

# RESEARCH PAPERS

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## THE RIGHT TO HEALTH AND MEDICINES: THE CASE OF RECENT NEGOTIATIONS ON THE GLOBAL STRATEGY ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY<sup>1</sup>

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## INTRODUCTION

**The purpose of this paper 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"<sup>2</sup>, 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"<sup>3</sup> 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 plan of action on public health, innovation and intellectual property" which was approved by the World Health Assembly in 2008.<sup>4</sup>

The intention of the Global Strategy and Plan of Action (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 paper is structured in five parts: I. The background of the IGWG negotiations, II. The stakeholders, III. The content, IV. The Process and V. Conclusions.

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<sup>2</sup> Intergovernmental Group on Public Health, Innovation and Intellectual Property

<sup>3</sup> WHO, "Public Health, Innovation and Intellectual Property", Geneva 2006

<sup>4</sup> WHA, "Global strategy and plan of action on public health, innovation and intellectual-property" Resolution 61.21, May 24, 2008.

## I THE BACKGROUND OF THE IGWG NEGOTIATIONS

Of the 20 million people which the WHO, UNICEF and UNAIDS in their 2010 report consider should have received a retroviral treatment, only 5 million had access to the therapy at the end of 2009<sup>5</sup>. A third of the world's population does not have regular access to essential medicines, 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.<sup>6</sup>

The financial burden of the expenditure in medicines in most of the 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 1,000 US dollars 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 4,000 to 5,000 US dollars per year. According to World Bank figures, one billion people currently live in extreme poverty (less than one dollar per day)<sup>7</sup>, 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 factor which determines 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."<sup>8</sup> Even though the TRIPS Agreement obliges WTO members 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

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<sup>5</sup> UNAIDS 2010 report.

<sup>6</sup> Seuba, X. "La protección de la Salud ante la regulación internacional de los productos farmacéuticos" doctoral thesis p.92 and following, Barcelona 2008.

<sup>7</sup> See <http://go.worldbank.org/MVH3AJAGC0>

<sup>8</sup> UK CIPR Commission on Intellectual Property Rights, executive summary, p.14, London 2002

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 (...)<sup>9</sup>.

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 (...)." <sup>10</sup>

Regarding the use of the flexibilities contained in the TRIPS Agreement, which were approved and confirmed in different international forums, developing countries which have tried to apply these mechanisms have, unfortunately, been subjected to bilateral pressures<sup>11</sup>. 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."<sup>12</sup>

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% of approved medicines were true innovations. According to Carlos Correa<sup>13</sup>, innovation in the pharmaceuticals 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% of all new chemical entities produced between 1975 and 1999 were for tropical diseases.<sup>14</sup> 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

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<sup>9</sup> OMS, "Public Health, innovation and intellectual property " Geneva 2006, op. cit. P.35

<sup>10</sup> WHA resolution 61.21 paragraph 5.2 p. 43

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

<sup>12</sup> AMS resolution 61.21 op. cit. Context paragraph 12

<sup>13</sup> Carlos Correa "Ownership of Knowledge - the role of patents in pharmaceutical R&D", WHO Bulletin, Volume 82, Number 10, October 2004, 719-810

<sup>14</sup> P. Trouiller, et al., "Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure", *The Lancet* 359 (2002): p. 2188.

the TRIPS Agreement and Public Health. Doha 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 so-called paragraph 6 system which is taking several years to implement to the point that even in 2010 the issue has still not been definitely solved. The amendment to the TRIPS Agreement (article 31 bis) 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 other much more simple solutions. The inclusion of limitations to the use of the TRIPS flexibilities in the bilateral free-trade agreements, to FTA’s 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 World Health Assembly 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<sup>15</sup>. The Commission, composed of international experts, some of whom did not always act with due independence, caused great “headaches” to its president, Ruth Dreifuss, the ex-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 World Health Assembly 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”<sup>16</sup>. Based on this recommendation, the 59<sup>th</sup> WHA approved resolution 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 60<sup>th</sup> 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,<sup>17</sup> NGOs in official relations with the WHO, expert observers and public and private entities.

The intergovernmental group held negotiations for nearly 2 years, between December 2006 and May 2008, with three meetings in Geneva which were attended by over one hundred 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.

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<sup>15</sup> World Health Assembly, “Intellectual Property Rights, Innovation and Public Health, WHA Resolution 56.27, 28 May 2003, parag. 2.

<sup>16</sup> CIPIH Report (2006), p. 187.

<sup>17</sup> *Ibid.*, para. 3.2. and 4. 2.

## **II 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 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**, non-for-profit, 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. The WIPO and the 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 invested their efforts fully in monitoring and supporting the negotiations process. According to some Geneva observers of the IGWG process, in great part due to the failure of the first meeting, the Assistant Director General, -ADG- who covered this topic, had to leave the Organization, 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's regional consultants in the field of medicines experienced the negotiations as if it was its own.

### III 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 the 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<sup>18</sup>. 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.

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<sup>18</sup> 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".

## **IV 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 which is less clear or full of

nuances and “diplomatic” equilibriums. It is quite surprising that, in the 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,<sup>19</sup> excluding other decisive aspects influencing the health sector. Nor could 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<sup>20</sup>. 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 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”<sup>21</sup>.

In this draft, an additional column was introduced in the action plan to indicate the “stakeholders” (WHO member states, secretariat of the 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

<sup>19</sup> WHO, Report of First Session, 25 January 2007, paras. 20, 21 and 31.

<sup>20</sup> 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].

<sup>21</sup> WHO Resolution 61.21, context para. 4 page 5

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:

- (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 October 22 and 23, 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 the WHO's 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.

Between August 15 and September 30 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.<sup>22</sup> "The unmanaged nature of Web-based hearings"<sup>23</sup> 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<sup>24</sup>.

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 basically two groups were formed. The first group promoted proposals such as the treaty on R&D, incentives, "patent pools" or "advance market commitments"<sup>25</sup>. The second group, which was led by the industry and certain institutes from the United States, preferred solutions based on

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<sup>22</sup> WHO, Report by the Secretariat, 31 July 2007, para. 11.

<sup>23</sup> 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

<sup>24</sup> Suwit Wibulpolprasert et al., "WHO's web-based public hearings: Hijacked by pharma?", (2007) *The Lancet* 370:24, p. 1754.

<sup>25</sup> 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, Track2.

the market, arguing that a strong intellectual property protection is the best incentive for stimulating R&D<sup>26</sup>. Some proposals, such as that of the Italian alliance for the defence of intellectual property, challenged the WHO's role in this field arguing that this role belonged exclusively to the WTO and the WIPO<sup>27</sup>. Regarding the old discussion on the scope of the strategy (whether it is restricted to a limited number of diseases, i.e. malaria, 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 to in Doha. The first article of the WTO's Doha Ministerial Declaration on TRIPS and 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".

### 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 eighteen NGOs, eleven experts, and four or five 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**"<sup>28</sup> - 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

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<sup>26</sup> 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.

<sup>27</sup> 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.

<sup>28</sup> Set in bold by the author

shows not only a refusal to study truly innovative solutions to fundamental problems, but it also seems to 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 parenthesis 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 of us did not understand, and suspended the meeting for almost 6 months to have it continue on April 28, 2008, the week prior to the 61 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 to 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 five, 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 five, the topic of intellectual property was the one that most suffered 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, the 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 assisting 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 during January 2009, and its results were transmitted to the WHA in May 2009 in document A62/16 Add.3<sup>29</sup> 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 Non-governmental Organizations (Essential Action, Health Action International, Health Gap, Knowledge Ecology International, Medecins Sans Frontieres, 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 Nongovernmental organizations indicate that such a decision would go against the spirit of resolution 61.21.

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<sup>29</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/A62/A62\\_16\\_Add\\_3.pdf](http://apps.who.int/gb/ebwha/pdf_files/A62/A62_16_Add_3.pdf)

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 EGW 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, appear 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.

### **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<sup>30</sup> 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 medicines, but also to increase medical innovation based on the needs".

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<sup>30</sup> referring to the informal consultations

## V 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 for which we unfortunately still do not have a clear answer. The 62 and 63 WHA in May 2009 and 2010, rather than shedding some light on this question only bolstered the uncertainty.

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"<sup>31</sup>

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 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:

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<sup>31</sup> Seuba, Xavier doctoral thesis 2009

- 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 63 WHA, but now, the new EWG would report to the 65WHA 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**

## **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;<sup>1</sup>

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,

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

2. URGES Member States:<sup>3</sup>

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

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<sup>1</sup> Document A61/9.

<sup>2</sup> On the specific actions and stakeholder components.

<sup>3</sup> Where applicable, also regional economic integration organizations.

- (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 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% of the world population. Of this number, 2.7 billion, representing 43% of the world population, live on less than US\$ 2 a day. Communicable diseases account for 50% of the developing countries' burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products<sup>1</sup> and medical devices, especially in developing countries.
3. Member States,<sup>2</sup> 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.
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.

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

<sup>2</sup> Where applicable, also regional economic integration organizations.

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<sup>1</sup>
- (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.

#### *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.

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<sup>1</sup> 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.

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.*

#### ***Element 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<sup>1</sup>*

*(c) prioritize health care in national agendas*

*(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality,*

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

*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<sup>1</sup> 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.

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<sup>1</sup> Where applicable, also regional economic integration organizations.

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<b>Element 1. Prioritizing research and development needs</b>			
(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>WHO</b> ; Governments; other relevant stakeholders	2008-2015
	(b) disseminate information on identified gaps, and evaluate their consequences on public health	<b>WHO</b> ; 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	<b>WHO</b> ; 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	<b>Governments; regional organizations</b>	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	<b>WHO</b> ; 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)	<b>Governments</b> ; 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	<b>Governments</b> ; 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	<b>Governments</b> ; <b>WHO</b> ; 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	<b>Governments</b> ; <b>WHO</b> ; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	(d) support South-South cooperation in information exchange and research activities	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders	2008-2015
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 2. Promoting research and development</b>			
(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>Governments; WHO;</b> 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	<b>Governments; regional organizations; WHO</b> (technical assistance); other relevant stakeholders	2008–2015
	(c) support governments in establishing health-related innovation in developing countries	<b>Governments; regional organizations; WHO</b> (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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(e) support early-stage drug research and development in developing countries	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Interested Governments;</b> [WHO]; <b>other relevant stakeholders (including nongovernmental organizations)</b>	[2008–2010]
	(d) support active participation of developing countries in building technological capacity	<b>Governments; WHO;</b> other relevant stakeholders	2008-2015
	(e) promote the active participation of developing countries in the innovation process	<b>Governments; WHO;</b> 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	<b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	publications by universities, institutes and technical centres, especially in developing countries	(including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	
	(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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments;</b> 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	<b>Governments</b>	

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
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 3. Building and improving innovative capacity</b>			
(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>Governments</b> ; 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	<b>Governments</b> ; 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	<b>Governments</b> ; <b>WHO</b> ; 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	<b>Governments</b> ; <b>WHO</b> ; 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	<b>Governments</b> ; 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	<b>Governments; WHO</b> ; 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	<b>Governments</b>	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	<b>Governments; WHO</b> ; 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	<b>Governments;</b> 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	<b>Governments;</b> 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	<b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, <b>concerned communities</b> )	
	(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments;</b> [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	<b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 4. Transfer of technology</b>			
(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>Governments;</b> 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	<b>Governments;</b> WHO; other intergovernmental organizations; other relevant stakeholders (including <b>health-related industries</b> )	

	(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	<b>Governments</b> ; WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>relevant health-related industries</b> ; 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	<b>Governments</b> ; 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	<b>Governments</b> ; 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	<b>Governments</b>	2008–2015

	(d) promote the necessary training to increase absorptive capacity for technology transfer	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<b>Element 5. Application and Management of intellectual property to contribute to innovation and promote public health</b>			
(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	[ <b>Governments; WHO</b> ; other international intergovernmental organizations (including <b>WIPO, WTO, UNCTAD</b> ); other relevant stakeholders (including international and national research institutions and development partners)]  [ <b>Governments; WHO</b> ; 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	<b>Governments; WHO</b> /[WHO]; other international intergovernmental organizations (including <b>[WIPO]/[WIPO], [WTO]/[WTO], UNCTAD</b> ; 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-	[Governments]/[ <b>Governments</b> ]; [WHO]/[ <b>WHO</b> ]; other international intergovernmental organizations (including <b>[WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]</b> ; other relevant stakeholders (including	

	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.	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	<b>Governments;</b> 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; <b>[WHO]/[WHO]</b> ; other international intergovernmental organizations (including <b>[WIPO]/[WIPO]</b> , <b>[WTO]/[WTO]</b> , <b>[UNCTAD]/[UNCTAD]</b> ); 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,	<b>Governments;</b> [WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>concerned communities</b> )	

	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	<b>Governments</b>	
	(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	<b>Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)</b>	
(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>Governments; WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)</b>	

	<p>(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</p>	<p><b>Governments;</b> [WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]</p>	
	<p>(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</p>	<p><b>Governments</b></p>	
	<p>(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</p>	<p><b>Governments</b></p>	

	(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	<b>Governments;</b> WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including <b>concerned communities</b> )	
(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>[Governments; [WHO]/[WHO];</b> other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]	
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 6. Improving delivery and access</b>			
(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>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)	

	(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016 <sup>1</sup>	<b>Governments</b> ; WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders	
	(c) prioritize health care in national agendas	<b>Governments</b>	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	<b>Governments; WHO</b>	
	(e) increase investment in human resource development in the health sector	<b>Governments</b> ; 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	<b>Governments</b> ; other relevant stakeholders (including development partners)	2008–2015

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

	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners)	2008–2015
	(d) strengthen the WHO pre-qualification programme	<b>Governments; WHO,</b> 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	<b>Governments; [WHO]/[WHO];</b> 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	<b>Governments; WHO;</b> 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	<b>Governments; WHO;</b> 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	<b>Governments</b>	

	“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	<b>Governments;</b> 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	<b>Governments</b>	
	(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	<b>Governments;</b> WHO; other international intergovernmental organizations; other relevant stakeholders (including <b>relevant health-related industries</b> )	
	(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	<b>Governments</b>	

	(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	<b>Governments</b>	
	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	<b>Governments; WHO</b> other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 7. Promoting sustainable financing mechanisms</b>			
(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	Governments; <b>WHO</b> ; other international intergovernmental organizations; other relevant stakeholders	
	(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	<b>Governments; WHO</b> ; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations,	

	maximize its effectiveness as recommended by the resolution WHA58.34	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	<b>Governments; WHO;</b> 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; <b>WHO;</b> 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; <b>WHO;</b> 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
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 8. Establishing monitoring and reporting systems</b>			
(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; <b>WHO</b>	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; <b>WHO</b>	[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; <b>WHO</b> ; 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	<b>Governments; WHO</b> ; 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; <b>WHO</b> ; other relevant stakeholders	

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