GTPI’s submission to the PAHO civil society regional consultation on the CEWG report

Introduction

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP, acronym in Portuguese), coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA, acronym in Portuguese), is comprised of several Brazilian civil society organizations¹ that work to ensure the right to health, including organizations working with people living with HIV/AIDS, human rights and consumers rights. Created in 2003, the Group conducts studies and advocacy actions to overcome the negative impact of pharmaceutical patents and other monopolistic mechanisms on the access to essential medicines and the implementation of health policies in Brazil.

We believe that regional consultations opened by the Pan America Health Organization (PAHO) are very important to generate debate around the proposals made by the Consultative Expert Working Group on R&D: Financing and Coordination (CEWG) in its final report. However, time was very short to send contributions online. We would have preferred real dialogue with debates in order to confront and convene different perspectives and opinions. Below, we address some of the questions opened for discussions during the consultation process. We also believe that most of the questions are not addressed to civil society but to governments and, therefore, we will not address them.

1. What proposals evaluated by the CEWG are most relevant to the context of the Americas?

We consider that the proposal for the negotiation of a Global Convention on Essential R&D, under Article 19 of World Health Organization (WHO) Constitution, is significantly relevant for the context of the Americas and for the world in general. A Global Convention would cover the other promising proposals presented in the CEWG report, as well as would ensure coordination and sustainable funding.

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Over the last decades, the protection of intellectual property rights (IPR) has been the main mechanism adopted by countries to promote R&D, follow-on treaties negotiated at international level. However, the IPR system has revealed to be inefficient to promote R&D to address the main health problems of the world’s population, especially the health needs of developing countries’ population. When medical products do exist, the IPR regimen has also been creating barriers jeopardizing the access to life-saving health products in most of the countries in the world. Moreover, we must remark that access problems affect mainly least developed and developing countries, but also poor people living in developed countries. Therefore, we believe that a new system to promote R&D, focused on creating an innovation framework able to address priority health-needs, and on making the products accessible and affordable, as proposed by CEWG, is urgent and necessary to promote the human right to health not only in the Americas, but around the world.

In Latin-America countries, a high burden of type III diseases (and some type II diseases) is observed. However, there are several missing medical tools to fight these diseases due mainly to the lack of R&D directed towards them. Even though this type of diseases affect millions of people, most of them are poor and therefore do not constitute a relevant market to the medical products that could be developed if more resources were directed to them. Since the current system to promote R&D is based in the sale of products at high prices to recover costs spent in generating innovation, it has fostered innovation based in market analysis and not in priority health needs. An R&D system based on public-health needs and not driven by market incentives, as proposed by CEWG, is very much necessary.

Also, the struggle against type I diseases (and some type II), when the medical tools do exists, consumes a large proportion of national health budgets. Very often, the high expenditures to address those diseases are due to the high prices of medicines and health products under patent protection. That has led to limitations on public health policies or even has put universal access programs, adopted by many countries in the region, at risk. The high prices charged for medicines under patent protection are a relevant obstacle to promoting the right to health in our region.

It is often stated by pharmaceuticals companies that those high prices are necessary to recover the costs of innovation. Even though that statement has been increasingly challenged, especially regarding the amount of resources actually spend to develop the drug, it generates a very important debate, somehow challenging the premises of the current system adopted to promote innovation. Is a system that depends on setting prices of...
products so high that it is not affordable for most of the world’s population really effective? Even more important in the case of products necessary to promote human rights, is that system even legal under human rights obligations? Is it ethical? We believe it is not. Therefore, it is necessary to shift the paradigm of the current system and adopt new mechanisms that separate the cost of innovation from the final price of the products. Promising proposals that consider the principle of de-linkage of the costs of R&D from the final price of the product have been analyzed by the CEWG and we fully support them.

The IPR system has also led to other inefficiencies, especially related to medical products. As alleged by pharmaceutical companies, the drug development is very expensive. The figures usually showed have raised many questions not only about its accuracy but also about its effectiveness. It is imperative to support innovation models that costs less and, therefore, can make products available at lower prices. Recent experiences have showed that collaborative models to deliver R&D based on open innovation mechanisms can lead to reduced costs in drug development and can also facilitate the development of products that meets health needs in developing and least developed countries. It is necessary to consolidate and improve the current open source initiatives and an R&D convention could create a normative framework to foster that.

As stated by the report released by the CEWG, an agreement on R&D relevant to the health needs of developing countries is not meant to replace the IPR system but to work as a supplementary instrument, aimed to fulfill the gaps of the current system. Latin-American countries are often in the center of those gaps, not only because the IPR system has failed to promote R&D to address diseases that affect most our countries, but also because countries from this region have been more and more excluded from policies and programs to promote access to existing medicines in the recent years. This exclusion is related to a growing trend of countries in this region becoming “middle-income” countries and, therefore, attractive markets for pharmaceutical companies, despite the fact that more than half of the world’s poor population live in middle income countries, according to the Human Development Index. A good example of this contradiction is the case of HIV/AIDS. According to recent UNAIDS report (2011); countries in this region have spent increasingly their scarce public resources to supply AIDS treatment. In addition, the current scenario of global retreat from international donors for projects on HIV/AIDS affects especially Latin America. The region has often been forgotten and is the only one from the global south that has not been cited in the recent UNGASS 2011 Political Declaration on HIV.
People in these countries in particular have been on HIV treatment for many years now and therefore need access to newer drugs, most of which are under patent protection and have no affordable generics versions available. The high prices of these drugs bring uncertainty about the sustainability of treatment programs. The forthcoming raising prices and lack of financial support in the following years can undermine universal and free of charge programs that many people rely on to stay alive or put the cost of the treatment out of reach for many people.

Experience has shown that promoting access to medicines by the use of flexibilities in the IPR system is often a difficult political process and that access policies driven by the market are not sustainable in the long-term. Given the current scenario it is unlikely that models to foster innovation and access currently adopted will be helpful for Latin-America. A new model is the most needed. Since WHO member countries have the obligation to provide health to their populations, governments must have a more prominent role on priority setting for R&D and the CEWG proposal for a binding convention allows for this necessary shift.

Also the historic role civil society groups in the region have played to ensure access to medicines converges with the opportunity promoted by the proposal on an R&D convention, which is bringing the debate about access to the early stage of the R&D process. The current model is likely to leave Latin America fall into its gaps and, for that reason, the negotiation of a convention on R&D is the best current option to build a path towards a more sustainable system, since it can empower countries to address market failures and fulfill their commitments with the right to health.

Finally, we believe that the report released by the CEWG also opens way for an important discussion on the nature of knowledge goods. Over the past decades we have watched a growing appropriation of knowledge goods by private actors through intellectual property rights. Following this model, what have been observed are insufficient rates of innovation, concentration of technology in a few actors, and limited access to essential goods. In addition, the entrance of some technologies in the public domain is often delayed by abusive practices endorsed by the patent system. Patent rights were aimed to provide a temporary monopoly situation to innovators and, at the same time, allow for disclosure of the innovation to benefit the public domain. However, evidences show that disruptions on the original purposes of the patent system have prevailed. That can be perceived by the fragility of the commitment with temporary monopoly, through the increasing practice of
evergreening strategies, and inefficient disclosure by private actors, who often file patent applications that don’t actually reveal the technology being protected. Despite all the analysis showing the lack of sustainability of this model, both private companies and developed countries governments still push to increase the scope of intellectual property rights, through legal actions and new trade agreements.

However, due to the insufficient results of the current system in the health field, we believe that the time has come to move to a new direction: knowledge as a public good.

Some efforts to discuss and implement the supply of public goods are already ongoing, but the debate on how to share the costs of financing such goods needs improvement and commitment. We believe that the CEWG proposal for a global binding instrument to promote a R&D system in which the outcomes are public goods, freely available for further research and production, is a powerful starting point to engage governments in a more substantive debate on sustainable funding on health R&D, and, therefore, in the negotiations of a global framework to determine how the money is going to be spent.

Providing knowledge as a public good needs involvement of all stakeholders, but we believe that a more prominent role given to governments on financing and priority-setting for R&D needs in least developed and developing countries is key to find a balance in relation to the existing intellectual property system, in which knowledge is framed as a private good accessible only for those who can afford it.

Conclusion

As products necessary to the fulfillment of human rights, the development and accessibility of medical products should not be dependent on market based incentives and rules. As the current system designed to promote R&D has failed to promote the development of products necessary to address the health needs of large sum of the world’s population and has imposed barriers to access of medical products when they do exist, we believe that a new framework for R&D is necessary to address those needs. We believe that a Global Framework for R&D that ensures sustainable funding driven by the priority health needs of the population and that guarantees access and affordability of the end products as global public goods is urgent.