



Alternatives to the drug research and development model

Alternativas al modelo de investigación y desarrollo de medicamentos

Velásquez, Germán¹

¹PhD on Health Economics.
Special Adviser, Policy
and Health, South Centre,
Geneva, Switzerland.
gvelasquez.gva@gmail.com

ABSTRACT One-third of the global population lacks access to medications; the situation is worse in poor countries, where up to 50% of the population lacks access. The failure of current incentive systems based in intellectual property to offer the necessary pharmaceutical products, especially in the global south, is a call to action. Problems related to drug access cannot be solved solely through improvements or modifications in the existing incentive models. The intellectual property system model does not offer sufficient innovation for developing countries; new mechanisms that effectively promote innovation and drug access simultaneously are needed. A binding international agreement on research and development, negotiated under the auspices of the World Health Organization, could provide an adequate framework for guaranteeing priority-setting, coordination, and sustainable financing of drugs at reasonable prices for developing countries.

KEY WORDS Access to Drugs; Patents; Intellectual Property; International Agreements; Innovation.

RESUMEN Un tercio de la población mundial carece de acceso a los medicamentos y la situación es peor en los países pobres, en los que hasta un 50% de la población carece de acceso. El fracaso de los sistemas actuales de incentivos, basados en la propiedad intelectual, para ofrecer los productos farmacéuticos necesarios, especialmente en los países del sur, llama a la acción. Los problemas relacionados con el acceso a medicamentos no pueden ser resueltos tan solo a través de mejoras o adaptaciones de los modelos de incentivos existentes. El modelo del sistema de propiedad intelectual no ofrece la innovación necesaria para los países en desarrollo, se necesitan nuevos mecanismos que de forma simultánea y eficaz promuevan la innovación y el acceso a los medicamentos. Un tratado internacional vinculante sobre investigación y desarrollo, que se negocie bajo los auspicios de la Organización Mundial de la Salud, puede proporcionar el marco adecuado para garantizar el establecimiento de prioridades, la coordinación y la financiación sostenible de los medicamentos a precios asequibles para los países en desarrollo.

PALABRAS CLAVES Acceso a Medicamentos; Patentes; Propiedad Intelectual; Tratados Internacionales; Innovación.

PATENT SYSTEM APPLIED TO DRUGS

One-third of the world's population has no regular access to essential drugs; this may account for more than half the population in some developing countries. The World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and the Joint Program of the United Nations on HIV/AIDS (UNAIDS) estimated, in a report in 2012,⁽¹⁾ that out of the 34 million people who live with the human immunodeficiency virus (HIV) and should be receiving treatment, only 8 million had access to the therapy by the end of 2012.⁽²⁾

As stated by Eric Goemaere in the book written by Boulet, Garrison, and Hoen,⁽³⁾ this situation is mostly due to the high prices of patent-protected drugs:

I am revolted when I hear claims that patent rights do not constitute a barrier to treatment here in South Africa. I have seen young women and men die from an AIDS-related brain tumour provoking unbearable headaches. I have seen children covered with scars due to AIDS-related dermatitis, unable to sleep for the pain. I knew that all of them could have been helped with antiretroviral therapy, but the cost of the patented drugs was the only barrier.⁽³⁾

Patents for pharmaceutical products have been one of the most debated topics concerning access to essential drugs since the creation of the World Trade Organization (WTO) in 1995 and the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

Patents are not the only obstacle to drug access, but they may increasingly become a more determining factor as patents provide monopoly over the drug to the patent holder, who has the freedom to set prices. This freedom to set the prices of patented products has caused a large number of drugs to be unavailable for the majority of the world population living in developing countries.

It is important to remember that a patent is a territorial right and, consequently, a patent for invention may be granted in a country but legally rejected in another. Similarly, a patent granted in

a country may be revoked if it is proved that it should not have been granted.

By virtue of the TRIPS Agreement, all countries who are members of the WTO are obliged to grant patents, for a minimum period of 20 years, to all those inventions of pharmaceutical products or procedures which comply with the established criteria regarding innovation, invention, and industrial application (utility).

It is important to highlight that in the pharmaceutical field *one product does not equal one patent*. An invention may be protected by several patents, and the production process of a product may be also protected by one or several patents. In many countries, a combination or a new clinical indication may be patented. As a consequence, one single drug may be protected by a large number of patents.

The TRIPS Agreement includes regulations which demand the change of the patent legislations in most of the developing countries to introduce, expand, and strengthen intellectual property of pharmaceutical products.

A few months after the creation of the WTO and the enforcement of the TRIPS Agreement, Carlos Correa stated:

The adoption of the Agreement has undoubtedly involved a major concession on the part of those countries which refused to grant patents for drugs in order to avoid the effects of market monopolies derived from exclusive rights. The information available shows that the universalization of pharmaceutical patents will not lead to increased R&D on new drugs by large companies nor to the possibility that this will be carried out to any significant degree in developing countries. Neither will developing countries receive increased flows of direct foreign investment or transfer of technology.⁽⁴⁾

Fifteen years later, as we will soon analyze here, it is proven that neither research and development (R&D), nor transfer of technology have increased. Rather on the contrary, there has been a downward trend.

At first, the patent system was conceived to assure that people would benefit from inventions. Currently, many people in developing countries

not only do not benefit from patents, but also patents act as an obstacle to access the drugs that may save their lives. This is simply due to the logic of trade prevails over the right to access healthcare.

THE PROBLEMS

Four main problems may be identified in the current patent system applied to drugs.

Decrease in pharmaceutical innovation

A recent study made by the magazine *Prescrire*, cited by Philippe Even and Bernard Devré, analyzed the drugs that were introduced in the French market between 2006 and 2011 (six years). The study arrived at the conclusion that the number of molecules that provided significant therapeutic progress drastically decreased: from 22 in 2006 to 15, 10, 7, and 4 in the following years up to 2011, the year in which the study stated that only one therapeutically significant drug was placed in the market.⁽⁵⁾ When it comes to France, one of the largest pharmaceutical markets in the world, where the State pays the drug bills, most drugs around the world which were released between 2006 and 2011 were supposed to have been introduced in the French market. In other words, the reduced innovation shown in France is a good indicator of the situation worldwide.

High prices

A recent article in the French journal *Le Monde* highlighted that the same drugs are, in average, three times more expensive in France than in Italy.⁽⁶⁾ It should be noted that the drug offer is very similar in both countries – the same drug companies, the same drugs, and, most of the times, the same dose.

Medical oncologists from fifteen countries have recently denounced the excessive costs of cancer treatments, which are necessary for cancer patients to stay alive, and urged that “moral implications” should prevail.⁽⁷⁾ According to this group of oncologists, 11 out of the 12 cancer treatments

approved by the American Food and Drug Administration (FDA) agency cost more than one hundred thousand US dollars every year for each patient.

In 2010, a group of English scholars analyzed the most prescribed drugs in the National Health System (NHS), and calculated that approximately one billion pounds Sterling are wasted every year because of the prescription of patented “Me-too drugs,” for which there is an equally effective non-patented drug.^(8 p.243) This is considered a waste of State funds due to the consumption of patented drugs in the English system. In developing countries, it simply deprives most part of the population from having access to drugs.

During the Summer of 2014, several European countries such as France and Spain spent several months negotiating with the company Gilead over the price of the new drug for hepatitis C (known by its brand name “Sovaldi”). The price set by Gilead was 56,000 euros per patient for a twelve-week treatment, that is, 666 euros for each pill. According to the journal *Le Monde*, the price of every pill was 280 times higher than the cost of production.⁽⁹⁾ In France, where an estimated number of 230,000 patients suffer from hepatitis C, it is calculated that, if only 25,000 patients received this new drug, the cost would represent 7% of the State’s yearly budget for drugs.

R&D costs

From the 1950s onwards there have been some references available about R&D costs for pharmaceutical products. According to some sources (Table 1), these figures would have risen from 1 to 2.5 billion US dollars for the development of one single product. As long as there is no clarity nor transparency in this field, the problem probably arising from high prices in drugs will remain unsolved.

Granting patents, based on the idea that researchers should recover the costs of their invention, when there is no clarity about real costs, is an issue that the States and society in general should raise for discussion. The duration of patents, for example, granted for a period of 20 years, as arbitrarily ruled by the TRIPS Agreement, should be granted based on the costs incurred in

Table 1. Average cost of research for a new pharmaceutical product.

Year	Average cost
1950	1 million dollars
1970 and 1980	between 48 and 54 million dollars
1991	231 million dollars ^a
2000	473 million dollars ^a
2002	802 million dollars ^a
2008	900 million dollars ^b
2012-2013	1.300 million dollars ^b
2014	2.500 million dollars ^a

Source: Own elaboration based on data from: ^aTufts Center (Boston); ^bInternational Federation of Pharmaceutical Manufacturers & Associations. ^aDoubles the cost in two-years time.

R&D activity for the product development.

An article of the scientific journal *BioSocieties*,⁽¹⁰⁾ published by the London School of Economics, claims that the real cost of the R&D is, in fact, a fraction of the commonly cited estimates. According to the authors, Donald Light and Rebecca Warburton, the average cost of the R&D for the development of a drug varies from 13 to 204 million dollars, depending on the type of product. The authors estimate an average cost of 43.4 million dollars incurred in R&D activities for every new drug. And they conclude: "These figures are very far from the 802 million or 1.3 billion dollars claimed by the pharmaceutical industry."

The project Drugs for Neglected Diseases Initiative (DNDi), founded by the non-governmental organization Doctors Without Borders (DWB) in 2004, has recently published their research costs after 10 years of experience.⁽¹¹⁾ The figures are the following:

- From 6 to 20 million euros to improve a treatment.
- From 30 to 40 million euros for a new chemical entity.

If these figures were to be readjusted based on the usual cost calculation approach applied in the pharmaceutical R&D for infectious diseases, in order to cover the risks of failure, the numbers would be the following:

- From 10 to 40 million euros to improve a treatment.
- From 100 to 150 million euros for a new chemical entity.

It is incomprehensible that after 15 years, or even longer years of debate there is no consensus on the real costs for the R&D of drugs. If this problem remains unsolved, it will be very difficult to make progress toward a constructive debate that can address the issue of access to drugs in the future. The difference in data collected as shown by the academic sector or non-profit initiatives such as DNDi and by the industrial sector go from one to ten. The WHO has not pronounced itself in the matter, most likely due to the increasing influence of the pharmaceutical industry over policy creation and decision making within the agency.

This is how monopolies granted by patents will enable, on the one hand, the obtention of disproportionate benefits and, on the other, the denial of access to drugs to a large number of people; in many cases, access to vital medicines.

The problem of the R&D costs is that there is no transparency regarding the real costs because there is no reasonable criterion in the price-setting of drugs. The prevailing logic is that prices correspond to the maximum that each market can accept or pay.

Patent proliferation

A research work conducted by the European Union (EU) about the behavior and practices of the pharmaceutical industry from 2000 to 2007 showed that one drug may be protected by up to 1,300 patents, or pending patent applications.^(12 p.81) The number of lawsuits between originators and generics has increased four times in the EU. These lawsuits delay the introduction of the generic product from six months to six years. The study estimates that the introduction of generic products would have saved approximately three billion euros, if the introduction would have been immediate after losing the exclusivity rights.^(12 p.82)

A change of policies and strategies in the patent office can lead to subsequent significant changes. For example, in Argentina, after the introduction of new standards for testing pharmaceutical

patents, at the beginning of 2012, the number of patents granted was 54. However in Mexico, a similar market to Argentina, the number of patents granted in 2012 for pharmaceutical products was 2,500. Other countries, recently Ecuador, have decided to raise the costs to register a new patent to 100,000 US dollars for foreigners. There are many possibilities to “improve” the current model and make it more transparent. The current model’s philosophy and logic proved its lack of viability. The model used to finance R&D of drugs which is based on the patent system does not longer work for most of the world population who live in developing countries, and industrialized countries are having increasing difficulties affording the bills for drugs, due to the high costs involved in this model. Because of this, it is necessary to search for alternatives to the current model of R&D for drugs.

A MANDATORY INTERNATIONAL TREATY TO FINANCE INNOVATION AND DEVELOPMENT OF DRUGS^(a)

The pharmaceutical R&D have not yet managed to make drugs accessible for a large number of people, especially those who live in developing countries. On one hand, there is limited investment in the R&D of diseases prevalent in developing countries, since large companies are focused on the development of products destined to meet the demand of rich markets. On the other hand, products under patents and other exclusivity rights approaches are generally commercialized at unreachable prices for a large portion of the population. Several reports and research works, such as the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), adopted by the member States of the WHO,⁽¹⁴⁾ have acknowledged these problems.

The report made by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) acknowledged that the incentives to the rights of intellectual property do not respond to the need for development of “new products to fight diseases when the payment capacity of the market is poor or uncertain.”^(15 p.115) The CIPRH report also recognized “need for an international mechanism to increase global coordination and

funding of medical R&D,” and recommended to continue working on the adoption of a treaty on medical R&D “to develop these ideas so that governments and policy-makers may make an informed decision.”^(15 p.91)

The failure of the current incentive systems to offer the necessary pharmaceutical products, especially in Southern countries, is a call to action. Infectious diseases are killing more than 10 million people every year; more than 90% of those deaths occur in developing countries. An important factor that contributes to this crisis is that one third of the world population does not have access to necessary drugs, and the situation is worse in poor countries, where up to 50% of the population does not have access to these drugs.

The problems faced in this field cannot be solved just through improvements or adaptations in the current existing models of incentive. The model of the intellectual property system does not offer the necessary innovation for developing countries, and the CIPRH report acknowledged that this problem may even affect developed countries:

This issue is important because even in developed countries, the rapidly rising costs of health care, including supplies of medicines, are a matter of intense public concern. In developing countries, and even in some developed countries, the cost of medicines, often not available through public healthcare systems, can be a matter of life and death.^(15 p.177)

New mechanisms are needed⁽¹⁴⁾ which simultaneously and efficiently promote innovation and drug access, especially for diseases that mostly affect developing countries. A binding international treaty over R&D negotiated under WHO sponsoring may provide the right framework to assure the setting of priorities, the coordination, and the sustainable funding of drugs at affordable prices for developing countries.

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)

The GSPOA, passed by the member States of the WHO, in May of 2008,⁽¹⁴⁾ acknowledged the

problems mentioned above and gathered a series of concrete proposals:

- The Strategy recognizes that the current initiatives to improve access to drugs are not sufficient.
- It also recognizes that the incentive mechanisms of the intellectual property rights are not offering results for people living in “small markets or countries with uncertain purchasing power.”
- The GSPOA recognizes that the current system of innovation based on the incentive provided by intellectual property has not managed to stimulate the development of drugs for diseases that disproportionately affect most of the world population living in developing countries.
- The Global Strategy seeks to promote new ideas about innovation and drug access.
- Subsection c of paragraph 2.3 of the GSPOA refers to a possible international treaty on research and development for new pharmaceutical products.

Therefore, the negotiation and adoption of an international treaty on pharmaceutical R&D would be a key element in the application of the GSPOA. In fact, if it is successful, this could be the most important achievement of the Strategy from the perspective of public health care interests of developing countries.

WHO expert working groups

Faced with the opposition of industrialized countries to agree on a convention or an international treaty, the World Health Assembly (WHA) of 2008 created a group of experts – the Expert Working Group (EWG) – to analyze and recommend actions to be taken on this matter. The report prepared by this group was fiercely criticized by the Executive Board of the WHO in January 2010, based on an allegation presented by one of the members of the group: Dr. Cecilia López. When rejecting the report above, the WHA of that year created the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) of the WHO to discuss the matter. In July of 2011, the president of the group of experts announced that the CEWG would recommend the Global

Assembly of 2012 to start formal, intergovernmental negotiations for the adoption of an international binding treaty that rules over R&D activities in health care.

Objective and scope: approach, setting priorities, sustainable funding and coordination of public R&D for pharmaceutical products

The objectives of an international binding treaty for the R&D and innovation in health care would be the following:

- 1) Promoting R&D for all diseases, health conditions or problems (including non-transmissible diseases) which are relevant to the needs of developing countries.
- 2) Developing mechanisms of sustainable funding.
- 3) Establishing R&D priorities based on health needs.
- 4) Coordinating public R&D.
- 5) Promoting the research capacity of developing countries.

Principles

When developing an international treaty on R&D, the following principles may be taken into account:

- The right to health is a universal and inalienable right and it is the duty of governments to secure the methods for its implementation.
- Health rights must prevail over the commercial interests of R&D for new pharmaceutical products.
- The right to health implies equitable and universal access to drugs.
- The R&D must be carried out in a sustainable way to address the priorities in public health.
- The international binding treaty for R&D must include mechanisms to ensure transparency in projected finance and costs of R&D.
- The international binding treaty for R&D must include mechanisms to separate costs incurred in R&D from prices. The price of drugs must be set based on the accessibility of those who need it.
- Strengthening the innovative capacity of developing countries is essential to address the needs of public health.
- The international binding treaty for R&D must not be limited to the diseases of type III^(a); the diseases which are prevalent in developing countries must be also included.

- The results of the R&D conducted within the framework of the international treaty must be considered as public property and remain in the public domain.

Prospective main components of a mandatory international treaty

To reach this objective, an international treaty must include the following:

- Setting of priorities based on public health care criteria.
- Coordination of public R&D activity for pharmaceutical products.
- Sustainable finance.

The objective of setting priorities should be to assure that the R&D program for drugs and health technologies is based on the public health needs of the population and not based on potential trade markets.

A key component of a binding global treaty on R&D must be the development of coordination mechanisms for R&D, in order to achieve clearly identified objectives with the lowest possible cost. All agents (public and private) should be informed or oriented about the distribution of resources and also R&D efforts should be monitored and evaluated. The agreed mechanisms may include the creation of networks for the existing institutions, especially in developing countries, and the creation of new programs and facilities. The CIPIH report of the WHO highlighted that there is an:

...urgent need for action to generate more and sustainable funding for R&D to address the health needs of developing countries, and to engage governments in this endeavour more than has been the case to date.^(15 p.187)

The international binding treaty on R&D should propose the establishment of a funding mechanism, based on transparency of the costs involved in research and development. The funding source would come from governments, based on their level of development, and their own voluntary contributions.

Possible elements of an international binding treaty for health R&D

For methodological purposes, we will refer to “components” (detailed above) as the substantial part of the convention and “elements” (dealt with here) as complementary mechanisms that may help the implementation of the main components for a convention. The list of elements we are including below is not exhaustive; other elements will be identified during the negotiations as it happened, for example, during the negotiations of the Tobacco Convention.

- Ethical criteria and financial mechanisms to conduct clinical trials with full disclosure of information obtained from trial.
- Mechanisms to build and strengthen research work and domestic capacity of developing countries.
- Mechanisms (attracting and promoting) to break down the cost of R&D from the price of the product, to promote access to drugs for everyone.⁽¹⁴⁾
- Mechanisms to assure that the results obtained from the R&D activities will be kept under public domain or will be made, in some other way, available to developing countries.
- Research and development of policies based on sections 12 and 15.1.b of the International Covenant on Economic, Social and Cultural Rights: the right to health and the right to enjoy the benefits of scientific progress and its applications.⁽¹⁶⁾

The authority of the WHO to adopt mandatory global treaties

Section 19 of the WHO 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.^(17 p.7)

As it has been already discussed, there is only one precedent in the history of the use of this section in a substantial context: the Framework Convention on Tobacco Control.

The tobacco epidemic is another example of the relationship between health and globalization. The spread of tobacco has been favored by elements such as the liberalization of trade, direct foreign investments, and the globalization of communications, and associated to the exportation of harmful health habits in this case.⁽¹⁸⁾ In May 2003, after three years of negotiations and six years of work,^(b) the World Health Assembly adopted unanimously^(c) the WHO Framework Convention on Tobacco Control.⁽²³⁾ Even if it had previously concluded different headquarters agreements with the respective States, and agreements with other international organizations, the WHO would use for the first time the power to adopt treaties and international agreements in a substantial matter,^(d) and within a legal framework, it would address on a global scale a threat to health which was also global.⁽²⁴⁾

Although it refers to several substantial matters, the Framework Convention of the WHO on Tobacco Control is a framework treaty that mainly establishes the objectives, principles, institutions and a working mechanism of what should be a more complete system. It adopts additional future protocols over technical matters like, for example, sponsorship and promotion, advertisement, illegal trade, and responsibility.⁽²⁵⁾

Therefore, the framework that should allow for a progressive legislative approach to the problem of tobacco addiction is established. In the same way, the treaty is conceived as a base document, and it not only enables but encourages the parties to take more strict measures.

The objective of the Agreement is to “to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.”^(23 p.5) The treaty is grounded in fundamental principles, such as information and protection regarding the harmful effects of tobacco, the inclusion of multisectorial measures, the help to economic re-conversion, the participation of civil society, the principle of cooperation, and the principle of responsibility.

The third part of the Agreement advocates measures aimed to obtain the reduction of tobacco

demand and measures addressing issues related to finance and taxes, information, advertisement, and health. At the same time, the fourth part collects the measures aimed to limit the supply of tobacco, while addressing tobacco contraband, selling tobacco to minors, and public support to activities to replace tobacco plantations. The treaty also includes matters in regards to the responsibility of tobacco companies, urging States to provide for regulations on the matter in their civil and criminal legislation.

In section 23, the treaty appoints the Conference of the Parties as the organ for control of its implementation and respect. This Conference “shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention.”^(23 p.22) The Agreement also established a permanent Secretariat, responsible for arranging the sessions involving the parties of the agreement, providing support to the States, transmitting the reports received, and preparing the reports assigned.

Some of the conclusions drawn from the 2010 Global Progress Report on the Implementation of the WHO Framework Convention on Tobacco Control^(26 p.51):

3. After five years of implementation a positive trend in global progress is visible. More than half of the substantive articles of the Convention attracted high implementation rates, with more than two thirds of Parties that reported twice indicating that they implemented key obligations under these articles.

4. Overall, Parties have reported high implementation rates for measures on protection from exposure to tobacco smoke (Article 8), packaging and labelling (Article 11), sales to and by minors (Article 16), and education, communication, training and public awareness (Article 12). Rates remained low in other areas such as regulation of the contents of tobacco products (Article 9), tobacco advertising, promotion and sponsorship (Article 13), provision of support for economically viable alternative activities (Article 17), protection of the environment and the health of persons (Article 18), and the use of litigation as a tool for tobacco control (Article 19).

CONCLUSIONS AND RECOMMENDATIONS

- There is need for innovative mechanisms capable of being sustainable in the long term, to promote R&D to meet the needs of public health, especially in developing countries.
- Initiating international negotiations for the adoption of “a binding global instrument for R&D and innovation for health,” as recommended by the CEWG of the WHO.
- Rethinking the structure of global public health: the adoption by the WHO of a binding treaty as allowed by section 19 of the WHO Constitution.⁽¹⁷⁾

According to health requirements, a successful binding international treaty ruling over R&D must be able to coordinate R&D to avoid unnecessary duplication of efforts, and to design public and sustainable mechanisms to fund R&D.

The World Health Assembly of May 2012 adopted the recommendations of the expert group (CEWG) and, particularly, the beginning of negotiations for a treaty or binding international agreement (by virtue of section 19 of the WHO's Constitution). Unfortunately, the USA, the European Union, and Switzerland managed to include in that resolution the order to carry out some “demonstration projects” without specifying very clearly what is to be demonstrated. These demonstration projects, which were not part of the recommendations made by the CEWG, were used to delay the beginning of negotiations over the binding convention and the same resolution mentions that the beginning of negotiations would be in 2016. During 2012 and 2013 the projects were selected, in a process which involved six regional offices of the WHO. This selection process was heavily criticized by non-governmental organizations and some observers. The initial concern

of the developing countries was confirmed: the projects for demonstration were only a distraction to cause a delay in the start up of the negotiations for a binding convention.

On September 30, 2014, in the United Nations Office located in Geneva a meeting summoned by France, Switzerland, South Africa, and the Secretariat of the WHO was held to discuss and announce how and who would finance the demonstration projects. Fifteen developed countries and six developing countries attended the meeting. The Secretariat of the WHO presented the financial situation for the implementation of the projects: an estimated cost of 50 million US dollars for the next four years, out of which only 3 million have been received (two from France, given directly to DNDi and not to the Secretariat of the WHO). The meeting ended up at an impasse since the developed countries stated that they would only announce their financial promises after the “non-traditional donors” announced theirs. This concept of “non-traditional donors” has been recently introduced by developed countries to promote the idea of having emerging countries participate as donors. South Africa only announced that BRICS countries (Brazil, Russia, India, China, and South Africa) would consider a possible financial promise. The African countries attending the meeting showed their concern about the Ebola epidemic by insisting that this was their priority on the matter of new economic contributions.

More than two years after the approval of the projects of “demonstration” have elapsed, and towards the end of 2014, there is still no funding to start this practice. The start up of negotiations for a convention is not formally subject to the results of the demonstration projects, but it will be certainly used as an argument in the debate of coming years.

ENDNOTES

a. This text and the following are mostly based on the research document "Repensando la salud global: un tratado internacional sobre innovación y desarrollo de productos farmacéuticos,"⁽¹³⁾ co-authored with Xavier Seuba, published by the South Centre.

b. For the WHO resolution 61.21 purposes, diseases type III are those which affect mainly or exclusively developing countries. The prevalence of diseases and, consequently, the categories they have in the classification may vary over time.

c. The World Health Assembly insisted in May 1999 on starting the negotiations to adopt a framework agreement against tobacco in the initiative WHA52.18.⁽¹⁹⁾ Prior to that in 1996, the World Health Assembly itself had adopted the resolution WHA49.17⁽²⁰⁾ in which it urged to start a preparatory study for the future convention. The treaty came into force on February 27, 2005.⁽²¹⁾

d. About the ambiguous US position, refer to Sean Murphy's article.⁽²²⁾

REFERENCES

1. UNAIDS. World AIDS Day Report 2012 [Internet]. Geneva: UNAIDS; 2012 [cited 10 Jul 2014]. Available from: http://www.unaids.org/sites/default/files/media_asset/JC2434_WorldAIDSday_results_en_1.pdf.
2. Velásquez G. Acceso a medicamentos en perspectiva global: retos, respuestas y derechos. En: Seuba Hernández X, coordinador. Salud Pública y patentes farmacéuticas: Cuestiones de economía, política y derecho. Barcelona: J. M. Bosch Editor; 2008.
3. Boulet P, Garrison C, Hoen E. Patentes de medicamentos en el punto de mira: Compartiendo conocimientos prácticos sobre las patentes farmacéuticas. Madrid: MSF; 2003.
4. Correa C. The Uruguay round and drugs. En: Lobo F, Velásquez G, editores. Medicines and the new economic environment. Madrid: Civitas; 1998.
5. Even P, Debre B. Guide des 4000 médicaments utiles, inutiles ou dangereux. Paris: Cherche Midi; 2012.
6. Cabut S. Le scandale du prix des médicaments. Le Monde [Internet]. 11 nov 2013 [cited 10 Jul 2014]. Available from: http://www.lemonde.fr/culture/article/2013/11/13/le-scandale-du-prix-des-medicaments_3510819_3246.html.
7. Experts in Chronic Myeloid Leukemia. The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts. Blood [Internet]. 2013;121(22):4439-4442 [cited 10 Jul 2014]. Available from: <http://www.bloodjournal.org/content/121/22/4439>.
8. Goldacre B. Bad pharma: how drug companies mislead doctors and harm patients. London: Fourth Estate; 2012.
9. Santi P. Hépatite C: le nouveau hold-up des labos. Le Monde [Internet]. 8 Jul 2014 [cited 10 Jul 2014]. Available from: http://www.lemonde.fr/sciences/article/2014/07/08/nouveaux-traitements-de-l-hepatite-c-le-hold-up-des-labos_4452689_1650684.html.
10. Light D, Warburton R. Demythologizing the high costs of pharmaceutical research. BioSocieties. 2011;6(1):34-50.
11. DNDi. An innovative approach to R&D for neglected patients: Ten years of experience and lessons learned by DNDi [Internet]. Geneva: DNDi; 2013 [cited 10 Jul 2014]. Available from: http://www.dndi.org/images/stories/pdf_aboutDNDi/DNDiModel/DNDi_Modelpaper_2013.pdf.
12. Commission of the European Communities. Commission staff working document: Accompanying the report from the Commission on Competition Policy 2008 [Internet]. Brussels; 2009 [cited 10 Jul 2014]. Available from: http://ec.europa.eu/competition/publications/annual_report/2008/part2_en.pdf.
13. Velásquez G, Seuba X. Repensando la salud global: un tratado internacional sobre innovación y desarrollo de productos farmacéuticos [Internet]. Ginebra: Centro del Sur; 2012 [cited 22 Apr 2014]. Available from: <http://apps.who.int/medicinedocs/documents/s21393es/s21393es.pdf>.
14. Asamblea Mundial de la Salud. Estrategia mundial y plan de acción sobre salud pública, innovación y propiedad intelectual (WHA61.21) [Internet]. Geneva: OMS; 2008 [cited 10 Jul 2014]. Available from: <http://apps.who.int/medicinedocs/documents/s21429es/s21429es.pdf>.

15. Organización Mundial de la Salud. Salud pública, innovación y derechos de propiedad intelectual: Informe de la Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública. Ginebra: OMS; 2006.
16. Naciones Unidas. Pacto Internacional de Derechos Económicos, Sociales y Culturales [Internet]. 1976 [cited 10 Jul 2014]. Available from: <http://www.ohchr.org/SP/ProfessionalInterest/Pages/CESCR.aspx>.
17. Organización Mundial de la Salud. Constitución de la Organización Mundial de la Salud [Internet]. 2006 [cited 10 Jul 2014]. Available from: http://www.who.int/governance/eb/who_constitution_sp.pdf.
18. Taylor A, Bettcher D. WHO Framework Convention on Tobacco Control: a global “good” for public health. *Bulletin of the World Health Organization*. 2000;78(7):920-929.
19. World Health Organization. WHA52.18 Towards a WHO framework convention on tobacco control [Internet]. 1999 [cited 10 Jul 2014]. Available from: http://www.who.int/tobacco/framework/wha_eb/wha52_18/en/#.
20. World Health Organization. WHA49.17 International framework convention for tobacco control [Internet]. 1996 [cited 10 Jul 2014]. Available from: http://www.who.int/tobacco/framework/wha_eb/wha49_17/en/.
21. World Health Organization. Global tobacco treaty enters into force with 57 countries already committed [Internet]. 2005 [cited 20 Jul 2014]. Available from: <http://www.who.int/mediacentre/news/releases/2005/pr09/en/>.
22. Murphy SD. Adoption of Framework Convention on Tobacco Control. *American Journal of International Law*. 2003;97(3):689-691.
23. Organización Mundial de la Salud. Convenio Marco de la OMS para el Control del Tabaco [Internet] 2003 [cited 20 Jul 2014]. Available from: <http://whqlibdoc.who.int/publications/2003/9243591010.pdf?ua=1>.
24. De Seixas Corrêa LF. The Framework Convention on Tobacco Control. *Bulletin of the World Health Organization*, 2002;80(12):924.
25. Devillier N. La Convention-cadre pour la lutte anti-tabac. *Revue Belge du Droit International*. 2005;(1/2):701-728.
26. Organización Mundial de la Salud. Informe mundial 2010 sobre los progresos realizados en la aplicación del Convenio Marco de la OMS para el Control del Tabaco [Internet]. 2010 [cited 20 Jul 2014]. Available from: http://www.who.int/fctc/reporting/global_progress_report_june_sp.pdf?ua=1.

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