research and access to health products.

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