

Ministry of Health of Brazil

INNOVATIVE MECHANISM FOR R&D FOR DEVELOPING COUNTRIES Brazil's Proposal

1. Introduction

Since the very beginning of the process, the Government of Brazil has been intensely involved in the debate regarding the relationship between public health, innovation and intellectual property. This debate conducted the negotiations that lead to the approval of resolution WHA61.21, during the 61st World Health Assembly, in May 2009.

One of the most relevant topics of the approved Global Strategy on Public Health, Innovation and Intellectual Property concerns the issue of promoting sustainable mechanisms as a means to securing activities of research and development on products that meet public health needs of developing countries.

Within the scope of WHA61.21., the Director-General was requested to establish a urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.

The Government of Brazil, aware of the importance of such an issue, has prepared a proposal to be discussed amongst member of the expert group and taken to the consideration of Member States.

Shortly, this proposal focus on a mechanism that would be based on a fund sustained with resources from taxation on remittance of profits of the pharmaceutical industry. This fund would be used only for R&D on medicines and vaccines that address public health needs of developing countries. The available resources could be drawn upon by the pharmaceutical industry, including the ones that paid the tax in the first place, in a partnership with national public or private laboratories from developing countries, on a public-private partnership fashion. Products resulting from those R&D activities would be made available to developing countries in accessible terms.

The innovation in such a system is related to the proposal of raising a sustainable fund from the taxation of the activities of pharmaceutical companies, *which could in turn use those same resources*, together with partners from the developing world, to R&D for diseases that affect those countries.

Not only developing countries would benefit from the outcomes of such an endeavor but they would also be benefited from engaging in the R&D activities and be able to build capacities from the exchange of experiences and the transfer of technologies from the pharmaceutical laboratories involved in the process.

2. Context

The debate over the necessity of more research and development (R&D) for diseases that affect in the developing world has long been sustained. Although more than 50% of all diseases spread worldwide concentrate in developing countries, 90% of the industrial production of the health sector concentrate on non-communicable diseases, which are predominant in developed countries, and thus constitutes the so-called “90/10” gap.

It is a consensus throughout the world that the process of developing new drugs is slow, highly risky and, most importantly, highly costly. In this sense, left to its doings, the market provides very low incentives to address the specific needs of the developing countries, whose availability of resources for the development of new treatments is very low or none if compared to developed countries.

However, in spite of the high costs inherent to the R&D process of new medicines, the gains of the pharmaceutical industry during the entire 1990 decade have grown exponentially, whilst its priority focus has been on innovations for the treatment of diseases highly prevalent in developed countries, such as cardiopathies and cancer.

This fact in itself highlights the weakness of the market regarding its capacity of fostering R&D undertakings aimed at meeting the needs of developing countries, which demands the establishment of new financial mechanisms for those activities.

The so-called Public-Private Partnerships have been proved a relatively efficient mechanism for the development of innovations for developing countries.

Notwithstanding, their sustainability has yet to be proven. In spite the fact the most interested actors in such partnerships are the big pharmaceutical industries themselves, there is an evident lack of tools that are able to decrease the amount of time and,

moreover, of cost for R&D of new drugs. It is also important that the outcomes of those PDP's relate specifically to the needs of developing countries.

In this context, it is also important to highlight the relevance of the recently approved WHO resolution on the Global Strategy and Plan of Action of Public Health, Innovation and Intellectual Property (WHA61.21), by which developing countries need to determine an agenda of research and development priorities, as well as to obtain transfer of technologies and to build capacity not only for R&D but also to manage intellectual property rights resulting there from.

In this sense, an efficient mechanism for research, development and innovation on diseases prevalent in the developing world is only justifiable if it incorporates, in the set of actors involved, the countries that will benefit, on a sustainable fashion, from the actions of such a mechanism.

This mechanism implies that the interested countries participate in the constitution of a fund for R&D on these diseases, whose income will be provided by a share of the remittance of profits from the pharmaceutical industry in developing countries.

2.a. An example of mechanism

In the last few years, as a result of the global consensus on the necessity of new tools aimed at the financing for the development as well as to combat poverty diseases, the Governments of Brazil and France jointly launched UNITAID, an innovative financial mechanism aimed at improving the access to drugs for the treatment of HIV/AIDS, TB and malaria. Initially, however, Chile, Norway and United Kingdom had joined forces with Brazil and France to support UNITAID.

This mechanism works by taxation of air tickets, as a sustainable means for the reduction of prices of second-line and pediatric anti-retroviral drugs, medicines for multi-resistant TB and combined fixed-dose for malaria. UNITAID is also used for supporting the WHO pre-qualification programme, as a means to accelerating the purchase of generic products for those diseases and producing an impact on the pharmaceutical market with more competitive prices.

3. Establishment and governance of the mechanism

The mechanism will be constituted by a Directing Council (DC), composed by representatives from Governments of the sub-regions of the group of developing

countries, as well as of representatives of Government from the Organization for Economic Cooperation and Development (OECD), representatives of international organizations, non-governmental organizations and of the main world pharmaceutical industry's association.

The DC would have the following duties:

- To establish the work plan and other relevant decisions;
- To assess, approve and monitor partnerships on the related subjects with other mechanisms and interested institutions;
- To monitor the progress of the mechanism and to approve its annual report;
- To approved the mechanism's budget;
- To designate the members to the Secretariat and the Executive Council;
- To approve any financial expenditures by the mechanism

Besides the DC, the mechanism would be constituted by an Executive Council, composed by scientists, public managers and representatives of the civil society, with the following functions:

- To set up terms of reference for public calls for proposals;
- To select the proposed in view of the previously discussed and approved criteria by the DC;
- To execute mid-terms assessments of the selected proposals;
- To recommend the discontinuity of proposals to the DC, whenever necessary;
- To certify the final products resultant from the proposal.

The DC would also be assisted by a short Secretariat, composed by a technical-administrative body.

4. Sustainability of the mechanism

As a means to ensuring the financial sustainability of the mechanism, Government of associate countries would apply to the pharmaceutical industries that undertake activities in their territories a percentage taxation on every remittance of profits to the offices in their countries of origin and those resources would compose the international fund for R&D initiatives for the specificities of developing countries.

Besides that source of income, the fund could also benefit from permanent and voluntary contributions from governments, representations and other institutions.

The available resources in the fund would be destined exclusively for R&D activities (including the production of pilot-lots for clinical trials) on medicines and vaccines that meet the public health needs of developing countries.

5. Functioning of the mechanism

The proposals will be selected in accordance with the calls for proposals for international partnerships that involved the industry sector of developed and developing countries.

The collaborative proposals will be eligible only if the conceptual proof is already clearly established and if these proposals meet the following requirements:

- Accessible prices;
- Explicit guarantees of technology transfer;
- Provision of intended market and duration of the exclusive exploration of the final product for a maximum five-year term.

All the proposals will have to consider three phases, to which will correspond a sequence of fund expenditures, taking into account the second and third phases will be preceded by a progress assessment.

6. Appropriation of the final product

The final product, under the conditions established in the approved proposals, will be offered to developing countries a market exclusivity for a maximum five-year period.

At any time, however, the technologies involved in the process of development and production of the final product, by decision of the partners, will be transferred to other firms established in other developing countries.

The final product can only be commercialized by other firms after the end of the exclusivity period established at the time of the submission of the collaborative proposal.

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Brasília, em 17 de abril de 2009