

RETHINKING GLOBAL HEALTH: A BINDING CONVENTION FOR R&D FOR PHARMACEUTICAL PRODUCTS

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RESEARCH PAPERS

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DECEMBER 2011

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INTRODUCTION

This South Centre Research Paper is a contribution to the debate and reform process of the WHO to enable it to respond to the health and health policy challenges of the twenty-first century. More specifically, this paper addresses the issue of the pharmaceutical innovation system within the perspective of access to medicines, exploring possible structural changes in the current system. To do so, it addresses the question of how the constitutional powers of the WHO, often ignored by the Organization itself, can contribute positively to a paradigm shift in biomedical research stimulation.

The WHO, as pointed out by documents submitted by its Secretariat and by interventions of Member countries and reflections of NGOs in the last year, is probably going through one of its most acute crises since its creation, 63 years ago. A crisis which is rooted in financial problems, since the resources approved by the World Health Assembly are far from those requested by the Secretariat of the Agency. But perhaps the most serious problem is the loss of control over its budget, to the extent that more than 80 per cent of available resources come from voluntary contributions (private or public), while regular contributions from the 193 Member States only account for less than 20 per cent of the Organization's budget. How can each and every priority be set without having full control over the budget?

Issues such as public-private partnerships, the management of the H1N1 virus pandemic, the financial crisis, the reform of the Organization, interaction with industry and the implementation of the right to health have been controversial and subject to serious criticism. In any case, most critics want a stronger, more independent WHO with undisputed leadership and vision of how to build the access to healthcare as a right of all citizens of the world.

For all who are concerned with the current state of the main global public health international regulating agency, this research paper analyses and illustrates what might be the course of WHO in a context characterized by the multiplicity of actors in Health. What can the WHO do based on its original mandate and Constitution that others cannot? What relevance could this potential have in the field of biomedical innovation?

The course of the WHO reform will not be easy, but it will undoubtedly be less painful if the possibilities in the Constitution of the Agency are known/used, what problems need to be answered, what other players are already doing and what resources are available. What kind of public health agency does the world need today? What is the vision for the next 15 or 20 years? One of the key elements for the reform should be to resume and strengthen the regulatory powers of the Organization, both in terms of international conventions and regulations. In particular, it seems appropriate to return to Article 19 of the Constitution, which states 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."

This power has been used only once in a substantive area in the 63 years of existence of the Agency.

I HISTORICAL CONTEXT: WHO, AN INITIATIVE OF THE SOUTH

The San Francisco Conference of 1945 is well known because it was there that the Charter of the United Nations was adopted. Less well known are, however, the movements of various countries to promote the creation, under the umbrella of the United Nations, of an organization dedicated to global health governance. And it is even less well known that these movements were promoted in particular by Brazil and China.

Indeed, during the San Francisco Conference, Brazil submitted a memorandum that emphasized the relationship between health and peace, and, along with China, proposed that an international health organization be created. Doctors Karl Evang of Norway, Geraldo de Paula Souza of Brazil, and Sze Szeming of China prompted the Chinese delegation to take the lead in the creation of an organization dedicated to health, while the Brazilian delegation succeeded in having the Charter of San Francisco make specific reference to health.¹ In the aftermath of the San Francisco Conference, China and Brazil jointly submitted a declaration in favour of the creation of an international health agency. This statement was unanimously endorsed by the other founding Members of the United Nations.

The events that occurred after this are better known. The International Health Conference was held between June and July 1946 in New York, where the WHO Constitution was adopted, an instrument that gave birth to the first specialized agency created under the auspices of the United Nations and which was unique in the health sector in terms of scope, functions and authority.² The WHO Constitution outlined an international health organization that would absorb, be inspired from and surpass its predecessors. An organization which also acknowledged receipt of the revolutionary changes which had occurred in the fields of preventive and curative medicine in the previous decade,³ and which opened up to a much broader and diverse international community than the International Office of Public Hygiene and the Health Organization of the League of Nations. The WHO replaced these and other previously existing regional organizations, and did so with a willingness to adopt an approach consistent with a world where power was no longer concentrated in Europe, and where new and exciting initiatives came from the South.

¹ Regarding the genesis of the proposal, See S. Sze, "WHO: from small beginnings", *World Health Forum*, vol. 9, (1988) pp. 29-34.

² T. Parran, "Charter for world health", *Public Health Reports*, vol. 61, n° 35, (1946) p. 1265.

³ W. R. Sharp, "The new World Health Organization", *The American Journal of International Law*, vol. 41, n° 3, (1947) p. 509.

II ACCESS TO HEALTH AS CITIZENS' RIGHT

II.1 At the National Level

While the transferral of the concern for the protection of public health in international legal texts dates back to the nineteenth century and the receipt of state duty by political science to protect health occurred during the Renaissance and the Enlightenment, recognition of the right to health came much later. In fact, until the first half of the twentieth century the right to health is not reflected in constitutional texts, and it was only later, into the second half of the twentieth century, that several international treaties recognized the right to health. This does not prevent from pointing out that the emergence of the right to health is rooted in the public health movement of the nineteenth century, whose most advanced versions, the English and German, were based on the premise that the State has an important responsibility in preserving the health of its subjects.⁴

Some of the sources of inspiration for the international codification of the right to health were the provisions regarding the right to health which began to be incorporated into many constitutions during the twentieth century. We are referring to the right to health as a social right, since the facet of the right to health regarding the respect for physical integrity emerges from the traditional liberties born in the late eighteenth century.⁵ Regarding the right to health as a social right, the first country to incorporate it in its Constitution was Mexico in 1917. The Soviet Union did so one year later and the Weimar Republic did it in 1919. After the Second World War, countries like France and Italy incorporated the right to health in their constitutions, as would also the European constitutional texts such as those of Portugal, or Spain in the late seventies.

II.2 At an International Level

The advance of health as an international concern in the mid-twentieth century did not only derive in the incorporation of international health cooperation in the United Nations Charter, but also, in a very special way, in the creation of the WHO. The definition of health in the WHO Constitution and the formula with which this agreement includes the right to health - which marked the first formal international recognition of the right to health- are those that have determined the text of the right to health which several international treaties have adopted. As a result, the mark of the WHO Constitution can be found not only in international human rights treaties, but also in constitutional texts of several countries that state, faithful to the WHO terminology, that health is a state of complete physical, mental and social well-being, and that people have the right to the highest attainable standard of health. It can be said that the WHO and its constituent treaty had a foundational role in the international legal recognition of the right to health.

⁴ See G. Rosen, *A History of Public Health*, (Baltimore-London, John Hopkins University Press, 1993).

⁵ This physical integrity is included within the notion of "security" of the Declaration of the Rights of Man and of the Citizen of 1789 and the prohibition of torture is reflected in the Norwegian Constitution of 1814. M. Boethe, "Les concepts fondamentaux du droit à la santé: le point de vue juridique», in *Le droit à la santé en tant que droit de l'homme. Colloque, La Haye*, R-J. Dupuy, (Ed.), 27-29.7.1978. (Alphen aan den Rijn, Sijthoff & Noordhoff, 1979) p. 15.

There was a change from that foundational moment to another moment in which, although there is no international treaty dedicated specifically to the right to health, this right can be identified in many treaties. This right can be differentiated depending on whether its geographic reach is universal or regional, or on whether its personal scope is unrestricted or specific. The definition of health contained in the WHO Constitution is particularly relevant in addressing the interrelationship between health and human rights, especially because it refers to the question of the interdependence and indivisibility of human rights by recognizing a comprehensive concept of health.⁶ The interdependence between the right to health and other rights is clear. And this is the same with respect to other social and economic type rights, such as the right to food and the right to education, as well as with respect to civil and political type rights, such as the right to life and freedom from inhuman or degrading treatment.

As indicated above, the first reference to the **right** to health in an international treaty can be found in the 1946 WHO Constitution. Two years later the Universal Declaration of Human Rights was adopted and it included the right to health within the concept of an "adequate standard of living,"⁷ thus recognizing the interrelationship between health and other rights such as the right to food or the right to housing.

A considerable number of regulations have been developed in international treaties that explicitly include the right to health. In addition to the International Covenant on Economic, Social and Cultural Rights (ICESCR), universal in scope, other treaties have defined the scope and content of the right to health, either in relation to certain groups or rights that deserve special protection, or with respect to certain geographic areas. The bodies responsible for ensuring compliance with these treaties, and national courts which have had occasion to invoke them to solve their cases have specified the practical implications of the right to health on issues such as access to medicines, pharmaceutical experimentation and the relationship between health and intellectual property rights. Significantly, for example, the Committee on Economic, Social and Cultural Rights indicated that access to essential medicines is part of the minimum and essential content of the right to health, while the Constitutional Court of Peru pointed out the preference which the Doha Declaration gave to health protection over intellectual property rights.

II.3 WHO and the Right to Health

The promotion and protection of the right to health has not been limited to the field of international human rights treaties and their monitoring mechanisms. On the contrary, it has been incorporated into the agenda of the main bodies of the United Nations as well as in the work of specialized agencies, funds and programmes of the Organization. Also, the link between health and human rights has been promoted through international conferences.⁸ A key document to explain the recent boost of the right to health is the United Nations Programme for Reform promoted by the Secretary General in 1997,⁹ who stressed that human

⁶ D. Tarantola and S. Gruskin, "Health and Human Rights", in *Oxford Textbook of Public Health. The Scope of Public Health*, vol. 1, R. Detels, et al, eds. (Oxford, Oxford University Press, 2002) pp. 311-336.

⁷ Article 25 of the *Universal Declaration of Human Rights*.

⁸ Especially the International Conference on Population and Development and the Fourth International Conference on Women, and also in the context of special sessions of the General Assembly of the United Nations.

⁹ Secretary General, *Report by the Secretary General on programme for reform*, 14/7/1997, UN Doc.A/51/950. The momentum that the report has meant for the inclusion of the human rights perspective in its work has been

rights are inherently transversal in nature in the Organization's work.¹⁰ Therefore, in relation to the specialized agencies of the United Nations, it should be noted that there is a double foundation -and duty- of its work in terms of human rights - that which actually derives from their founding treaties, and that which is due to their belonging to the United Nations family.

The revitalization of the role of human rights in WHO activities is not particularly strange. Other references in important texts referring to the link between health and human rights progressively appeared in addition to the references to the right to health contained in its Constitution. Because of its impact on the right to health, the **Declaration of Alma-Ata** stands out from among these texts; WHO stated that "one of the most important contributions of WHO to human rights is the adoption of the Health for All goal and the Primary Health Care Strategy"¹¹ that was promoted precisely in Alma-Ata, and the **Ottawa Declaration**, which was adopted in the wake of the First International Conference on Health Promotion¹² and which highlights the link between health promotion, participation and right to health.

While in 1993 WHO declared itself "determined to keep the focus on human rights as part of its programme,"¹³ and understood that several of its programmes had been the instrument through which it had contributed to implement Article 12 of the ICESCR,¹⁴ the fact is that the first global outreach strategy specifically on health and human rights was prompted as a result of the Corporate Strategy of the WHO Secretariat of 1999,¹⁵ at which time the interaction between health and human rights was emphasized and promoted beyond the Organization itself.¹⁶ The seed of this strategy can probably be found within the WHO itself ten years earlier, when the Global Programme on HIV/AIDS began to emphasize that States must respect their obligations under the International Law of Human Rights in their fight against the pandemic.

While the terminology which is specific to the field of human rights has become customary in the work of the WHO, the treatment given to human rights is frequently more similar to programme principles than to enforceable rights. In the 1990s and early twenty-first century, real progress was certainly observed in the involvement of the WHO in the purely legal aspects of the right to health. Nevertheless, this commitment seems to have moved to another one, less based on law and more public policy-focused. This change is not in line with the WHO constitutional treaty, which views health as a human right and not merely as a guide to human aspirations.

recognized from within the WHO itself: See WHO, *Meeting Report: Informal Consultation on Health and Human Rights*, WHO, Geneva, 13-14 December 1999, HSD/GCP (June 2000) p. 4.

¹⁰ *Ibid.* pfs. 78-79

¹¹ World Health Organization, *Contribución de la Organización Mundial de la Salud a la Conferencia Mundial de Derechos Humanos*, (29 March 1993), A/CONF.157/PC/61/Add.8, pf. 16.

¹² *Organización Mundial de la Salud, Carta de Ottawa para la promoción de la Salud*, (21 November 1986), WHO/HPR/HEP/95.1.

¹³ *Organización Mundial de la Salud, Contribución de la Organización Mundial de la Salud a la Conferencia Mundial de Derechos Humanos*, *op. cit.*, pf. 10.f)

¹⁴ *Ibid.* pfs. 17-21.

¹⁵ World Health Organization, Executive Board, *A Corporate Strategy for the WHO Secretariat*, (10 December 1999), EB105.3, pf. 9.

¹⁶ See G. H. Brundtland, "Fifty years of synergy between health and human rights", *Health and Human Rights: An International Journal*, vol. 3, n° 2, (1998) p. 24.

III WHO OBJECTIVES AND MANDATE

Given the broad definition of health contained in the WHO Constitution, and the explicit linking of health, peace and human rights, the objective of the WHO -to get all people to achieve the highest level of health possible-¹⁷ is very broad in scope. This explains why the activities of the WHO have expanded to encompass very disparate issues. Thus, strategies, programmes and initiatives have been developed within the WHO and there are specific departments dedicated to purely medical issues, as well as to issues that indicate a broader conception of health, such as environmental health or nutrition.

The second article of the WHO Constitution is a long and detailed list of functions of the Organization, of which there have been different classifications. From among these, the W. R. Sharp classification is particularly graphic- he grouped the functions of the Organization together into five broad categories; coordination and administrative, technical and research (including biological and pharmaceutical standardization), information, technical assistance and regulatory promotion.¹⁸ The analysis of the overall work programmes shows that until the 1960s, WHO focused its activities in technical, regulatory and administrative questions,¹⁹ at a time marked by caution and stability.²⁰ However, since then and as a result of the emergence of developing countries, there has been a marked change and the WHO ventured into direct assistance to countries.²¹

IV THE USE OF REGULATORY POWERS

The WHO occupies the main position among the organizations that adopt international health standards. As we shall see, however, the potential for WHO to use the law in its activity to promote health has been, to date, underutilized.

To determine the extent of the legislative competence of an international organization, it is necessary to examine its legal order and how its legal will is formed within its institutional structure.²² An essential distinction is that concerning the internal legislative competence and external regulatory powers.²³ As far as external regulatory competence is

¹⁷ Art. 1 of the WHO Constitution, in *Documentos Básicos*, WHO: Geneva, 45th Edition, (2005) p.1.

¹⁸ W. R. Sharp, "The new World Health Organization", *The American Journal of International Law*, vol. 41, n° 3, (1947) p. 521.

¹⁹ See WHO, *Los diez primeros años de la Organización Mundial de la Salud*. (Geneva, WHO, 1958) p. 113-115.

²⁰ G. Walt, "WHO under stress: implications for health policy", *Health Policy*, vol. 24, n° 2, (May, 1993) pp. 133-134.

²¹ See Y. Beigbedier, *L'Organisation Mondiale de la Santé*, (Paris, PUF, 1997) p. 18

²² J. M. Sobrino Heredia, "La formación del derecho internacional por las organizaciones internacionales", in *Instituciones de Derecho internacional público*, M. Díez de Velasco, (Madrid, Tecnos, 2007) pp. 217-218.

²³ The first is interesting in that it serves to regulate the operation of the institution itself, and allows certain bodies to create other bodies, or to make decisions which are binding for other bodies. This is the way it happens in the case of WHO with the creation of committees by the World Health Assembly (Article 18.e) of the Constitution of the World Health Organization .) or with the orders from the World Health Assembly to the WHO Executive Board (Articles 18 d) and g.)

concerned, some international organizations may adopt standards meant for other international subjects. In addition to treaties concluded between States and international organizations, such standards may be mere recommendations²⁴ or binding decisions,²⁵ with a wide variety of instruments for both cases.

The adoption of **soft law** instruments varies depending on the programmatic objective. Certain forward-looking statements, adopted at international health conferences or by WHO, have been of great importance for the management and design of public health worldwide.²⁶ Moreover, specific issues have received more specific attention from codes of conduct or guidelines,²⁷ while others characterized by their technical complexity have been the subject of model lists, codes of conduct and technical standards.²⁸ One of the responsibilities of WHO is to propose conventions, regulations and recommendations regarding international health issues,²⁹ as well as the regulatory activity which is considered to be part of its work as director of international health.³⁰ The World Health Assembly can promote international conventions or agreements,³¹ a competence which it has exercised only in a substantive area and only recently.³² Under the technique of “opting out” it can also adopt regulations on technical issues, among others, the regulation of safety, purity and potency, and the advertising and labelling of biological, pharmaceutical and similar products for international trade.³³ Finally, the Assembly may also make recommendations to Members,³⁴ a formula that has been favoured since it is understood that they have the advantage of being flexible and subjected to little formality.³⁵

Despite the notorious regulatory powers that have been conferred upon it, the truth is that WHO has paid only little attention to the law -especially the **hard law**- as a tool for protecting and promoting health. On the contrary, it has been more in favour of seeking political agreement and has excused itself in its medico-sanitary profile in order to take on more of a health care than a legal role.³⁶ Also, the economic dependence of the Organization regarding the special programmes and the evolution of the health diplomatic policy may have resulted in the refusal to continue the momentum of regulatory projects which did not meet the interests of the principal donors. Examples of this vulnerability to political pressures are the failed draft regulations relating to breast milk substitutes and probably the internal debates

²⁴ Article 23 of the Constitution of the World Health Organization.

²⁵ Article 21 of the Constitution of the World Health Organization.

²⁶ Kickbusch, I., “The Contribution of the World Health Organization to a new public health and health promotion”, *American Journal of Public Health*, vol. 93, n° 3, (2003) pp. 383-388. For example, this is the case of the concept of primary health care.

²⁷ For example, in the field of child nutrition, *International Code of Marketing of Breast-milk Substitutes*, and that of hemoderivatives, *WHO Guidelines on viral inactivation and removal Procedures Intended to Assure the viral safety of human blood plasma products*.

²⁸ In this sense, pharmaceutical regulation is a paradigmatic case

²⁹ Art. 2 k) of the Constitution of the World Health Organization.

³⁰ WHO, *9th General Programme of Work, (1996-2001)*, Geneva: WHO, pp. 23-24.

³¹ Article 19 of the Constitution of the World Health Organization.

³² See below section on the Convention on tobacco control.

³³ Art. 21 of the Constitution of the World Health Organization. The other subjects for which it may adopt regulations are the health and quarantine requirements and the procedures to prevent the international spread of diseases, the nomenclatures of diseases, the causes of death and public health practices and the adoption of uniform standards for diagnostic procedures.

³⁴ Art. 23 of the Constitution of the World Health Organization.

³⁵ OMS, *El segundo decenio de la Organización Mundial de la Salud*, (Geneva, WHO, 1968) p. 335-115.

³⁶ D. Fidler, “The Future of the World Health Organization: What Role for International Law?”, *Vanderbilt Journal of Transnational Law*, vol. 31, n° 5, (1998) pp. 1079-1126.

about the Organization's involvement in promoting the treaty on innovation and health.³⁷ Furthermore, the fact that in 60 years it has adopted only one international regulation on a sensitive issue (the control of infectious diseases), and only a single international treaty in a substantive area (the fight against tobacco), allows to point out that the WHO still has a long way to go as far as the promotion of health through law is concerned.

The WHO Framework Convention on Tobacco Control (FCTC) has been referred to as the vaccine against cancer and cardio-vascular diseases. The FCTC is certainly the most efficient binding global instrument negotiated in WHO through Article 19 of the WHO Constitution. Tobacco is the first killer in the world. In the present international context of multiple health actors, WHO may recover its identity and leadership through the use of article 19 of the constitution in negotiating and adopting global treaties and conventions that will help Members States to exercise the right to access to health as a right of the citizens.

In the following pages we are designing general lines, principles, and main components of a possible binding convention for R&D for pharmaceutical products.

V A BINDING GLOBAL INSTRUMENT FOR R&D AND INNOVATION FOR HEALTH

Research and development (R&D) for pharmaceutical products has failed to deliver medicines for a large number of people, particularly those living in the developing countries. On the one hand, there is little investment in R&D for diseases prevalent in these countries, as large companies concentrate on the development of products that address demand in rich markets. On the other, products subject to patent and other modalities of exclusivity rights are normally commercialized at prices unaffordable to a large part of population. Several reports and studies, as well as the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) adopted by WHO Members States (2003-2008)³⁸, acknowledged these problems.

The Report of the Commission on Intellectual Property, Innovation and Public Health (known as the "CIPIH Report") recognized that the incentive of intellectual property rights does not meet the need for the development of "new products to fight diseases where the potential paying market is small or uncertain"³⁹ The CIPIH Report also recognized "the need for an international mechanism to increase global coordination and funding of medical R&D", and recommends to undertake further work on the proposal of the medical R&D treaty "to develop these ideas so that governments and policy-makers may make an informed decision."⁴⁰

The failure of the current incentive systems to deliver the pharmaceutical products needed, particularly in the countries of the South, calls for decisive action. Infectious diseases

³⁷ See G. Velásquez, *Acceso a medicamentos. retos, respuestas y derechos*, (Editorial Universidad de Caldas, 2010), pp. 173-219.

³⁸ World Health Organization, Global strategy and plan of action on public health, innovation and intellectual-property. WHA Resolution 61.21, (May 24, 2008).

³⁹ World Health Organization, CIPIH Report (2006) p. 115

⁴⁰ World Health Organization, CIPIH Report (2006) p. 91

kill over 10 million people each year, with more than 90 per cent in the developing world. A major factor contributing to this crisis is that one-third of the global population lacks access to needed medicines and the situation is worse in poor countries where as much as 50 per cent of the population lacks access.⁴¹

At the same time, the context for addressing the challenge of access to pharmaceutical products is changing. Developing countries—including India, the largest supplier of generic medicines—implemented the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) with regard to the patentability of pharmaceutical products. As a result, the share of medicines that are protected by patents is on the rise and is expected to translate into higher prices.⁴²

The problems faced in this area cannot be solved only through improvements on or adaptations to existing incentive models. The model of the IP system does not deliver innovation needed for developing countries. And the CIPIH Report recognized 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”.⁴³

There is a need for new mechanisms⁴⁴ that simultaneously and effectively promote innovation and access to medicines, particularly for diseases that disproportionately affect developing countries. A binding international instrument on pharmaceutical R&D, to be negotiated under the auspices of the WHO, may provide the appropriate framework to ensure priority setting, coordination, and sustainable financing of affordable medicines for developing countries.

V.1. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)

The GSPOA approved by WHO Member States in May 2008 (WHA Resolution 61.21) recognized the problems referred to and contained a number of specific proposals:

- The strategy recognizes that the current initiatives to increase access to pharmaceutical products are insufficient.⁴⁵
- It also recognizes that the incentive mechanisms of the intellectual property rights are not delivering for people living in "small or uncertain potential paying markets".⁴⁶

⁴¹ WHO and HAI, *Measuring medicine prices, availability, affordability and price components*, second edition (2008), p1.

⁴² Gehl Sampath, P., “India's product patent protection regime: less or more of ‘pills for the poor’?”, *The Journal of World Intellectual Property*, (2006) 9 (6):694–726

⁴³ World Health Organization, CIPIH Report (2006) p. 177

⁴⁴ WHA GSPOA point 13

⁴⁵ World Health Organization (2008), GSPOA WHA Resolution 61.21 : « The context » point 3.

- The GSPOA recognizes that the present system of innovation based on the IP incentive has failed to deliver medicines for diseases that disproportionately affect the majority of world's population living in developing countries.
- The Global Strategy aims to promote new thinking on innovation and access to medicines.
- Importantly, paragraph 2.3. (c) of the GSPOA⁴⁷ refers to a possible international treaty on research and development of new pharmaceutical products.

The negotiating and adoption of an international instrument on pharmaceutical R&D, would hence be a key element in the implementation of the GSPOA. Indeed, if successful, this could be the most significant achievement under the GSPOA from the perspective of public health interests in developing countries.

Following the rejection of the report submitted by the WHO Expert Working Group set up by the WHA to consider issues of coordination and financing of pharmaceutical R&D, the WHO Consultative Expert Working Group (CEWG) was established at the beginning of 2011 to deal with the matter. In July 2011 the chair of the CEWG announced that "CEWG intends to recommend that formal intergovernmental negotiations begin for a binding global instrument for R&D and innovation for health".

VI OBJECTIVE AND SCOPE: THE FOCUS, PRIORITY SETTING, SUSTAINABLE FINANCING AND COORDINATION OF PUBLIC R&D FOR PHARMACEUTICAL PRODUCTS

The objective of a binding global instrument for R&D and innovation for health would be:

- (i) to promote R&D for all diseases, conditions or problems (including NCD) relevant to developing countries' needs;
- (ii) to develop mechanisms for sustainable financing;
- (iii) to set R&D priorities based on health needs; and
- (iv) to coordinate public R&D; and
- (v) to promote the research capacity of developing countries.

VII THE PRINCIPLES

The following principles may be considered in developing a global instrument on R&D:

- The right to health is a universal and inalienable right and is the governments' duty to ensure the means for its realization.
- The right to health should take precedence over commercial interests in R&D for new pharmaceuticals.

⁴⁶ World Health Organization (2008), GSPOA WHA Resolution 61.21 : « The context » point 7.

⁴⁷ World Health Organization (2008), GSPOA WHA Resolution 61.21 : « The Plan of Action 2.3.C) page 27.

- The right to health implies equitable and universal access to medicines.
- R&D should be conducted in a sustainable manner to address public health priorities.
- The binding global instrument for R&D should include mechanisms to assure transparency with regard to R&D funding provided and the cost of R&D incurred.
- The binding global instrument for R&D should include mechanisms to de-link the cost of R&D from the price. Prices of medicines produced should be fixed on the basis of affordability to all in need.
- The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.
- The binding global instrument for R&D should not be limited to Type 3 diseases but should also address other diseases prevailing in developing countries.
- The outcomes of R&D undertaken in the context of the global instrument should be considered as a public goods and remain in the public domain.

VIII POSSIBLE MAIN COMPONENTS OF A BINDING GLOBAL INSTRUMENT FOR R&D AND INNOVATION FOR HEALTH

In order to attain this objective, an international instrument should include the following:

- Priority setting based on public health criteria
- Coordination of public R&D for pharmaceutical products;
- Sustainable financing.

Priority setting would aim at ensuring that the agenda for R&D on medicines and health technologies is based on public health needs of the population rather than on the potential commercial markets.

A key component of a binding global instrument on R&D should be to develop mechanisms to coordinate R&D in order to achieve clearly identified targets at the minimum possible cost. It should advise/guide all actors (public and private) on allocation of resources, and it can also monitor and evaluate efforts on R&D. The mechanisms to be agreed upon may include networking of existing institutions, particularly in developing countries, and the setting up of new programmes and facilities.

The CIPIH report stressed that there was “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 more in this endeavour...”⁴⁸

The binding global instrument for R&D should propose that a financing mechanism be established, based on transparent costing of R&D activities. The source of financing for the fund would be from governments according to their level of development and from governments’ voluntary contributions.

⁴⁸ World Health Organization, CIPIH Report, (2006), Geneva, page 209.

VIII.1 Some Possible Elements of a Binding Global Instrument for R&D and Innovation for Health

For methodological purposes, we refer to the components (section VIII) as the substantive part of the Convention and the elements (this subsection) the complementary mechanisms that can help the implementation of the main components of the Convention. The elements mentioned here are not exhaustive; others will be identified during the negotiation, as happened during the negotiation of the Tobacco Convention:

- Ethical criteria and financial mechanisms to conduct clinical trials with full disclosure of test data.⁴⁹
- Mechanisms to build and strengthen research and local capacity of developing countries.
- Mechanisms (push and pull mechanisms) which de-link the cost of R&D from the price of the product in order to promote access to medicines for all. (cfr. WHO GSPOA).
- Mechanisms to ensure that the result of R&D will remain in the public domain or be otherwise accessible for use in developing countries.
- Research and development policies based on articles 12 and 15.b of the International Covenant on Economic, Social and Cultural Rights: right to health⁵⁰ and right “to enjoy the benefits of scientific progress and its applications”⁵¹

IX WHO AUTHORITY TO ADOPT BINDING GLOBAL INSTRUMENTS, INTERNATIONAL CONVENTIONS OR TREATIES

Article 19 of the WHO Constitution provides 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.”

There is only a single precedent in WHO history on the use of article 19: the WHO Framework Convention on Tobacco Control. (See Annex 1).

⁴⁹ Clinical trials are research studies that test how well new medical approaches work in people. Each study should answer scientific questions and tries to find better ways to prevent, screen for, diagnose or treat a disease. Most of the time clinical trials are performed by the industry. There is increasing concern about the quality, reliability, and independence of practice guidelines, because no information is available on the methodological quality of the guidelines developed by specialty societies belonging or pay by the pharmaceutical industry.

⁵⁰ Article 12 of the International Covenant on Economic, Social and Cultural Rights

⁵¹ Article 15.1(b) of the International Covenant on Economic, Social and Cultural Rights

X CONCLUSIONS AND RECOMMENDATIONS

- There is a need for sustainable long term innovative mechanisms to promote pharmaceutical R&D to address public health needs, particularly in developing countries.
- To start international negotiations for “a binding global instrument for R&D and innovation for health” as recommended by the WHO-CEWG.
- Re-thinking of the global public health governance: adoption by WHO of a binding instrument as allowed by Article 19 of the WHO Constitution.

A successful binding global instrument for R&D must be able to prioritize R&D in accordance to health needs, to coordinate R&D to avoid unnecessary duplication of efforts and to design sustainable public mechanisms and models for financing for R&D.

On 18 November 2011, the Chairman of the WHO Consultative Expert Working Group (CEWG) announced that the report of the expert group was going to: “recommend a binding convention (under Article 19 of WHO constitution)”.

ANNEX 1

THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

The tobacco epidemic is another example of the links between health and globalization. The spread of smoking has been favoured by factors such as trade liberalization, foreign direct investment and globalization of communications, in this case associated with the export of harmful health habits.⁵² In May 2003, and after three years of negotiations and six years of work,⁵³ the World Health Assembly unanimously adopted⁵⁴ the WHO Framework Convention on Tobacco Control (FCTC).⁵⁵ Thus, for the first time the WHO exercised the prerogative to adopt treaties and make international agreements on a substantive area,⁵⁶ and gave a global legal response to an equally global health threat.⁵⁷

The FCTC is a framework treaty which, although refers to many substantive issues, fundamentally establishes the objectives, principles, institutions and operation of what should be a more comprehensive system, thanks to the future adoption of additional protocols on technical issues.⁵⁸ It therefore sets up the framework to allow a progressive normative approach to the problem of smoking. Moreover, the treaty was designed as a document of minimums, and allows and even encourages the parties to adopt stricter measures.

The objective of the Convention is "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke."⁵⁹ To do so, this treaty is based on a series of fundamental principles, such as information on and protection from the harmful effects of tobacco, multisectoral measures, support for economic conversion, the participation of civil society, the principle of cooperation and the principle of responsibility.

In its third part, the Convention calls for measures aimed at achieving the reduction in demand for tobacco, financial and tax, information, advertising and health measures. In turn, the fourth part includes measures to limit the supply of tobacco, which refers to smuggling, the sale of tobacco to minors and public support for farming alternatives to tobacco. The

⁵² Taylor, A and Bettcher, D., El convenio marco de la OMS para la lucha antitabáquica: una baza mundial para la salud pública”, *Bulletin of the World Health Organization, Recopilación de artículos*, nº 4, (2001) p. 33.

⁵³ In May 1999, the World Health Assembly urged to begin negotiations to adopt a framework convention on tobacco control, See WHA52.18. Earlier, in 1996, the World Health Assembly adopted a resolution (WHA49.17) urging the start of the preparatory study of the future convention. The treaty entered into force on February 27, 2005. See WHO, Press Release, WHO/10 of February 24, 2005.

⁵⁴ On the ambiguous American position, see S. D. Murphy, "Adoption of Framework Convention on Tobacco Control", *American Journal of International Law*, vol. 97, nº 3, (2003) pp. 689- 691.

⁵⁵ WHO Framework Convention on Tobacco Control, adopted in Geneva on May 21, 2003, *BOE*, (February 10, 2005).

⁵⁶ It had previously concluded several headquarter agreements with the respective states, and agreements with other international organizations.

⁵⁷ L. F. De Seixas, “The framework convention on tobacco control”, *Bulletin of the World Health Organization*, Vol. 80, nº 12, (2002) p. 924

⁵⁸ Future issues to be addressed could be those regarding promotion and sponsorship, advertising, illicit trade and responsibility. N. Devillier, “La Convention-cadre pour la lutte anti-tabac”, *Revue Belge du Droit International*, nº 1-2, (2005) p. 722.

⁵⁹ Article3 of the WHO Framework Convention on tobacco control, op.cit.

treaty also provides for such issues as the responsibility of the tobacco industry, urging States to include provisions in their civil and criminal law to this respect.

The agreement designates the Conference of the Parties as the body which will monitor that the Convention is respected and implemented. The 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."⁶⁰ The agreement also designates a permanent secretariat, which is entrusted with the preparation of meetings of the Convention bodies, giving support to States, transmitting reports received and preparing reports it has been entrusted with.

Some of the conclusions of the 2010 global progress report on the implementation of the WHO Framework Convention on Tobacco Control:

“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 (...)

Half of the Parties that reported twice implemented more than 80% of measures contained in all substantive 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).

Countries signatories of the WHO FCTC : 168

⁶⁰ Article 3.23.5 of the WHO Framework Convention on Tobacco Control, *op.cit.*

ANNEX 2

THE INTERNATIONAL HEALTH REGULATIONS

The Expert Committee on International Epidemiology and Quarantine, created in the first World Health Assembly, undertook a review of existing agreements on infectious diseases, and merged them into a single international instrument, which can be adapted depending on the evolution of diseases. The resulting text, amended according to comments from States, was approved on May 25, 1951 by the Fourth World Health Assembly, and became Regulation No. 2 of the WHO, which took effect on October 1, 1952.

Although the International Sanitary Regulations were revised in 1969, 1973 and 1981, they proved to be insufficient and scientifically obsolete in the 1990s.⁶¹ States often do not meet the obligations under the agreement, both in regard to the maximum adoptable measure⁶² as well as to the periodic submission of reports,⁶³ in face of which the WHO's accountability mechanisms were weak⁶⁴. On the other hand, the exclusive focus on three diseases made it insufficient given the emergence of new infectious diseases, re-emerging diseases and health emergencies not generated by communicable diseases.⁶⁵ As a result, in May 2003, the Assembly established an intergovernmental working group to review the Regulations; the revision was adopted in 2005 and came into force on June 15, 2007.

The Health Regulations intend to achieve maximum security in face of the international spread of diseases⁶⁶ with minimum obstacles to global circulation. The Regulations cover all forms of international transport, and points to health conditions to be maintained and to the health conditions which are to be complied with in international ports and airports. The Regulations contain specific provisions on each of the diseases addressed and prescribe when vaccination is required to enter a country, the circumstances which may require passengers to be disinfected or watched and the measures to adopt with regards to ships or airplanes which are infected or suspected to be infected.⁶⁷ Annexes to the Regulations include, among others, models of international certificates of vaccination, the Maritime Declaration of Health and the Health Part of the General Aircraft Declaration.

⁶¹ L. Gostin, "International infectious disease law. revision of the world health organization's international health regulations", *Journal of the American Medical Association*, vol. 291, n° 21, (2004), p. 2627.

⁶² Perhaps one of the most remarkable examples, which has also been addressed in areas such as human rights, is the restriction on freedom of movement imposed on persons infected with HIV.

⁶³ P. Dorolle, "Old plagues in the jet age: international aspects of present and future control of communicable diseases", *WHO Chronicle*, n° 23, (1969), p. 109.

⁶⁴ B. Velimirovic, "Do we still need international health regulations?", *Journal of Infectious Diseases*, n° 133, (1976), p.478.

⁶⁵ D. Fidler, "The future of the World Health Organization: what role for international law?", *Vanderbilt Journal of Transnational Law*, vol. 31, n° 5, (1998), pp. 1079-1126.

⁶⁶ Initially, cholera, plague, yellow fever, typhus, smallpox, relapsing fever. In 1969, cholera, plague and yellow fever. The revised International Health Regulations (2005) covers the existing infectious diseases, the re-emerging, and also non-infectious diseases that may pose an international health emergency

⁶⁷ In the field of infectious diseases the International Health Regulations replaced policy and fear with epidemiological criteria. It puts an end to the concept of quarantine and replaces it with the provision that sets the period of isolation or supervision only during the incubation period of the suspected disease.

The Regulations also establish a system of epidemiological surveillance. An order was issued for the health administrations to notify and report not only on the appearance and evolution of diseases that could be quarantined in their territory, but also on health emergencies that may have international repercussions.⁶⁸ Moreover, unlike the previous regulations, the WHO also collects pertinent independent information, for example from research centres or NGOs, and makes it public. The information is collected by the National Focal Points, which in turn transmit it to the Contact Points of the WHO for the Regulations, and these in turn to other National Focal Points.

The International Health Regulations are the current framework to determine the existence of an international health emergency,⁶⁹ in order to gather information and seek assistance. The Regulations provide for the creation of an Emergency Committee responsible for determining the existence of a health emergency⁷⁰ and advising the Director General to this regard. For its part, the Director General may recommend measures to be applied by both the State affected by a public health emergency, and by other States or international transport operators.⁷¹ The importance of these aspects, and the power of the WHO to condition international behaviour, even based on a non-conventional text, was revealed to its full extent when a pandemic situation was declared during the outbreak of the H1N1 virus.

An analysis of the Regulations revised in 2005 highlights a fundamental change of approach in relation to their predecessors. The regulations, which had previously been designed as a document of maximums that included the most restrictive measures which could be taken to protect the territory and population, and from which it was not possible to clearly deduce if the priority was health or commerce,⁷² has changed currently to allow measures aimed at providing a higher level of security to be applied⁷³. However, as demonstrated by the H1N1 pandemic, implementation of the regulations must be optimized as far as the management of conflicts of interest, the communication of the reasons for the decisions and clarity with respect to pandemic levels are concerned.

⁶⁸ For example, if the prevalence of certain diseases which do not require quarantine, such as polio or flu, reach epidemic levels, States also must report them and they are also included in the Weekly Epidemiological Record.

⁶⁹ According to Article 1 of the Regulations, a "public health emergency of international concern" represents an extraordinary event which, in accordance with the Regulations, it has been determined constitutes a risk to the public health of other States through the international spread of disease, and may require a coordinated international response.

⁷⁰ World Health Organization (2008). *International Health Regulations (2005)*, 2nd edition. Article 48. In addition, Annex 2 contains the "Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern"

⁷¹ World Health Organization (2008). *International Health Regulations (2005)*, 2nd edition. Articles 15 and 16, respectively. One of the most notable precedents is the measures recommended by the WHO during the SARS outbreak in 2002 in southern China.

⁷² L. O. Gostin, "Revision of the World Health Organization's international health regulation", *op. cit.*, p. 2627.

⁷³ *See art. 43.1*

ANNEX 3

INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

There are multiple nutritional, medical and hygienic reasons which make breastfeeding preferable. However, in the 1950s, the consumption of breast milk substitutes soared, spurred largely by the aggressive and not always reliable advertising of their manufacturers. Starting from 1970, the WHO began holding meetings and publishing studies on the effects the substitution was having. In 1974, the Assembly noted that one of the causes of child malnutrition was the abandonment of breast milk, and invited States to take measures to prevent aggressive advertising.⁷⁴ Between 1974 and 1978 several NGOs, with the remarkable leadership of Health Action International and companies dedicated to child nutrition engaged in a bitter debate on the veracity of the health information and business practices of these companies.

In 1979, jointly with UNICEF, the WHO, which was embroiled in a controversy that was not limited to medical issues, called a conference on infant and child feeding. The conference was attended by various specialized agencies of the United Nations, scientists, multinational food companies and NGOs which mandated the WHO and UNICEF to draft an international code of marketing of breast-milk substitutes. This editorial was provided by the Director General of WHO, which opened a consultation process with the various parties involved on the basis of the points of agreement which had been reached at the conference in 1979. The resulting draft was submitted to the Executive Council in 1981, which recommended to the World Assembly to adopt the code under the formula of a recommendation and not a regulation, as originally proposed.⁷⁵ The Council argued that the legal instrument should be the one to contribute the most to achieving the objective of the Code, and felt that a unanimous recommendation was better for it than a regulation which several States might perhaps dissociate themselves from.⁷⁶ Thus, in May 1981, the World Health Assembly, with all but one vote against, adopted the International Code of Marketing of Breast-milk Substitutes.⁷⁷

The assessments on this process coincide in pointing out that the WHO was in the middle of an argument with significant ideological overtones. NGOs and companies embroiled in the discussion did not so much seek scientific objectivity of the Organization as a stage on which to continue their line of argument. Ultimately, the fight was more for the media than scientific, and the instrument which was adopted did not seem to satisfy any of the sides. In any case, the Secretariat of the WHO was the most chastened, and this would increase its traditional reluctance regarding regulatory procedures set out in its Constitution.⁷⁸

⁷⁴ World Health Organization, World Health Assembly, WHA27.43. WHO, *Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 1973-1984*, (Geneva, WHO, 1985), pp. 89-90.

⁷⁵ World Health Organization, Executive Board, *Proyecto de Código Internacional de Comercialización de Sucedáneos de la Leche Materna*, (28 January 1981), EB67.R12.

⁷⁶ World Health Organization, *International Code of Marketing of Breast-Milk Substitutes*, (Geneva, WHO, 1981) p. 25.

⁷⁷ World Health Organization, World Health Assembly, *WHA Resolution 34.22*, 21/5/1981, WHA34.22

⁷⁸ Y. Beigbedier, *L'Organisation Mondiale de la Santé*, op. cit., p. 51.

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ISSN 1819-6926