Comments to the European Commission on WHO draft global strategy and plan of action on public health, innovation and intellectual property.
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Further to our meeting in Brussels on 31st March 2008, please find below the written comments by Médecins Sans Frontières (MSF) on the WHO draft global strategy and plan of action on public health, innovation and intellectual property, and our suggestions for improving the documents during forthcoming negotiations at the IGWG2bis (28th April – 3rd May 2008).

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1. Limiting the scope of diseases is harmful

1.1 The IGWG is not the first forum where the question of limiting the scope of diseases to a few named diseases is raised. Discussions at Doha, and later at the WTO TRIPS Council in 2002/2003 on the issue of compulsory licenses for export to countries with insufficient production capacity (which resulted in the August 30th solution) also focused on this point. On both occasions the outcome was clear: delegates concluded that the measures to overcome the barriers to access to medicines caused by intellectual property - and the right of countries to implement such measures - should not be limited in scope to a named list of diseases or treatments. Nevertheless, footnote 1 (p5) of the IGWG global strategy and plan of action represents a further attempt to limit the scope of diseases.

1.2 In addition, a limitation would be in flagrant disregard of the CIPIH report's recommendations - which the IGWG is supposed to build upon. The CIPIH report covers Type I, II and III diseases. Such a classification is helpful, as it offers an analysis of the economic and commercial factors that create access and R&D problems. The classification also provides a frame which delegates can use to design solutions that are tailored to specific problems, problems that may be relevant to one type of disease, but not the others.

1.3 MSF sees it as crucial, for the strategy and the plan of action to be effective, that there be no limitation to the scope of diseases. The IGWG aims to address problems that encompass both R&D and access to medicines. These problems vary considerably between the different types of diseases, as classified by the CIPIH. Any limitation in the scope to certain types of diseases only would therefore be extremely counter-productive to the IGWG reaching the full range of objectives it has been entrusted with.

1.4 We therefore ask the Commission to support the deletion of the two sentences that start with "For the purpose of the Strategy …" in the footnote on page 5 [Element 1].

2. R&D priority setting and financing: Proposals that address the de-linkage of the cost of R&D and the price of health products must be encouraged and brought forward

2.1 At a 2007 symposium in New York convened by MSF on tuberculosis drug R&D needs, more than 100 experts from around the world including drug developers, clinical researchers, health professionals, policy makers, donors, drug company representatives and activists recognised that "the lack of TB drug development is a result of the failure of current profit-driven drug research and development model…With respect to TB drug development, participants of the New York symposium support current discussion at the WHO for a treaty on essential health R&D that addresses the question of who pays for essential medical R&D and de-links incentives from drug prices, instead rewarding the impact of inventions according to health care outcomes".[1]

2.2 There is growing recognition of the need for alternative approaches to stimulate and direct medical research and development. Relying predominantly on the patent system to stimulate and finance health R&D has clearly shown it is unable to deliver for patients in developing countries, or for those affected by diseases that do not represent a commercial market.

2.3 The funding gap for R&D is colossal - tuberculosis R&D needs alone, for example, are estimated at US$ 950 million per year[2]. In a worldwide pharmaceutical market already worth US$ 600 billion in 2005[3] steering some of that towards R&D for priority areas could make an enormous difference. It is crucial to bear in mind, however, that it is not just a question of extra funding. A strategy based solely on raising extra financial resources - and relying on product development partnerships to substitute for the pharmaceutical industry for diseases of little commercial value - clearly has its limitations. Indeed, addressing the gap will require new approaches that go beyond good will and philanthropy.

2.4 Relying on patents for financing R&D will merely perpetuate what is recognised as an inefficient system, in particular for Type II and III diseases. We ask the Commission to request the WHO Secretariat move forward with Resolution WHA60.30's call for the development of further proposals that **address "the linkage of the cost of research and development and the price of medicines, vaccines and diagnostic kits"**. The Commission should therefore express its willingness to engage as a stakeholder in the exploratory discussions on other instruments or mechanisms that have a pro-health approach to priority setting and financing of R&D and the management of intellectual property, including inter alia, prize funds, patent pools and an essential health and biomedical R&D treaty.

[1] Conference Statement - *No Time to Wait, Overcoming Gaps in TB Drug Research and Development*, New York, January 2007. Available at: http://www.doctorswithoutborders.org/events/TbSymposium/
[2] *Tuberculosis Research and Development: A Critical Analysis*, Treatment Action Group, October 2006, available at: http://www.aidsinfonyc.org/tag/tbhiv/tbrandd2.html
[3] IMS Health Total Market Estimates and Global Pharma Forecasts, available at http://www.imshealth.com

2.5 Element 5.3 on incentive schemes for research and development therefore needs strengthening. It is essential that it be grounded in practical and timely next steps to encourage the development of such proposals. In that sense, a meeting to discuss proposals included under Element 5.3 (a), such as prize funds, should be convened much earlier than the excessively and unjustifiably lax proposed timeframe 2008-2015. We also ask the Commission to support prize funds and specifically a prize fund for the development of an easy to use at point-of-care tuberculosis diagnostic test.

2.6 Advance Market Commitments are one of the mechanisms – and one that has yet to be seen to deliver efficiently. Any consideration about expanding the use of AMCs therefore seems highly premature. MSF believes the first step must be to assess their effectiveness and efficiency before considering expanding their use [Element 5.3 b].

2.7 The IGWG also provides an opportunity to find better ways to manage IP, to facilitate the developments of new products. One such proposal is the patent pool currently under discussion at the UNITAID. Patent pools offer a potential solution to patent barriers in product development, for example for the development of generic fixed-dose combinations (FDC) of the new WHO recommended first-line regimen for HIV/AIDS, where three different patent holders are involved. As such they deserve to be mentioned under Element 2.3. In addition, the draft envisages a meeting devoted to patent pools only in the timeframe 2008-2015 [Element 4.3 (a)]. Given the urgency of these needs, this meeting must happen earlier.

2.8 A pro-health management of IP also includes proposals on access to compound libraries, policies to ensure access to publicly funded research and access to compounds resulting from such research for development for treatments needed in developing countries [Element 2.2 (b) and 2.4 (c)]. We ask the Commission to support these proposals.

2.9 In the process of implementing Resolution WHA60.30, the European Commission must recognize the WHO as a lead stakeholder (notably concerning discussions on a biomedical R&D Treaty [Element 2.3 (c)].

2.10 Any endeavours to further alternative mechanisms to stimulate R&D will also deal with the question of sustainable financing and how to reach new international agreements on burden sharing of R&D cost. These must therefore also be mentioned in the text that calls for addressing sustainable financing mechanisms for R&D that do not come at the expense of access to medicines. [Element 7.1 (b)]

2.11 In order to aid the task of developing sustainable financing mechanisms, the European Commission should request WHO to carry out an objective assessment by independent experts of the costs of R&D, so that the contested figures about the cost of R&D per drug may be clarified. [Element 7]

3. Access and delivery: Availability of generic products and competition between manufacturers must be encouraged and the use of the TRIPS flexibilities reinforced

3.1 MSF has documented how competition between manufacturers has been the single most effective mechanism in pushing prices down and enabling access to medicines. Without the 99% decrease in the price of first-line AIDS drugs, MSF would not now be able to provide antiretrovirals for over 100,000 patients in 30 countries.[4]

3.2 The role of competition is ever more crucial in a "post-TRIPS" era. Here the CIPIH warns: "now that the [TRIPS] transition period is over, companies can patent new products in all WTO members (…). It is uncertain how this might affect worldwide pricing and the accessibility of new products, and how, in the absence of potential competitive pressure, pricing of the kind that emerged to date in the antiretroviral market can be sustained"[5]. Newer generation antiretrovirals are particularly affected – with the adoption of new WHO recommendations for first-line regimens, the best generic price for a first-line is set to skyrocket from US$99 (old regimen) to, at best, US$487 (new regimen). Second-line regimens are a further problem: as HIV increasingly becomes a chronic disease for which life-long treatment must be given, WHO must have a strategy that addresses how to make these treatments affordable in a post-TRIPS era, when generic competition can no longer be expected to come to the rescue.

3.3 Developing countries are increasingly dealing with the double burden of infectious and non-communicable diseases. Indeed, the World Bank estimates that by 2015, chronic non-communicable diseases will be the leading cause of deaths in the developing world[6]. As such, problems related to the access of new drugs are likely to increase.

3.4 The CIPIH recommends that developing countries "adopt or effectively implement competition policies and apply the pro-competitive measures allowed under the TRIPS Agreement in order to prevent or remedy anti-competitive practices related to the use of medicinal patents"[7]. Yet the draft plan of action's [Element 6.3] on the role of competition and the pricing of medicines fails to heed that warning, contenting itself with stimulating generic competition only *after* a patent has expired. But patients cannot afford to wait the twenty-year terms for a patent to expire before being able to access life-saving medicines. The draft plan - with its proposal to stimulate generic competition after patent expiry - shows a lack of understanding of the TRIPS flexibilities such as compulsory licensing, and a lack of understanding of how they should be used to increase access while patents are still in force.

3.5 The official European Commission's position is that it supports the use of TRIPS flexibilities as per the Doha Declaration on the TRIPS Agreement and Public Health, to

[4] MSF pricing guide to antiretrovirals - Untangling the Web of Price Reductions www.accessmed-msf.org
[5] CIPIH report p135
[6] Public Policy and the Challenge of Noncommunicable Diseases, IBRD/World Bank, July 2007
[7] CIPIH recommendation 4.23 p147

increase access to medicines. The Commission also prides itself on the role it played in the negotiations that led to the adoption of the Declaration in 2001. However recent positions by the Commission with regard to the compulsory licenses issued in Thailand (as illustrated by the EU Commissioner for Trade Peter Mandelson's letters to Thailand Minister of Commerce, dated 10th July 2007 and 21st February 2008) suggest that in practice the Commission's activities are at odds with its public pledges, and are reason for considerable concern.

3.6 We urge the Commission and in particular DG Trade to show its unequivocal support for the use of the TRIPS flexibilities and the full implementation of the Doha Declaration in the IGWG process, as requested by the European Parliament.[8] The Commission should support unambiguous language in Element 5 that calls for the use of these provisions to increase access, produce and export generics and to overcome patent barriers in research. The Commission should not accept any restriction as to diseases or products or circumstances, nor support procedural requirements that are 'TRIPS plus' (such as prior negotiations in a case of public non-commercial use).

3.7 It is important to note here that the progress indicator for Element 6.3 (d) on compulsory licensing for export to "developing countries *declaring a public health emergency"* is an inaccurate interpretation of international legislation enshrined in the TRIPS Agreement, including the amendment of December 2005, and the Doha Declaration. A declaration of public health emergency is not a pre-requisite for the issuance of compulsory licenses for export. This inaccuracy must be corrected and the italicised fragment removed.

3.8 The IGWG draft addresses issues related to 'TRIPS plus' in Element 5. Developing countries have agreed to abide by TRIPS and the Doha Declaration, partly on the understanding that this multilateral agreement would free them from bilateral pressures to adopt higher standards in intellectual property protection. Yet the European Commission's trade policy involves promoting a 'TRIPS plus' agenda in health - as is evidenced by its position on the recent Thai compulsory licenses and through the promotion of data exclusivity rules that go well beyond the TRIPS Agreement requirement on data protection.

3.9 We therefore ask the Commission to support proposals that are aimed at countering 'TRIPS plus' provisions. An example is the proposal to discourage or avoid the incorporation of 'TRIPS plus' provisions in bilateral agreements in Element 5.2 (b).

3.10 In addition, the European Commission should support the recommendation of the CIPIH report with regard to protection of pharmaceutical test data. Where the CIPIH report is explicit, recommending that "developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair

[8] Resolution of the European Parliament November 30, 2006 & Resolution of the European Parliament July 12, 2007

competition or impede the use of flexibilities built in to TRIPS"[9] the draft plan of action is vague and non-committal, only requiring a diffuse group of stakeholders to "assess the impact of data-exclusivity regulations" [Element 5.3 (c)]. The draft plan should build on this analysis and recommendation and not seek to repeat work that has already been done by the CIPIH.

3.11 Finally, Element 5.1 (b) calls for the exchange of information between national regulatory authorities (NRA) and patent offices in developing countries to be established or strengthened. It is important that this does not result in the NRA playing an active role in patent enforcement, as is foreseen in some countries' trade agreements or regulations. What is crucial is that health experts, including those at the NRA, play the important role of providing a health perspective to patent examiners. It is also essential that the action plan addresses the need for NRAs including in developing countries to play a role in stimulating R&D for diseases that disproportionately affect developing countries. This will require developing regulatory practices that weighs risks and benefits in a manner that reflects the reality of those countries. The European Commission should request WHO to guide efforts to strengthen drug regulatory agencies in developing countries and in particular drug regulation processes that aim at finding practical solutions regarding drug registration for new medicines disproportionately affecting developing countries.

4. The role of WHO in IP and public health must be strengthened

4.1 WHO should be encouraged to provide technical and policy support on issues related to measures to ensure access to medicines for all. This should not be confined to 'upon request' only as this will hamper WHO's efforts to develop briefing material for general use and only act on a per country basis.

4.2 WHO's failure to provide timely technical assistance to date is to the detriment of procurement practices in developing countries. NGOs are often called upon to fill these gaps. The Commission should take a firm stand and ensure that WHO can fulfil its mandate and not obfuscate the debate by supporting the view that all trade matters belong to the WTO and all IP matters to WIPO, or that the WHO can only act 'upon request' by a member state. While there may be a need for coordination between WHO, WIPO and WTO on the issue of public health and intellectual property [Element 5.1 (i)], it is of vital importance that WHO retain its independence in providing health-based advice and information on IP issues.

4.3 The recent past has shown how WHO has experienced pressures from certain key countries when providing information on IP and health – to the extent of calls to withdraw publications and remove WHO's logo from publications. [10] [11]

[9] CIPIH recommendation 4.2 p122
[10] See for example: http://www.ip-watch.org/weblog/index.php?p=409&res=1024_ff&print=0.
[11] Letter from William R. Steiger to Acting Director General of the WHO Anders Nordström, 18 August 2006

4.4 The Commission should actively reject this kind of pressure on the WHO when it engages in IP issues and support clear language in the IGWG that strengthens WHO's role in IP and health.

5. The proposal to set up a Global Fund for Neglected Diseases should be amended to ensure that certain conditions are fulfilled: such a fund should be based on the principle that when R&D is financed up front, the results of such R&D should be put in the public domain and available for all to produce and further improve. The Fund should favour open source and open access R&D and focus on capacity development in developing countries and diversity in research. It should also go hand and in hand with prize fund proposals. Instead of patent buy-out – which may only be an incentive to take out more, and not fewer patents in the area of neglected diseases – it may be more sensible to set up a patent pool to overcome patent barriers to production and R&D carried out with financing of the Fund. In addition, in order for the Fund not to be an empty promise, countries need at the next IGWG meeting to indicate how much they are willing to pledge to such a mechanism.