

Second Public Hearing on Public Health, Innovation and Intellectual Property  
Submission to Section 1 – Draft Global Strategy and Plan of Action  
Médecins Sans Frontières - Campaign for Access to Essential Medicines

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Médecins Sans Frontières (MSF) welcomes the opportunity to participate in the second public hearing held in view of the upcoming second meeting of the Intergovernmental Working Group on Public Health, Innovation & Intellectual Property (IGWG).<sup>1</sup> We wish to raise the following points:

**1. The draft global strategy and plan risks failing to build on the CIPIH report’s analysis**

The Commission on Intellectual Property, Innovation and Public Health (CIPIH) published a landmark report with rich analysis into the barriers concerning both accessing essential medicines, and the innovation environment that fails to allow such medicines to be developed. MSF is concerned to note that the draft plan does not sufficiently build on the report’s findings and sixty recommendations. Some of the points of the plan of action seem to disregard the analyses and conclusions of the CIPIH report and want to redo the work, or to water down the language or strength of the report’s recommendations considerably.

On the one hand, it **overestimates the importance of IP in relation to innovation** for diseases disproportionately affecting developing countries, by stating that “intellectual property is a vital concept in ensuring the development of new health products continues” [Element 5 para. 16]. Here the draft contradicts the CIPIH report’s analysis that “for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market”.<sup>2</sup> The CIPIH also concluded that increasing levels of intellectual property will not reverse the neglect of R&D: “there is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor”.<sup>3</sup>

A look at diagnostics R&D illustrates how the lack of market incentives influences the R&D agenda. Take Chagas disease- the need for highly sensitive and specific tests to protect blood bank stocks in wealthier countries has pushed R&D efforts towards high tech diagnostics unsuitable for patients living where the disease actually takes its heaviest toll. For them, no adapted test exists. Another example is HIV/AIDS; for all the high tech solutions offered to patients in the North, diagnostic needs adapted to developing countries remain acute, particularly for simplified patient management such as point-of-care viral load or CD4 counts.

R&D into drugs tells a similar tale. The current model for developing treatments for HIV/AIDS for resource-poor settings is to make drugs that are developed for the West work in poor countries. The lack of an HIV/AIDS R&D agenda tailored to needs in Africa means that questions critical to treating the disease in the South are not addressed. For example, the interaction of antiretrovirals with other

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<sup>1</sup> The November 2006 submission by Médecins Sans Frontières to the first IGWG public hearing is available at: [http://www.who.int/phi/public\\_hearings/first/15Nov06EllentHoenMSF.pdf](http://www.who.int/phi/public_hearings/first/15Nov06EllentHoenMSF.pdf)

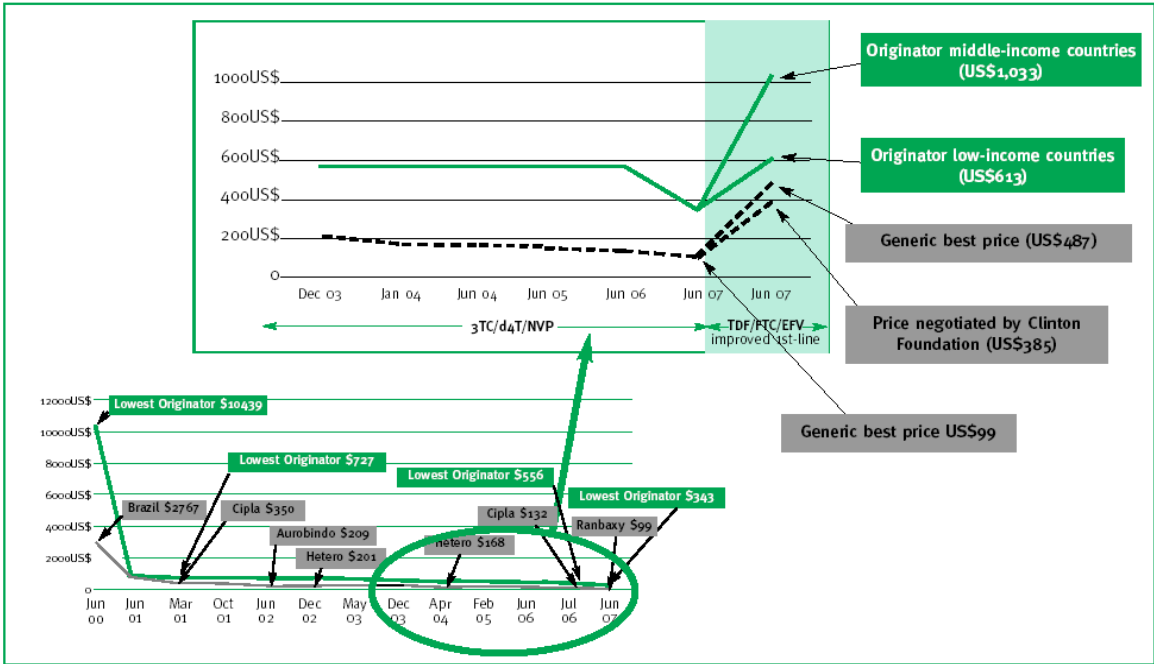
<sup>2</sup> CIPIH report p34

<sup>3</sup> CIPIH report p102

treatments such as those for malaria and tuberculosis, or trials to determine the most relevant drug combinations or dosages in resource poor settings. Logistical needs like avoiding refrigeration - are largely ignored. Key research questions relevant for resource-limited settings are often raised long after a drug has been registered and marketed in the US and Europe.

At the same time, the draft **underplays the consequences of IP in relation to access** to medicines. MSF has documented how competition between manufacturers has been the single most effective mechanism in pushing prices down and allowing 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.

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”.<sup>4</sup> Newer generation antiretrovirals are particularly affected - the best generic price for the new WHO recommended first-line regimen is set to skyrocket from US\$99 to at best US\$487. (See graph).<sup>5</sup> Second-line regimens are a further problem: as HIV increasingly becomes a chronic disease for which life-long treatment must be given, WHO must give an indication of how to make these treatments affordable in a post-TRIPS era where generic competition can no longer be expected to come to the rescue.



Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest prices per patient per year. Improved first line: tenofovir (TDF) + entricitabine (FTC) + efavirenz (EFV)

The CIPIH goes on to recommend 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”.<sup>6</sup> Yet the draft plan of action’s Element 6.3 on the role of **competition and the pricing of medicines** fails to

<sup>4</sup> CIPIH report p135

<sup>5</sup> *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of Antiretrovirals for Developing Countries*, 10<sup>th</sup> edition, July 2007 (revised), available at: [http://www.accessmed-msf.org/documents/UTW\\_REVISIED\\_10.pdf](http://www.accessmed-msf.org/documents/UTW_REVISIED_10.pdf)

<sup>6</sup> CIPIH recommendation 4.23 p147

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 therefore shows a lack of understanding of how TRIPS flexibilities such as compulsory licensing could be used to increase access while patents are still in force.

Recent controversies surrounding compulsory licensing illustrate the need for clarity here. In a July 2007 letter to the Thai minister of Commerce, the European Commissioner for Trade claimed to “strongly support the Doha Declaration on TRIPS and Public Health, including the flexibilities it contains. We recognise the right of WTO members to grant compulsory licenses”. The same letter goes on to criticise Thailand heavily for having done exactly that, calling compulsory licensing an “exceptional measure”, a view that is not supported by the Doha Declaration. It is important to note on this issue 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 Doha Declaration. This inaccuracy must be corrected and the italicised fragment removed.

It is important to note here that developing countries are increasingly dealing with the double burden of infectious and non-communicable diseases and that problems with access to new drugs are likely to increase. The World Bank estimates that by 2015 chronic non-communicable diseases will be the leading cause of deaths in the developing world.<sup>7</sup>

A further example of where the draft action plan needs strengthening concerns **the 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 competition or impede the use of flexibilities built in to TRIPS”,<sup>8</sup> 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.

## **2. The draft strategy and plan of action does not give a strong enough leadership role to WHO on key policy issues**

It remains unclear how WHO will seek to engage such a wide variety of stakeholders on such a vast range of issues. Several areas covered by the plan require greater and more proactive involvement from WHO, particularly in areas where the agency must show concrete policy leadership.

WHO must show greater leadership, for example, on the **full and immediate implementation of the Doha Declaration** on TRIPS and Public Health. Here WHO must implement WHA60.30, which called for the Director-General to provide “technical and policy support to countries that intend to make use of flexibilities contained” in the TRIPS Agreement. This must be done without delay, proactively and continuously. As the leading agency for health, WHO must not limit itself to an intervention “upon request” basis, nor solely to “promoting legislation to apply flexibilities consistent with TRIPS” [Element 5.2 (a)]. Nor should WHO be “promoting bilateral trade agreements” [Element 5.2 (b)]. Instead WHO must inform and advise countries on the negative consequences trade agreements may have on public health, if they include restrictive IP provisions. WHO should also commit to monitoring their impact continuously and proactively guiding countries and others such as donor agencies on how to deal with patent barriers to access to medicines.

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<sup>7</sup> Public Policy and the Challenge of Noncommunicable Diseases, IBRD/World Bank, July 2007

<sup>8</sup> CIPIH recommendation 4.2 p122

With regard to the implementation of Doha, the documentation and dissemination of best practice, although by no means sufficient, are useful. In this respect, WHO must immediately disseminate the joint WHO/South Centre publication on the use of TRIPS flexibilities.<sup>9</sup>

MSF would like to see WHO move forward with 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”**. There is growing recognition of the need for new approaches and the limitations of a 'more of the same' strategy focusing exclusively on raising extra financial resources or relying on product development partnerships. At a 2007 symposium 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”.<sup>10</sup>

WHO must lead this forward. We note here that in addition to the present call for responses to the draft strategy and plan of action, this public hearing includes a second section – a call for “proposals in response to Resolution WHA60.30”. It must be stressed however that such a call for proposals, although welcome, does not mean in our view that WHA60.30's instructions to the Director-General to “encourage the development” of such proposals is fulfilled.

### **3. MSF welcomes the fact that the draft embraces the idea of exploring new mechanisms for financing for R&D, but more needs to be done**

It is very encouraging that the draft urges further work on proposals, including the R&D treaty, prize funds, patent pools or other mechanisms that have a pro-health approach to priority setting and financing of R&D and the management of IP. Nevertheless Element 5.3 on complementary incentive schemes for research and development needs strengthening. A meeting to discuss proposals included under Element 5.3 (a) such as prize funds should be convened much earlier than the proposed timeframe 2008-2015. It would also be important to look into the effectiveness and efficiency of advanced market commitments.

Such endeavours 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 also be mentioned under the Element 7.1 (b) addressing sustainable financing mechanisms for R&D that do not come at the expense of access to medicines. The funding gap for R&D is colossal - tuberculosis R&D needs alone, for example, are estimated at US\$ 950 million per year.<sup>11</sup> In a worldwide pharmaceutical market already worth US\$ 600 billion in 2005,<sup>12</sup> steering some of that towards R&D for priority areas could make an enormous difference. But addressing the gap will require new approaches that go beyond good will and philanthropy. Relying on patents for financing R&D will merely perpetuate what is recognised as an inefficient system.

In order to aid the task of developing sustainable financing mechanisms, WHO should also 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]

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<sup>9</sup> *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* WHO/South Centre, April 2006. Currently available at:

<http://www.southcentre.org/publications/SouthPerspectiveSeries/TheUseOfFlexibilitiesInTripsFinal.pdf>

<sup>10</sup> 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/>

<sup>11</sup> *Tuberculosis Research and Development: A Critical Analysis*, Treatment Action Group, October 2006, available at: <http://www.aidsinfonyc.org/tag/tbhiv/tbrandd2.html>

<sup>12</sup> IMS Health Total Market Estimates and Global Pharma Forecasts, available at <http://www.imshealth.com>

#### **4. The draft global strategy and plan of action risks not being translated into concrete action**

There are several points to make here. Firstly, the draft **lacks urgently needed prioritisation**. Inevitably perhaps, the scope of the draft is extremely vast. Yet the list of eighty potential actions offered in the action plan represents an all-inclusive smörgåsbord of policy options. Giving no sense of prioritisation to individual actions risks diluting the process to the point where coherent progress is impossible. WHO must identify specific key areas where immediate action is urgently required, and prioritise individual actions under the plan to give a sense of hierarchy.

Secondly, **the timeframes for individual actions are too loose** and need to be tightened up. The reference to patent pools is an example here. Patent pools may be a potential answer to barriers (as such they deserve to be mentioned under Element 2.3) 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. 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.

There is also a need to give particular attention to specific medical gaps where urgent action is required, in order to ground the IGWG in reality and give it focus. WHO should give more substantial guidance on priorities for essential health R&D. The draft plan of action reads as if these still need to be determined whereas in fact considerable progress has been achieved in this area, and WHO should build on such initiatives as the CIPIH, the WHO report on priority medicines for Europe and the World, the MSF Neglected Disease Group, TDR and others.

Thirdly, the draft **fails to allocate individual responsibilities**. For each of the action points in the draft, there is no mention of specific responsibilities, and only a reference to a list of stakeholders, with on occasion a 'lead stakeholder' in bold. But without allocating concrete action points to individual actors, it is difficult to see how the process will be driven forward and by whom. This represents a dangerous step back from the detailed allocation of recommendations to individual actors proposed by the CIPIH.

The passage on compound libraries illustrates this point [Element 1.2 (a)]. Here the draft strategy and plan of action lumps a loose coalition of six actors together -with WHO and the pharmaceutical industry designated as lead stakeholders - and merely states a vague objective of 'improved accessibility'. But this leaves no sense of *how* things will happen: how proactive use of the research exemption by developing countries will be encouraged, how pharmaceutical companies will be compelled to screen their libraries for possible activity in a number of priority diseases, of how the lead stakeholders should coordinate. The CIPIH in contrast allocates individual tasks to individual actors – including developing country governments, WHO, developed country public research institutions.

Finally, the draft strategy and plan **fails to define concrete meaningful progress indicators**.

Progress indicators must be qualitative and not quantitative. Yet many of the progress indicators in the draft are not pertinent to the task at hand. These include, but are not limited to, the following:

- Given the lack of evidence of the value of patents in promoting R&D for diseases disproportionately affecting developing countries, how can measuring the “number of patents held by developing country research and academic institutions” be considered an indicator of progress for research into Type II and Type III diseases? [Element 2.3 (c)]
- Element 5.1 (b) seeks to measure the number of national databases on patent status. MSF believes these to be of limited usefulness. A more appropriate action for WHO would be to compile an international database of the patent status of essential health-related products. Such a database, requested for a number of years already by Member States, manufacturers and civil society alike, and

recommended by the CIPIH,<sup>13</sup> should include information on whether and where patents have been amended, opposed, rejected or revoked, in order to be comprehensive and objective.

- Element 5.1 (b) also 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 trade agreements. What is crucial is that NRAs 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. WHO must 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.

- What will the number of developed countries that do not agree to TRIPS+ protection in trade agreements, or the number of trade agreements containing TRIPS flexibilities actually tell us, without an analysis of the effects of such measures? [Element 5.2 (b) and (c)]

- Although counterfeits are a serious issue, it is a problem distinct from that posed by drugs of substandard quality. WHO's focus on counterfeits under Element 6.2 (e) must not be to the detriment of addressing the need for capacity building and support for regulatory agencies and good manufacturing capacity in developing countries to effectively tackle the problem of substandard drugs.

## **CONCLUSIONS**

The IGWG must focus on the principle of essential medicines, diagnostics and vaccines. WHO and governments have an obligation to make those essential health tools available and affordable to their populations. In today's post-TRIPS environment, this will entail reviewing the rules and regulations that hamper either access to medicines or the development of new health tools that respond to diseases that disproportionately affect developing countries. At the same time the IGWG should focus on ensuring that new essential medicines and other health technologies are being developed.

MSF believes that the draft strategy and plan of action must be given a sense of prioritisation; it must be given stronger and more pertinent indicators; the timelines need to be shortened to reflect the urgency of the task at hand; and a clearer sense of specific responsibilities by individual actors, and particularly WHO's leadership on policy issues must be included.

Above all, the draft must be grounded in the reality of urgent R&D needs today, and respond to the problems of access to medicines, diagnostics and vaccines caused by more widespread pharmaceutical patenting. The strategy and plan must build on and not water down or sidestep the analysis and directions given by the CIPIH analysis and WHA Recommendations. As a first next step, proposals on incentive mechanisms for R&D that assure access should be developed.

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<sup>13</sup> CIPIH recommendation 4.17 p140