



**COCIR Priorities and comments on WHO  
IGWG document  
Draft global strategy and plan of action on public health,  
innovation and intellectual property<sup>1</sup>**

COCIR, in addition to its Position Paper issued on 16 April 2008, provides hereafter priorities and comments on the draft IGWG document.

***Negotiating Priorities***

Summary

**1. Question the asserted relationship between intellectual property rights and healthcare dysfunction.** Rather, IP promotes innovation and, hence, access to diagnostic tests and treatments that improve and extend life.

**2. Foreclose negotiation of an R&D Treaty.** While we support enhanced R&D funding to promote innovation, a treaty would attempt to overturn the current system of protecting IP and stimulating research and development of new technologies.

**3. Member States should discourage involvement of WHO on IP matters.** This should include preventing WHO from advising others on the purported trade-IP-healthcare relationship.

Discussion

**1. Relationship between IP and health system dysfunction**

COCIR Views

Among all possible outcomes of the IGWG debate, the most dangerous and damaging result would be a consensus that IP undermines innovation and access to medical technology. Such a position would more likely discourage, rather than promote, exactly the kinds of technology development to benefit patients sought by WHO and member states. It could also be used as a pretext for reducing IP protections generally and as a pretext for industrial policy programs. (For example, a "study" by the research arm of China's National Development and Reform Commission indicated that innovation fosters a "technological monopoly" that "causes market monopoly, and the result of market monopoly is price monopoly.")

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<sup>1</sup> Document A/PHI/IGWG/2/Conf.Paper No.1 Rev.1 dated 14 December 2007



The NDRC was using this analysis as a justification for unwarranted price controls. It could also, not incidentally, benefit local producers at the expense of importers.)

Rising healthcare costs are a significant policy and public concern in all countries, developed and developing. Acquisition costs can be one factor in reducing access to innovative medical technologies in developing countries. With limited budgets – either government or private – expenditures on relatively expensive technologies might not occur. However, these technologies would not even be available, and such choices would not exist, were it not for the R&D spending, primarily by the private sector. Such expenditures include development of medical technologies suitable for developing countries – which will be demonstrated by the examples we will provide in the near future. As the costs of developing new and increasingly sophisticated medical technologies rises, expenditures on such technologies by private and government healthcare providers necessarily increase.

Given the critical need for basic healthcare in developing countries and even the necessity for diagnostic tests and treatments for the range of conditions under consideration by WHO, it is unclear why so many drafting suggestions in the draft IGWG document single out IP as a concern, without addressing other more pressing impediments. There appears to be no demonstrated relationship between IP protection for innovative technologies and lack of access to diagnostic tests and treatments for the range of conditions under priority consideration by WHO. In order to have informed recommendations, WHO should identify the possible range of treatments for the various conditions being considered in order: (1) to determine IP's role in developing such treatments; (2) to evaluate whether IP contributed to, or inhibited, access to treatments, and (3) consider how and to what extent other factors may also affect access.

Other local government policies affecting access should also be explored. For example, the regulatory approval process is one of the major drivers of the overall costs for the development of drugs, medical devices and diagnostics. If WHO wishes to promote the development of products to diagnose and treat those diseases particularly pertinent to developing countries, then it would go a long way to minimize the costs for approval by, for example, promoting regulatory harmonization, and at the same time minimize the costs of litigation. Elimination of national tariffs would also contribute.

Likewise, efforts by governments of developing countries to allocate their own resources to health care should be included in the discussion. For example, on page 8, footnote 3, it is noted that developing countries pledged 2% of the national health budget on R&D. Has this been achieved?

Also, the long-term benefits of continuing innovation on healthcare expenditures must be considered. Innovative medical technology enhances peoples' lives and reduces long-term health costs. Medical technology increases productivity by allowing workers to recover from illness faster, remain longer in the workforce, support their families, and live without expensive long-term care. Studies show that funds invested in medical technology yield far greater benefits than costs to society. WHO should not be allowed to focus solely on costs without regard to benefits, to patients and to society at large.



Suggested Changes to Text

**P.3, paragraph 4** implicitly concludes that the cost of R&D increases the prices of healthcare products used for medical conditions disproportionately affecting developing countries. While not ideal, if the word “addressing” is changed to “examining” or “considering” and the words “and benefits” are added after the word “costs,” there would at least be an opening for demonstrating either a positive or neutral relationship between R&D costs and the prices of such healthcare products.

**P. 3, paragraph 6:** Inasmuch as the cited CIPIH report did not directly address the question of whether country-level access to appropriate drugs or technologies could address the manifold problems of distribution and application of these technologies within a country, we do not support the draft strategy’s proposed characterization of the CIPIH Report as “an effective analysis of the problems”. Instead, we believe it should be characterized as outlining points to consider in addressing broader questions of impediments to access to health products.

**P. 4, paragraph 11,** should be deleted. While currently referring only to medicines, this paragraph could easily be interpreted and/or extended to include medical technology. This statement is made without any supporting evidence of the purported relationship between price and access, (NB: also as regards cheap products access is impeded because of a whole range of problems from which developing countries suffer) nor is it clear or specific about WHO’s intentions, including the reference to “new thinking” on a mechanism. Prices are only one of many factors determining patient access to diagnostic tests and treatment. And, as paragraph 26 notes, there are a range of factors that contribute to price determination, not simply IP. “New thinking” and “mechanisms” clearly imply a change in IP rights. A possible alternative text could read: “Some medicines are priced too high for a substantial number of people with Types II and III conditions in developing countries, requiring additional mechanisms to support access.”

**P. 9, paragraph 30 (2.2 (c)):** We oppose this provision and prefer that it be deleted. There is no evidence of a generalized negative relationship between IP and R&D. Also, this provision limits its assessment to IP and not to other important factors, such as availability of trained researchers, adequate research facilities, sufficient funding, and supportive government policies. If necessary to achieve consensus, we could accept this provision if it were worded in a more neutral and fact-finding manner, such as: “assist member states in identifying the full range of factors, including IP, that might affect increased research on public health, and suggest ways to enhance the R&D environment.”



## 2. Foreclose Negotiation of an R&D Treaty

### COCIR Views

While COCIR supports enhanced R&D funding to promote innovation to achieve a genuine improvement of healthcare in developing countries, the EC Delegation should strenuously oppose a consensus to negotiate any “treaty” on R&D. Most likely the objective of such a treaty would be to overturn, without a credible alternative, the current system of IP protection, including in the WTO TRIPS agreement. While such a treaty would (we presume) aim at healthcare products, the effect would extend well beyond medical technology and pharmaceuticals, creating a precedent for other IP-dependent products. For example, many of the patents on designs, materials, and methods used in electronic medical devices would be relevant for other electronic products. The entire negotiation process for such a treaty would be a damage-limiting exercise by the EC, with no upside for innovative industries. Furthermore, the postulated beneficial effects for patients of such a treaty are undemonstrated and speculative at best.

### Suggested Changes to Text

**P. 5, paragraph 14(e)** is troubling because it implies that IP should be “managed” by WHO, which presumably leads to the need for an R&D Treaty. We prefer “and management” be deleted. In terms of the bracketed text, we prefer “innovative” to “alternative,” since the latter implies that the current system needs to be replaced. For the same reason, we prefer the retention of “to complement the existing one.”

**P. 6, paragraph 17:** While, in principle, we support the aspirations of these statements, we do not believe this right should be used unilaterally to take precedence over other established rights. In addition, this statement does not appear to give any consideration to generation of the means by which individuals may strive to attain the “enjoyment of the highest attainable standard of physical and mental health”.

**P. 6, paragraph 18:** We prefer the former formulation in support of striking a balance. The latter formulation would be used by governments for compulsory licensing and possibly expropriation of IP. In addition, it appears not to recognize the strong commercial interests that make possible advances in public health. Finally we believe that industry has a role to play together with governments, finance, NGOs and Development agencies to provide affordable healthcare. A “black and white” approach as put forth in alternative two undermines this collaboration.

**P. 10, paragraph 30 (2.3) (c):** While apparently agreed by consensus, we are very concerned about this provision, which could lead to the negotiation of a treaty. We appreciate that the current language is vague and non-committal (using “encourage further exploratory discussions...”), but such discussions could lead to pressure to launch negotiations.



**P. 23, paragraph 42 (7.1):** We can accept the first formulation, provided this statement is confined to governments. We oppose the second version, as advocating an entirely different R&D funding architecture – most likely in the context of a new treaty. We do not see the need for the expert task force, which could seek to recommend the negotiation of a new treaty. We support the phrase “and promote good financial management to maximize its effectiveness.”, something often lacking and probably a significant contributing factor to lack of access to technology.

### **3. Member States should discourage involvement of WHO on IP matters**

#### COCIR Views

WHO has not established a causal or even a correlative relationship between IP and health system dysfunction. WHO has also not proposed convincing alternatives to the current IP system. Understanding the details, rationale and scope of IP requires considerable expertise, far beyond that in WHO. WIPO, the WTO, as well as experts in many countries have such knowledge. With its obvious lack of IP expertise and impartiality, the WHO should not be allowed to continue its role in advising member states on IP matters. Furthermore, WHO work with governments should be distinguished from any role it might seek over private sector R&D.

#### Suggested Changes to Text

**P.4, paragraph 12** begins to set the basis for WHO officials claiming that they have, or must develop, such IP expertise. The wide range of “obstacles” listed in the brackets, and the proposed “technical assistance” would reinforce and expand the range of WHO work. As such, the text in brackets should be deleted. Importantly, a major obstacle for applying the “flexibilities” is a realization that compulsory licenses etc. will not achieve better healthcare because they do not address the host of factors impeding healthcare in developing countries, as is clear from the fact that even pharmaceutical products that are completely free from IP cannot be provided when and where needed.

**P.5, paragraph 15** should be deleted. While the “strategic and pro-active role” could possibly be later limited to minimize damage to the current IP system, WHO’s aims are clearly to intrude in and overturn this system. The more resources and mandate given to WHO by its member states, the larger its role will be. The EC could credibly argue that such a role would be a diversion of scarce resources away from the needs of the poor in developing countries.

**P. 7, paragraph 27:** The proposed assertion that “Health research and development policies of developed countries need to reflect adequately the health needs of developing countries” raises important questions about the respective roles of the public and private sectors in determining priorities for research investments. It also appears to downgrade the political accountability national governments have to address the needs of their own citizens and taxpayers. Also, this paragraph refers to all types of conditions. A possible way to address the former concerns would be to insert “governments in” before “developed” and to replace “need to reflect



adequately” with “should take into account.” We believe these changes would allow national governments to address the healthcare R&D needs of developing countries as each sees fit, and without encroaching on private sector R&D. Also, in order to ensure a full analysis of the issues, we suggest inserting “all aspects” after the word “understanding” in the last sentence.

**P. 7:** While we agree to the need for greater attention to prioritizing R&D needs, because we question the primary WHO role footnote 1 should be deleted or modified by deleting the word “lead.” While this is a consensus footnote, it seems relevant to paragraphs (1.2) (d) and (e) on page 8.

**P. 7:** For similar reasons, paragraph 28 (1.1) (c) should be deleted.. An alternative would be to have member states identify the gaps in the needs of their respective countries and report to a subsequent meeting of the WHO. The purpose of this alternative exercise would be to have member states, which should know better the needs of their individual countries, identify the gaps in a way that could point to specific treatments – instead of the WHO Secretariat performing gap analysis in the aggregate and abstract.

**P. 8, paragraphs 28 (1.2) (d) and (e):** Paragraph (d) is unclear about which organizations will ensure leadership. It should be noted that “one size does not fit all” and that different countries have different diseases profiles and resource bases with which to address those public health needs. Regarding (e), if this is confined to “government” R&D efforts, we view this as a EC issue, not COCIR’s.

**P. 9, paragraph 30 (2.1) (a):** We prefer “on research and development,” which is the topic of this report, and not the broader formulation “in support of national health programmes,” which is beyond the scope of the private sector. That is, while the private sector can be involved, the WHO should not have a role in promoting this involvement. We support the voluntary creation of appropriate public-private R&D partnerships.

**P. 10, paragraph 30 (2.2) (g):** We oppose the first formulation, which could easily be interpreted as having WHO advocate and support the “acquisition” of IP, taking the form of compulsory licenses or even expropriation. We can accept the second formulation.

**P. 10, paragraph 30 (2.3) (a):** We oppose the bracketed text which would result in a large new role for WHO, involving resources it currently does not have but presumably would seek to justify.

**P. 10, paragraph 30 (2.4) (d):** We prefer the deletion of paragraphs (d) and (e). Regarding (d), how are “medical inventions” defined? It is also not clear whether this provision would apply only to “inventions” that have been commercially introduced and “proven” in clinical use, or would apply to unproven inventions. Regarding (e), this provision encourages exemptions for IP protection.



**P. 13, paragraph 34 (4.1) (b):** We oppose the development of a list of technologies – “essential” or otherwise. This WHO effort has been explored in other WHO forums and rejected, as being inappropriate and unnecessary. There is no single “list” of technologies appropriate to all developing countries and all disease burdens. WHO should instead explore developing principles each member state could use to determine the medical technologies appropriate for its needs.

**P.13, paragraph 34, (4.1) (d):** How does the proposed “information contained in patents” differ from that in “published patent applications”? Would this language require disclosure of information that is not already disclosed in a published patent application?

**P.13 paragraph 34 4.2(d):** Technology transfer requires a strong IP regime. Otherwise transfer of knowledge would present unacceptable risk to innovators who have invested money to create the knowledge. The IGWG text suggests that low IP levels including use “TRIPS flexibilities” will foster technology transfer. To the contrary, it is the existence of strong IP rights that allows innovators to share innovation knowing that his or her rights remain protected.

**P. 14, paragraph 34, (4.3):** What is meant by “key health related technology”? How does that term differ from others such as “essential medicines” or “essential health technologies”?

**P. 14, paragraph 34, (4.3) (a) and (b):** We urge retention of the proposed “voluntary” nature of such mechanisms. Managing IP rights, which are private legal rights, is the role of users and owners. Governments can only provide a legal framework – provided by TRIPS. They can not actually manage the rights themselves. Patent pools to the extent they are voluntary and not imposed by government fiat are fine.

**P. 14, paragraph 34, (4.3) (c):** We have very serious concerns that “licensing policies” will encourage compulsory licensing of medical technology. We prefer deletion.

**P. 14 paragraph 35**

The IGWG document treats TRIPS flexibilities as if they are to be used as a mere strategic, economic or policy instrument. This runs counter to their purposes as a measure to deal with singular emergency situations or other clearly defined circumstances.

**P. 15, paragraph 36, (5.1) (a):** We prefer the second alternative formulation (i.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”) However, we prefer the deletion of “and management,” if possible, since this implies a WHO role in directing the R&D agenda and how IP maximizes innovation.

**P. 15, paragraph 36, (5.1) (e):** We are concerned that WHO would encourage “flexibilities” in TRIPs in a way that discourages IP protection. It is, however, useful to see the WTO listed as a key stakeholder.



**P.16, paragraph 36, (5.2), 9a) boxed text:** We prefer the second bold face text proposal and the third italicized proposed texts beginning with “upon request.”

**P. 17, paragraph 36, (5.2), (b) boxed text:** We support deletion. The EC surely cannot join a consensus that directly attacks EC trade policy and agreements. Every sovereign nation has the right to negotiate any agreement that is consistent with WTO requirements. TRIPs-plus is obviously consistent with the WTO. WHO has shown no evidence that there is a relationship between such provisions and access to R&D for healthcare and has no legitimate role to discourage such agreements

**P. 17-18, paragraph 36, (5.2), (c):** We believe the EC should only accept text that informs member states, but does not advise them, on WTO flexibilities. The WHO, however, should not be the body that provides this information. The WTO could, if the EC believes there are appropriate experts there. Regarding the last phrase in (5.2), we question the meaning of “misappropriation” but assume this implies that foreign companies, in effect, steal such knowledge.

**P. 18, paragraph 36, (5.3):** Instead of trying to wordsmith this section, we support the weakest formulation. We oppose an assessment of particular features of IP protection, such as data exclusivity and, therefore support deletion of (c).

**P. 19: paragraph 36, (5.3) (d) and (g):** We oppose the implications that IP per se is an anti-competitive practice and, therefore, there should be policies to address this. These paragraphs should be deleted.

**P. 19, paragraph 2.3(f) boxed text:** While we understand the need to assist developing countries in drafting national legislation on IP and TRIPs, we remain concerned about giving a role to WHO in drafting such legislation. Again, this is not the best use of WHO’s limited resources or expertise.

**P. 20, paragraph 39 (6.2):** We support mechanisms to improve regulatory mechanisms, and the national regulatory capacity of member states, that evaluate the safety and effectiveness of medical technology. The drafting of this section should ensure that such mechanisms are consistent with international standards – such as the regulatory guidance developed by the Global Harmonization Task Force (GHTF). We urge that WHO continue to support the adoption of GHTF guidance in member states, but do not believe WHO should have a role in standards-setting or regulatory oversight. We are unsure of some of the terms used, such as “ethical review,” and “operational studies” and oppose WHO doing either.

**P. 21, paragraph 39, (6.2) (g):** This provision should be deleted. We endorse “harmonization of processes employed by the regulatory authorities for drug marketing approvals” (on the assumption this would extend to medical technology). However, we oppose the “elements” listed because they are not normally associated with established regulatory evaluation processes for safety and effectiveness or performance of medical devices. These factors do not pertain to safety and effectiveness, which should be the overriding objective of any regulatory system. Given the limited resources in developing countries, WHO should not be piling on additional and unnecessary regulatory hurdles and requirements. Doing so only contributes to the costs of research and development, ultimately reflected in the



purchase prices of healthcare products. Also, it is unlikely any developing country would have expertise in these areas. Finally, the suggested involvement of “patent offices” in the regulatory process is without precedent or foundation and exceeds the competence of patent authorities.

**P. 21, paragraph 39, (6.3):** We endorse (c) on the removal of tariffs and taxes on health care products, which is consistent with the EC healthcare initiative in the WTO DDA negotiations. We oppose WHO efforts to encourage compulsory licensing. As long as the other provisions in this paragraph do not apply to medical technology, we will refrain from commenting.

**P. 22. paragraph 39, (6.3) (f):** This paragraph should be deleted. We oppose proposals to advocate any form of price monitoring.

**P. 26. box text:** We oppose paragraph 4, since it implies that price is the cause of inequitable access. While not pertaining directly to medical technology, the concept could easily be extended.