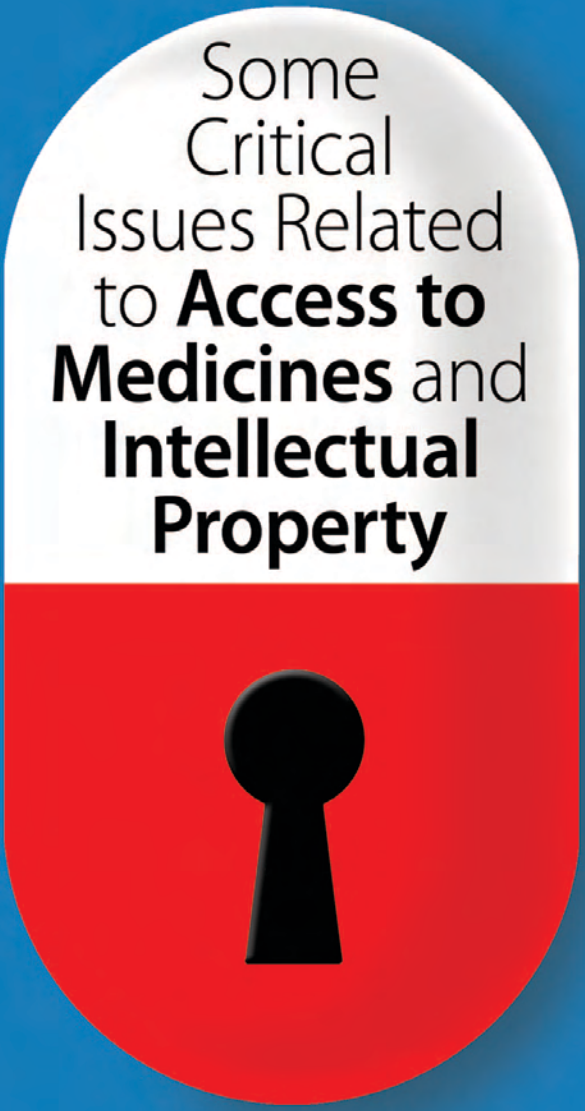
Some Critical Issues Related to **Access to Medicines** and **Intellectual Property**



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SOUTH CENTRE

SOME CRITICAL ISSUES RELATED TO ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY

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This South Perspectives series comprises authored policy papers and analyses on key issues facing developing countries in multilateral discussions and negotiations and on which they need to develop appropriate joint policy responses. It is hoped that the publications will also assist developing country governments in formulating the associated domestic policies which would further their development objectives.

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
BITs	Bilateral Investment Treaties
BMGF	Bill and Melinda Gates Foundation
CEWG	Consultative Expert Working Group on Research and Development: financing and coordination
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
DAP	Drugs Action Programme
DNDi	Drugs for Neglected Diseases Initiative
EU	European Union
EWG	Expert Working Group on R&D financing and coordination
FTA	Free Trade Agreement
GSK	GlaxoSmithKline
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV	Human Immunodeficiency Virus
IGWG	Intergovernmental Working Group
IP	Intellectual property
MPP	Medicines Patent Pool
NGO	Non-Governmental Organization
PAHO	Pan American Health Organization
PDPs	Product Development Partnerships
PhRMA	Pharmaceutical Research and Manufacturers of America
PPPs	Public-Private Partnerships
R&D	Research and development
SEARO	World Health Organization South East Asia Regional Office
TCM	WHO Department of Technical Cooperation for Essential Drugs and Traditional Medicines
TDR	WHO Special Programme for Research and Training in Tropical Diseases
TRIPS	(The Agreement on) Trade-Related Aspects of Intellectual Property Rights
UN	United Nations

UNAIDS	Joint United Nations Programme on HIV/AIDS
UNASUR	Union of South American Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNICEF	United Nations Children's Fund
US	United States of America
WHA	World Health Assembly
WHO	World Health Organization
WHO EB	Executive Board of the World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

PREFACE

This book is a collection of papers by the South Centre between 2011 and 2014 on the deliberations and negotiations in the World Health Organization (WHO) on access to medicines and their relationship with international trade and intellectual property regimes. The South Centre is an intergovernmental research organization of developing countries on critical development issues for the South and is an observer to the governing bodies of the WHO. It is hoped that the collection of papers presented in this book will be useful for policy makers and researchers interested in the deliberations in the WHO on the critical issues pertaining to public health, particularly access to medicines.

Chapter 1 provides an account of the contribution of the WHO to the debate on access to medicines and intellectual property in the aftermath of the adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In 1996 the World Health Assembly had adopted a unanimous resolution which requested the WHO Director-General to conduct a study on the impact of the WTO rules, particularly the TRIPS Agreement, on national drug policies and essential drugs. Pursuant to this resolution, the WHO published a study in 1997 titled "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement" which concluded that the standards of the TRIPS Agreement are not necessarily appropriate for all countries' level of development and that public health concerns should be considered before implementing TRIPS. Though the study was severely criticized by multinational pharmaceutical companies, independent reviews carried out by the WHO found the study to be technically accurate. Between 1997 and 1999, the WHO carried out a series of technical assistance and capacity building activities on the relationship between pharmaceuticals and trade. The WHO began analyzing existing trade agreements and trade agreements under negotiations with regard to their impact on access to drugs. In 1999 the World Health Assembly encouraged the WHO to continue and expand this work. The WHO also provided assistance to countries in resolving impediments to access to medicines arising from such trade agreements. In this regard, the WHO

provided exemplary support to South Africa in advising on drug legislation and creation of an essential medicines list in order to use the TRIPS flexibilities. The WHO also supported a series of resolutions adopted in the UN human rights bodies to integrate access to medicines as a part of the human right to health. The work of the WHO played a very influential role in the adoption of the WTO Doha Declaration on TRIPS and Public Health which reaffirmed the right of countries to use the flexibilities in the TRIPS Agreement to support public health objectives. In 2003, the WHO established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) which found that the TRIPS Agreement did not incentivize investments on medical research and development (R&D) especially for diseases that predominantly affect the developing countries. The report of the CIPIH (2006) recognized the need for creation of a mechanism to increase global coordination and funding of medical R&D and recommended the continuation of work for the adoption of a treaty on pharmaceutical R&D. An Intergovernmental Working Group (IGWG) was established to deliberate on the recommendations of the CIPIH, based on which the WHO adopted the "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property" (GSPOA) in 2008. However, the GSPOA could not resolve issues pertaining to the plan of action on intellectual property, which made up more than 60 recommendations of the CIPIH. Thus, in 2008 the World Health Assembly established an Expert Working Group (EWG) to examine issues of coordination and funding of medical R&D, particularly on the issue of an international treaty on R&D. However, the report of the EWG failed to address this issue and therefore the World Health Assembly rejected the report and established a new Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in 2011. The CEWG recommended to the Assembly in 2012 to commence formal intergovernmental negotiations for a binding global instrument on medical R&D based on Article 19 of the WHO Constitution. However, several developed countries opposed this recommendation and the Assembly established an intergovernmental group to analyze the CEWG recommendations. Discussion in the intergovernmental group have so far remained inconclusive on the critical need for negotiating a binding international instrument on biomedical R&D.

Chapter 2 provides an analysis of the negotiations in the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The chapter observes that the IGWG negotiation is the most important exercise ever carried out by the WHO Member States on questions of access to medicines and provided an excellent opportunity for the WHO to exercise its leadership by providing a vision on access to medicines for the next 15 to 20 years. Under Article 19 of the WHO Constitution, the World Health Assembly has the authority to adopt conventions or agreements with respect to any matter within the competence of the organization. However, so far WHO has paid limited attention to hard law instruments as tools for protecting and promoting health and has been inclined towards a political agreement. It will be important for the WHO to use its powers to legislate rather than recommend in the quest for a binding mechanism for supporting R&D for diseases that predominantly affect the developing countries where most of the world's population live.

Chapter 3 further explores how constitutional powers of the WHO can contribute positively to stimulate biomedical research in the context of current resource constraints of the WHO which has structural implications. It also points to possible elements of a binding global instrument for R&D and innovation for health.

Chapter 4 examines the increase in use of public-private partnerships (PPPs) and product development partnerships (PDPs) in many areas of work of the WHO and other international public health initiatives. It points to the risk of creation of PPPs and PDPs with their own "advisory bodies" which may compete with the governing bodies of the WHO. There could be risks of businesses using the relationship with UN agencies to set the global public agenda in furtherance of their commercial interests which was seen in the case of the massive purchase of vaccines for H1N1 flu. While in 1999 the WHO had developed guidelines on interaction with commercial enterprises, this has been implemented without any formal approval from the WHO Executive Board. There is thus need for greater transparency in the process of development and approval of guidelines on WHO interaction with commercial enterprises. In this context, the proliferation of PPPs and PDPs has impeded the WHO's capacity to safeguard the multilateral, independent and public character of the organization. More

significantly, the PPPs and PDPs tend to sustain a relationship of dependency of the developing countries on developed countries since these are voluntary mechanisms undertaken by donors and developed country governments, where priorities are determined by them. There is need for rules governing such partnerships that they are established based on the needs of developing countries as determined by the developing countries, that intellectual property issues do not come in the way of access to products developed through such mechanisms, etc. Hence, there is a need for a global moratorium on the creation of new PPPs and PDPs until the WHO sets clear rules and principles governing the relationship of such partnerships with the WHO. There is also need for exploring alternative mechanisms to PDPs such as a binding international treaty for biomedical R&D or open source models of drug discovery.

CHAPTER 1

ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY: THE CONTRIBUTION OF THE WORLD HEALTH ORGANIZATION[1]

I. INTRODUCTION

The topic of intellectual property first appeared in the WHO in 1996 and coincided with the end of the Uruguay Round and the creation of the World Trade Organization. In 1995 the Charles III University of Madrid and the WHO Drugs Action Programme (DAP) organized a conference where Professor Carlos Correa[2] presented a paper titled "The Uruguay Round and Drugs"[3]. The 40 page article analyzes the possible implications of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on access to medicines and discloses the "room to manoeuvre" that the Agreement has to protect Public Health. This article, "The Uruguay Round and Drugs", was the first document that specifically alerted the health sector of the possible implications of the TRIPS Agreement on public health and in particular, on access to medicines.

Even during negotiations of the Uruguay Round (1986-1994) some negotiators from developing countries foresaw that the TRIPS Agreement would have important implications in relation to pharmaceuticals and health. Shortly after its adoption, the United

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[1] The author thanks Carlos Correa and Vicente Paolo Yu III for their valuable comments and inputs.

[2] Negotiator of the TRIPS Agreement during the Uruguay Round, as Under-Secretary for Science and Technology of the Government of Argentina.

[3] Carlos M. Correa, "The Uruguay Round and drugs", WHO/TFHE/97.1, Distr: General, Original: English, 1997, p. 40.

Nations Conference on Trade and Development (UNCTAD) published a study on the TRIPS Agreement and developing countries[4].

II. FIRST MANDATE OF THE WORLD HEALTH ASSEMBLY

In the World Health Assembly in 1996, a resolution on drugs was adopted[5] that constituted the first mandate given by member states to the Secretariat of the WHO to work on intellectual property in relation to health. Originally it was a classic draft resolution dealing with all the components of a drug policy; selection, rational use, quality control, etc., until the last minute, before its adoption by the World Health Assembly, when the delegate of Iran requested an amendment that involved asking the Director-General of the WHO to conduct a study on what the impact of the rules of the World Trade Organization – especially the TRIPS Agreement – would be on national drug policies and essential drugs. The 49th World Health Assembly subsequently unanimously adopted the resolution (Resolution 49.14) which incorporated the amendment proposed by Iran.

III. "THE RED BOOK"[6]

The request in resolution 49.14 of 1996 for the Director-General to prepare a study on the implications of the TRIPS Agreement, was entrusted to the DAP which published a document: "Globalization and

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[4] United Nations Conference on Trade and Development (UNCTAD), *The TRIPS Agreement and Developing Countries*, U.N. Pub. 96.II.D.10 (1996) (prepared for the UNCTAD secretariat by Carlos Correa, Keith Maskus, J. H. Reichman, and Hanns Ullrich).

[5] WHA 49.14 "Revised Drug Strategy", WHO, Geneva, 1996.

[6] "This (WHO) monograph, nicknamed the Red book", see Velásquez, G., Correa, C., Balasubramaniam, T., "WHO in the frontlines of the access to medicines battle: The debate on Intellectual property rights and public health", in *Intellectual Property in the context of the WTO TRIPS Agreement: Challenges for public health*, edited by Bermudez, J., (FIOCRUZ, ENSP, WHO, PAHO, Rio de Janeiro, 2004), p. 87.

Access to Drugs: Implications of the WTO/TRIPS Agreement" [7] in November 1997.

The executive summary of the document clearly expresses its objective: "The aim of this document is to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs, and especially about the WTO agreement on intellectual property (TRIPS Agreement) that may have repercussions in the pharmaceutical field". And later in the executive summary the document affirms that "the TRIPS standards derive from those of industrialized countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement."[8]

The document, published by the WHO, provoked a series of violent criticisms by the Pharmaceutical Research and Manufacturers of America (PhRMA). According to a letter from PhRMA dated June 30, 1998, the document published by the WHO is "a deeply flawed document that misleads its readers and creates a false impression of how the WTO's TRIPS agreement will affect pharmaceuticals. The paper seeks to rationalize the continued piracy of pharmaceuticals inventions (…) and encourage WHO members not to implement adequate and effective intellectual property protection for pharmaceuticals".[9] The letter from PhRMA was followed by a letter from the Government of the United States dated 28 July 1998[10] accusing the document of "attacking" the WTO TRIPS Agreement and, more than "inform", it spreads "propaganda" against the Agreement.[11] In light of these attacks, the

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[7] Velásquez, G., and Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997.

[8] Ibid, pp. 3-4.

[9] Benkimoun P. "Morts sans ordonnance" Ed. Hachette Literatures, Paris, 2002, p. 185.

[10] Benkimoun P. op.cit. p. 185 Letter from the Government of the United States of America, signed by the Commissioner of Health Affairs of the FDA, Stuart Nightingale.

[11] The secretariat of the WTO provided a series of commentaries mostly regarding editorial and translation issues and some dissident opinions that the WHO decided to maintain, but the message and the objective of the document was not changed in any way. The original WHO document was in French and the WTO analyzed the English version.

Director-General of the WHO, G.H. Brundtland, decided to send the document to be revised by three independent academics specialized in intellectual property from the University of Louvain, Belgium; University of Buenos Aires, Argentina and the Vanderbilt Law School, USA. The experts concluded that the WHO's document is technically correct and fully consistent with the TRIPS Agreement.[12]

The WHO document was printed, by chance, with a red cover and was referred to as the "red book" even in official correspondence. Subsequently, in its first re-print, it became the "blue book".[13]

In 1996 DAP began what F. Antezana and X. Seuba called the fourth phase of the WHO drugs action programme: "Economic, Technological and Social Determinants of Health and New Tools"[14].

The economic dimension of drugs was always linked to DAP, a relationship that was deepened from the beginning of the 1990s in the publications and advice given to countries. The publication of the "red book" on "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement" "anticipated what the Doha Declaration later came to recognize: the right of WTO members to fully exploit the flexibilities contained in the Agreement in order to protect public health".[15]

Between 1997 and 1999, pursuant to World Health Assembly resolutions[16], DAP carried out a series of activities involving pharmaceuticals and trade. Among the activities was the analysis and dissemination of information regarding the effect of trade agreements on health, advising States to guarantee access to medicines under such agreements, and participation in international conferences on the relation between trade and public health.

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[12] Benkimoun P. op.cit pp. 187-188.

[13] The cover of the first edition of the WHO document was red, the same color as the first edition of the TRIPS Agreement. Apparently this was not appreciated by some individuals who requested that the color of the cover of the WHO document be changed, so today the cover is blue.

[14] Antezana, F. and Seuba, X., Thirty Years of Essential Medicines, The challenge. Ed. Icaria, Milenrama, Barcelona, 2008, p. 42.

[15] Op. cit., p. 44.

[16] 1996 WHA49.14: Revised drug strategy, 1999 WHA52.19: Revised drug strategy.

In 1999, Director-General G.H. Brundtland stated that "when trade agreements affect health, the WHO should be involved from the very beginning",[17] therefore the WHO and DAP in particular, began to analyze existing agreements as well as trade agreements under negotiation in relation to their effects on access to drugs. After considering the Revised Drug Strategy, in 1999 the World Health Assembly encouraged the continuation and expansion of work undertaken, especially regarding the impact of trade agreements on access to patented drugs.[18]

The work of DAP and the WHO was not limited to the analysis of trade agreements but it also extended to the resolution of problems caused by certain interpretations of these agreements. For example, at the end of the 1990s the WHO came out in support of South Africa following a lawsuit by 39 pharmaceutical companies against the South African government's attempt to make use of TRIPS flexibilities. In fact, DAP collaborated with the national South African drug programme, which was considered particularly important because of its possible impact on other countries, performing activities such as advising on drug legislation and the creation of an essential medicine list.

During the second half of the 1990s, DAP incorporated human rights into the work of the WHO regarding access to drugs as a part of the right to health. In the year 2000, the Committee on Economic, Social and Cultural Rights stated that access to essential medicines is a vital element of the right to health,[19] which was supported by a series of resolutions of the United Nations Sub-commission and Commission on Human Rights.[20] In 2001, both the UN General Assembly[21] and the World Health Assembly supported this stance.[22]

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[17] "WHO gets the mandate to tackle trade impacts on health", Essential Drugs Monitor. No. 27, 1999, p.18.

[18] WHA52.19: Revised drug strategy.

[19] Committee on Economic, Social and Cultural Rights, General Comment No. 14 The Right to the Highest Attainable Standard of Health, 2000, E/C.12/2000/4, para. 43.

[20] Sub-Commission on the promotion and protection of human rights, Globalization and its impact on the full enjoyment of all human rights, 2001, E/CN.4/sub.2/Res/2001/5.

In its intervention at the Fourth Ministerial Conference of the WTO which adopted the Doha Declaration on TRIPS and public health, the WHO stated that "access to health care is a human right (...) includes access to health facilities, prevention, care, treatment and support, and of course access to medicines"[23].

In-depth work on access to healthcare as a human right began in 2002 and the "2003 Annual Report of the Department of Essential Drugs includes an explicit reference to access to medicines as a human right. The result of this development, the Strategy 2004-2007 of the Department of Essential Drugs, included among the new areas of work the promotion of access to medicines as a human right."[24]

In 2002 the Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines[25] was created in response to the decision of the World Health Assembly requesting the Director-General to "cooperate with Member States, at their request, and with other international organizations in monitoring and analyzing the implications of international trade agreements on pharmaceuticals and health (...) in order to maximize the positive effects and mitigate the negative impact of these agreements."[26]

In 2003, the Department of Essential Medicines was restructured into two departments: the Department of Medicines Policies and Standards, and the Department of Technical Cooperation for Essential Drugs and Traditional Medicines – TCM; the latter being in charge of work in the field of intellectual property and access to medicines. At the same time, the Member States of the WHO urged "to take into account in bilateral trade agreements the flexibilities contained in the TRIPS Agreement and recognized by the Declaration on the TRIPS Agreement

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[21] United Nations General Assembly, Declaration of Commitment on HIV/AIDS, 2001, A/RES/S-26/2, para. 15.
[22] WHA 54.11, WHO medicines strategy.
[23] Statement by the WHO in the WTO Ministerial Conference, Doha, Qatar, 2001.
[24] Antezana, F., Seuba X. op.cit. p.48.
[25] WHO, "Network for monitoring the impact of globalization and TRIPS on access to medicines", Meeting Report, Thailand, February 2001. Geneva: WHO, Health Economics and Drugs, EDM Series No. 11, 2002. Available from http://apps.who.int/medicinedocs/en/d/Js2284e/.
[26] WHA.52.19 Revised Drug Strategy.

and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)."[27] The TCM department for instance drafted in 2005 a letter sent by Dr. Jim Yong Kim, the former Director of the Department of HIV/AIDS at WHO (and current President of the World Bank) to the Indian Minister of Health and Family Welfare, expressing the concerns relating to the continuous availability of affordable drugs supplied by Indian firms to other developing countries. The 1st April 2013 Decision of the Supreme Court of India on the Novartis case fully reproduced the Jim Yong Kim letter. The ruling by the Supreme Court of India dismissing the petition by Novartis AG is a historic decision with positive global implications. Novartis had challenged the interpretation given by the Indian Patent Office to Section 3(d) of the Patents Act that seeks to prevent the grant of patents on non-inventive new forms of known medicines.

IV. ORIGIN OF THE TERM TRIPS "FLEXIBILITIES"

In the UNCTAD document cited earlier,[28] C. Correa et al. spoke of the "room to manoeuvre" that TRIPS gives in order to formulate national public policies. According to one opinion, the term "room to manoeuvre" was too harsh for the diplomatic environment in the United Nations, therefore the WHO Red book spoke of "Margins of freedom"[29] (1997). Subsequently, in March 2001, in a document widely distributed in the six official WHO languages, the WHO adopted the term "safeguards"[30].

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[27] WHA 57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS.

[28] United Nations Conference on Trade and Development (UNCTAD), *The TRIPS Agreement and Developing Countries*, U.N. Pub. 96.II.D.10 (1996) (prepared for the UNCTAD secretariat by Carlos Correa, Keith Maskus, J. H. Reichman, and Hanns Ullrich).

[29] Velásquez, G., Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, p. 34.

[30] WHO Policy Perspectives on Medicines, "Globalization, TRIPS and access to pharmaceuticals", No. 3, (WHO, Geneva, March 2001), p. 5.

The European Communities, in June 2001, spoke of a "sufficiently wide margin of discretion"[31] in reference to the implementation of the TRIPS Agreement. A few months later, in November 2001, in the Doha Declaration on TRIPS and Public Health the WTO referred to "the provisions in the TRIPS Agreement which provide flexibility". It was in June 2001, where the WHO, in a document authored by Carlos Correa analyzing the implications of the Doha Declaration, referred to the "flexibilities" of the Agreement.[32]

Today, there is wide consensus on the use of the term "flexibilities" in reference to mechanisms and provisions for the protection of public health in TRIPS.

V. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (CIPIH)

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was created in 2003 by means of a resolution[33] of the World Health Assembly. Member States of the WHO requested that the WHO prepare a report by independent experts regarding intellectual property, innovation and public health, so as to continue and deepen the work already done in the report of the British Commission in 2002[34] on the same issue.

The group of experts, chaired by Swiss former president, Ruth Dreifuss, was quite complex and difficult to manage as there were people from the industry and different conflicts of interest arose. The situation was handled masterfully by Mrs. Dreifuss and at the end of 2006, the product of the group's work was presented to the WHA; the

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[31] Communication from the European Communities and their member states to the TRIPS Council (IP/C/W/280), June 12, 2001.

[32] C. Correa, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", WHO/EDM/PAR/2002.3, Geneva, 2002, see the chapter entitled Flexibility in TRIPS, p. 13.

[33] WHA Resolution, WHA56.26 Intellectual Property Rights, Innovation and Public Health.

[34]" Integrating Intellectual Property Rights and Development Policy", Report of the Commission on Intellectual Property Rights, London, September 2002.

report on "Public Health, Innovation and Intellectual Property Rights"[35]. The said report contained 60 recommendations, the majority of which dealt with intellectual property; what countries can and should do in order to protect the health sector from new international trade rules.

The report recognized "the need for an international mechanism to increase global coordination and funding of medical R&D"[36] and recommended, among other things, the continuation of work for the adoption of a treaty on pharmaceutical R&D "to develop these ideas so that governments and policy-makers may make an informed decision".[37]

The report even suggests that the problem of access to medicines is not limited to developing 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."[38]

VI. THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (GSPOA)

The United States took a forward stance in the face of the possibility that the World Health Assembly would possibly adopt this report. After complicated debates, an inter-governmental group was formed in order to analyze and propose what should be done with the recommendations of the CIPIH report, as in 2006 the WHA did not manage to adopt the report. The inter-governmental group was envisioned as a small group of around 10 countries represented by their missions in Geneva, but more than 100 countries attended the group's first meeting held at the

[35] "Public Health, Innovation and Intellectual Property Rights", Report of the Commission on Intellectual Property Rights, Innovation and Public Health, ISBN 92 4 356323 8, Geneva, 2006, 204 pages.
[36] Ibid, p. 87.
[37] Ibid, p. 91.
[38] Ibid, p. 177.

end of 2006. Deliberations and negotiations took two years, from start to approval, in the 2008 WHA of a "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property".[39]

These two-year negotiations may be considered the most relevant and important negotiations that have ever occurred in the 65 years of the existence of the WHO, after the negotiation and the adoption of the convention against tobacco, (FCTC)[40]. It was especially interesting because the developed countries in the WHO were there with the "ghost" of the Mrs. Dreifuss report, particularly in light of what it already recommended, exploring the possibility of making an international treaty for pharmaceutical funding and research and development (R&D). Before the idea of a binding mechanism came about, the drafting of a non-binding resolution like resolution 61.21 on Global Strategy was a negotiation where every word and comma counted.

During the negotiation, developing countries pointed out that the document presented by the WHO Secretariat[41] as the basis of the discussion omitted aspects related to intellectual property. These aspects made up the central focus of the 60 recommendations of the report chaired by Mrs. Dreifuss on which the inter-governmental group was asked to give guidance.

It was evident that in the context of the negotiations the topic of intellectual property was the common denominator that crossed all the topics of the document proposed by the WHO Secretariat. Instead of admitting that each component of the proposed elements clearly contained aspects of intellectual property, the WHO created a separate item, element 5: "Application and management of intellectual property to contribute to innovation and promote public health"[42]. At the end there were eight elements with only one element dealing with intellectual property.

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[39] Resolution WHA61.21 "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property", Geneva, 2006.
[40] FCTC: Framework Convention on Tobacco Control.
[41] WHO, Report of the IGWG First Session, 25 January 2007.
[42] Element 5 of Resolution WHA61.21 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property ', Geneva, 2006.

The Global Strategy managed to approve various elements in its action plan[43], but there was a deadlock regarding element 5, which concerned the issue of intellectual property and various elements of the plan of action were placed in brackets. As a result, in 2008 the World Health Assembly created an expert working group to examine the issues of coordination and funding of medical R&D that was known as the EWG (Expert Working Group on R&D financing and coordination). The mandate of the EWG was to advise countries and the WHO, regarding the recommendations of the report by the expert group chaired by Mrs. Dreifuss. The report, as mentioned referred mainly to intellectual property and among other things, the possibility of a binding international treaty on R&D.

It is important to note that paragraph 2.3.(c) of the GSPOA made reference to a possible international treaty on R&D of new drugs as a topic on which the EWG should advise. Therefore, the negotiation and the adoption of an international instrument on medical R&D should be a key element in the implementation of the GSPOA. Despite the insistence of some members of the EWG, the group's report completely omitted any reference to the possibility of a binding convention or treaty, the main reason why the report was not adopted by the 2010 WHA.[44]

VII. CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION (CEWG)

Following the failure of the report by the Expert Working Group (EWG), a new group called the Consultative Expert Working Group on Research and Development: financing and coordination (CEWG) was created at the start of 2011. The aim of the CEWG was to deal with issues relating to intellectual property. On 18 November 2011, the Chairman of the CEWG announced that "the CEWG will recommend to the 2012 Health Assembly to commence formal intergovernmental

[43] During a 'drafting group' that lasted an entire week during the World Health Assembly in 2008.

[44] Velasquez, G., Seuba X., Rethinking Global Health: A binding convention for R&D for pharmaceutical products, South Centre Research Paper No. 42, p. 10.

negotiations for the adoption of a binding global instrument on medical R&D based on Article 19 of the WHO Constitution".[45]

The 65th World Health Assembly in 2012, which was supposed to analyze and adopt the recommendations of the CEWG report, met with a new obstacle as several industrialized countries opposed the commencement of negotiations for the adoption of a binding convention. The result of difficult negotiations was, once more, as was the case in 2006, the creation of an inter-governmental group[46] to analyze the CEWG recommendations and propose a solution.

The meeting of the new inter-governmental group took place from 26-29 November 2012. The industrialized countries proposed the establishment of a "global health R&D observatory within WHO's Secretariat in order to monitor and analyze relevant information on health R&D", the commencement of some pilot projects in the field of pharmaceutical R&D and "to convene another open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in May 2016, in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health R&D; taking into account all relevant analyses and reports, including the analysis of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination." However, it is difficult to understand that negotiations on resolving an urgent problem like the lack of pharmaceutical R&D for the production of accessible medicines must wait four years. It seems as if the protection of the pharmaceutical market is worth more than human life.

"Several Member States seem to support the establishment of a WHO-hosted global health R&D observatory. Such an observatory would be a positive first step. However, given the extent of the challenge, efforts that solely aim to improve monitoring of global health R&D and assist with priority-setting, are not enough. An observatory will not provide adequate coordination, increase sustainable financing or

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[45] Velásquez, G., Seuba, X., "Rethinking Global Health: A binding convention for R&D for pharmaceutical products", South Centre Research Paper No. 42, December 2011.

[46] Resolution WHA65.22 Follow up of the report of the CEWG on Research and Development: Financing and Coordination.

result in new medical tools that are needed. If this is the only outcome to result from more than ten years of deliberations it would be woefully inadequate".[47] At the ill-fated November 2012 meeting, industrialized countries including the US, Members of the European Union, Japan and Switzerland conducted an assiduous campaign of attrition to weaken support for WHO future work on the de-linkage paradigm to decouple the costs of R&D from the price of health technologies in lieu of the current system of patent monopolies.[48]

The 2012 meeting of the Intergovernmental Group prepared a draft resolution to be revised by the WHO Executive Board (EB) in January, 2013. A draft resolution[49] that made no reference to the clear recommendation of the CEWG to start negotiations for the adoption of a treaty; a draft that was viewed by various observers and NGOs as "weak and unambitious"[50]. A draft resolution that was presented to the Executive Board in 2013 with a report attached[51] that recommended to the WHO EB, and the 2013 WHA, to adopt the draft resolution without discussion.

On Friday, 25 January 2013, the 132nd session of the WHO Executive Board held a "rich and heated" discussion on the Director-General's report (EB132/21) of the proceedings of the open-ended meeting (26-28 November 2012) on the follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG).

Despite the recommendation of the inter-governmental group, and advice of its Chairman to adopt the resolution, at the January 2013 WHO EB, the understanding reached at the end of Friday's lengthy debate (lasting around 90 minutes) on the CEWG was that the Executive

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[47]See MSF, Open letter to WHO Member States at follow-up meeting on the report of the CEWG, signed by 60 NGO's and Organizations, 25 November 2012.
[48] Knowledge Ecology International, 26 January 2013.
[49] EB132/21 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.
[50] http://www.msfaccess.org/content/joint-letter-132nd-who-executive-board-follow-report-cewg.
[51] WHO Report of the open-ended meeting of Members States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, Geneva.

Board would take note of EB/132/21 (containing the Report by the Director-General and draft resolution) and submit the document in open form to WHA66 for consideration along with a record of the EB's discussion of the item showing that there was no consensus reached. At WHA66, as confirmed by the WHO Legal Counsel, "(…) WHO Member States can comment on the draft CEWG resolution including submitting textual changes to amend and strengthen the Organization's mandate to work on a de-linkage paradigm for biomedical R&D."[52]

VIII. ADVANCES IN THE IMPLEMENTATION OF A "GLOBAL STRATEGY"

Finally, it would be worth analysing what advances there have been in the implementation of the "global strategy" and its 25-page plan of action. The progress to date can be summarized in three points:

1. The "Patent Pool"[53], a timely initiative that constitutes one element out of many others that form the mandate given by WHA Resolution 62.21. Patent pools can facilitate equal access and make new treatments against HIV cheaper, and facilitate the development of new fixed-dose combinations suited to meet the treatment needs of developing countries. These patent pools can be made up of voluntary licenses by the patent holder, as is the present case with the Medicines Patent Pool (MPP) created with resources from the Franco-Brazilian initiative, UNITAID.
2. The second activity that has been developed in the Americas is called "Platform on Innovation" which PAHO has promoted in the region, is a type of "Pharmaceutical Facebook" – a virtual network to share information on various activities in the field of pharmaceuticals.
3. The third element in the implementation of a global strategy is the publication of a tripartite report by the WTO, WIPO and WHO. On 5 February 2013, in a ceremony at the WTO, the three Director-Generals of WTO, WIPO and the WHO

[52] KEI op. cit.
[53] http://www.medicinespatentpool.org/.

launched the trilateral publication titled: "Promoting Access to Medical Technologies and Innovation", the fact that a publication regarding public health was launched at the headquarters of the WTO is a reflection of the increasing importance of public health issues in the context of WTO and WIPO, an issue on which the WHO has been the leader.

The study shows progress on the part of the WTO and WIPO since they talk about these issues without "taboo", however it does not give a complete picture of the extent to which WHO has led this issue over the past decade. Seventeen resolutions by the World Health Assembly adopted between 1996 and 2012 are cited in the report in a table on page 44 concerning intellectual property and health. These resolutions are of highly prescriptive character, for the secretariat and for countries on how to protect public health from the possible negative impact of new international trade rules. Despite numerous resolutions and publications in the last 15 years by the WHO on this issue, many of which are not mentioned in the report, the disclaimer of the document says that "(…) the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the WHO, WIPO and the WTO be liable for any consequences whatsoever arising from its use".

This could give the wrong impression to the reader of this report that the WHO has no opinion on whether a compulsory license may, in special circumstances, facilitate access to drugs, or if an international exhaustion regime, that allows parallel imports from any country can reduce the cost of drugs and therefore contribute to access. The 17 WHA resolutions give a mandate to the WHO to engage, promote and defend mechanisms and policies in favour of access. Thus, it is important to ensure that the Trilateral Cooperation with WTO and WIPO does not lead the WHO to share a "neutral" vision, totally disengaged from its mandate of protection of health and putting business before health at the WHO. This would be contrary to the exemplary leadership from the WHO on "The

Revised Drug Strategy", WHA 52.19 in 1999 or the "WHO Policy Perspectives on Medicines" published in 2001 that says: "National patent and related legislation should: Promote standards of patentability that take health into account. (…) Incorporate exceptions, trademark provisions, data exclusivity and other measures to support generic competition. Permit compulsory licensing, parallel importation and other measures to promote availability and ensure fair competition. Permit requests for extension of transitional period for TRIPS implementation, if needed and if eligible. Carefully consider national public health interests before instituting TRIPS-plus provisions."[54]

As expressed by the three NGOs that addressed the Executive Board in January 2013, the Trilateral Report is a weak and unambitious document in which the WHO does not fully reflect the work it has done on these issues in accordance with its mandate.

The question that Member States of the WHO, international organizations with a clear vision regarding the priority of health such as UNDP or UNAIDS, or UNICEF, non-profit NGOs working on public health, the academia and all the sectors concerned with the promotion of health and access to medicines should ask is what is the relevance and status of this report in the face of the 17 resolutions by the WHA giving a clear mandate that is not reflected in this document.

It would seem that while the debate that began in the early 2000s about which one comes first, the right to health or international trade rules, has been resolved in favour of the right to health, but in this trilateral publication, the mandate of the WHO to promote public health seems to have been subordinated to accommodate IP and trade interests.

The Trilateral Report is a report that describes what others have said on the issue, without any of the three organizations

[54] WHO Policy Perspectives on Medicines No. 3, "Globalization, TRIPS and access to pharmaceuticals", Geneva, 2001, p. 4.

saying what they think. The 251 page document contains no recommendations, not even a conclusion, or any guidance. In comparison, the 2006 WHO report on Public Health, Innovation and Intellectual Property rights (CIPIH report), led by the former president of Switzerland Ruth Dreifuss, contained 60 recommendations.

A Japanese saying goes: "what a man does not say is the salt of a conversation".

IX. A STEP BACKWARDS FOR THE WHO?

The "patent pool", the platform on innovation and the tripartite report that we have just mentioned, are the three elements that the implementation of the Global Strategy has been reduced to between 2010 and today. The WHO, however, since 2006, the date on which the 60 recommendation report was published, had been undertaking a series of activities under the mandate given by the resolutions adopted by the WHA since 1996[55].

The main activities that the WHO was undertaking before 2010 were:

- Training for officials from health, trade and industry ministries and patent offices, on intellectual property and health. This training was done for four consecutive years in the Americas at the University of Buenos Aires, in Africa at the University of Cape Town and in the University of Bangalore for Asian countries.

  Among the objectives of this course, were the following: a better understanding of the importance of applying intellectual property laws and policies in accordance with the rights of patients and public health; improve the knowledge of legislation as well as national and international legislation

[55] See Annex I.

relating to intellectual property (including patents, trademarks and data protection); and to strengthen national capacity for the formulation and application of intellectual property policies in accordance with public health needs and patient rights. In the case of Latin America close to 100 participants from 19 countries (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, the Dominican Republic, Uruguay and Venezuela) attended. In Asia and Africa there was a similar level of participation.

- Another important aspect was training patent examiners from patent offices in developing countries. Between 2006 and 2010 workshops for national patent offices were conducted for more than forty countries. The development of a public health perspective in patent examinations is one of the main aspects in the work towards access to medicines.

  It is necessary to watch and analyze trends in the grant of patents for pharmaceutical products in order to respond to the growing concerns about the increase in the number of patents that protect variations of medicines or existing procedures while the number of patents for new molecular entities is diminishing. Those responsible for the formulation of policies on health as well as patent examiners should be aware that decisions regarding the grant of a patent (which is generally considered valid until the contrary is proven) may directly affect the health and life of people in the country where the patent is granted. The WHO undertook a study on the different categories of patent claims for pharmaceutical products with a view to guide the practice of patent offices.[56]

  The study suggested some mechanisms that can be adopted in order to incorporate public health perspectives in procedures for the granting of pharmaceutical patents. It proposed a

[56] WHO-ICTSD-UNCTAD, "Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective", Working Paper by Correa, C. M., Geneva, 2007. Available from http://ictsd.org/i/publications/11393/.

combination of general directives for the evaluation of some of the common modalities of patent claims for pharmaceutical products and it suggested elements for the elaboration of directives that bear public health in mind and the examination of patents for pharmaceutical products at the national level in developing countries.

- For several years the WHO gave technical assistance to countries that were developing or reviewing their intellectual property laws. A substantial number of countries were assisted. In the last 3 years the WHO Secretariat has not reported that this type of activity has taken place.

  The report of one WHO mission in 2008, with the participation of the WTO, UNDP and UNCTAD, at the request of the Government of Thailand[57], is a good example of the type of support that international organizations should give to countries that decide to use the flexibilities contained in the TRIPS Agreement.

  Among the recommendations of this report were the following: In seeking greater access to essential medicines 1. (…) "the introduction and use of all possible cost-containment mechanisms and the use of TRIPS-compliant flexibilities (…) 2. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies. 3. The use of compulsory license and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes."[58]

- Between 2002 and 2009 the WHO, in its capacity as an observer on the TRIPS Council at the WTO, made several

[57] See the most relevant points of this report in Annex III, Sections II, III, V and VI. Report published by the National Health Security Office of Thailand (NHSO), 2008.
[58] Improving Access to Medicines in Thailand: The use of TRIPS flexibilities, Report of WHO Mission, Bangkok, 31 January to 6 February 2008.

interventions on issues regarding access to medicines and particularly on the mandate of the Doha Declaration. An extract of the WHO intervention of September 17, 2002 at the WTO TRIPS Council states:

> "WHO re-affirms its commitment to support WTO Members and the Council for TRIPS in finding an expeditious solution to this problem raised in Paragraph 6 of the Declaration.
>
> To this end, WHO has published a paper entitled, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health."[59] This paper describes the features of a solution to the so-called "paragraph 6 problem" which are desirable from a public health perspective. These include: a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines.
>
> Thus, the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory license provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of

[59] WHO/EDM/PAR/2002.3.

> producing the product. Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs."

X. THE WAY FORWARD

In a little more than 10 years the WHO has produced important technical material in the area of public health and intellectual property; by the 17 WHA resolutions, numerous analyses and guiding publications[60] with the aim of protecting access to health in light of new international trade rules, required by the WTO, and recently by free trade agreements (FTAs) and bilateral investment treaties (BITs).

In terms of technical assistance to countries regarding the use of TRIPS flexibilities, the WHO seems to have changed direction in the past 3 years, marked by closer collaboration with WTO and WIPO. The collaboration of WHO with WTO and WIPO is a good thing so long as the mandates given by the WHA resolutions are respected and put into practice. With respect to international trade and investment treaties, the WHO cannot have a "neutral vision"; its mandate is directed toward the perspective of public health in conjunction with the various WHA resolutions in recent years. By speaking of international trade rules and issues related to public health we are speaking of two different regimes; and on different levels – in the first instance we are talking about economic rules and regulations while in the latter case we are dealing with the right to health as a part of human rights.

It remains to be seen in the future if the Secretariat of the WHO and its Member States will view the work and support of countries in

[60] See the list of WHO publications related to intellectual property and public health, in the Annex II.

intellectual property and health as an opportunity than a problem to avoid, particularly in the case of a possible international treaty on the funding of pharmaceutical R&D, that may contribute to this specialized UN agency re-discovering its identity and "raison d'être" in the twenty-first century.

ANNEX I[61]
RELEVANT WORLD HEALTH ASSEMBLY RESOLUTIONS

1996 WHA49.14: Revised drug strategy

1999 WHA52.19: Revised drug strategy

2000 WHA53.14: HIV/AIDS: confronting the epidemic

2001 WHA54.10: Scaling up the response to HIV/AIDS

2001 WHA54.11: WHO medicines strategy

2002 WHA55.14: Ensuring accessibility of essential medicines

2003 WHA56.27: Intellectual property rights, innovation and public health

2003 WHA56.30: Global health sector strategy for HIV/AIDS

2004 WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS

2006 WHA59.24: Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

2006 WHA59.26: International trade and health

2007 WHA60.30: Public health, innovation and intellectual property

2008 WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property

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[61] WTO, WIPO, WHO, "Promoting Access to Medical technologies and Innovation", 2012, p. 44.

2009 WHA62.16: Global strategy and plan of action on public health, innovation and intellectual property

2011 WHA64.5: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

2011 WHA64.14: Global health sector strategy on HIV/AIDS, 2011-2015

2012 WHA65.22: Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

ANNEX II
WHO PUBLICATIONS ON INTELLECTUAL PROPERTY AND PUBLIC HEALTH

1. WHO Task Force on Health Economics, "The Uruguay round and drugs". Correa C. M., WHO/TFHE/97.1, Geneva 1997.

2. WHO and Civitas "Medicines and the New Economic Environment," Lobo F., and Velásquez G., eds. Madrid: Civitas and World Health Organization, 1998.

3. WHO, Health Economics and Drugs, EDM Series No. 7 (Revised). "Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement". Velásquez, G. and Boulet, P., WHO/DAP/98.9, Geneva, 1999. Available from: http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.html.WHO.

4. WHO Policy perspectives on medicines. No. 3 "Globalization, TRIPS and access to pharmaceuticals", Geneva 2001.

5. WHO. "Network for monitoring the impact of globalization and TRIPS on access to medicines." Meeting Report, Thailand, February 2001. Geneva: WHO, Health Economics and Drugs, EDM Series No. 11, 2002. Available from: http://apps.who.int/medicinedocs/en/d/Js2284e/.

6. WHO/South Centre, "Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement". Correa, C. M. Geneva, 2002. Available from: http://www.southcentre.org/index.php?option=com_content&view=article&id=68%3Aprotection-of-data-submitted-for-the-registration-of-pharmaceuticals-implementing-the-standards-of-the-trips-agreement&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.

7. WHO/South Centre, "Protection and Promotion of Traditional Medicine. Implications for Public Health in Developing Countries". Correa, C. M. Geneva, 2002. Available from: http://www.southcentre.org/index.php?option=com_content&view=article&id=74:protection-and-promotion-of-traditional-medicines-implications-for-public-health-in-developing-countries&catid=41:innovation-technology-and-patent-policy&lang=es.

8. WHO, Health Economics and Drugs, EDM Series No. 12 "Implications of the Doha Declaration on the TRIPS Agreement and Public Health." Correa, C. M., Geneva, 2002. Available from: http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf.

9. WHO. 25 Questions & Answers on Health and Human Rights. Geneva: WHO, 2002. Available from: http://www.who.int/hhr/activities/en/25_questions_hhr.pdf.

10. WHO/AFRO. "Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Implementation of TRIPS Safeguards in Relation to Pharmaceuticals in the WHO African Region". Summary Report of a Workshop, Zimbabwe. August 2001, Brazzaville, WHO: Regional Office for Africa, 2002.

11. WHO, Health Economics and Drugs, EDM Series No. 13, 2003. "Cost-containment Mechanisms for Essential Medicines, Including Antiretrovirals, in China". Velásquez, G., Correa C. M., and Weissman R., Geneva 2003.

12. WHO Regional Office for the Eastern Mediterranean. "Report on the Consultative Meeting on TRIPS and Public Health". Cairo: WHO Regional Office for the Eastern Mediterranean, 2005.

13. World Health Organization. Health Economics and Drugs, TCM Series No. 18 "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies". Love, J. Geneva, 2005.

14. WHO, "Public health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property

Rights, Innovation and Public Health". Geneva, 2006. Available from: http://www.who.int/intellectualproperty/documents/thereport/SPPublicHealthReport.pdf.

15. WHO/South Centre "The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?" by Musungu, S. F. and Oh C. Geneva, 2006. Available from: http://www.southcentre.org/index.php?option=com_content&view=article&id=70:the-use-of-flexibilities-in-trips-by-developing-countries-can-they-promote-access-to-medicines&catid=41:innovation-technology-and-patent-policy&Itemid=67&lang=es.

16. WHO-ICTSD-UNCTAD "Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective". Working Paper by Correa, C. M., Geneva, 2007. Available from: http://ictsd.org/i/publications/11393/.

17. WHO/PHI/2009.1 "Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents". Correa, C.M., Geneva 2009.

18. WHO Regional Office for South-East Asia. "International Health and Trade, a reference guide". New Delhi, 2009.

19. World Health Organization (WHO) Regional Office for the Eastern Mediterranean and the International Centre for Trade and Sustainable Development (ICTSD), "Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region". El Said, Mohammed. Cairo, 2010 Available at: http://ictsd.org/i/publications/99149/.

20. WHO Regional Office for South-East Asia. "Intellectual Property and Access to Medicines: Papers and Perspectives". World Health Organization, SEA-TRH, 2010. Available from: http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf.

21. Bulletin of the World Health Organization, 1999, 77(3): 288-292. "Essential drugs in the new international economic environment". Velásquez, G., and Boulet P. Available from: http://www.who.int/bulletin/archives/77(3)288.pdf.

22. Bulletin of the World Health Organization, 2001, 79(5): 461-470. "Study of the implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand". Supakankunti, S., et al. Geneva, 2001. Available from: http://www.who.int/bulletin/archives/79(5)461.pdf.

23. Bulletin of the World Health Organization. "Ownership of knowledge – the role of patents in pharmaceutical R&D". Correa, C. M. 2004, 82(10): 784-786. Available from: http://www.who.int/bulletin/volumes/82/10/784.pdf.

24. Bulletin of the World Health Organization, 2004, 82 (11). "Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?" Costa Chaves, G., Oliveira M. A., Velásquez G., and Zepeda Bermudez J. Available from: http://www.who.int/bulletin/volumes/82/11/en/815.pdf.

25. Bulletin of the World Health Organization, 2006, Volume 84(5). "Implications of bilateral free trade agreements on access to medicines". Correa, C. M., Geneva 2006. Available from: http://www.who.int/bulletin/volumes/84/5/399.pdf.

26. Bulletin of the World Health Organization. "Special Theme: Intellectual Property Rights and Public Health". 2006, 84(5), 337-424. Available from: http://www.who.int/bulletin/volumes/84/5/itmb.pdf.

27. Bulletin of the World Health Organization, 2006, 84(5): 360-365. "Managing the effect of TRIPS on availability of priority vaccines". By Milstein, J., and Kaddar M., Available from: www.who.int/bulletin/volumes/84/5/360.pdf.

ANNEX III
IMPROVING ACCESS TO MEDICINES IN THAILAND: THE USE OF TRIPS FLEXIBILITIES
Report[62] of a WHO Mission, Bangkok 31 January-6 February 2008

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement and other international agreements, in order to promote greater access to pharmaceutical products.

The report of the mission is not intended to make any evaluation or assessment of the use of TRIPS flexibilities in Thailand.

Although the mission met with the various stakeholders during its visit to Bangkok, the discussions were aimed at facilitating an understanding of the context and circumstances related to the granting of compulsory licences in Thailand, and identifying the appropriate technical and policy support required on the use of TRIPS flexibilities.

This report has been prepared under the responsibility of WHO. In the context of resolution WHA60.30, resource persons from UNCTAD, UNDP and WTO participated in the mission to provide technical and factual information with regard to the TRIPS Agreement.

Members of the mission:

Germán Velásquez, WHO/HQ (Team Leader)
Bill Aldis, WHO/SEARO
Karin Timmermans, WHO/SEARO
Cecilia Oh, UNDP
Kiyoshi Adachi, UNCTAD

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[62] This is an extract of the report. Sections I and IV as well as the Annexes have been left out by the author.

Roger Kampf, WTO
Xavier Seuba, WHO temporary adviser, Pompeu Fabra University, Barcelona

Introduction

In the context of resolution WHA60.30, the Minister of Health of Thailand requested WHO, in collaboration with other competent international organizations, to provide technical and policy support on use of the flexibilities contained in the WTO TRIPS Agreement in order to promote access to pharmaceutical products.

WHO, in its Medicines Strategy (2004-2007), identified four key objectives; namely: the strengthening of national medicines policies; improving access to essential medicines; improving the quality and safety of medicines; and promoting their rational use. In order to ensure that national medicines policies are effectively implemented to achieve the objective of improving access to priority medicines, WHO has identified the need to support countries in their efforts to use public health safeguards in international, regional and bilateral trade agreements.[63]

WHO's policy perspectives are informed by the following basic principles:

- "Access to essential medicines is a human right
- Essential medicines are not simply another commodity
- TRIPS safeguards are crucial
- Patent protection has been an effective incentive for R&D for new drugs
- Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles

[63] WHO Medicines Strategy: Countries at the Core (2004-2007) (WHO/EDM/2004.2).

- WHO supports measures which improve access to essential medicines, including application of TRIPS safeguards"[64].

Since 1997, resolutions of the World Health Assembly have provided WHO with a broad mandate in the area of intellectual property and access to medicines. More recently, resolution WHA60.30 of May 2007 requested the Director-General "to provide… in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products".

Consistent with its mandate, WHO advocates to Member States the importance of the TRIPS flexibilities to protect public health and promote access to essential medicines and draws attention to the need to include them in national laws.

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement.

II. Non-voluntary licences for government use: practical aspects and procedures[65]

Article 31 of the TRIPS Agreement regulates "other use of the subject matter without the authorization of the right holder", addressing what is commonly known as compulsory licensing. While, as was made clear in the Doha Declaration on the TRIPS Agreement and Public Health, the TRIPS Agreement leaves each Member free to determine the grounds on which compulsory licences can be granted, it does mention a number of possible grounds, including national emergency or extreme urgency,

[64] WHO Policy Perspectives on Medicines No. 3, Globalization, TRIPS and access to pharmaceuticals, March 2001 (WHO/EDM/2001.2).

[65] Cost-containment mechanisms for essential medicines, including antiretrovirals, in China (WHO/EDM/PAR/2003.6).

public non-commercial use, dependency of patents and to remedy anti-competitive practices.

This section specifically deals with the requirements and steps to be followed when granting a non-voluntary licence for government use. Similar requirements must also be complied with when granting non-voluntary licences under other grounds. Taking into account the provisions of the TRIPS Agreement, the granting of a non-voluntary licence for public non-commercial use would require a number of steps which are described below, and for which references to the Thai legislation are provided merely as an example of its national implementation.

Identify relevant patents

In most cases, pharmaceutical products are protected by a patent on the active ingredient (the main patent) and by a number of patents on formulations, manufacturing processes, new indications, etc. (secondary patents). It is advisable to include all relevant patents in a compulsory licence to allow freedom to operate with the needed product. Otherwise, the use of the invention under the compulsory licence may be blocked on the basis of allegations of infringement of secondary patents (as illustrated by the well-documented case of didanosine in Thailand almost a decade ago), making it necessary to resort, for instance, to alternative drug formulations, such as powder forms.

Explore possible sources of supply based on local production

The analysis to be undertaken should include:

- availability of technical resources for reverse engineering
- cost and duration of developing manufacturing processes and formulations
- the need for technology transfer
- good manufacturing practices and quality assurance of products made by local producers
- estimates of the investment required and of the marginal cost of production.

Identify possible sources of importation of the required medicine

The analysis to be undertaken should include:

- compliance with good manufacturing practices and product quality assurance by potential suppliers
- cost comparisons *vis-à-vis* local production
- prices of supply over time
- the sustainability of the exporter's supply.

Marketing approval

Registration is an important safeguard to ensure quality of the product. However, registration requirements may pose obstacles to the speedy distribution of needed medicines (see, for example, Section III, Bolar exemptions) hence; analysis of the scope of such obstacles and identification of the required remedial measures may be needed. Countries could consider creating a fast-track mechanism and/or giving priority to the evaluation and registration of a medicine that is considered urgently needed or important.

Request for a non-voluntary licence for government use[66]

A compulsory licence or 'non-voluntary licence' allows a government to authorize itself or a third party to use the subject matter of a patent without the consent of the right holder for reasons of public policy. A 'non-voluntary licence' authorizing the government itself to use a patented invention is known as a government use authorization. Article 31 of the TRIPS Agreement allows the grant of compulsory licences subject to certain conditions, and the Doha Declaration reaffirms that countries have "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".[67] These rights and freedom do not mean that compulsory licences are not

[66] Flynn, S. Thai Law on Government Use Licences. American University, December 2006.

[67] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WTO/MIN(01)/DEC/W/2, 20 November 2001, paragraph 5(b).

regulated. States have to fulfil certain procedures and criteria in order to grant a non-voluntary licence.

It has to be noted that the TRIPS Agreement does not define the meaning of "public non-commercial use". However, the Vienna Convention on the Law of Treaties commands, as a general rule of interpretation, to interpret a treaty "in good faith in accordance with the ordinary meaning given to the terms" (Article 31). Following this rule, it has been argued that the meaning of "public non-commercial use" may be found in the nature of the transaction or the purpose of the use of the patent. Regarding the nature of the transaction, "non-commercial" may be understood as "not-for-profit" use, while, as far as the purpose of the use is concerned, "non-commercial" may refer to the supply of public institutions that are not functioning as commercial enterprises. The fact that the licence will be used to support a public interest programme may be sufficient grounds for justification.

Article 31 of the TRIPS Agreement makes the use of the subject matter of a patent without the authorization of the right holder, including use by the government, conditional on its admissibility under domestic law. In the case of Thailand, for instance, non-voluntary licences for government use can be granted on the basis of Section 51 of the Patent Act B.E. 2522 (1979), as amended by the Patent Act (No. 2) B.E. 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999). Section 51 of Thailand's Patent Act recognizes the right of "any ministry or department of the Government", "by themselves or through others" to exercise any right conferred by the patent in order to carry out any service "for public consumption".

Section 51 specifically states:

> *"In order to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others,*

> *exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis.*
>
> *In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis."*

Licensing authority

Under the Thai Patent Act, the Director-General of the Department of Intellectual Property is authorized to grant various types of compulsory licences. Complementing this, under Section 51, a public use licence may be also issued by "any ministry, bureau or department of the Government" by "themselves or through others."

Notice to the patent holder

Article 31 (b) of the TRIPS Agreement establishes as a general obligation to try to obtain authorization from the right holder on reasonable commercial terms and conditions when granting a non-voluntary licence. When such efforts are not successful, the use of the patent's subject matter without the authorization of the right holder can be permitted. The same article waives this obligation in cases of public non-commercial use and national emergency or other circumstances of extreme urgency. In cases of public non-commercial use, there is an obligation to promptly notify the title holder. In cases of national emergency or urgency, this notification is required as soon as reasonably practicable.

Section 51 of the Thai Patent Act requires that the licensing authority "shall notify the patentee in writing without delay,

notwithstanding the provisions of Section 46, 47 and 47bis." The exemption from the requirements of Section 46, 47 and 47bis makes clear that the Government is not required to: (1) wait until "the expiration of three years from the grant of a patent or four years from the date of application," or (2) have "made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances".

In relation with the aforementioned notification, a communication to the patent holder should be sent. The TRIPS Agreement is silent on the content of this notification. However, regarding compulsory licences in general and extrapolating the practice in certain countries with regard to the request to the patent holder,[68] the notification may include:

- information about the requesting party
- the expected volume of production;
- the royalty to be paid
- the form of payment
- the intended mode of use of the invention
- quality controls
- trademark to be used, if any
- the duration of the licence
- the licensee's right to control sales for determination of royalties due
- the applicable law and jurisdiction in case of disputes.

Scope and duration of the licence

According to Article 31 (c) and (g) of the TRIPS Agreement, the competent department will have to define the scope of the licence and its duration. The scope and duration shall be limited to the purpose which led to its authorization, and the authorization shall be liable to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. In the same vein, the Thai Patent Act lays down that "the scope and duration of the license shall not be more than necessary under the circumstances" (Section 50.1).

[68] WHO/EDM/PAR/2003.6, op. cit., p. 8.

It would be advisable for the scope to include all commercial and non-commercial uses of the relevant invention required to meet the purpose of the licence, and for the licence to last until the purpose which led to such granting so requires. In any case, authorization for such use should terminate if and when the circumstances which led to it cease to exist and are unlikely to recur. The fulfilment of this requisite can only be evaluated when a prudential period of time expires.

Royalties

Article 31 (h) of the TRIPS Agreement affirms that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The TRIPS Agreement allows Members "to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice" (Article 1). This is a broad authorization to design the mechanisms to implement TRIPS obligations, precluding the necessity to copy or follow the procedures that are in place in other countries.

Regarding royalties, it has to be taken into account that there are no internationally agreed criteria – and frequently, no national ones either – to set up the payable fee. This vacuum and the associated controversies not only affect government use licences, but also voluntary commercial licences, which are characterized by their variability. To reduce uncertainty and promote predictability in this regard, it is advisable to formulate explicit guidelines or criteria to determine the remuneration rate or royalty fee payable in the case of non-voluntary licences (see Section V).

The Thai Patent Act, for example, in Section 51 states that the ministry or bureau or department issuing the non-voluntary licence "shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General [of the Department of Intellectual Property]". The royalty rate and terms shall be "as agreed upon by the ministry or bureau or department and the patentee or his licensee", and the provisions of Section 50 "shall apply mutatis mutandis" (i.e. with necessary changes).

After the granting of the compulsory licence, *bona fide* negotiations could be undertaken with the patent holder to evaluate the fee for the exploitation of the patent. Generally, fees are expressed as a percentage of the net sales price of the product made under the licence (and not the patentee's own product), but other modalities can be adopted, for instance, a fixed sum per unit sold.

Commercial practice in voluntary licensing is to use royalties ranging between 2 per cent and 5 per cent, though they may be higher or lower in certain cases. There is some evidence available on the royalties determined by national authorities in Canada, the USA[69] and developing countries[70] for the granting of compulsory licences. (A full discussion on how various countries have chosen to establish royalty rates is set out in Section V.)

Factors that may be considered in negotiating the fee include: launch date of the product; possible substitutes; coverage and possible invalidity (total or partial) of the patent(s); pending challenges to the patent(s), if any; accumulated sales and recovery of R&D investment made by the patent holder; global and local market for the product (units and value); expected volume of production and price under the compulsory licence; royalties agreed upon in voluntary licences on the same or similar products; and the nations' economic and health situation.

Acceptance of the terms of the licence

The terms of the government use licence may be appealed by the title holder. Lacking an appeal, it will be legally understood that the licence's terms are accepted. The Thai Law does not expressly fix the period of time for the patent holder to accept or reject the terms of the licence for government use. However, this period is the same as that established for compulsory licences granted to remedy anti-competitive practices, dependent patents and the non-working of a patent (Section 50): should the parties fail to reach an agreement within the period prescribed by the Director-General, the Director-General will set forth the royalty and

[69] WHO/UNDP. Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (WHO/TCM/2005.1).
[70] See Section IV of the Report.

conditions, and this decision may be appealed to the Board of Patents within sixty days.

Determination of fee and conditions by the Director-General of the Department of Intellectual Property

Section 50 of the Thai Patent Act establishes that "if no agreement has been reached by the parties within the period prescribed by the Director-General, the Director-General shall fix the royalty and prescribe the conditions and restrictions as he deems appropriate" following a set of requirements also contained in Section 50.

Appeal

The relevant provisions in the TRIPS Agreement envisage that "the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority", and "any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority" (Article 31 (i) and (j)). These provisions must be read in conjunction with Article 44.2 of the TRIPS Agreement regarding injunctions. This article establishes that Members may limit the remedies available against government use licences to those related to the payment of remuneration. This means that the decision to use the patent, to grant a compulsory licence for "government use", need not be subject to injunctive relief (see also Section IV).

Section 50 of Thai Patent Act B.E. 2522 states that the decision of the Director-General of the Department of Intellectual Property on the terms and conditions of the compulsory licence is appealable to the Board of Patents within a period of sixty days. In turn, the Board's decision may be appealed to the Court also within sixty days, otherwise its decision will be final (Section 74). It should be noted that it is not the decision to grant a compulsory licence that it is appealable to the Board of Patents and later to the Court, but the terms of the licence.

The explanation is as follows: Section 50, to which refers Section 51 when defining the requirements of the government use licence, states that "the decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days". The first paragraph of Section 51 deals with the conditions of the licence, but not with the decision to grant a licence, which is based either on Section 51 or Sections 46, 46bis or 47. This means that the evaluation of the grounds to grant a licence exclusively concerns the Director-General of the Department of Intellectual Property (and, in the case of public non-commercial use, any ministry, bureau or department of the Government). Consequently, the possible appeal to the Board of Patents, and later on to the Court, does not suspend the execution of the compulsory licence, limiting possible judicial claims to the terms of the licence. Thus, the patent holder has no right to appeal the grounds for the decision to grant a government use licence but rather is limited to contesting the compensation due for the non-voluntary licence.

Other considerations

1) Patent holders (or their governments) may attempt to use legal measures, such as injunctions, to delay or prevent the execution of a non-voluntary licence.

2) It would also be useful to check the possible application of other instruments, such as bilateral agreements on investment (which often consider intellectual property as an "asset" subject to their rules) or free trade agreements with intellectual property provisions.

3) Article 31 (a) of the TRIPS Agreement lays down the requisite to consider on its individual merits the authorization of use without the consent of the patent holder. Each of the licences granted must be duly justified, which means that it is not possible to indiscriminately grant licences, but only after an assessment of their necessity has been undertaken.

4) The TRIPS Agreement also states that "such use shall be non-exclusive" (Article 31 (d)). This implies that the grant of a non-exclusive licence does not preclude the patent holder from exploiting the national market or exporting the patented product.

III. Other important TRIPS flexibilities to promote access to medicines

It is important to underline the fact that compulsory and government use licences are not the only flexibilities under the TRIPS Agreement that can have an impact on access to medicines. The range of measures that can be taken by governments under the TRIPS Agreement before a pharmaceutical patent is issued is often referred to as "pre-grant" flexibilities. "Post-grant" flexibilities, on the other hand, are policy options that, if incorporated into national law, are generally employed to address particular cases in the exercise of exclusive patent rights. The following non-exhaustive list of flexibilities is available to all WTO Members. It should also be noted that a number of these options are the subject matter of negotiations in preferential trade and investment agreements.

Pre-grant flexibilities

Many of the pre-grant flexibilities are intended to help ensure that the patent system confers upon an applicant the reward of exclusive rights for a true and genuine innovation. While certainly not exhaustive, the following flexibilities may be of particular interest to a developing country, such as Thailand, seeking to encourage the local production of low cost, high quality pharmaceuticals as one means to meet the objective of greater access to medicines.

First, the TRIPS Agreement is silent on the establishment of administrative procedures for patent opposition. Particularly relevant in this regard is the establishment of **observation procedures**. Observation procedures provide third parties with the possibility to file an observation with the patent office on a pending patent application.

Third parties may use the observation procedures to claim, for example, that there has been insufficient disclosure by a patent applicant (Article 29 requires Members to provide for sufficiently clear and complete disclosure of an invention when submitting a patent application). An important additional flexibility in this regard is contained in Article 29.1, which allows Members to require the

applicant to indicate the **best mode** known to the applicant for carrying out the invention.

Another important pre-grant flexibility is that of being able to **define the criteria for patentability**. Articles 27.1 states that inventions covering patentable subject matter need to be new, involve an inventive step, and capable of industrial application. None of these terms are defined in the TRIPS Agreement, however, and Members are generally free to define what constitutes a patentable invention. As an example, a strict novelty standard (which may stipulate that novelty should be judged internationally, rather than domestically), would narrow the scope of patentability. In the pharmaceutical context, new uses of an existing non-medical product for a medical purpose (first indications) and an existing medication for a new medical purpose (second indications) could conceivably be denied a product patent on grounds of lack of novelty. In this regard, it should be noted, for instance, that the new Indian Patent Act (2005) applies a strict standard on inventiveness (see also Section IV). Other countries apply relatively narrower or broader interpretations of the term "inventive step". It should be noted, importantly, that existing practice differs considerably from country to country with the result that patent protection received in one country does not necessarily mean that such protection is granted in another country.

The TRIPS Agreement authorizes Members to **exclude certain subject matter from patentability**. Article 27.3 (a) permits Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Some countries treat discoveries of substances existing in nature, extractions/purifications from natural substances as excludable on the grounds that they do not constitute an "invention" under Article 27.1.

Post-grant flexibilities

As far as post-grant flexibilities and the patent application procedures are concerned, an important flexibility is the freedom given for Members to have a system where **opposition** of a patent is permitted. Under this option, a third party may file an opposition with the patent office after a patent has been granted, within a pre-determined period

after the publication of the patent grant. The grounds for opposition are left open to each country, and may be the same as that for pre-grant observation procedures.

National laws may also permit **parallel importation** of patented products. This is related to a concept that needs to be addressed in the national law, namely that of the **exhaustion** of patent rights. Upon the first sale of a patented product, the patent holder loses the right to control the further distribution and resale of that particular product. Parallel importation involves the purchase of certain patent-protected products at lower prices and their importation into higher priced countries. These lower priced imports are not counterfeits, but merely lower-priced patented products that are purchased and subsequently re-sold by a third party. Parallel imports can be facilitated or hindered depending upon the type of exhaustion regime a country decides to adopt. Under international exhaustion regimes, distribution rights available under the domestic patent will be exhausted by a first sale abroad in the same way as if that first sale happened domestically (thereby facilitating parallel imports). National exhaustion limits exhaustion to the domestic market and first sales of patented products outside the country will not affect the domestic patent (thereby inhibiting parallel imports).

In addition, a number of limited **exceptions to patent rights** exist under Article 30 and related TRIPS jurisprudence. Legally, this type of flexibility permits others to engage in activity that would normally be considered a patent right violation absent the consent of the right holder, due to overriding policy concerns. The two most notable ones, from the perspective of local pharmaceutical production and access to medicines, are the *scientific research/experimental use exception* (creating a safe harbour for scientific activities that might otherwise be blocked by patents – particularly for basic research and experimentation) and the *regulatory review (Bolar) exception*, which allows generic manufacturers to make use of a patented substance before the actual date of expiry of the patent for the sole purpose of obtaining marketing approval for that product.

An important flexibility exists in the compulsory licence system as well. Under Article 31 (f), pharmaceuticals produced under

compulsory licence should normally be predominantly for the supply of the domestic market. The 2003 WTO Paragraph 6 Decision created a means by which it is possible to obtain a waiver from this general rule and therefore permits the production of a drug solely for export to needy countries. The TRIPS Agreement sets out, *inter alia*, detailed notification requirements for exporters and importers to avail of the waiver. In this regard, while least developed countries automatically qualify as an importing country under the system, developing countries may also take advantage of the system as importers if they can establish that they have insufficient or no manufacturing capacities.

A final post-grant flexibility that could potentially be of interest to Thailand is the use of **competition law** to address the abuse of the exercise of exclusive intellectual property rights. This flexibility is contained first in Article 8.2, which authorizes Members to adopt appropriate measures to prevent: the abuse of intellectual property rights by right holders, the resort to practices which unreasonably restrain trade, and practices which adversely affect the international transfer of technology, as long as such measures are TRIPS compatible. Further, Article 40.2 recognized the right of Members to take action against licensing practices or conditions pertaining to intellectual property rights which restrain competition and have adverse effects on trade and impede the transfer and dissemination of technology. The flexibility to use competition law and its related remedies (including fines, price regulation, compulsory licences (under Article 31(k)), etc.), requires not only enabling legislation that reflects the interrelationship between intellectual property and competition, but also professional and well-functioning competition authorities and interagency cooperation among the relevant authorities (in the case of pharmaceutical patents, between the patent and competition authorities and the ministry of health).

A comprehensive examination of Thailand's patent law vis-à-vis the above flexibilities is an exercise that is beyond the scope of this mission report. The mission recognizes that a number of flexibilities, such as the "best mode" requirement and pre-grant observation procedures, are already incorporated into Thai law. This report is meant only to list key TRIPS Agreement flexibilities that may be of interest to Thailand, with the understanding that the extent to which Thailand opts

to deploy any of these flexibilities is a strategic one to be made by the Government.

V. Guidelines and tools on the use of TRIPS flexibilities to promote access to medicines

Although the right of countries to make full use of the TRIPS flexibilities, including the granting of compulsory licences, for public health purposes is affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, the absence of an appropriate national administrative and legal infrastructure and/or procedures to implement the compulsory licensing system may prevent effective exercise of this right. In this context, a number of issues were brought to the attention of the mission on which further guidance and technical support would be of use. These include the following:

- Guidelines and processes for public health-sensitive intellectual property rights management to ensure a clear and efficient decision-making process;
- A coherent approach that takes into account medium to long-term considerations for increasing access to medicines, including issues related to competition policy, technology transfer and local production;
- Relevant information and lessons learnt from experiences of other countries in the exercise and use of the TRIPS flexibilities;
- Access to relevant pharmaceutical patent data and determining the patent status of essential medicines; and
- Technical assistance, in particular, in relation to the determination and calculation of the remuneration rate for non-voluntary use of a patent.

This section below provides a summary of the options available to governments in terms of guidelines and tools on the use of TRIPS flexibilities.

Guidelines and processes for public health-sensitive management of intellectual property rights

It is acknowledged that the decision to grant compulsory licences and use other TRIPS flexibilities is often complicated and involves different stakeholders. It is therefore important to establish clear decision-making processes, including the determination or designation of the authorities or bodies charged with responsibility for the various stages of decision-making. It is noted that the TRIPS Agreement does not specify the nature of the authority or process that is mandated to grant compulsory licences or determine the level of compensation.

In this regard, WTO Members may designate the appropriate competent authority(ies) and process or system for the processing and granting of compulsory licences. It is noted that the systems vary in different countries, with some adopting administrative procedures and others a mixed system, where initial decisions relating to the grant of compulsory licences and compensation are made administratively and appeals are made to the judicial system.

The UK Commission on Intellectual Property Rights[71] in its 2002 Report identified some of the key features for such a system, as follows:

- legislation that fully exploits the flexibilities in the TRIPS Agreement for determining the grounds for compulsory licensing, as well as for non-commercial use by government;
- straightforward, transparent and fast procedures;
- clear, easy-to-apply and transparent guidelines for setting royalty rates; and
- a procedure for appeals that does not suspend the execution of the compulsory licence or government-use provision.

Some of the specific features of an appropriate administrative system are discussed in further detail below.

[71] UK Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy. London, September 2002.

A coherent approach

As described above, different authorities and/or bodies may be charged with the responsibility of ensuring the careful consideration of factors and requirements involved in the grant of compulsory licences. While these are not required under the TRIPS Agreement, it is also advisable to facilitate the consideration of the medium- to longer-term considerations relevant to ensure the effective and sustainable use of the TRIPS flexibilities as well as to meet the objectives of increased access to medicines. The introduction of an appropriate monitoring and data collection system to assess the impact of the use of the TRIPS flexibilities is an important consideration. Other considerations that may be made within or outside the designated decision-making process for compulsory licensing could include issues related to competition policy, technology transfer and local production, for example.

Country experiences and lessons learnt in the exercise and use of TRIPS flexibilities

As described in Section IV above, a number of countries, in the recent years, have used compulsory licences as one means of promoting access to medicines. Information is also provided on the use of compulsory licensing in developed countries, as well as the use of other TRIPS flexibilities by countries in the pharmaceutical sector. Information on the policy and legal measures adopted by other governments in the exercise of their rights in this area could provide useful lessons for others.

Determining the patent status of medicines

Accurate and up-to-date information about the patent status of pharmaceutical products is not always easily accessible or available in an easily understood form. This may stem from the lack of capacity and/or resources in national patent offices to administer the patent system (including managing effective search mechanisms) and to respond to the public health needs. The patent status of essential medicines is clearly a crucial factor in ensuring effective decision-making on use of TRIPS flexibilities.

Patent searches are complicated and highly technical endeavours. Searches are much more difficult where national patent data is not available electronically in robust form and is not incorporated in public or commercial databases. Moreover, patent information is generally searchable by technical description of the patented invention. In the case of pharmaceuticals, searches can be done on the chemical compounds, formulations or compositions related to the medicine but not on the brand-name (or generic name) of a product in which the invention is eventually incorporated. Although professional patent search companies are available, they are often expensive and may not present a feasible option for under-resourced agencies.

For this reason, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) had recommended the creation of a patent database for key pharmaceutical products, maintained by international organizations such as WHO and WIPO, in order to increase transparency of the patent system and to remove potential barriers to availability of and access to products and to facilitate informed decision-making[72]. WHO, UNAIDS and MSF jointly published, in 2004, a patent status analysis of 18 ARV and HIV-related medicines in 29 developing countries, which included the priority patent numbers and the corresponding patents in these countries. The document provides patent data related to the chemical compound, key formulations or modifications of the selected medicines, and where available, patent data on the combination of the selected medicines with other medicines[73]. WHO has also initiated a project[74] to develop a methodology to obtain patent data from public sources, including from the databases maintained by the drug regulatory agencies of the US and Canada, which makes publicly available the lists of medicines approved for marketing and the patents claimed as relevant to them. This patent information provides an initial list of potentially relevant patents from which searches can be made to identify corresponding application and patent documents in other countries. It should however, be noted that

[72] CIPIH Report recommendations 4.16 and 4.17. op. cit.

[73] Determining the Patent Status of Essential Medicines in Developing Countries. WHO/UNAIDS/MSF (WHO/EDM/PAR/2004.6).

[74] See Communication from WHO to WTO TRIPS Council, Technical Cooperation Activities: Information from Other Intergovernmental Organizations – World Health Organization (WHO), IP/C/W/478/Add.4, 23 October 2006.

there are limitations to this methodology; the most notable being that it will not work for drugs or drug combinations not marketed in the US or in Canada.

Developing a public health perspective for the examination of pharmaceutical patents

Although only a small number of new chemical entities are approved annually, the number of patents applied for protection of pharmaceutical products are increasing. In the circumstances, the criteria applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. In this specific context, Thailand has been very much involved in the WHO/UNCTAD/ICTSD project to examine the various categories of patent claims for pharmaceutical products. The project suggests some of the mechanisms that may be adopted to incorporate public health perspectives in procedures for the granting of pharmaceutical patents. It proposes a set of general guidelines for the assessment of pharmaceutical patent claims, and suggests elements for development of public health sensitive guidelines for the evaluation and review of pharmaceuticals patents at the national level in developing countries[75].

Guidelines for determining adequate remuneration for compulsory licensing

Article 31 (h) of the TRIPS Agreement provides that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". Most national legislation adopts a similarly flexible approach, using terms such as "reasonable" or "adequate", including the Thai legislation which provides that "the remuneration fixed shall be adequate for the circumstances of the case"[76].

[75] Guidelines for the examination of pharmaceutical patents: developing a public health perspective. Working Paper. Geneva, WHO/ICTSD/UNCTAD, January 2007.
[76] Section 50.5, to which refers Section 51, on compulsory licences in the public interest.

There are a number of considerations related to the determination of the remuneration rate. The term "adequate remuneration" is not defined in the TRIPS Agreement, and WTO Members are free to determine their approach. The TRIPS Agreement allows Members "to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice" (Article 1). This is a broad authorization to set up the appropriate mechanisms to implement TRIPS obligations. There is however, no internationally agreed criteria for determining the adequate rate of remuneration[77]. Similar issues exist in the case of voluntary commercial licences.

State practice regarding the determination of "reasonable" royalties or "adequate" remuneration is extensive and varied. A number of royalty systems have also been adopted or proposed in recent years, and establish useful frameworks for consideration. The evidence of compensation for voluntary technology licensing in the private sector also provides an important context for making determinations of remuneration rates. These different options are documented in the WHO/UNDP publication, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*[78], and can be summarized as follows:

i) The remuneration rates paid by developing countries in recent cases of compulsory licensing. They range from the aforementioned 0.5 per cent of Indonesia to a royalty rate of 4 per cent in Malaysia.
ii) The UNDP royalty guidelines for compulsory licences, which are simple and predictable, contributing to ease the non-voluntary licensing process. The standard UNDP royalty is 4 per cent of the price of the generic product, which can be raised or reduced by 2 per cent depending on a set of circumstances, such as the therapeutic value or the government contribution to the costs of R&D.

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[77] "There is wide variation in the way responsible government agencies and courts have set the amount of remuneration awarded to patent holders when patents have been subject to compulsory licensing". Scherer, FM. The Economics of Compulsory Drug Patent Licensing, Paper presented at the World Bank, 2 June 2003.
[78] (WHO/TCM/2005.1), op. cit.

iii) The Canadian approach, as set out in the Use of Patented Products for International Humanitarian Purposes Regulations (P-4 – SOR/2005-143)[79], establishes a sliding scale of 0.02 per cent to a maximum of 4 per cent royalty rate on the price of the generic product, based on the rank of the importing country in the United Nations Human Development Index (UNHDI). For most developing countries, the royalty rate would be less than 3 per cent. The formula is: add 1 to the number of countries on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. This rate is then applied to the generic sales price. The application of this formula to Thailand, 79 in the 2007/2008 UNDP Index, results in a 2.259 per cent rate.

iv) The Japanese Patent Office guidelines for setting royalties on government-owned patents. The standard royalty under these guidelines ranges from 2-4 per cent, but it can be increased or decreased by as much as 2 per cent, resulting in a range of 0 to 6 per cent. The criteria to determine the precise rate are diverse, such as the public interest in working of the patent, the importance of the patented invention to the final product or the novelty of the product.

A framework for remuneration

In determining appropriate policies and practices for determining reasonable royalties or adequate remuneration for the manufacture or sale of a medicine, countries should consider approaches that address practical concerns regarding the administration of a system, as well as policy objectives. Two factors can be considered in establishing systems for determining remuneration in compulsory licensing cases:

1. the system of setting remuneration rates should not be overly complex or difficult to administer, taking into account the capacity of the government managing the system. Guidelines will reduce complexity and provide guidance for adjudicators, as well as increase transparency and predictability. Such guidelines, or any system for setting remuneration for

[79] Use of Patented Products for International Humanitarian Purposes, SOR/2005-143, available on: http://laws.justice.gc.ca/en/p-4/sor-2005-143/text.html.

compulsory licensing, should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents.

2. the amount of the remuneration should not present a barrier for access to medicines. Where a compulsory licence is issued on a pharmaceutical product, the purpose will be to lower price and improve access. Remuneration mechanisms should be designed so as to assist rather than defeat this purpose.

For countries able and willing to make somewhat more complex determinations of royalties, a range of appropriate factors should be assessed, though not all are required, and not all will apply in any given circumstance. These include but are not limited to:

- therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- the ability of the public to pay for the medicine;
- actual, documented expenditures on development of the medicine;
- the extent to which the invention benefited from publicly funded research;
- the need to respond to public health exigencies;
- the importance of the patented invention to the final product;
- cumulative global revenues and profitability of the invention; and
- the need to address anti-competitive practices.

VI. Final remarks

1. In seeking greater access to essential medicines, national authorities may consider the full range of mechanisms available to contain costs of essential medicines and examine how the various tools may complement one another.
2. A sustainable system for the funding of medicines could be based on 3 main components: 1) the creation or enhancement of a national/social health insurance or of medicine prepayment mechanisms; 2) the introduction and use of all possible cost-containment mechanisms, and 3) the use of TRIPS-compliant

flexibilities. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies.

3. The use of compulsory licence and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes.
4. WHO supports measures which improve access to essential medicines, including application of TRIPS flexibilities.

CHAPTER 2

THE RIGHT TO HEALTH AND MEDICINES: THE CASE OF RECENT NEGOTIATIONS ON THE GLOBAL STRATEGY ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY[1]

I. INTRODUCTION

The purpose of this chapter is to describe, above all, a negotiating process which many have described as historical. More than an analysis on the subject of public health and intellectual property, this is an analysis of a negotiating process which could change the course and the nature of an organization such as the WHO. It is still too early to say whether this was achieved or not, but we are starting to write a chapter in the history of public health in the 21st century.

The negotiations of the intergovernmental group known as the "IGWG"[2], undertaken by the Member States of the WHO, were the result of a deadlock in the World Health Assembly held in 2006 where the Member States of the WHO were unable to reach an agreement on what to do with the 60 recommendations in the report on "Public Health, Innovation and Intellectual Property"[3] submitted to the Assembly in the same year by a group of experts designated by the Director-General of the WHO. The result of these negotiations was the "Global strategy and

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[1] Extracted from a conference given by the author at the Universidad de Barcelona in June 2009. The author wishes to thank Carlos Correa, Xavier Seuba, Francisco Rossi, Nirmalya Syam and Vicente Paolo Yu III for their invaluable comments; however, the author is the sole responsible for the ideas expressed herein and which do not necessarily represent the South Centre's point of view.

[2] Intergovernmental Group on Public Health, Innovation and Intellectual Property.

[3] WHO, "Public Health, Innovation and Intellectual Property", Geneva 2006.

plan of action on public health, innovation and intellectual property" (GSPOA) which was approved by the World Health Assembly in 2008.[4]

The intention of the GSPOA which was produced by the IGWG was to substantially reform the pharmaceuticals' research and development system in view of the findings that this system, whose purpose is to produce medicines for diseases which affect the greater part of the world population which lives in developing countries, had failed. The intellectual property rights imposed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the recent trade agreements could become one of the main obstacles to access to medicines. The GSPOA makes a critical analysis of this reality, and opens the door to searching for new solutions to this problem.

These negotiations leave several questions unanswered: 1) Will the IGWG be able to address the problem of access to medicines in all its complexity? 2) Is the problem which the IGWG has identified restricted to developing countries, as suggested in different parts of the strategy, or is it a global problem which even the developed countries will have to face sooner or later? 3) And finally, what can be the expected outcome of this exercise? Will these negotiations change the nature of the WHO?

This chapter is structured in five parts: 1) The background of the IGWG negotiations, 2) The stakeholders, 3) The content, 4) The Process and 5) Conclusions.

II. THE BACKGROUND OF THE IGWG NEGOTIATIONS

Of the 20 million people who according to the WHO, UNICEF and UNAIDS 2010 report should have received a retroviral treatment, only 5 million had access to the therapy at the end of 2009[5]. A third of the world's population does not have regular access to essential medicines,

[4] WHA, "Global strategy and plan of action on public health, innovation and intellectual-property" Resolution 61.21, May 24, 2008.
[5] UNAIDS 2010 Report.

and this ratio even reaches levels of half the population in certain developing countries. Medicines are a key tool which society has in order to prevent, relieve or cure diseases, and having access to them is a fundamental right of the citizens, it is a part of the right to health as established by some international treaties, or even by the Constitution itself in many countries.[6]

The financial burden of the expenditure in medicines in most developing countries falls on the individuals and not on the health insurances (private or public) as occurs in the developed countries. In countries where the per capita income (PCI) is less than US$1,000 per year, individuals as well as the State will not be able to bear the cost of an anti-retroviral treatment at a cost of US$4,000 to US$5,000 per year. According to World Bank figures, one billion people currently live in extreme poverty (less than US$1 per day)[7], and this is precisely the population which has the most serious health problems.

Today, it is recognized that the current patent protection system as imposed by the TRIPS Agreement has a significant impact on the entire pharmaceutical sector, and more specifically on medicine prices, to the extent where it may even hamper access to medicines by the poor populations of the Southern countries. It is also alarming that rules which are included in the TRIPS Agreement are not necessarily appropriate for those who are making an effort to meet health and development needs. Patents are the main factors which determine the prices of medicines, and the TRIPS Agreement requires that all WTO member countries grant exclusive patent protection for a period of 20 years.

In its 2002 report, the United Kingdom Commission on Intellectual Property Rights (CIPR) recommended countries to "ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies."[8] Even though the TRIPS Agreement obliges WTO Members

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[6] Seuba, X. "La protección de la Salud ante la regulación internacional de los productos farmacéuticos" doctoral thesis pp.92 ff., Barcelona 2008.
[7] See http://go.worldbank.org/MVH3AJAGC0.
[8] UK CIPR Commission on Intellectual Property Rights, executive summary, p.14, London 2002.

to provide patent protection for medicines, it also allows them to take certain social interest measures, such as compulsory licenses, parallel imports, and exceptions to patent rights, defining patentability criteria – measures which can cancel or restrict patent rights under certain conditions. These mechanisms have been implemented by developed countries as a means to balance patent rights with public interest, to stimulate competition, to protect consumers, and in the case of pharmaceutical products, to allow substitution by generics and to encourage access to medicines, ensuring that the cost is affordable for the state's or the consumers' budget.

In 2006, the WHO report on Public Health, Innovation and Intellectual Property Rights stated that "the TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws, subject to meeting its minimum standards including the criteria for patentability laid down in TRIPS. Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs. Thus, developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights conferred on patent owners and what exceptions to patentability are permitted (...)."[9]

During the May 2008 World Health Assembly, the WHO approved the Global Strategy on Public Health, Innovation and Intellectual Property. The Global Strategy gave the WHO the mandate to "provide (...), in collaboration with other competent international organizations technical support (...) to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health (...)."[10]

Regarding the use of the flexibilities contained in the TRIPS Agreement, which were approved and confirmed in different

[9] OMS, "Public Health, innovation and intellectual property" Geneva 2006, op. cit. p. 35.
[10] WHA resolution 61.21 para. 5.2 p. 43.

international forums, developing countries which have tried to apply these mechanisms have unfortunately been subjected to bilateral pressures[11]. The Global Strategy recognizes this problem and proposes technical assistance as one of the elements to overcome this obstacle. "International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, *inter alia*, from technical assistance."[12]

As regards the relation between patents and the research and development of new products, one of the main arguments in favour of the use of patents in the pharmaceutical field is that they allow research and development of new products to be carried out thanks to the substantial benefits which monopolies provide. However, a study carried out by the United States National Institute of Health showed that, over a period of 12 years (1989-2000), only 15 per cent of approved medicines were true innovations. According to Carlos Correa[13], innovation in the pharmaceutical field started declining just after the use of patents became generalized as a result of the TRIPS agreement; he also points out that research on diseases which prevail in developing countries has been practically non-existent. As Trouiller's well-known work points out, only 0.1 per cent of all new chemical entities produced between 1975 and 1999 were for tropical diseases.[14] The so-called forgotten diseases seem to have been ignored rather than forgotten.

Tensions between public health and the new intellectual property rules introduced by the WTO's TRIPS Agreement started with the lawsuits filed by 39 transnational pharmaceutical companies against South Africa's medicines law. The subject of access to medicines was set before the WTO TRIPS Council in June 2001, and concluded with the Doha Declaration on the TRIPS Agreement and Public Health. Doha

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[11] See Richard D. Smith, Carlos Correa and Cecilia Oh, "Trade, TRIPS and Pharmaceuticals", (2009) *The Lancet* 373, p. 687.

[12] AMS resolution 61.21 op. cit. Context para. 12.

[13] Carlos Correa "Ownership of Knowledge – the role of patents in pharmaceutical R&D", WHO Bulletin, vol. 82, no. 10, October 2004, 719-810.

[14] P. Trouiller, et al., ''Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure'', *The Lancet* 359 (2002): p. 2188.

is undoubtedly an important moment of this international discussion, but Doha contributes to increase the tension in the sense that an important point remains unresolved, that is, the mandate of the ministerial conference to find a "expeditious" solution to the so-called paragraph 6 system which is taking several years to implement to the point that even in 2010 the issue was still not definitely solved. The amendment to the TRIPS Agreement (article 31bis) for implementing the paragraph 6 system has still not been ratified by three quarters of the WTO members, and the TRIPS Council of 27 October 2009 extended the deadline for ratification to 31 December 2011. However, non-ratification is not the problem with the paragraph 6 system. Rather, the problem is the complexity of the system which makes it scarcely viable, when there are much simpler solutions. The inclusion of limitations to the use of the TRIPS flexibilities in the bilateral free-trade agreements, to FTAs which have been signed by several countries with the United States and later with the EU, also increase the tension between public health and the international intellectual property rules.

It is in this tense international context that the WHA requested the WHO to set up the Commission on Intellectual Property, Innovation and Public Health (CIPIH) to analyze the connections between intellectual property and access to medicines[15]. The Commission, composed of international experts, some of whom did not always act with due independence, caused great "headaches" to its president, Ruth Dreifuss, former president of Switzerland, who finally, in a masterly fashion, managed to build a consensus, and in April 2006 the Commission's final report was published. As mentioned previously, that same year's WHA did not manage to adopt the report's sixty recommendations, and found a "UN-type" solution which was to create a commission which turned into the IGWG process.

As part of the 60 recommendations, the CIPIH report recommended that the "WHO should develop a global plan of action to secure more sustainable funding to develop new products and make products that mainly affect the developing countries more accessible"[16]. Based on this recommendation, the 59th WHA approved resolution

[15] World Health Assembly, "Intellectual Property Rights, Innovation and Public Health, WHA Resolution 56.27, 28 May 2003, para 2.
[16] CIPIH Report (2006), p. 187.

59.24 which requested that an intergovernmental working group open to all WHO members be established.

The resolution requested the intergovernmental working group to report to the 60th WHA through the Executive Board on the progress made. The resolution also requests the Director-General to include in the intergovernmental group organizations of the United Nations,[17] NGOs in official relations with the WHO, expert observers and public and private entities.

The intergovernmental group held negotiations for almost 2 years, between December 2006 and May 2008, with three meetings in Geneva which were attended by over 100 countries, and several other meetings in all the WHO regions. Many articles and studies have been made regarding this process, which some have called historical. This analysis intends to provide a view from within, and to describe the mistakes, the manipulations and the failures so that those who tell the story as seen through rose-coloured glasses are not the only ones to narrate the events.

III. THE STAKEHOLDERS

The WHO Member States were obviously the main stakeholders in the negotiations. As it usually happens in United Nations negotiations, there were groups, alliances and mediators which helped build a consensus.

A first group, which was led by the United States and Switzerland, was supported by Australia, Japan, South Korea, Colombia and Mexico, and in some way, Canada. A second group, which was led by Brazil, Thailand and India, was supported by a great majority of the developing countries, including a discreet but clear support from China. The European Union, which spoke with one voice, was led by Portugal during the first part of the IGWG, and then by Estonia in their capacities as presidents of the European Union. Although the European Union did, at certain times, try to act as an intermediary between the countries of

[17] Ibid. paras. 3.2. and 4. 2.

the first and second group, this role was actually taken up by the Norwegian delegation which actively worked to build a consensus.

As far as the role played by the countries is concerned, the cohesion of the African group should be pointed out since it spoke with one voice in coordination with the rest of the developing countries in most cases, as during the WTO Doha Ministerial Conference discussion in 2001.

The NGOs and non-for-profit organizations in the field of public health played an important role. The role the NGOs have played with regard to promoting access to medicines in the WHO governing bodies is well known and recognized. Maybe because of the enthusiasm generated by the negotiations, some organizations abandoned their "discreet and effective lobbying" for an open and visible promotion of certain issues, which did not always help the public health agenda to move forward or to build the consensus.

The pharmaceutical industry: perhaps fearing the negotiations' scope and sensing the risk of seeing its commercial interests impacted on the long-term – in particular with regard to intellectual property – was permanently present in the hallways and corridors, actively and ostentatiously trying to influence the different stakeholders. More than 80 industry representatives (associations and private industries) were to be found in the Palais des Nations in Geneva during the 2008 WHA.

Academia: An initiative such as that of the IGWG, which led to the Strategy, was closely followed and analyzed by academia. University professors from different parts of the world gave their opinion and tried to develop the new issues of the IGWG, no doubt bringing vision and analysis with greater depth than the flow of discussions within the United Nations.

Other United Nations agencies: Unfortunately, several United Nations agencies which fully share a public-health vision, such as UNICEF, UNDP and UNAIDS were practically absent from the discussion. WIPO and WTO participated throughout the negotiations, and the group of industrialized countries as well as the Secretariat of the

WHO requested their comments and points of view on subjects related to the interpretation and management of intellectual property.

The Secretariat of the WHO: At first disoriented and confused, a situation which led to the failure of the first IGWG meeting – in view of the strength of the negotiations – the Director-General and the Deputy Director-General in particular, fully invested their efforts in monitoring and supporting the negotiations process. According to some Geneva observers of the IGWG process, the Assistant Director-General, (ADG) who covered this topic, had to leave the Organization, in great part due to the failure of the first meeting and a special PHI group (Secretariat of the WHO for Public Health, Innovation and Intellectual Property) was created in the office of the Director-General. Many technical departments of the WHO, such as the TDR or the Department of Ethics, Trade and Human Rights, followed the discussions with interest; the Department of essential drugs, which was the birthplace of the discussion, kept some distance, but the WHO regional consultants in the field of medicines experienced the negotiations as if it was their own.

IV. THE CONTENT

Since 1996, twelve WHA resolutions have referred to intellectual property and access to medicines. This mandate of the Assembly can be summarized in two points:

1. monitor the impact on health of the international trade agreements and
2. support the countries in formulating policies and measures intended to optimize the positive aspects and to lessen the negative impact of these agreements.

The "Global strategy and action plan on public health, innovation and intellectual property", which was approved by the WHA in May 2008, confirms and extends the previous mandate given by 12 WHA resolutions regarding the involvement of the WHO in public health and intellectual property.

Main elements of the 2008 Global Strategy:

- The strategy recognizes that the current initiatives to increase access to pharmaceutical products are **insufficient.**
- It also recognizes that the incentive mechanisms of intellectual property rights is not delivering for people living in "small or uncertain potential paying markets".
- While it does recognize the role of intellectual property, the Global Strategy specifically recognizes that "**the price** of medicines is one of the factors that can impede access to treatment."
- There is **no restriction** on the scope in terms of diseases or products as was negotiated in Doha and in the IGWG process.
- It recognizes that the "international intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities."
- The Global Strategy aims to **promote new thinking** on innovation and access to medicines.
- The strategy also recognizes that the public policies to **promote competition** can contribute to the reduction of the price of medicines.

Additional mandate of the "2008 Global Strategy"

- Reinforce education and training regarding the application and management of intellectual property rights from a public-health perspective.
- To establish urgently an expert working group (EWG) to examine proposals for new and innovative sources of funding for research and development of pharmaceutical products[18]. The WHA 2010 rejected the report delivered by the EWG and the creation of another EWG was requested by a WHA resolution of the same year.

[18] WHA 61.21 (7), 2008.

However, the final wording of the Strategy is, in many cases, vague, weak, and full of conditions and nuances. For example: What do most countries want? They want the WHO to provide technical and regulatory support to make use of the flexibilities contained in the TRIPS Agreement. The finally agreed-to text "… providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of ....". Another example of how the wording became weaker: The countries wanted that the possibility of an international agreement or convention as an alternative form of funding R&D for pharmaceutical products be studied (as was recommended by the report of the commission on intellectual property). The finally agreed-to text says: "2.3 (c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including *inter alia*, an essential health and biomedical research and development treaty".

V. THE PROCESS

A. The First Meeting in Geneva: 4-8 December 2006

The preparation of this meeting and the documents which were to serve as a reference were not totally in the spirit of the CIPIH recommendations. There were attempts to not only dilute or hide the intellectual property topic, which was at the core of this discussion's background as well as in the CIPIH report, but even to replace it by an ambiguous speech on miscellaneous subjects regarding research with reference to health.

The first meeting of the IGWG should have produced a first draft of the Strategy and Action Plan as requested by resolution 59.24, based on the CIPIH report. The consultation on the Internet regarding the draft prepared by the Secretariat, which took place before the meeting, already gave an indication of all the controversial topics which would appear throughout the negotiations. Thirty one contributions from different countries, industries, academia and NGOs were received. The

subject of a possible international agreement on research and development of new products as an alternative system to that of the patented medicines, as of the main or even sole source of R&D funding was undoubtedly the main subject of disagreement between the negotiating parties. The issue of whether to include the concept of access to treatment as a human right also made certain delegations nervous.

The six elements of a strategy to be presented by the WHO secretariat at the first meeting were: 1) priorities of the requirements in terms of R&D, 2) identification of the flaws in the research agenda, 3) promotion of R&D, 4) build and improve the capacity for innovation, 5) improve access and 6) ensure sustainable funding mechanisms. The issue of intellectual property, which should have been a common denominator between these six elements, had practically disappeared. During the chaotic discussions which characterized the entire meeting, the group of developing countries managed to have general acceptance of the need to reintroduce the issue of intellectual property. The WHO secretariat, probably due to pressure from certain Member States, decided to isolate this issue in a separate chapter (now element 5: "Application and management of intellectual property to contribute to innovation and promote public health."). This constitutes, in our opinion, the first and perhaps the most fundamental problem of the negotiations. Due to the insistence, mostly from the African Group, a second element regarding the transfer of technology was included (point 4 of the approved strategy).

Speaking of the African group, the organization and coherence of all their well-prepared interventions was the most positive aspect of this first meeting. Another point which the developing countries achieved was to include the possible negative impact of the free-trade agreements along with their requirements which go beyond the TRIPS requirements, known as the TRIPS-plus measures.

An attempt was made to solve the disagreements in the discussions regarding intellectual property issues or references to human rights via the well-known technique of "looking for a previously agreed-to text in other resolutions or forums", which often resulted in a final wording which was weaker than the one which had been decided on in

the past. In many cases the previously agreed-to text was not simply copied, but it was used as a basis for negotiations which, in most cases, led to a more general wording, less clear or full of nuances and "diplomatic" equilibriums. It is quite surprising that, in negotiations on innovation, people should be afraid of looking for new wording.

It was clear, during the discussions that for most of the developing countries the new intellectual property rules required by TRIPS and the free-trade agreements are a negative factor with regards to access to medicines and for innovation in the developing world. On the other hand, a small group of industrialized countries defended the position that the problem does not lie in the intellectual property rights and the patents, but rather in the lack of funding, defective health infrastructures and lack of political will. During the meeting (and practically throughout the negotiations), this same group of countries questioned the WHO's authority in the area of intellectual property, insisting that this is an issue which should be dealt with by the WIPO and the WTO. According to these countries, the WHO should only be involved in health care aspects,[19] excluding other decisive aspects influencing the health sector. Nor could an agreement be reached regarding the inclusion of a reference to human rights, or to state that public health has priority over intellectual property rights.

The meeting ended abruptly without any conclusions or consensus. The WHO secretariat announced that it would be receiving comments and suggestions regarding the draft of the Global Strategy, which had been presented, setting a deadline of February 2007. The WHO sent two circulars to the countries requesting contributions. At the end of the deadline, 22 contributions had been received[20]. In July 2007 the IGWG secretariat issued a new version of the Global Strategy and Plan of Action. The new draft reflected the new contributions and, in element 5, explicitly recognized the need to explore and implement "**complementary, alternative** and/or **additional** mechanisms to incentivize research and development". The three words in bold type were the subject of several hours of discussion during the second meeting since two or three countries did not want a qualifier such as

[19] WHO, Report of First Session, 25 January 2007, paras. 20, 21 and 31.
[20] WHO, "Draft Global Strategy and Plan of Action: Report by the Secretariat", 31 July 2007, EB122/12, para 6 (WHO, Report by the Secretariat, 31 July 2007).

alternative, complementary or additional. The developing countries proposed the expression "innovative mechanisms", but it was rejected and the expression which was finally approved in the strategy was "a range of incentive mechanisms"[21].

In this draft, an additional column was introduced in the action plan to indicate the "stakeholders" (WHO member states, secretariat of WHO, WIPO, WTO, national institutions, academia, industries, PPPs, NGOs). This initiative by the secretariat, perhaps with the intention of "clarifying" the responsibilities, turned into a problem since it was used by certain countries as a means to try to exclude the WHO from certain activities, especially those regarding intellectual property.

B. Regional Consultations

Regional and inter-country meetings took place during the second semester of 2007 throughout the WHO regions – AFRO in the Congo, AMRO/PAHO in Washington DC, Bolivia, Rio de Janeiro and Canada; EMRO in Egypt; EURO in Serbia, SEARO in the Maldives and WPRO in the Philippines.

The most relevant meeting was undoubtedly the one in Rio de Janeiro which produced what was referred to as "the Rio document", and which had the greatest influence on the final document of the strategy. The countries which took part in the meeting were Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay and Venezuela. It should be noted that Colombia, whose delegation was quite active during the last meeting on the IGWG at the 2008 World Assembly and supported the positions of the industrialized countries, did not take part in any of the meetings in the region of the Americas. The originality and correct choice of the Rio document was to try to include a context, a goal and a set of principles based on citizens' rights in the strategy; the Rio document's eleven principles give a vision and, in a way, unveil the "philosophy" of how the problem should be approached; we will just quote the first three principles to show the spirit behind this document:

[21] WHO Resolution 61.21, context para. 4, p. 5.

a) The right to health protection is a universal and unalienable right, and it is the governments' obligation to guarantee that the instruments to implement it are available.
b) The right to health takes precedence over commercial interests.
c) The right to health implies access to medicines.

Although the only regional consultation officially organized by AMRO/PAHO was the one in Ottawa, Canada, on 22-23 October 2007, this consultation was limited to debating some controversial points contained in the Rio document. Canada was especially opposed to including items from the Rio document, in particular the reference to human rights. Another point which was contested by the North American countries was WHO leadership in actions related to intellectual property, and trying to restrict the strategy's scope to three diseases, malaria, tuberculosis and AIDS, like in the old Doha discussions. Some of the participants at the meeting in Canada insisted on the technique already mentioned above, which consists in solving controversies by looking for a previously agreed-to text.

From 15 August to 30 September 2007, the WHO Secretariat organized the second round of contributions through its web page. Sixty five contributions were received from governments, national institutions, NGOs, academicians, patients' associations and the pharmaceutical industry. [22] "The unmanaged nature of Web-based hearings"[23] was a problem for many. Indeed, in the second public consultation, the number of presentations supporting a strong intellectual property protection increased enormously. This was answered by many NGOs which pointed out that the industry was distorting the spirit and the aim of the IGWG[24].

[22] WHO, Report by the Secretariat, 31 July 2007, para. 11.
[23] Op. cit. Forman. L., "desk review of the intergovernmental working group on public health, innovation and intellectual property from a right to development perspective" unpublished paper, Geneva, March 2009.
[24] Suwit Wibulpolprasert et al., "WHO's web-based public hearings: Hijacked by pharma?", (2007) The Lancet 370:24, p. 1754.

This second round was characterized by the richness of the proposals, and the focus was on the discussion on intellectual property and the possible alternative mechanisms for funding R&D for pharmaceutical products. The discussions became more intense, and two groups were formed. The first group promoted proposals such as the treaty on R&D, incentives, "patent pools" or "advance market commitments"[25]. The second group, which was led by the industry and certain institutions from the United States, preferred solutions based on the market, arguing that a strong intellectual property protection is the best incentive for stimulating R&D[26]. Some proposals, such as that of the Italian alliance for the defence of intellectual property, challenged the WHO role in this field arguing that this role belonged exclusively to WTO and WIPO[27]. Regarding the old discussion on the scope of the strategy, (whether it is restricted to a limited number of diseases, i.e. malaria, HIV/AIDS and tuberculosis, or if it includes any disease representing a public health priority for a specific government) some industrialized countries managed to reopen the debate, forcing developing countries to renegotiate what had already been agreed upon in Doha. The first article of the WTO's Doha Ministerial Declaration on TRIPS an Public Health recognizes the gravity of the public health problems afflicting developing countries, especially those resulting from the three previously mentioned diseases (HIV/AIDS, malaria and TB), but at the end, it also includes the words "… and other epidemics".

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[25] Frederick M. Abbott and Jerome H. Reichman, "Strategies for the Protection and Promotion of Public Health Arising out of the WTO TRIPS Agreement Amendment Process", Florida State University and Duke University; James Love, Knowledge Ecology International; Itaru Nitta, Green Intellectual Property Scheme System to impose a levy on patent applicants to establish a trust fund to facilitate eco-Aidan Hollis, A Comprehensive Advanced Market Commitment; Thomas Pogge, Track 2.

[26] Jeremiah Norris, Hudson Institute, USA; Harvey Bale, IFPMA; Ronald Cass, Centre for the Rule of Law; Wayne Taylor, Health Leadership Institute, McMaster University; Anne Sullivan, International Association for Business and Health; Hispanic-American Allergy Asthma and Immunology Association; the National Grange of the Order of Patrons of Husbandry; International Chamber of Commerce; Healthcare Evolves with Alliance and Leadership; and US Chamber of Commerce.

[27] Daniele Capezzone, Benedetto Della Vedova, Veaceslav Untila and Kelsey Zahourek, Government Institution, European Parliamentarians and the Property Rights Alliance, Italy; Harold Zimmer, German Association of Research-based pharmaceutical manufacturers; and Ronald Cass, Centre for the Rule of Law.

C. Second Meeting: 5-10 November 2007

Thanks to the regional and inter-country exercises, interest in the discussions increased to the point that the number of countries represented reached 140, with 18 NGOs, 11 experts, and 4 or 5 specialized United Nations agencies. Two working groups were created on elements 5 and 6 of the strategy (management of intellectual property and improving access), as well as a subgroup which started working on the plan of action.

The draft, which had been produced at the end of the second global meeting, was clearly influenced by the Rio document, above all with regard to the inclusion of the context, the aim and the principles. Negotiations were slow and complicated, at times with extended discussions over a word, an adjective or a simple comma. Although it could be said that great progress had been made, at the end of the meeting several key points remained in parentheses because no consensus had been reached. Surprisingly enough, point 30.2.3.c – "encourage further exploratory discussions on the utility of possible instruments or mechanisms or essential health and biomedical research and development, including, *inter alia*, an essential health and biomedical research and development **treaty**"[28] – was approved at this second meeting. This is undoubtedly the central and most important point of the Global Strategy, and the one the industry, as well as some industrialized countries, were most opposed to. It is possible that the support of the Chinese delegation at this point was the deciding element for the idea of a possible international treaty for the funding of pharmaceutical R&D to be agreed upon at the end of this meeting, leaving only the determination of the role of the WHO pending, which remained in parentheses in the "stakeholders" column. One and a half years later, at the January 2009 Executive Board, and at the 2009 WHA, a group of nine countries, with the presence of the WHO secretariat acting as an "observer", used the WTO "green room" technique and agreed to exclude the WHO as one of the stakeholders of this activity of the plan of action. This is undoubtedly the most serious error of the entire negotiations since it shows not only a refusal to study truly innovative solutions to fundamental problems, but it also seems to

[28] Set in bold by the author.

indicate that there is no clear vision regarding the future of access to medicines.

On 10 November 2007, when the second global meeting ended, many of the element 5 activities relating to intellectual property still remained in parentheses due to lack of consensus. The Secretariat and some industrialized countries refused the idea of a third meeting, although it was obvious that it was needed. Here, the WHO Secretariat did some "juggling" which many did not understand, and suspended the meeting for almost 6 months to have it continue on 28 April 2008, the week prior to the 61st WHA. This was not a "third meeting", it was simply the continuation of the meeting which had been suspended several months earlier.

D. Continuation of the Second Meeting of the IGWG: 28 April-3 May 2008

"This is the same meeting, let's go on as if this had just been a weekend recess" said the WHO Secretariat over and over again, but the weekend had lasted six months. Negotiations resumed with 147 registered Member States, 11 experts, over 20 NGOs, and specialized United Nations agencies. After negotiating one sentence at a time and sometimes even one word at a time, consensus was reached on four of the seven elements. The remaining elements were **element 4**: transfer of technology, **element 5**: management of intellectual property and **element 6**: improving delivery and access.

Many of the open points in parenthesis pending consensus had been blocked only by the United States, and several countries requested that "pending USA approval" be indicated on the draft with respect to these elements. The most problematic element for the United States delegation was element 5, in aspects such as: "the need to find new incentive schemes for research", the role of the WHO with regard to intellectual property, protection of test data, and the reference to TRIPS-plus measures in bilateral trade agreements.

E. 61st World Health Assembly: 24 May 2008

During the 61st World Health Assembly, practically a third meeting of the IGWG was held. In fact, it was somewhat like a parallel World Health Assembly, since most of the countries participating in the assembly also took part in the negotiations, to the extent that some countries with small delegations preferred to be present at the IGWG negotiations and not at the "normal" Assembly activities. During the week the WHA lasted, the eight working hours of the day were not enough and, starting from Wednesday, night sessions took place. In the last day the activities went on until three o'clock in the morning.

For the first time in two years of negotiations, on the Friday prior to the close of the Assembly, the WHO Secretariat authorized a "WTO green room" type meeting (a closed-door meeting with a group of nine countries). This was initially called by the president as a lunch with "the president's friends", which then went on as a simple closed-door meeting until five o'clock in the afternoon. This practice, the first one in the history of the WHO (with the exception of some negotiations on the anti-tobacco convention) was strongly criticized by many countries in public and they even threatened to not recognize the consensus reached by the nine countries in the "green room", in the 2008 WHA plenary session. The criticism from the countries was even much stronger during the 62nd WHA in May 2009, when the countries found out about another round of negotiations in the "green room" to solve the problem on the points in parenthesis which were pending. This round of negotiations led to the exclusion of WHO as a stakeholder in the activity related to the treaty on R&D.

As this was the final stretch of the negotiations, the Secretariat and the countries wanted to finish the exercise (only a few NGOs unsuccessfully tried to extend the IGWG). Hence, this was the moment when the technique of referring to "previously agreed-to documents and other forums" was most used. Since most of the pending elements belonged to element 5, the topic of intellectual property was the one that suffered most or profited from this technique.

Certain aspects were deleted, and others were adapted with nuances which in some cases weakened the text. References to TRIPS-

plus provisions, parallel imports, the concepts of patent expiration or invalid patents, patentability criteria, and even test data exclusivity were eliminated. The aspiration of certain developing countries, in particular the Rio group, to produce a document which would be as comprehensive as possible, trying to include issues which were already mentioned in previous resolutions, implied the risk of restricting the existing mandate. This problem was detected at the very end of the negotiations and was solved by the Brazilian delegation which requested an explicit reference to all the previous resolutions included in resolution 61.21, thus reaffirming the existing mandate. The desire to have everything that could make reference to intellectual property included led to almost schizophrenic moments during the negotiations such as, for example, when Colombia and the United States radically objected to the WHO working on the patentability criteria from a public health perspective, when the "Guide for patent examiners: developing a health perspective" was circulating in the room, and most of the people in attendance knew that training courses had already been carried out in patent offices in more than 25 countries.

F. World Health Assembly: 18 May 2009

Regardless of the strong criticism of the "green room" negotiations during the 2008 WHA, another informal closed-door consultation among a small number of countries took place in January 2009, and its results were transmitted to the WHA in May 2009 in document A62/16 Add.3[29] where the parentheses had been removed from the open points, above all in the stakeholders' column in element 5 of the strategy which refers to the management of intellectual property. The introduction of this document stated: "as a result of informal consultations among Member States in order to reach agreement on the open paragraphs on stakeholders in the plan of action [Note 1: Document A62/16, paragraph 12], the attached table presents the final proposals for the remaining specific actions".

In an open letter to all WHO Member States, dated 18 March 2009, seven NGOs (Essential Action, Health Action International,

[29] http://apps.who.int/gb/ebwha/pdf_files/A62/A=.

Health Gap, Knowledge Ecology International, Médecins Sans Frontières, Oxfam International and Third World Network) indicated that "We wish to call your attention to document A62/16 Add.3 which presents the results of informal consultations between certain Member States. We are surprised that the WHO has been eliminated as a stakeholder in activity 2.3(c) which requests to 'encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including *inter alia*, an essential health and biomedical research and development treaty' (...). The WHO is the United Nations agency with the world mandate for health. It is unacceptable that there may have been opposition to the WHO having a role in this discussion...". Further on, the seven NGOs indicate that such a decision would go against the spirit of Resolution 61.21.

Several developing countries (Argentina, Bangladesh, Barbados, Bolivia, Cuba, Ecuador, Ghana, India, Jamaica, Nicaragua, Suriname and Venezuela) expressed their disagreement about the way the closed-door informal consultations were carried out, as well as to the result of these consultations to exclude the WHO as a stakeholder in future discussions regarding a possible international treaty.

The answer of the WHO Secretariat to its "exclusion" from future discussions regarding the treaty was that this issue was open since it is part of the mandate of the group of experts which was to present its conclusions in November 2009. As mentioned before, the report of the EWG was rejected by the WHA 2010.

On the last day of the Assembly, and at the last moment, a resolution sponsored by Canada, Chile, Iran, Japan, Libya, Norway and Switzerland and with the support of the United States was approved. This resolution made reference to and approved document A62/16 Add.3, which excluded the WHO from future discussions regarding the treaty. It is important to point out that many of the main stakeholders during the two-year negotiations, such as Brazil, India, Thailand, Philippines, or the African group did not cosponsor this resolution. It is also somewhat surprising that countries such as Japan, who were absent from the negotiations, or whose participation was rather low-profile

during the negotiations, appeared at the last moment as cosponsors of the resolution.

It is obvious, as many commented during the 2009 assembly, including the official answer from the Secretariat, that the Member States may, at any time, propose the issue for discussion at the WHO; however, by excluding the WHO, an important opportunity to analyze the fundamental problems of access to medicines and to search for original and innovative medium and long-term solutions is lost.

G. Explanation of the Vote of Some Developing Countries

Bolivia, in the name of a group of countries including Bangladesh, Barbados, Cuba, Ecuador, Nicaragua, Suriname and Venezuela expressed that:

> "We are pleased with the approval of the resolution of point 12.8 of our agenda, but let me express the position of several countries which became involved yesterday, at the last moment, in the negotiations. Taking into consideration that the President of the Committee kindly expressed that our concern with regard to the process[30] would be included in the minutes of this meeting, we will focus on the content of our discussions (…).
>
> For our delegations, a central point of the World Strategy is sub element 2.3(c) which requests to "encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including *inter alia*, an essential health and biomedical research and development treaty".
>
> (...) we consider that the exploratory discussions on the global rules for R&D are crucial to meeting the promise of the global strategy, not only to improve access to

[30] Referring to the informal consultations.

medicines, but also to increase medical innovation based on the needs".

VI. CONCLUSION

The IGWG negotiations is undoubtedly the most important exercise ever carried out by the WHO Member States in questions of access to medicines, and an exceptional opportunity for the WHO Secretariat to exercise its leadership by proposing a vision and mechanisms for the following 15 to 20 years. Does the WHO currently have a vision and clarity regarding the direction of the strategy, and enough independence and courage to accompany the countries' efforts? This is the fundamental question to which we unfortunately still do not have a clear answer. The 62nd and 63rd World Health Assemblies in May 2009 and 2010 only bolstered the uncertainty rather than shedding some light on the question.

According to Article 19 of the WHO Constitution: "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." Despite the notorious regulatory powers its constitution confers it "the WHO has paid but scarce attention to law – especially the **hard law** – as a tool to protect and promote health. On the contrary, the Organization has shown itself to be more in favour of seeking a 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".[31]

We are facing a structural problem which requires innovative answers. The Member States negotiated the Global Strategy and Plan of Action in the way a treaty is discussed and approved, and although we are still far from a "treaty", it at least shows the importance the negotiators gave the matter. As far as sustainable long-term access to

[31] Seuba, Xavier doctoral thesis, 2009.

medicines for the developing countries and the developed world is concerned, it is clear that the WHO should, rather than recommend, use its capacity to legislate: a convention or a treaty on R&D is undoubtedly the path to follow.

The finding that the current system of incentives through the protection of patents has failed to respond to the problems of the developing countries where most of the world population lives is a clear starting point. The global strategy clearly recognizes that the incentive mechanisms of the intellectual property rights do not stimulate pharmaceutical innovation for diseases which exist in "small or uncertain" commercial markets.

The Strategy's final wording is – in many cases – weak, full of conditions and nuances, and this is perhaps the price which has to be paid in order to formulate the fundamental problem. In the future, we will see what the priority will be for the world health authorities, whether to build up stocks of medicines and vaccines for diseases which have not arrived yet, or to build a system which allows to deal with diseases which currently kill millions of people in developing countries.

In any case, there are many positive aspects which represent important progress:

- The scope of the Strategy is not restricted to the three diseases (malaria, AIDS and tuberculosis), a discussion which had been reopened by certain industrialized countries regardless of the Doha agreement.
- A consensus was reached on the need of new mechanisms to incentivize R&D, a possible treaty, premiums, "patent pools" and "advance market commitments".
- A special group of experts to examine the R&D funding systems was established. This group had to report to the 63rd WHA, but now, the new EWG would report to the 65th WHA in 2012.
- The topic is still on the agenda, at least until 2015, and the Secretariat will have to report to the WHA every two years.

- The previous mandate on intellectual property granted by previous resolutions was reinforced or, as many expressed, has been legitimized.
- Finally, for the third time after the anti-tobacco convention and the international sanitary code, the idea of the treaty raised the need (although without much progress) that the WHO should exercise the function conferred to it by article 19 of its Constitution which allows its "recommendation" on public health to take on a compulsory character.

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ANNEX

SIXTY-FIRST WORLD HEALTH ASSEMBLY **WHA61.21**

Agenda item 11.6 **24 May 2008**

Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;[1]

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, *inter alia*, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Recalling resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on international trade and health; and WHA60.30 on public health, innovation and intellectual property;

Welcoming the progress made by the Intergovernmental Working Group in elaborating the global strategy and the identification of the stakeholders in the plan of action,

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[1] Document A61/9.

1. ADOPTS the global strategy and the agreed parts of the plan of action[2] on public health, innovation and intellectual property, attached to this resolution;

2. URGES Member States:[3]

(1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;

(2) to support actively the wide implementation of the global strategy and plan of action on public health, innovation and intellectual property, and to consider providing adequate resources for its implementation;

3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and intellectual property;

4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:

(1) to provide support for Member States, upon request, in implementing the global strategy and plan of action on public health, innovation and intellectual property and in monitoring and evaluating its implementation;

(2) to support effective promotion and implementation of the global strategy and plan of action on public health, innovation and intellectual property;

(3) to continue to implement the mandates contained in resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10, WHA57.14 and WHA56.30 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation

[2] On the specific actions and stakeholder components.
[3] Where applicable, also regional economic integration organizations.

and public health, WHA59.26 on international trade and health, and WHA60.30 on public health, innovation and intellectual property, as well as WHA55.11 on health and sustainable development, WHA55.14 on ensuring accessibility of essential medicines, and WHA60.18 on malaria, including proposal for establishment of World Malaria Day;

(4) to finalize urgently the outstanding components of the plan of action, concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;

(5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;

(6) notwithstanding the request in subparagraph (4) above, to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO;

(7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board;

(8) to reflect, as appropriate, the global strategy and plan of action on public health, innovation and intellectual property in the further development of WHO's research strategy;

(9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and intellectual property;

(10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and intellectual property, and to report progress to the Sixty-third World Health Assembly through the Executive Board, and subsequently every two years, until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.

ANNEX

Global strategy on public health, innovation and intellectual property

The context

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries.

2. Currently, 4.8 billion people live in developing countries, representing 80 per cent of the world population. Of this number, 2.7 billion, representing 43 per cent of the world population, live on less than US$2 a day. Communicable diseases account for 50 per cent of the developing countries' burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products[1] and medical devices, especially in developing countries.

3. Member States,[2] the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals and to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.

[1] The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

[2] Where applicable, also regional economic integration organizations.

4. Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.

5. Advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries.

6. The Report of the Commission on Intellectual Property Rights, Innovation and Public Health provides an analysis of the problems and makes recommendations that form a basis of future actions.

7. Intellectual property rights are an important incentive for the development of new health-care products. This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.

8. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all.

9. Article 7 of the TRIPS agreement states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation into the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

10. The Universal Declaration of Human Rights provides that "everyone has the right freely to participate in the cultural life of the

community, to enjoy the arts and to share in scientific advancement and its benefits" and that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

11. The price of medicines is one of the factors that can impede access to treatment.

12. International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, *inter alia*, from technical assistance.

The aim

13. The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will:

> (a) provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels

(b) promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases[1]

(c) build and improve innovative capacity for research and development, particularly in developing countries

(d) improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries

(e) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D

(f) improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access

(g) secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries

(h) develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems.

[1] For the purposes of this strategy, the definitions of Type I, II and III diseases, are as referred to by the Commission on Macroeconomics and Health and as further elaborated in the CIPIH report: Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. The prevalence of diseases and thereby their categorization in the typology can evolve over time.

The principles

15. The WHO Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health". Accordingly, the WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant WHA resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, the WHO, including the regional and, when appropriate, country offices, need to strengthen its institutional competencies and relevant programs in order to play its role in implementing this global strategy with its plan of action.

16. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

17. *(Deleted)*

18. *(Deleted)*

19. The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by intellectual property rights.

20. Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.

21. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.

22. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.

23. Research and development of developed countries should better reflect the health needs of developing countries.

24. The global strategy and the plan of action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:

(i) developed in an ethical manner

(ii) available in sufficient quantities

(iii) effective, safe and of good quality

(iv) affordable and accessible

(v) used in a rational way.

25. Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.

26. Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.

The elements

Element 1. Prioritizing research and development needs

27. Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases need to be identified urgently. A better understanding of the developing countries' health needs, and their determinants is essential to drive sustainable research and development on new and existing products.

28. The actions to be taken to prioritize research and development needs are as follows:

(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries

(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases

(b) disseminate information on identified gaps, and evaluate their consequences on public health

(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs.

(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels

(*a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments*

(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries

(c) include research and development needs on health systems in a prioritized strategy

(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health need

(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public

health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples

(a) set research priorities in traditional medicine

(b) support developing countries to build their capacity in research and development in traditional medicine

(c) promote international cooperation and the ethical conduct of research

(d) support South-South cooperation in information exchange and research activities

(e) support early-stage drug research and development in traditional medicine systems in developing countries.

Element 2. Promoting research and development

29. There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential.

30. The actions to be taken to promote research and development are as follows:

(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area

(a) promote cooperation between private and public sectors on research and development

(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding

(c) support governments in establishing health-related innovation in developing countries.

(2.2) promoting upstream research and product development in developing countries

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products

(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries

(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools

(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases

(e) support early-stage drug research and development in developing countries

(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries

(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries.

(2.3) improving cooperation, participation and coordination of health and biomedical research and development

(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources

(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities

(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty

(d) support active participation of developing countries in building technological capacity

(e) promote the active participation of developing countries in the innovation process.

(2.4) Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries

(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers, especially in developing countries

(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts

(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries

(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms

(e) consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(2.5) Establishing and strengthening national and regional coordinating bodies on research and development

(a) develop and coordinate a research and development agenda

(b) facilitate the dissemination and use of research and development outcomes.

Element 3. Building and improving innovative capacity

31. There is a need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

32. The actions to be taken to build and improve innovative capacity are as follows:

(3.1) building capacity of developing countries to meet research and development needs for health products

(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health

(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries

(c) strengthen health surveillance and information systems.

(3.2) Framing, developing and supporting effective policies that promote the development of capacities for health innovation

(a) establish and strengthen regulatory capacity in developing countries

(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans

(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries

(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations.

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries

(a) develop successful health innovation models in developing innovative capacity

(b) intensify North–South and South–South partnerships and networks to support capacity building

(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments

(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine

(b) encourage and promote policies on innovation in the field of traditional medicine

(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards

(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine

(e) promote South-South collaboration in traditional medicine

(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation.

(3.5) developing and implementing, where appropriate, possible incentive schemes for health- related innovation

(a) encourage the establishment of award schemes for health-related innovation

(b) encourage recognition of innovation for purposes of career advancement for health researchers.

Elements 4. Transfer of technology

33. North-South and South-South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the TRIPS Agreement states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.

34. The actions to be taken in relation to this element are as follows:

(4.1) promoting transfer of technology and the production of health products in developing countries

(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries

(b) promote transfer of technology and production of health products in developing countries through investment and capacity building

(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.

(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

(a) encourage North-South and South-South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry

(b) facilitate local and regional networks for collaboration on research and development and transfer of technology

(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights

(d) promote the necessary training to increase absorptive capacity for technology transfer.

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies

(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices

> *(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.*

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

35. The international regimes on intellectual property aim, *inter alia*, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific R&D needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

36. The actions to be taken in relation to this element are as follows:

> (5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries
>
> > *(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries*

(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries

(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.

(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs

(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement

(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries

(g) promote active and effective participation of health representatives in intellectual property-related

negotiations, where appropriate, in order that such negotiations also reflect public health needs

(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries.

(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products

(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States

(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003

(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge.

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases

(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries

(b) (Deleted)

(c) (Deleted)

(d) (Deleted)

(e) (Deleted)

Element 6. Improving delivery and access

37. Support for and strengthening of health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

38. International agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the TRIPS agreement and recognized by the Doha Declaration on the TRIPS Agreement and Public Health that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

39. The actions to be taken to improve delivery and access are as follows:

(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system

(a) *invest in developing health-delivery infrastructure and encourage financing of health products*

(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016[1]

(c) prioritize health care in national agendas

[1] In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines

(e) increase investment in human resource development in the health sector

(f) develop effective country poverty reduction strategies that contain clear health objectives

(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate.

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices

(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards

(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings

(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products

(d) strengthen the WHO pre-qualification programme

(e) (Deleted)

(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal

of harmonization of processes employed by the regulatory authorities for drug marketing approvals

(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines

(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.

(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs

(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or "Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement

(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements

(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access

(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law

(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing

(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products

(g) increase information among policy makers, users, doctors and pharmacists regarding generic products.

Element 7. Promoting sustainable financing mechanisms

40. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed.

41. It is important to make maximum use of and complement as appropriate and feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.

42. The actions to be taken to promote sustainable financing mechanisms are as follows:

(7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries

(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases

(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34

(c) create a database of possible sources of financing for R&D.

(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices

(a) document and disseminate best practices in public-private and product development partnerships

(b) develop tools to periodically assess performance of public-private and product development partnerships

(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries.

Element 8. Establishing monitoring and reporting systems

43. Systems should be established to monitor performance and progress of this strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.

44. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action

(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action

(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries

(c) continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly

(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices

(e) monitor and report on investment in research and development to address the health needs of developing countries.

Appendix

Plan of Action

Explanatory Notes

***Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

Reference to **Governments** means that WHO Member States[1] are urged to take action.

WHO means that the Director-General is requested to take action.

Other international intergovernmental organizations, both global and regional**,** means that WHO Member States, or WHO Secretariat as mandated by Member States through this plan of action, invite these organizations to take action. Member States are urged to raise appropriate issues in the governing bodies of the organizations. The Director-General is requested to bring this global strategy and plan of action to the attention of all relevant international organizations and invite them to consider the relevant provisions of this global strategy and plan of action.

Other relevant stakeholders means that WHO Member States, or WHO Secretariat as mandated by its Member States through this plan of action, invite these relevant actors to take action. These include *inter alia*, as appropriate, international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public-private partnerships; public-private and product development partnerships; nongovernmental organizations; concerned communities; development partners; charitable foundations; publishers; research and development groups; and regional bodies; and regional organizations.

[1] Where applicable, also regional economic integration organizations.

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 1. Prioritizing research and development needs			
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases	**WHO;** Governments; other relevant stakeholders	2008-2015
	(b) disseminate information on identified gaps, and evaluate their consequences on public health	**WHO;** Governments; other relevant stakeholders	2008-2015
	(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs	**WHO;** Governments; other relevant stakeholders	2008-2015
(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments	**Governments; regional organizations**	2008-2015

	(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public-private partnerships)	2008-2015
	(c) include research and development needs on health systems in a prioritized strategy	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public-private partnerships)	2008-2015
	(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs	**WHO**; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	2008-2015

	(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)	**Governments**; WHO; other relevant stakeholders (including academia, relevant health related industries, national research institutions, and public-private partnerships)	2008-2015
(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples	(a) set research priorities in traditional medicine	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public-private partnerships; and concerned communities)	2008-2015

	(b) support developing countries to build their capacity in research and development in traditional medicine	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public-private partnerships)	2008-2015
	(c) promote international cooperation and the ethical conduct of research	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(d) support South-South cooperation in information exchange and research activities	**Governments; WHO**; other international intergovernmental organizations; regional organizations; other relevant stakeholders	2008-2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 2. Promoting research and development			
(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	a) promote cooperation between private and public sectors on research and development	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	**Governments**; **regional organizations; WHO** (technical assistance); other relevant stakeholders	2008-2015
	(c) support governments in establishing health-related innovation in developing countries	**Governments**; **regional organizations**; **WHO** (technical assistance); other relevant stakeholders	2008-2015
(2.2) promoting upstream research and product development in developing countries	(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools	**Governments; WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	2008-2015
	(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	(e) support early-stage drug research and development in developing countries	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health- related industries, academia, international and national research institutions; donor agencies; development partners; nongovernmental organizations)	2008-2015
	(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health- related industries; academia; development partners; charitable foundations; public-private partnerships; nongovernmental organizations)	2008-2015

	(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries	**Governments**; WHO; other international intergovernmental organizations, other relevant stakeholders (including; academia, international and national research institution; relevant health-related industries and development partners)	
(2.3) improving cooperation, participation and coordination of health and biomedical research and development	(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities	**Governments; WHO**; other relevant stakeholders	2008-2015
	(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including *inter alia*, an essential health and biomedical R&D treaty	**Interested Governments;** [WHO]; **other relevant stakeholders (including nongovernmental organizations)**	2008-2010

	(d) support active participation of developing countries in building technological capacity	**Governments; WHO**; other relevant stakeholders	2008-2015
	(e) promote the active participation of developing countries in the innovation process	**Governments; WHO;** other relevant stakeholders	2008-2015
(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries	(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centres, especially in developing countries	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	2008-2015
	(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia and research institutions)	2008-2015

	(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries	**Governments; WHO**; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries)	2008-2015
	(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)	2008-2015
	(e) consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	

2.5 establishing and strengthening national and regional coordinating bodies on research and development	(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	2008-2015
	(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	2008-2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 3. Building and improving innovative capacity			
(3.1) building capacity of developing countries to meet research and development needs for health products	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008-2015
	(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	2008-2015

	(c) strengthen health surveillance and information systems	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008-2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(a) establish and strengthen regulatory capacity in developing countries	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies)	2008-2015
	(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including development partners; international and national research institutions)	2008-2015
	(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	**Governments; WHO**; other international intergovernmental organizations (including International Organization for Migration and ILO); other relevant stakeholders	2008-2015

	(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	**Governments**	2008-2015
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	**Governments;** WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health related industries and developmental partners)	2008-2015

	(b) intensify North-South and South-South partnerships and networks to support capacity building	Governments; WHO; other International intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)	2008-2015
	(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries	**Governments;** WHO; other relevant stakeholders (including academia and research institutions)	2008-2015
(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	2008-2015

	(b) encourage and promote policies on innovation in the field of traditional medicine	**Governments;** WHO**;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, **concerned communities**)	
	(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)	
	(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; relevant health-related industries; concerned communities)	

	(e) promote South-South collaboration in traditional medicine	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions, regional bodies, academia)	2008-2015
	(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)	2008-2015
(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation	(a) encourage the establishment of award schemes for health-related innovation	**Governments**; [WHO]/[~~WHO~~]/[**WHO]**; other international intergovernmental organizations [(including WIPO)]; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	

	(b) encourage recognition of innovation for purposes of career advancement for health researchers	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 4. Transfer of technology			
(4.1) promoting transfer of technology and the production of health products in developing countries	a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries	**Governments**; WHO; other international intergovernmental organizations (including WTO, UNCTAD, UNIDO, WIPO); other relevant stakeholders (including; international and national research institutions; relevant health-related industries)	
	(b) promote transfer of technology and production of health products in developing countries through investment and capacity building	**Governments; WHO;** other intergovernmental organizations; other relevant stakeholders (including **health-related industries**)	

	(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including **relevant health-related industries;** academia; nongovernmental organizations; development partners; charitable foundations)	2008-2015
(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development	(a) encourage North-South and South-South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry	**Governments**; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health- related industries; international and national research institutions; academia; nongovernmental organizations; development partners)	2008-2015

	(b) facilitate local and regional networks for collaboration on research and development and transfer of technology	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health- related industries, national research institutions, academia; nongovernmental organizations)	2008-2015
	(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	2008-2015
	(d) promote the necessary training to increase absorptive capacity for technology transfer	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including research institutions)	2008-2015

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)	
	(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health	**Governments;** WHO**;** other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	

Elements and sub-elements	Specific actions	Stakeholder(s)*	
Element 5. Application and Management of intellectual property to contribute to innovation and promote public health			
(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries	(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries	[**Governments; WHO;** other international intergovernmental organizations (including **WIPO, WTO, UNCTAD**); other relevant stakeholders (including international and national research institutions and development partners)] [**Governments;** WHO**;** other international intergovernmental organizations (including WIPO**,** WTO**,** UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]	

	(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries	**Governments; WHO**/[WHO]**;** other international intergovernmental organizations (including [**WIPO]/[**WIPO]**, [WTO]**/[WTO]**, UNCTAD;** other relevant stakeholders (including international and national research institutions and development partners)	
	(c) Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.	[Governments]/[**Governments**]; [WHO]/[**WHO**]; other international intergovernmental organizations (including [WIPO]/[**WIPO**], [WTO]/[**WTO**], [UNCTAD]; other relevant stakeholders (including international and national research institutions and development partners)]	

	(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs	**Governments**; WHO; Other international intergovernmental organizations; Other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health- related industries)	
	(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement	Governments; [**WHO]/**[WHO]**;** other international intergovernmental organizations (including [WIPO]/[**WIPO]**, [WTO]/**[WTO],** [UNCTAD]/**[UNCTAD]**); other relevant stakeholders (including international and national research institutions and development partners)	

	(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries	**Governments;** [WHO; other international intergovernmental organizations; other relevant stakeholders (including] **concerned communities**)	
	(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs	**Governments**	
	(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries	**Governments;** WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)	

(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products	(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments;** WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	

	(b)Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States	**Governments;** [WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]	
	(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003	**Governments**	

	d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments**	
	(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge	**Governments;** WHO**;** other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including **concerned communities**)	

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	**[Governments**; [WHO]/[**WHO**]; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 6. Improving delivery and access			
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	(a) invest in developing health-delivery infrastructure and encourage financing of health products		

	(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016[1]	**Governments;** WHO**;** other international intergovernmental organizations (including WTO); other relevant stakeholders	
	(c) prioritize health care in national agendas	**Governments**	2008-2015
	(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines	**Governments; WHO**	

[1] In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

	(e) increase investment in human resource development in the health sector	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners; nongovernmental organizations; charitable foundations)	2008-2015
	(f) develop effective country poverty reduction strategies that contain clear health objectives	**Governments;** other relevant stakeholders (including development partners)	2008-2015
	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies and development partners)	

	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	
	(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products	**Governments; WHO;** other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners	2008-2015
	(d) strengthen the WHO pre-qualification programme	Governments; **WHO**, other international intergovernmental organizations; other relevant stakeholders (including development partners)	

	(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	**Governments;** [**WHO**]/[WHO]; other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	
	(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies)	
	h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval	**Governments, WHO,** other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	

(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs	(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or "Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement	**Governments**	
	(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements	**Governments;** WHO; other international intergovernmental organizations (including WTO and WIPO); other relevant stakeholders	
	(c) consider where appropriate, *inter alia*, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access	**Governments**	

	(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including **relevant health-related industries)**	
	(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing	**Governments**	
	(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on TRIPS, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	**Governments**	

	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	**Governments;** WHO other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 7. Promoting sustainable financing mechanisms			
(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases		

	(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, international and national research institutions, academia, private sector and relevant health-related industries)	
	(c) create a database of possible sources of financing for R&D	**Governments; WHO;** other relevant stakeholders	
(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices	(a) document and disseminate best practices in public-private and product development partnerships	Governments; **WHO;** other relevant stakeholders (including research institutions, public-private and product development partnerships)	2008-2015

	(b) develop tools to periodically assess performance of public-private and product development partnerships	Governments; **WHO;** other relevant stakeholders (including research institutions; public-private and product development partnerships; charitable foundations)	2008-2009
	(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	2008-2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 8. Establishing monitoring and reporting systems			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; **WHO**	From 2009

	(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries	Governments; **WHO**	[From 2009]
	(c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; **WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	
	(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices	**Governments; WHO;** other international intergovernmental organizations (including WIPO and WTO); Other relevant stakeholders	

	(e) monitor and report on investment in research and development to address the health needs of developing countries	Governments; **WHO;** other relevant stakeholders	

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CHAPTER 3

RETHINKING GLOBAL HEALTH: A BINDING CONVENTION FOR R&D FOR PHARMACEUTICAL PRODUCTS[1]

I. INTRODUCTION

This chapter 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 section 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, 66 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 of the budget?

Issues such as public-private partnerships, the management of the H1N1 virus pandemic, the financial crisis, the reform of the

[1] This chapter was initially published as a South Centre Research Paper, in collaboration with Xavier Seuba, University Pompeu Fabra, Barcelona.

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 66 years of existence of the Agency.

II. 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.[2] 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.[3] 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,[4] and which

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

[3] T. Parran, "Charter for world health", *Public Health Reports*, vol. 61, no. 35, (1946) p. 1265.

[4] W. R. Sharp, "The new World Health Organization", *The American Journal of International Law*, vol. 41, no. 3, (1947) p. 509.

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.

III. ACCESS TO HEALTH AS CITIZENS' RIGHT

III.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.[5]

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.[6] Regarding the right to health as a social right, the

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

[6] 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

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.

III.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.

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

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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.

rights by recognizing a comprehensive concept of health.[7] 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,"[8] 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.

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[7] 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.

[8] Article 25 of the *Universal Declaration of Human Rights.*

III.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.[9] 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,[10] who stressed that human rights are inherently transversal in nature in the Organization's work.[11] 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"[12] that was promoted precisely in Alma-Ata, and the **Ottawa Declaration**, which was adopted in the wake of the First

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[9] 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.

[10] 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 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.

[11] Ibid. pp. 78-79.

[12] 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, p. 16.

International Conference on Health Promotion[13] 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,"[14] and understood that several of its programmes had been the instrument through which it had contributed to implement Article 12 of the ICESCR,[15] 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,[16] at which time the interaction between health and human rights was emphasized and promoted beyond the Organization itself.[17] 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.

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[13] *Organización Mundial de la Salud, Carta de Ottawa para la promoción de la Salud,* (21 November 1986), WHO/HPR/HEP/95.1.
[14] *Organización Mundial de la Salud*, *Contribución de la Organización Mundial de la Salud a la Conferencia Mundial de Derechos Humanos*, op. cit., pp. 10 ff.).
[15] *Ibid*. pp. 17-21.
[16] World Health Organization, Executive Board, *A Corporate Strategy for the WHO Secretariat*, (10 December 1999), EB105.3, p. 9.
[17] *See* G. H. Brundtland, "Fifty years of synergy between health and human rights", *Health and Human Rights: An International Journal,* vol. 3, no. 2, (1998) p. 24.

IV. 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[18] – 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.[19] The analysis of the overall work programmes shows that until the 1960s, WHO focused its activities in technical, regulatory and administrative questions,[20] at a time marked by caution and stability.[21] 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.[22]

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[18] Art. 1 of the WHO Constitution, in *Documentos Básicos*, WHO: Geneva, 45th Edition, (2005) p. 1.
[19] W. R. Sharp, "The new World Health Organization", *The American Journal of International Law*, vol. 41, no. 3, (1947) p. 521.
[20] WHO, *Los diez primeros años de la Organización Mundial de la Salud*. (Geneva, WHO, 1958) pp. 113-115.
[21] G. Walt, "WHO under stress: implications for health policy", *Health Policy*, vol. 24, no. 2, (May, 1993) pp. 133-134.
[22] Y. Beigbedier, *L'Organisation Mondiale de la Santé*, (Paris, PUF, 1997) p. 18.

V. 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.[23] An essential distinction is that concerning the internal legislative competence and external regulatory powers.[24]As far as external regulatory competence is 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 recommendations[25] or binding decisions,[26] 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.[27] Moreover, specific issues have received more specific

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[23] 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.

[24] 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)].

[25] Article 23 of the Constitution of the World Health Organization.

[26] Article 21 of the Constitution of the World Health Organization.

[27] Kickbusch, I., "The Contribution of the World Health Organization to a new public health and health promotion", *American Journal of Public Health*, vol. 93, no. 3, (2003) pp. 383-388. For example, this is the case of the concept of primary health care.

attention from codes of conduct or guidelines,[28] while others characterized by their technical complexity have been the subject of model lists, codes of conduct and technical standards.[29]

One of the responsibilities of WHO is to propose conventions, regulations and recommendations regarding international health issues,[30] as well as the regulatory activity which is considered to be part of its work as director of international health.[31] The World Health Assembly can promote international conventions or agreements,[32] a competence which it has exercised only in a substantive area and only recently.[33] 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.[34] Finally, the Assembly may also make recommendations to Members,[35] a formula that has been favoured since it is understood that they have the advantage of being flexible and subjected to little formality.[36]

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

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[28] 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*.

[29] In this sense, pharmaceutical regulation is a paradigmatic case.

[30] Article 2(k) of the Constitution of the World Health Organization.

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

[32] Article 19 of the Constitution of the World Health Organization.

[33] See below section on the Convention on tobacco control.

[34] Article 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.

[35] Article 23 of the Constitution of the World Health Organization.

[36] OMS, *El segundo decenio de la Organización Mundial de la Salud,* (Geneva, WHO, 1968) pp. 335-351.

to take on more of a health care than a legal role.[37] 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 about the Organization's involvement in promoting the treaty on innovation and health.[38] 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.

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[37] D. Fidler, "The future of the World Health Organization: what role for international law?", *Vanderbilt Journal of Transnational Law,* vol. 31, no. 5, (1998) pp. 1079-1126.

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

VI. 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)[39], 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"[40] 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."[41]

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 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

[39] World Health Organization, Global strategy and plan of action on public health, innovation and intellectual property. WHA Resolution 61.21, (May 24, 2008).
[40] World Health Organization, CIPIH Report (2006), p. 115.
[41] World Health Organization, CIPIH Report (2006), p. 91.

in poor countries where as much as 50 per cent of the population lacks access.[42]

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.[43]

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".[44]

There is a need for new mechanisms[45] 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.

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[42] WHO and HAI, Measuring medicine prices, availability, affordability and price components, second edition (2008), p. 1.
[43] 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.
[44] World Health Organization, CIPIH Report (2006) p. 177.
[45] WHA GSPOA point 13.

VI.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.[46]
- 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".[47]
- 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 GSPOA[48] 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

[46] World Health Organization (2008), GSPOA WHA Resolution 61.21: "The context" point 3.
[47] World Health Organization (2008), GSPOA WHA Resolution 61.21: "The context" point 7.
[48] World Health Organization (2008), GSPOA WHA Resolution 61.21: "The Plan of Action 2.3.C)" page 27.

CEWG announced that "CEWG intends to recommend that formal intergovernmental negotiations begin for a binding global instrument for R&D and innovation for health".

VII. 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;
(iv) to coordinate public R&D; and
(v) to promote the research capacity of developing countries.

VIII. 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.
- 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 of medicines. 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.

IX. 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…"[49]

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.

IX.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.[50]
- 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).

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[49] World Health Organization, CIPIH Report, (2006), Geneva, page 209.

[50] Clinical trials are research studies that test how well new medical approaches work in people. Each study should answer scientific questions and try 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 to or paid by the pharmaceutical industry.

- 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 health[51] and right "to enjoy the benefits of scientific progress and its applications"[52]

X. 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).

XI. 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.

[51] Article 12 of the International Covenant on Economic, Social and Cultural Rights.
[52] Article 15.1(b) of the International Covenant on Economic, Social and Cultural Rights.

- 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)".

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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.[53] In May 2003, and after three years of negotiations and six years of work,[54] the World Health Assembly unanimously adopted[55] the WHO Framework Convention on Tobacco Control (FCTC).[56] Thus, for the first time the WHO exercised the prerogative to adopt treaties and make international agreements on a substantive area,[57] and gave a global legal response to an equally global health threat.[58]

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.[59] It therefore sets up the framework to allow a

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[53] 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.

[54] 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.

[55] 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.

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

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

[58] L. F. De Seixas, "The framework convention on tobacco control", *Bulletin of the World Health Organization*, vol. 80, no. 12, (2002) p. 924.

[59] Future issues to be addressed could be those regarding promotion and sponsorship, advertising, illicit trade and responsibility. N. Devillier, "La

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."[60] 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 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."[61] 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.

Convention-cadre pour la lutte anti-tabac", *Revue Belge du Droit International*, no. 1-2, (2005) p. 722.

[60] Article3 of the WHO Framework Convention on tobacco control, op.cit.

[61] Article3 23.5 of the WHO Framework Convention on Tobacco Control, op.cit.

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 per cent 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

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 25 May 1951 by the Fourth World Health Assembly, and became Regulation No. 2 of the WHO, which took effect on 1st October 1952.

Although the International Sanitary Regulations were revised in 1969, 1973 and 1981, they proved to be insufficient and scientifically obsolete in the 1990s.[62]States often do not meet the obligations under the agreement, both in regard to the maximum adoptable measure[63] as well as to the periodic submission of reports,[64] in face of which the WHO's accountability mechanisms were weak[65]. 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.[66] 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.

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[62] L. Gostin, "International infectious disease law. revision of the world health organization's international health regulations", *Journal of the American Medical Association*, vol. 291, no. 21, (2004), p. 2627.

[63] 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.

[64] P. Dorolle, "Old plagues in the jet age: international aspects of present and future control of communicable diseases", *WHO Chronicle*, no. 23, (1969), p. 109.

[65] B. Velimirovic, "Do we still need international health regulations?", *Journal of Infectious Diseases,* no. 133, (1976), p.478.

[66] D. Fidler, "The future of the World Health Organization: what role for international law?", *Vanderbilt Journal of Transnational Law,* vol. 31, no. 5, (1998), pp. 1079-1126.

The Health Regulations intend to achieve maximum security in face of the international spread of diseases[67] 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.[68] 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.

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.[69] 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,[70] in

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[67] 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.

[68] 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.

[69] 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.

[70] According to Article 1 of the Regulations, a "public health emergency of international concern" represents an extraordinary event which, in accordance with

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 emergency[71] 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.[72] 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,[73] has changed currently to allow measures aimed at providing a higher level of security to be applied[74]. 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.

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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.

[71] 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".

[72] 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.

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

[74] 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.[75] 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.[76] The Council argued that the legal

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[75] 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.

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

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.[77] Thus, in May 1981, the World Health Assembly, with all but one vote against, adopted the International Code of Marketing of Breast-milk Substitutes.[78]

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.[79]

[77] World Health Organization, *International Code of Marketing of Breast-Milk Substitutes*, (Geneva, WHO, 1981) p. 25.
[78] World Health Organization, World Health Assembly, *WHA Resolution 34.22,* 21/5/1981, WHA34.22.
[79] Y. Beigbedier, *L'Organisation Mondiale de la Santé*, op. cit. p. 51.

CHAPTER 4

PUBLIC-PRIVATE PARTNERSHIPS IN GLOBAL HEALTH: PUTTING BUSINESS BEFORE HEALTH?[1]

I. INTRODUCTION

Public and private sector interaction in health has always existed at the national level. In the United Nations (UN) system, public-private partnerships (PPPs) started at the end of the 1990s with the reform of the UN system launched by Kofi Annan. In response to Resolution 55/215 "Towards global partnerships"[2] the United Nations General Assembly asked the Secretary-General "to seek the views of all Members States on ways and means to enhance cooperation between the United Nations and all relevant partners, in particular the private sector, on how to enhance cooperation with the United Nations". The introduction of the report of the Secretary-General states that " [o]ver the past decade (…) there has been an increase in the number of non-state actors interacting with the United Nations (…) such as through consultative status with governing bodies, procurement contracts, and philanthropic-based fund raising activities"[3] and reiterates later on that "[t]he number, diversity and influence of non-state actors has grown dramatically over the past 10 years" and concludes that "[s]pecial efforts are needed to ensure that

[1] This chapter is a part of the research project funded by SNIS (Swiss Network for International Studies) grant (Millennium Development Goal 8 – target 8-E, 2001 – 2013), undertaken by the EPFL (Ecole Polytechnique Féderale de Lausanne, Lausanne, Switzerland and the South Centre, Geneva, Switzerland. The author thanks Carlos Correa, Dominique Foray, Viviana Muñoz, Fabiana Visentin, Jean-François Alesandrini, for their valuable comments and inputs; however, the author is the sole responsible for the ideas expressed herein.

[2] UN General Assembly, Fifty-fifth session Agenda item 173, doc. A/res/55/215, 6 March 2001.

[3] UN General Assembly, Fifty-fifth session Item 50 of the provisional agenda: Cooperation between the United Nations and all relevant partners, in particular the private sector, Report of the Secretary-General, 28 August 2001.

cooperation with business community and other non-state actors adequately reflects the Organization's membership and pays particular attention to the needs and priorities of developing countries."[4]

Until 1998 the World Health Organization (WHO) remained relatively unaffected by the influence of the private sector. Member States insisted that the regular, multilateral public budget should be at least 51 per cent of the Organization's budget and that all the normative programmes should be completely financed by the regular budget coming from regular contributions by Member States.

In her first address to the World Health Assembly (WHA), Gro Harlem Brundtland, Director-General of the WHO from 1998 to 2003, stated that in order to achieve the mandate entrusted to her: "We must reach out to the private sector (…) The private sector has an important role to play both in technology development and the provision of services. We need open and constructive relations with private sector (…) I invite industry to join in a dialogue on the key issues facing us".[5]

During the five years of the Brundtland administration at the WHO, PPPs and PDPs (Product Development Partnerships) increased in many of the areas of work of the WHO and in other public health initiatives conducted at the international level. Partnerships mostly related to innovation and access to medicines in many cases created their own "advisory bodies". These "advisory bodies" may interfere in some cases with the governing bodies of the Organization: the Executive Board and the World Health Assembly.

In the context of WHO, the Special Programme for Research and Training in Tropical Diseases (TDR) can be considered as a precursor of the PDPs. The TDR was created by WHO in 1975, co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP) and the World Bank. The aim of the programme was to promote and intensify research on tropical diseases, taking into consideration that such activities should be carried out

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[4] Richter, J., "Public-private Partnerships for Health: A trend with no alternatives?" *Development* (2004) 47(2), 43-48. doi:10.1057/palgrave.development.1100043.

[5] Gro Harlem Brundtland speech to the Fifty-first World Health Assembly, doc. A51/DIV/6, 13 May 1998, pp. 4-5.

mainly in endemic countries, define the research priorities, extend cooperation with national institutions and other governmental and non-governmental organizations in regard to the coordination of research in this field, and mobilize extra-budgetary resources for scaling up these objectives.[6] The TDR was set up mainly as a partnership between public donors, co-sponsors and endemic country governments represented in an independent board-type structure. Its research priorities were defined by a scientific committee of experts which oversaw the selection of research projects for funding and evaluated progress of various scientific working groups and technical staff, with representation of endemic countries.[7]

A study suggested that: "TDR-supported research contributed to the development of a number of important new products, including demonstrating the effectiveness in humans of Merck's veterinary drug ivermectin for the treatment of onchocerciasis (river blindness)."[8]

The relationship of the TDR with the pharmaceutical industry has been referred to as friendly: "TDR has seen it useful to develop friendly relations with the pharmaceutical industry, and to avoid taking positions that would alienate companies and undermine collaborations. This has, in some cases, extended to views on intellectual property right issues; and TDR has often aligned itself with conventional industry views." [9]

Some of TDR's practices during the 1970s and 1980s established a precedent that the PDPs would later follow; for example, TDR set up an international network of academic centres to screen compounds from pharmaceutical companies for usefulness against its target tropical diseases. TDR was certainly a precursor to PDPs, and perhaps a

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[6] WHA 27.52. In May 1974, The WHA adopted Resolution WHA 27.52, a brief document that called for intensification of research on Tropical Diseases.

[7] See UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, *Making a Difference – 30 Years of Research and Capacity Building in Tropical Diseases* (2007).

[8] S. Moon, "Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health", *GHG*, V. II, N. 2 (F2008/S2009).

[9] J. Love, Implementation of the Workplan for the Period of 2008-2010 Endorsed by the Human Rights Council in Resolution 9/3, A/HRC/12/WG.2/TF/CRP.4/Rev.1, 18 June 2009, http://keionline.org/sites/default/files/A-HRC-12-WG2-TF-CRP4-Rev1.pdf.

precursor of the problems and lack of transparency that we are seeing today.

II. SOME CONCEPTS, DEFINITIONS AND VISION

II.1 PPPs

As Judith Richter observed, a global definition of PPPs does not exist, neither is there a shared vision of the new partnerships. "The first question that arises in this debate, is what is understood by the term public-private partnership. Even though many UN leaders have been promoting closer interactions with the commercial sector and wealthy business figures under the partnership label for years, there is in fact no single agreed-upon definition within the UN system."[10]

It should be noted that the report of the UN Secretary-General on "Enhanced cooperation between the United Nations and all relevant partners, in particular the private sector" (August 2003) makes the following definition: "Partnerships are commonly defined as voluntary and collaborative relationships between various parties, both State and non-State, in which all participants agree to work together to achieve a common purpose or undertake a specific task and to share risks, responsibilities, resources, competencies and benefits."[11]

II.2 Views of the UN Global Compact

The UN Global Compact is a strategic policy initiative with private sector corporations that are committed to aligning their operations and strategies with universally accepted principles in the areas of human rights, labour, environment and anti-corruption. "The Global Compact asks companies to embrace universal principles and to partner with the

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[10] J. Richter, op. cit., pp. 42-43.

[11] Quoted by Richter, J., "Public-Private Partnerships and International Health Policy-making", ISBN 951-724-464-9. Available from http://formin.finland.fi/public/download.aspx?ID=12360&GUID=%7B3556FE5F-6CBC-4000-86F3-99EBFD2778FC%7D, p. 6.

United Nations. It has grown to become a critical platform for the UN to engage effectively with enlightened global business."[12][13]

According to a report commissioned by the UN Global Compact "there has been a tendency, within the United Nations system and elsewhere, to use the concept of partnership very loosely to refer to almost any kind of relationship."[14]

The UN Global Compact Initiative asks companies to embrace, support and enact, within their sphere of influence, 10 principles in the areas of human rights, labour standards, the environment and anti-corruption (see Box 1). The WHO however, does not participate in the UN Global Compact.

As one of the UN agencies with the largest number of PPPs, it is paradoxical that the WHO is not one of the agencies that signed into this initiative and none of the 10 principles on which the "core values" of the initiative are based refers to Public Health or to the right to access to health care.

II.3 PPPs in Public Health

The most cited definition of PPPs in the area of public health comes from Kent Buse and Gill Walt[15]: "a collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an

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[12] UN Secretary-General Ban Ki-moon, www.unglobalcompact.org.

[13] The UN Global Compact is participated in by the following core UN agencies:
Office of the High Commissioner for Human Rights
United Nations Environment Programme
International Labour Organization
United Nations Development Programme
United Nations Industrial Development Organization
United Nations Office on Drugs and Crime
United Nations Entity for Gender Equality and the Empowerment of Women
See: http://www.unglobalcompact.org/AboutTheGC/.

[14] Quoted by Richter, J., op. cit., p. 44.

[15] WHO does not have an official definition of Health PPPs.

intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour"[16].

Box 1
Principles of the UN Global Compact Initiative[17]

Human Rights

- Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and
- Principle 2: make sure that they are not complicit in human rights abuses.

Labour

- Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
- Principle 4: the elimination of all forms of forced and compulsory labour;
- Principle 5: the effective abolition of child labour; and
- Principle 6: the elimination of discrimination in respect of employment and occupation.

Environment

- Principle 7: Businesses should support a precautionary approach to environmental challenges;
- Principle 8: undertake initiatives to promote greater environmental responsibility; and
- Principle 9: encourage the development and diffusion of environmentally friendly technologies.

Anti-Corruption

- Principle 10: Businesses should work against corruption in all its forms, including extortion and bribery.

[16] Buse, K. and G. Walt, "Global Public Private Partnerships for Health: Part I- a new development in health?" (January 2000), p. 4. Available from http://www.scielosp.org/scielo.php?pid=S0042-96862000000400019&script=sci_arttext.
[17] http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html.

For Buse and Walt the collaboration should be between "at least three parties", because many of the PPPs involved in public health, such as the Global Alliance for Vaccines and Immunizations (GAVI), the Global Alliance for Improved Nutrition (GAIN) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, include representatives of nongovernmental organizations (NGOs). This "at least three parties" definition was always defended by the WHO Director-General Gro Harlem Brundtland: "In a world filled with complex health problems, WHO cannot solve them alone. Governments cannot solve them alone. Nongovernmental organizations, the private sector and Foundations cannot solve them alone (...) Whether we like it or not, we are dependent on the partners (…) to bridge the gap and achieve health for all."[18]

According to J. Richter[19] partnerships in public health include interaction such as:

- fundraising – requesting, accepting or channelling corporate donations in cash or in kind;
- negotiations or public tenders for lower product prices (for example, of pharmaceuticals and vaccines);
- research collaborations;
- negotiations, consultations and discussions with corporations and their business associations about public health matters;
- co-regulatory arrangements to agree and implement 'voluntary' (that is, legally non-binding) codes of conduct;
- corporate social responsibility projects (many of which are, in fact, cause-related marketing – or other strategic sponsorship projects); and
- contracting out of public services, such as water supplies.

Brundtland's invitation to the private sector was greatly influenced by what Buse and Walt called "the growing disillusionment

[18] Brundtland, G.H., "Address by Dr Gro Harlem Brundtland, Director-General, to the Fifty-fifth World Health Assembly, Geneva, Monday, 13 May 2002".
[19] Richter, J., "Public-Private Partnerships and International Health Policy-making", ISBN 951-724-464-9. Available from http://formin.finland.fi/public/download.aspx?ID=12360&GUID=%7B3556FE5F-6CBC-4000-86F3-99EBFD2778FC%7D, p. 7.

with UN and its agencies. Concerns about the effectiveness of UN, including increasing evidence of overlapping mandates and interagency competition, led directly towards the establishment of partnerships to deal with specific and limited issues."[20]

The lack of credibility of the WHO during the final years of the administration of Director-General Nakajima (1988 to 1998) and its financial problems due to the developed countries' refusal to increase the Organization's regular budget led to the Brundtland administration's call for the private sector to help in solving these two problems. This involved bringing into the WHO senior people who had worked for transnational pharmaceutical companies.

Brundtland's call to the private sector was very "productive"; upon her arrival the 1998-1999 WHO Programme Budget was US$1.8 billion and in 2003, by the end of her term, the WHO Programme Budget went up to US$2.8 billion, all from voluntary (public and private) contributions. This trend continued and increased during successive WHO administrations. By 2012-2013, the WHO Programme Budget had more than 80 per cent – US$3.9 billion – coming from voluntary contributions and not from regular quotas from Member States. PPPs in health have been promoted in such a way that the WHO itself has become a big public/private partnership. The WHO, in this sense, has become a public multilateral agency that is primarily funded by the private sector and/or voluntary specified contributions.

Thus, in the view of Buse and Walt there has been an ''honest recognition by the public sector of the unique, unrivalled monopoly of the pharmaceutical industry in drug and vaccine development: They own the ball. If you want to play, you must play with them".[21] However according to G-Finder 2012 the public sector is still first in terms of research and development (R&D) for neglected diseases and 64 per cent of PDP funding comes from the public sector. But, if the industry "owns the ball" it would be important to ensure that there is a referee to supervise the game.

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[20] Buse, K. and G. Walt, "Global Public Private Partnerships for Health: Part I- a new development in health?" (January 2000), p. 4. Available from http://www.scielosp.org/scielo.php?pid=S0042-96862000000400019&script=sci_arttext.
[21] Ibid, p. 5.

According to Cattaui, economic globalization may also have provided impetus to the private sector to enter into partnerships with the UN: ''Business believes that the rules of the game for the market economy, previously laid down almost exclusively by national governments, must be applied globally if they are to be effective. For that global framework of rules, business looks to the United Nations and its agencies''[22]. The problem with this type of analysis is what would be the role of national governments. A key aspect of the debate over the WHO reform launched by the current Director-General Margaret Chan is what the role of the private pharmaceutical industry will be, as major shareholders. Most of the voluntary contributions to the WHO budget are specified and in this sense donors are fixing the priorities of the Organization.

The Global Forum for Health Research[23] defines a partnership as ''... a group of allies sharing the goals, efforts and rewards of a joint undertaking''. The allies, however, may have different levels of knowledge, different interests, and different levels of influence in terms of health policies. And not only different points of view but at times contradictory points of view. Commercial interests do not necessarily coincide with public interests and combining these two sometimes contradictory or incompatible interests is not always easy. Which comes first, business or health?

As Buse and Walt state "Allies may use different terms to describe themselves: as partners in a partnership to one audience and as donors to another. The International AIDS Vaccine Initiative describes itself as having just five partners, but has an additional 17 organizational donors (not including many individuals). The role of any one partner may change over time, from active to passive. Partners may be defined by organization or individual, and might also be involved at different levels within the partnership. For example, although the corporate sector might not be involved in the governing bodies it may act as an integral partner at a task force, expert committee or other level"[24].

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[22] Cattaui, M. S., "Business and the UN: common ground", *ICC Business World* (Paris, 3 August 1998).
[23] Global Forum for Health Research, "The 10/90 Report on Health Research 2000" (Geneva, The Global Forum for Health Research, 2000, ISBN 2-940286-01-9).
[24] Buse, K. and G. Walt, op. cit., p. 3.

This is where the debate on WHO reform has come over the last two years: what will be the role of new funders in the WHO governing bodies? Since the Brundtland administration, many private partners are part of task forces, expert committees and advisory groups; what is now at stake is what will be their role in the Executive Board and the World Health Assembly as they now provide 80 per cent of the Organization's budget.

II.4 Different Types of PPPs[25]

The following types of PPPs may be distinguished:

- Product-based PPPs consist primarily of drug donation programmes, for example, AIDS (acquired immunodeficiency syndrome) medicines. Drug donation programmes are generally established after the discovery that an existing drug (for animals or humans) is found to be effective in the treatment of some condition for which there is limited effective demand, due to lack of willingness and ability to pay, as was seen with AmBisome for the treatment of leishmaniasis. These types of partnerships are usually initiated by the private sector and the objective is to market their ethical concerns and social responsibility. This objective is not always guaranteed, as medicines donation partnerships have been subject to controversy, and seen sometimes as a market entry strategy or a mechanism for dependency-creation.
- Product-development PPPs differ from product-donation partnerships in a number of respects. They are not limited to specific countries and they are generally initiated by the public sector. Product-development PPPs usually require the public sector to assume a number of risks associated with product discovery, development and/or commercialization for which usually the government provides some subsidies.

[25] Buse, K. and G. Walt, "Global Public Private Partnerships for Health: Part II – What are the health issues for global governance?", *WHO Bulletin* 78 (5), 2000. Available from http://www.scielosp.org/scielo.php?pid=S0042-96862000000500015&script=sci_arttext.

Pharmaceutical Companies may engage in product-development partnerships to obtain a subsidy for research or to pursue their own longer-term interests, in the emerging economies, for instance.

- The issues-based PPPs are a more diverse group. Some have arisen to overcome market failures, such as the Malaria Vaccine Initiative, the Roll Back Malaria Global Partnership or the Stop TB Initiative.

Trying to classify the different types of PPPs is not very helpful if one takes into account that, as with PDPs, within each category the PPPs themselves can be completely different. Common standards do not exist.

For example, in many cases agreements entered into with PPPs are confidential, or as it is the case with the TDR in the WHO, there is no clear and transparent policy on how the intellectual property aspect of the products will be dealt with once developed by the PPP. Should they be patented or not? And if they should be patented, by whom? Should the PPP seek a patent? Or should a private partner of the PPP be allowed to apply for patents as sometimes happens in the case of TDR at the WHO.

All of the foregoing brings us to ask whether the vision and the objectives of PPPs in the health sector are clear and if they are the most appropriate way to address the current challenges of the health sector.

II.5 PDPs

"Product Development Partnerships (PDPs) are one variant of public private partnerships focused on improving health in developing countries. PDPs are focused on product discovery and development, as opposed to partnerships focused exclusively on delivery of existing technologies (so called "access partnerships") or health service delivery."[26]

[26] Cheri Grace, "Product Development Partnerships (PDPs): Lessons from PDPs established to develop new health technologies for neglected diseases" (London, HDRC DFID, 2010).

Over the last decade the number of PDPs increased significantly in the area of medicines and diagnostics. From a research project funded by the Swiss Network for International Studies (SNIS) implemented by the École Polytechnique Fédérale de Lausanne (EPFL) and the South Centre, 23 PDPs have been identified.[27]

The figures presented by G-FINDER 2012 indicate that there is a relatively important investment dedicated to PDPs in the order of US$3,000 million (2011). However, these figures should be taken with caution as they are usually taken from pharmaceutical industry reports which are known for the lack of transparency in relation to the cost of R&D and there are difficulties for verifying the figures reported.

In relation to the cost of R&D reported by industry an article in the journal BioSocieties (Feb. 2011), a publication of the London School of Economics (LSE), argued that the real cost of R&D is, in fact, a fraction of the commonly cited estimates. According to the authors, the average cost of R&D for developing a medicine varies between US$13 million and US$204 million depending on the type of product. The authors estimated an average cost of US$43.4 million for the R&D of every new drug. They concluded that: "this is very far from the US$802 million or US$1.3 billion claimed by the industry".[28]

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[27] The list of PDPs includes, in alphabetical order: AERAS, Consortium for Parasitic Drug Development (CPDD), Contraceptive Research and Development (CONRAD), Dengue Vaccine Initiative (DVI), Drugs for Neglected Diseases (DNDi), European Vaccine Initiative (EVI), Foundation for Innovative New Diagnostics (FIND), Global Alliance for TB Drug Development (TB Alliance), HIV Vaccine Trials Network (HVTN), Infectious Disease Research Institute (IDRI), Innovative Vector Control Consortium (IVCC), International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), International Vaccine Institute (IVI), Malaria Vaccine Initiative (MVI), Medicines for Malaria Venture (MMV), Meningitis Vaccine Project (MVP),Microbicides Development Programme (MDP), One World Health (iOWH), Pediatric Dengue Vaccine Initiative (PDVI), Sabin PDP, South African AIDS Vaccine Initiative (SAAVI), and Tuberculosis Vaccine Initiative (TVI).

[28] Donald W. Light, and Rebecca Warburton, "Demythologizing the high costs of pharmaceutical research", *BioSocietie*s, a publication of the LSE (Feb. 2011). BioSocieties advance online publication, 7 February 2011; doi:10.1057/biosoc.2010.40.

According to DNDi[29] the cost of R&D for a new product ranges between US$40 million to US$50 million.[30]

If the figures claimed by the "research based industry", can be up to 20 times more than the real cost, as Donald W. Light and Rebecca Warburton have pointed out, it is evident then that the 2012 G-FINDER figures must be considered with care, although they may be used as an indicator, since unfortunately, it is practically the only consolidated information on the current PDPs.

"In 2011, total Industry or PDP's reported funding for neglected disease R&D was $3,045m. (…) The three 'top tier' diseases – HIV/AIDS, malaria and tuberculosis (TB) – again received approximately one-third to one-fifth of total global neglected disease R&D funding each, with HIV/AIDS receiving 33.8 per cent, malaria 18.4 per cent and TB 17.3 per cent."[31]

According to information from G-FINDER 2012, investment in R&D for neglected diseases covers:

- 31 neglected diseases
- 134 product areas for these diseases, including drugs, vaccines, diagnostics, microbicides and vector control products
- Platform technologies (e.g. adjuvants, delivery technologies, diagnostic platforms)
- All types of product-related R&D, including basic research, discovery and preclinical, clinical development, Phase IV and pharmacovigilance studies, and baseline epidemiological studies

Most of the PDPs present themselves as not-for-profit institutions. Their objective is product development of medicines, vaccines and diagnostics for neglected diseases. The majority are based

[29] Drugs for Neglected Diseases Initiative.
[30] Pecoul, Bernard, "The DNDi Cost Model", communication at the International Seminar 2013 Building a Global Health Social Contract for the 21st Century, Barcelona, November 2013.
[31] G-FINDER 2012, Executive Summary.

on a "virtual R&D facility": very little or no in-house R&D activities. They work with different partners from the public and private sector such as government institutions, academia, research organizations, UN agencies such as WHO, the pharmaceutical industry. The majority of their "new" products are only incremental innovations. In general they have a relatively small core staff, a board and advisory committees. 50 per cent of current PDPs receive funds from the Bill & Melinda Gates Foundation (BMGF)[32]. And the BMGF as a private donor is part of the majority of the PDPs' boards and advisory committees.

According to G-FINDER 2012, the public sector continued to play a key role in the PDP for neglected disease R&D, providing almost two-thirds (64.0 per cent) of global funding, predominantly from the public sector of the developed country governments. The philanthropic sector contributions (18.7 per cent) were closely matched by investments from industry (17.2 per cent). 15 PDPs out of 23 are funded by the BMGF.

In the PDP of Malaria Vaccine Initiative (MVI) by PATH,[33] the Gates Foundation gave GlaxoSmithKline (GSK) US$200 million. The RTS,S AS01 candidate malaria vaccine is already in clinical trials phase III and the Glaxo Chief Executive Officer (CEO), Andrew Witty, announced that if clinical trials are successful, the vaccine will be patented and the price will be the cost plus a "modest" 5 per cent of the cost. Although the results of clinical trials were disappointing (only 31 per cent of efficacy against clinical malaria and 37 per cent of efficacy against severe malaria in the group of infants, 6 to 12 weeks of age at the date of vaccination), three remarks should be made regarding Witty's announcement: Firstly, is it acceptable from ethical and public health perspectives that a vaccine be patented? When Jonas Salk, discoverer and developer of the first poliomyelitis vaccine and also winner of the Nobel Prize in medicine was asked in a televised interview who owned the patent to the vaccine, Salk replied: "There is no patent.

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[32] R&D Financing and Incentives at the Product Development Partnership (PDP) Forum, 24-26 May 2011, Washington. Available from http://healthresearchpolicy.org/blog/2011/jun/17/rd-financing-and-incentives-pdp-forum.

[33] The PATH Malaria Vaccine Initiative (MVI) is a global programme established at PATH through an initial grant from the Bill & Melinda Gates Foundation.

Could you patent the sun?"[34]. As a second comment, the 5 per cent of the mentioned benefits means that all the PDPs are not really "not-for-profit" as they are generally characterized. Finally, regarding the "the cost plus 5 per cent of benefit", it is not clear whether we are going to know one day what the real cost of production is.

In connection with the same Gate Foundation/Glaxo partnership, when Dr. Pierre Druilhe, former Chief of the Parasitology Laboratory of the Institut Pasteur, was asked if he considered the vaccine against malaria – the RTS,S AS01 vaccine candidate – a failure because of such low coverage in clinical trials, he stated that Glaxo would be in any case happy for the adjuvants that it developed as an outcome of the project and patented which can be used for other products GSK may commercialize.[35] Therefore, during research paid for by public-private partnerships, a partner of the PDP can innovate and patent products that are not for neglected diseases and later commercialize them. In contracts (which are usually confidential) regarding the PDPs, for the use of some of the pharmaceutical companies' compounds, it is always stipulated that of what is found, whatever is not used for neglected diseases will remain the intellectual property of the drug company that has licensed or ceded its compounds. Therefore PDPs (in principle not-for-profit) can use public-private funding to identify substances that can then be commercially exploited by the industry.

With regard to PDPs, if we consider their limited scale (concentrated in neglected diseases), the majority of them dealing with minor innovations, the diversity in the way they function and their objectives not necessarily being public health oriented[36], one cannot really speak of a new model, but rather as an experiment. The operation of PDPs shows that:

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[34] "See It Now", CBS, 12 avril 1955: interview du Dr. Jonas Salk inventeur du premier vaccin contre la poliomyélite, par le journaliste Edward R. Murrow. In "The vaccine according to Bill Gates", Documentary film by Frédéric Castaignède, a ZED production for ARTE French and German TV, 2013.

[35] See "The Vaccine According to Bill Gates", Documentary film 52' by Frédéric Castaignède, a ZED production for ARTE French and German TV, 2013.

[36] Representatives of private companies who are members of PDPs boards participate on the definition of priorities, policies and strategies.

- The current R&D model based on the patent system is not the only option, nor the most efficient,
- the cost of R&D is only a fraction of what is currently claimed by the industry, and
- the way that intellectual property rights are being used is causing more impediment than incentive to innovate.[37]

A recent IP Watch study concluded that: "It could be summarised that the efficiency results of PDPs are mixed. On the one hand, PDPs do provide results, there are more and more used and demonstrated qualitative achievements. On the other hand, it is striking to see that PDPs attract most of the resources but the money invested is not proportionate with the results they lead to…The PDP mechanism then appears like an interesting step forward but one may wonder if in itself, this tool is enough to achieve the public health needs of most developing countries."[38]

Box 2
How PDPs can be a Laboratory of a "New Model" – DNDi Case

The Drugs for Neglected Diseases initiative (DNDi) is as an independent, international not-for-profit R&D organization working to deliver new treatments for the certain neglected diseases, in particular sleeping sickness (human African trypanosomiasis), Chagas disease, leishmaniasis, filarial and malaria. DNDi is also carrying out research for a paediatric HIV/AIDS medicine.

DNDi was founded by Médecins Sans Frontières/Doctors Without Borders (MSF), Indian Council of Medical Research, Kenya

[37] An investigation by the EU on the pharmaceutical sector (2009) found that in 2000-2007, a single medicine may be protected by up to 1,300 patents or pending patent applications. Available from http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[38] Tiphaine Nunzia Caulier for Intellectual Property Watch, *Special Feature*: A Look At Product Development Partnerships And Innovation For Neglected Diseases, Published on 3 July 2013. Available from http://www.ip-watch.org/2013/07/03/special-feature-a-look-at-product-development-partnerships-and-innovation-for-neglected-diseases/.

Medical Research Institute, Brazil's Oswaldo Cruz Foundation, Ministry of Health of Malaysia, and Institut Pasteur in France, with the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) as a permanent observer.

DNDi does not have its own laboratories or manufacturing facilities. Consequently DNDi leverages partners' specific assets, capacities, and expertise to implement projects at all stages of the R&D process, integrating capabilities from academia, public-sector research institutions, particularly in neglected disease-endemic countries, pharmaceutical and biotechnology companies, as well as non-governmental organizations including other PDPs, and governments worldwide. While investing in drug discovery for entirely new drugs, the imperative to respond to urgent patient needs guided a short-term strategy, implemented immediately upon the start of activities, and focused on improving existing treatments. The latter, as part of the core mission of the organization, aimed to deliver innovations to neglected populations as quickly as possible, notably opportunities that others were unable or unwilling to seize.

Within 10 years and with a budget of approximately EUR 210 million, the initiative has established a solid drug development pipeline, including 12 new chemical entities (NCEs), either in pre-clinical or clinical development and delivered six new treatments for neglected diseases (two fixed-dose antimalarials (ASAQ and ASMQ); nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness; sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa; a set of combination therapies for visceral leishmaniasis in Asia; and a paediatric dosage form of benznidazole for Chagas disease.

According to DNDi's funding policy established in 2003, it seeks to diversify funding sources, maintain a balance of public and private support, minimize as much as possible earmarked donations, and ensure that no one donor contributes more than 25 per cent of the overall budget.

Since 2003, DNDi has received support from a wide range of donors, including: governments, such as those of the United Kingdom, the Netherlands, Germany, France, Switzerland, and Spain; MSF as a founding partner; private philanthropic organizations, including the Bill & Melinda Gates Foundation and Wellcome Trust; and also through innovative financing mechanisms such as UNITAID.

III. CONTRIBUTION VERSUS RISKS OF PPPS AND PDPS IN HEALTH

The PPPs in health were initiated based on the assumption that they create a "win-win" situation. However, Gro Harlem Brundtland in her second round table with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) on 15 November 2000 stated that: "I recognize that the differences in the objectives and accountability of the research based pharmaceutical industry and WHO mean that joint working is not easy."[39]

This assumption of a "win-win" situation contributed to the rapid increase in the number of health PPPs without clear mechanisms for evaluation. If everyone wins there should not be too much danger, however, if in these alliances there are "winners" and "losers" one must evaluate who wins and loses what.

According to Richter, PPPs lead to certain "trade-offs" that make it necessary to see what the risks are in terms of public policies and interests. These risks include:

- commercial actors using the interaction with UN agencies to gain political and market intelligence information in order to gain political influence and/or a competitive edge;
- business actors using the interaction to set the global public agenda for commercial interest;

[39] Brundtland, Director-General of WHO, Opening remarks, IFPMA roundtable, Geneva, 15 November 2000.

- business actors using the interaction to 'capture' and/or sideline intergovernmental public agencies; as was, for example, the purchase of massive amounts of vaccines for the H1N1 flu; and
- weakening of UN agencies efforts to hold transnational corporations publicly accountable to society for their practices and actions.

III.1 Guidelines on Interaction with Commercial Enterprises

The private sector and the WHO have tried to develop codes of conduct and guidelines that some have called: "The development of safeguards within the WHO". [40]

In 1999 the WHO developed "WHO Guidelines on interaction with Commercial Enterprises". This document, criticised by some NGOs, was presented in 2000 to the WHO Executive Board which did not approve it. However the WHO Director-General "decided that formal approval of the Guidelines by the Member States was not needed. She adopted the revised November 2000 Guidelines as a 'managerial tool' for WHO without change"[41]. Comments and concerns from developing countries and NGOs were simply ignored.

The entire process of development and approval of the WHO Guidelines on interaction with Commercial Enterprises and all the documents on conflict of interest in WHO relations with the private sector has been a slow process that has gone on for over 10 years now and is still not concluded. Furthermore "Not enough information is available to evaluate whether the situation has fundamentally changed in 2011-2012, when Member States are again being urged to approve a path towards closer interactions with the private sector."[42]

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[40] Richter, J., "Public-Private Partnerships and International Health Policy-making", op. cit., pp. 11-17.
[41] Ibid. p. 14.
[42] Richter, J., "WHO Reform and Public Interest Safeguards: An Historical Perspective", *Social Medicine* (www.socialmedicine.info), p. 141, vol. 6, no. 3 (March 2012).

During the management of the A (H1N1) pandemic outbreak in 2009-2010, as well as in the debate on the reform of the WHO launched by the current Director-General, a recurring issue was the possible conflicts of interest. "As reported by Deborah Cohen and Philip Carter, in the BMJ, some of the experts advising the WHO on the pandemic had declarable financial ties with drug companies that were producing antivirals and influenza vaccines. According to Cohen and Carter, the WHO's guidance on the use of antivirals in a pandemic was authored by an influenza expert who, at the same time, was receiving payments from Roche, the manufacturer of Oseltamivir (Tamiflu), for consultancy work and lecturing."[43] Another recent example was Dr. Chan's defence of the presence of a Novartis representative on the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, which discussed new mechanisms on how to finance pharmaceutical R&D.[44]

Dr. Chan dismissed concerns over conflicts of interest and undue industry influence on several occasions. She argued that she is 'transparent' about industry representatives on particular advisory committees and "told NGOs who criticized multi-stakeholder approaches (…) that 'her' Member States have told her to do this."[45]

In November 2000, a seminar in Rome, co-sponsored by WHO, entitled "Global Public-Private Partnerships (GPPP) for Health and Equity", concluded that before moving forward there should be a broad analysis and justification for GPPP and it encouraged the WHO to: "examine the evidence for the pros and cons of GPPP, when they are appropriate and when not, and to define an open process about how to decide for or against partnerships… Furthermore the WHO should encourage the broadest possible range of inputs to this inquiry."[46]

Ten years after at the Executive Board meetings in 2011 and 2012 there was a lively discussion on the Guidelines for Public Private

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[43] Velasquez, G., "The management of A (H1N1) Pandemic: An alternative view", *Journal of Health Law*, vol. 13, no. 2 (July August 2012), pp. 123-136.
[44] See Beigbeder, Y., *L'OMS en péril* (Paris, Editions de Santé, 2011), p. 36.
[45] Richter, J., "WHO Reform and Public Interest Safeguards: An Historical Perspective", op. cit., p.144.
[46] Buse, K. and Waxman, A., "Public-private health partnerships: a strategy for WHO", Bull World Health Organ. 2001, 79(8):748-54. Epub 2001 Oct 24.

Interactions (PPIs). Many members of the board expressed serious concerns about the potential of the for-profit sector to distort public health priorities and programmes.

In the financial crisis that the WHO is experiencing, the proliferation of PPPs and PDPs creates a situation where the WHO Secretariat's ability to safeguard its multilateral, independent and public character will be compromised.

IV. MULTILATERALISM, PPPS AND WHO REFORM

For 50 years, the means of funding United Nations specialized agencies, including the WHO, was mainly public contributions by Member States. This permitted a sense of ownership of the organization on the part of Member States and the fixing of priorities, policies and strategies by the Member States.

In 1998, the WHO had a budget made of a little over 50 per cent of contributions coming from regular Member States. At present, ongoing regular and public contributions do not even cover 20 per cent of the organization's funding, leading the WHO to depend on public and private voluntary contributions coming from foundations, some states and the private sector or industry. The loss of control on funding diminishes the Organization's capacity to fix priorities and to make decisions.

At the Sixty-fourth World Health Assembly and at the Executive Board's 129th session (2011), three objectives were defined for WHO reform:

> "1. Improved health outcomes, with WHO meeting the expectations of its Member States and partners in addressing agreed global health priorities, focused on the actions and areas where the Organization has a unique function or comparative advantage, and financed in a way that facilitates this focus.

> 2. Greater coherence in global health, with **WHO playing a leading role**[47] in enabling the many different actors to play an active and effective role in contributing to the health of all peoples.
>
> 3. An Organization that pursues excellence; one that is effective, efficient, responsive, objective, transparent and accountable." [48]

Since the special meeting in November 2011 regarding WHO reform many documents have been produced by the Secretariat upon countries' request but many developing countries and a large majority of NGOs (not-for-profit organizations working in the health sector) have expressed their dissatisfaction with the direction that the said reform has taken. Many stakeholders insist that the WHO should play a leading role among the many different actors, but it is not clear how.

The recovery of the WHO public mission and its multilateral character and therefore its independence should be the starting point of any reform.

In the reform process in the last two years including the discussions at the 66th World Health Assembly (20-28 May 2013), WHO's priority setting process dominated the discussion.

The current real problem of the WHO is the increasing dependence on discretional donors; and the inability to align the available resources with priorities and outputs agreed by Member States. The WHO has lost implementation capacity, and coherence between priorities and the actual activities.

The switch in power from the WHA of Member States to donors seems inevitable based on the way that the debate on reform is taking place. Numerous PPPs are originated at the initiative of the donors and not necessarily arising from the priorities fixed by governing bodies. Donors in many cases act as "owners" of their own initiatives.

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[47] Emphasis added.
[48] WHO Special session on WHO reform doc. (EBSS/2/2), 7 November 2011.

Various NGOs expressed their concerns again, before the Executive Board and the WHA in 2013. In its statement to the WHA, Medicus Mundi said: "Under the proposed arrangements, the Assembly will adopt a budget and the DG will try to persuade the donors to fund the budget. It seems unlikely that, just because of these new arrangements, the donors will suddenly reorient their perspectives and support the programs they have frozen until now. And once the gaps become evident, how will the DG fill in these gaps?"[49]

With regards to the Financing Dialogue proposed as a form of financing the WHO (an annual meeting where all current funders, private and public, would give their pledges), the concern of NGOs is clear: "The proposed financing dialogue will not prevent the distortions of resource allocation arising from donor interests. Important areas of WHO's work which do not attract donor funding will continue to be starved of funds."[50]

The Democratising Global Health Coalition on the WHO Reform (DGH)[51] goes much further, questioning the role that the private sector may play in global health policy setting:

> "We are concerned that the reform may undermine, rather than reinforce, WHO's constitutional task. It may jeopardize the ability of the organisation to work for its mandate of the universal right to health by

[49] Statement by Medicus Mundi International to the 66th session of the World Health Assembly on agenda item 11: WHO Reform delivered by Alice Fabbri, 2013.
[50] Statement by Medicus Mundi International and the People's Health Movement to the 66th session of the World Health Assembly on agenda item 12.2: General Programme of Work delivered by Marianna Parisotto, May 2013.
[51] Democratising Global Health Coalition on the WHO Reform (DGH) is a group of 8 NGOs:
Health Innovation in Practice (HIP)
International Baby Food Action Network (IBFAN)
Medico International
People's Health Movement (PHM)
Third World Network (TWN)
WEMOS/Medicus Mundi International Network (MMI)
World Council of Churches (WCC)
World Social Forum on Health and Social Security

> opening the door to corporate and private for-profit entities to take part into policy setting in global health. This runs counter to basic democratic principles. We advocate for clear regulations to be set in place to protect the WHO from undue private sector influence through the development of a comprehensive conflicts of interest policy."[52]

IBFAN[53] comments on WHO's "engagement with non-state actors" (EB 133/16) on the 30th of May 2013, expressing their worries regarding the reform of WHO concerning PPPs: "The report does not define how will WHO principles applying to the agency's relations to non-state actors, as discussed in part 1, be carried over and implemented also in the global health governance, i.e. application of the same rules in e.g. partnerships hosted by WHO, International Health Partnership (IHP+) and other health alliances to ensure greater coherence in global health."[54]

The loss of the public and multilateral character of the WHO, may compromise the norms and standards set in of the Organization. How can WHO effectively and independently regulate and control for instance, the pharmaceutical or the food industries if these industries are the funders of the Organization?

In recent years a common "agenda" is being developed between the WHO, WIPO (World Intellectual Property Organization) and the WTO (World Trade Organization) although the objectives and mandate of the three organizations are different and, in some cases, contradictory. The promotion of patents (WIPO) can go against access in the case of medicines (WHO).

One would expect that the multilateral agency for health would set rules and priorities for PPPs and PDPs but unfortunately this does not seem to be the case. Moreover, the multiplication of these PPPs and

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[52] Democratising Global Health Coalition on the WHO Reform (DGH) CORE STATEMENT.

[53] The International Baby Food Action Network.

[54] IBFAN brief comments on WHO's engagement with non-state actors (EB 133/16), Agenda item 5 to be discussed at the 133th EB (29-30th May 2013).

PDPs without clear rules and without control or coherence risks aggravating instead of solving the problem.

V. ARE PPPS AND PDPS THE ONLY SOLUTION?

Gro Harlem Brundtland's statement "Whether we like it or not, we are dependent on the partners"[55] sends the message that there are no alternatives to the shift towards PPPs and PDPs. Until the partnerships came into fashion it was recognized that some interactions in the health sector with the private sector were useful, others harmful and best avoided, and we realize today that all interactions with business actors need to be carefully assessed and monitored.[56]

PPPs and PDPs in health are voluntary exercises started by donors from developed countries. They are the new form of aid to the countries of the global South. The North decides what the South needs… More than financial, the problem is how the global health relations are structured.

PPPs and PDPs are still a kind of humanitarian aid that emerged after the colonial period; the only difference is that they give more power to control the implementation avoiding, as before, to question the philosophy of the North-South cooperation. It is not intended at any time to end these partnerships, but it would be important to think of some measures which can help to better ensure that public-private partnerships are guided by public interest such as:

- Formulate general rules, criteria and objectives that are clearly public health oriented
- Define a clear understanding of what are PPPs and PDPs
- Assuring that PPPs and PDPs are initiated on the basis of developing countries' needs and not, for instance, to show

[55] Brundtland, G.H., "Address by Dr Gro Harlem Brundtland, Director-General, to the Fifty-fifth World Health Assembly, Geneva, Monday, 13 May 2002".
[56] Richter, J., "Public-private Partnerships for Health: A trend with no alternatives?", op. cit.

"social responsibility of the private sector" as a marketing strategy
- Intellectual Property (IP) issues related to final products developed should be transparently defined in advance
- Health Innovation alternatives must be always clearly linked to ACCESS to the new needed products
- Overlap and competition between "not-for-profit" entities in the health sector should be avoided

Some elements of the PDP's can be interesting and useful for the estimation of the real R&D cost, for instance, but if the search is for a "new model", PDPs are far from being that model; they are an experiment that can help to find new alternatives. One of the complexities of PDPs which still not clear is the treatment of intellectual property, the dilemma between innovation and access.

In May 2012, the WHA adopted a resolution that may change the rules of the game. The Resolution requested the Director-General to organize a meeting of Member States "that will thoroughly analyse the report and the feasibility of the recommendations proposed by the CEWG"[57]. This experts' report proposes to re-examine the funding and coordination of pharmaceutical R&D to meet the health needs of developing countries. Its main recommendation is the negotiation of an international convention committing all countries to promote R&D, which the market alone is not enough to stimulate.

Article 19 of the WHO Constitution provides for "two-thirds of the World Health Assembly" for the adoption of such a treaty. The later could set up a public international fund, whose sustainability would derive from a compulsory contribution, adapted – and this is a major innovation – to the level of economic development of each country. The products of the research thus supported (transparently) by the fund would be considered as common goods of benefit to all.

Noting the failure of current incentives – patents – to generate sufficient R&D in the private and public sectors, the expert panel also

[57] 65th World Health Assembly, resolution WHA65.22 (p.37), Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, 26 May 2012.

suggested experimenting with innovation systems that are "open", not based on intellectual property. It mentions a number of "innovations based on open access knowledge": this expression defines the research activities which produce knowledge that can be reused freely without legal or contractual restriction or exclusivity.

In the first place, we find platforms for pre-competitive research, combined with open source instruments and free access. All teams from universities, government institutions and private laboratories benefiting from public funding could share their discoveries. Today, this is far from being the case: many research outputs of institutions are sold to private industry, which sometimes gets the patents on these products developed with public funds. Accordingly, the community pays twice for these products!

The industry, whose set of new molecules at its disposal continues to dwindle, could also benefit from a revival of research. In addition, the open publication of results would facilitate the transfer of technology to developing countries. India offers an example of the "open source model for drug discovery" developed by the Council for Scientific and Industrial Research, which focuses on new therapies against malaria, tuberculosis and leishmaniasis.

VI. CONCLUSIONS

PPPs like PDPs are far from truly being a new model to solve the problem of access to health, particularly in developing countries. The PDPs are more an experiment than a model. They may have some common characteristics like interaction between the public and private sectors, product development as an objective, virtual R&D[58] but their common principles and rules are not transparent.

The first and most important conclusion resulting from this brief analysis is the need to put a global moratorium on the creation of new

[58] Not all of them.

PPPs and PDPs until WHO is able to use its authority to set clear rules and principles for the creation of new partnerships on global health.

In the health sector, PPPs are threatening the democratic, multilateral functioning on which the United Nations system and its specialized agencies such as the WHO are based. There are some concerns with the PDPs:

- Most of the products so far developed by PDPs are incremental innovations – "low-hanging fruit". There is no evidence yet that PDPs can deliver breakthrough innovations. There is the risk of "evergreening".
- Their capacity is quite modest.
- They are, in some cases, competing between themselves. This may result in overlapping and waste of resources. Duplication it is not necessarily bad in terms of promotion of competition, but in the case of not for profit initiatives, some collaboration would be important.
- Potential conflict of interest as the private sector is part of their boards and advisory committees.
- Based 100 per cent on donations. PPPs and PDPs are not sustainable on a long term basis.
- In the majority of PDPs it is not known what treatment will be given to intellectual property. Will the product be patented or not? What are the consequences that this can have on access?
- The "not for profit" character of PDPs is not completely clear; in some cases PDPs may just be a profitable investment in marketing the social responsibility of some companies.
- Patenting intermediate steps for non-neglected diseases, for commercial purposes, as is the case for PDP adjuvants for the malaria vaccine.
- They are all started by donors from the North who decide what the problems and the priorities of the South are.
- Some PDPs are only between two partners, like for instance the BMGF and GSK malaria vaccine. Other PDPs chose to have multiple private and public partners, as is the case of DNDi. It is clear that in terms of transparency and above all

> sustainability, the latter is preferable.[59] As mentioned before, 50 per cent of current PDPs receive funds from the Bill & Melinda Gates Foundation (BMGF). And the BMGF as a private donor is part of the majority of the PDPs' boards and advisory committees.[60]

Talking about conflict of interest and filling out forms by individuals and/or private companies is not enough. One must ask whether PPPs and PDPs are the most appropriate route, whether their contribution is more significant than their risks, whether their growth is not complicating the problem and squandering funds due to overlap, and finally, whether there are no other, more coherent and efficient options to explore, such as a binding international treaty to finance R&D or an open source model of drug discovery.

[59] DNDi, is funded by more than 15 partners, most of them government, public entities or not for profit foundations.

[60] Op. cit. R&D Financing and Incentives at the Product Development Partnership (PDP) Forum, 24-26 May 2011, Washington. Available from http://healthresearchpolicy.org/blog/2011/jun/17/rd-financing-and-incentives-pdp-forum.

The international debate and negotiations over access to medicines in the last ten years have been one of the most important moments in the recent history of public health. This debate is taking place at the UN specialized agencies like WHO, UNDP, UNCTAD, UNAIDS, WIPO, WTO, the Commission of Human Rights, NGOs working in health, philanthropic foundations, and the pharmaceutical industry. Dr Germán Velásquez has been a protagonist and witness of this struggle. He narrates in detail the most difficult moments of the negotiations, the victories, failures, challenges and the roles of the different actors.

This book is a collection of papers by the South Centre between 2011 and 2014 on the deliberations and negotiations in the World Health Organization (WHO) on access to medicines and their relationship with other actors dealing with international trade and intellectual property regimes. The South Centre is an intergovernmental research organization of developing countries on critical development issues for the South and is an observer to the governing bodies of the WHO. The author has extensive experience of the work of the WHO on the issue of the impact of trade agreements on public health, particularly access to medicines and intellectual property rights. It is hoped that the collection of papers presented in this book will be useful for policy makers and researchers interested in the deliberations in the WHO on the critical issues pertaining to public health, particularly access to medicines.

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