Towards a health needs driven framework for R&D and access to medicines

Médecins Sans Frontières (MSF) welcomes the opportunity to respond to the call for contributions to the public hearings held in view of the upcoming Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property. For the purpose of this contribution, we have chosen to follow the guidance of the questions provided in the instructions for contributors.

1. Would you recommend any other issue to be considered within the proposed plan?

The report of the Commission on Intellectual Property, Innovation and Public Health (CIPIH) is a comprehensive analysis that encompasses key aspects of problems related to both accessing essential medicines, and to the innovation environment that allows such medicines to be developed. This report, and its recommendations, should be the starting point of the debates to be held by the IGWG.

The IGWG should approach essential health research and the products that develop from such research as global public goods.

2. What issues do you feel would be most important to be considered in the plan?

The analysis contained in the CIPIH report is an extremely important contribution that adds to the now considerable body of evidence provided by a number of other sources. [1,2] These studies converge to conclude that making the medical research and development (R&D) system prevailingly dependent on patents and other forms of intellectual property (IP) protection carries significant consequences for the setting of R&D priorities, with a detrimental effect for diseases that disproportionately affect developing countries.

One crucial consequence is the absence of financial incentives to drive the discovery and development of medical tools – be they diagnostics, drugs, vaccines or others – when the client population has insufficient purchasing power. [3]

MSF is well placed to witness this first-hand. Indeed, MSF doctors face the extreme frustration of lacking reliable, adapted, safe and efficacious tools to diagnose, treat or prevent a range of diseases in patients attending our clinics. This is of course true of the most neglected diseases, such as sleeping sickness – diagnosing this fatal disease requires lumbar puncture, putting it far beyond the reach of most health facilities – or kala azar, where treatment developed in the 1930s is still the mainstay of therapy despite considerable toxicity and complexity. Recent research shows how neglected diseases still only account for 1% of new chemical entities reaching the market. [4]

But the problem is not restricted to neglected diseases, for it also applies to far more visible illnesses that are responsible for high levels of mortality and morbidity in considerable patient populations. The HIV-fuelled tuberculosis (TB) epidemic in Africa is now further exacerbated by the spread of multi-drug-resistant and even extensively drug-resistant strains. Yet the lack of reliable easy-to-use tests to detect infection is insufficiently addressed by current research efforts. [5] Nor will the drug pipeline bring the necessary breakthroughs for treatment, unless greater prioritisation and further resources are allocated to R&D efforts. [6, 7] Another illustration of the crisis is the lack of research undertaken into the development of diagnostic or treatment tools for children with HIV/AIDS. Here again, when patients cannot afford to pay, the market provides no pull mechanism into certain areas of R&D, and essential medicines are left undeveloped.

The under-investment into the development of newer antibiotics is a further example of the shortcomings of market mechanisms for medical R&D. [8]

These concerns should be viewed against the backdrop of generally disappointing innovation levels. [9, 10] In France, for example, a survey published in April 2005 concluded that 68 percent of the 3,096 new products approved in the country between 1981 and 2004, brought 'nothing new' over previously available preparations. [11] Similar data showing the decline in innovation levels could be given for Canada [12], or for the United States [13].

But arguably the CIPIH report's most important contribution is its consideration of the entire innovation cycle that includes not just discovery and development, but also delivery. In other words, one must also examine the uptake an innovation receives once it has been developed. If patients desperately needing new medical tools cannot access them, innovation remains useless. Here the CIPIH report for the first time addresses problems related to *both* innovation *and* ensuring access, where previously the debates on access and innovation had been divorced.

Although there are many barriers to accessing essential medicines, a key obstacle is the question of price. IP here has a crucial role to play: MSF documentation has shown how competition between manufacturers, which IP protection is designed specifically to prevent, is the only way to bring prices of medicines down to a sustainable level so that patients or ministries of health can afford them. [14]

The price of antiretroviral (ARV) drugs that have been available for a number of years for the treatment of HIV/AIDS has fallen dramatically and continues to drop with the advent of competition from a number of manufacturers. Newer ARVs, on the other hand, still protected by patents and other forms of intellectual property, cost up to 50 times as much. [14] Indeed, the cost of providing the essential medicines for AIDS today is actually increasing, due to the need for newer drugs. Five years after the Doha Declaration promised to re-establish the balance between intellectual property and public health, this fatal imbalance prevails, and the positive developments of recent years are being lost.

The urgency to these issues should not be underestimated. MSF sees a growing number of patients in its HIV/AIDS and other programmes who need to access newer drugs now, or in the very near future. But they will continue to be denied them, if today's paradigm of financing R&D through IP, and at the expense of access to medicines for the poor, is maintained. Price reductions offered by pharmaceutical companies are not the solution, as they are insufficient and make funding of medical programmes unsustainable.

Both of these questions – those relating to innovation and those concerned with access - call for governmental intervention. The CIPIH report makes it clear that "relying on purely economic mechanisms cannot solve the problem" [15], and that government action, and indeed global action, is needed to ensure that innovation is steered to meet real health needs, and that access to innovations is secured for all.

What is needed is a concerted effort towards a sustainable plan to promote innovation and access for diseases that disproportionately affect developing countries. Such a plan would need to be a global plan of action for both WHO and its Member States to implement the CIPIH recommendations. Whilst some recommendations will be for immediate implementation, others may require a longer political process. But it is vital that the plan focus both on innovation, and on access.

For questions related to innovation, the plan must include:

- The priority setting of R&D, so that medical innovation is steered by and responds to identified health needs, and not by commercial concerns dictated by the market;
- Innovative solutions to tackle the problems created by the current dependence on IP to finance R&D. Many interesting ideas have been suggested in recent years and deserve to be given full attention in this forum. They include patent pools, prize funds for R&D and proposals for a convention on R&D;
- New ways to finance essential health R&D in a sustainable matter. R&D costs must be separated from the end costs of products. Financing plans must also address the gap in translational research, as identified by the CIPIH.

For questions related to access, the plan must include:

- Clear avenues and actions to promote the use of existing mechanisms that facilitate access to medicines, by encouraging the production and exportation of generic medicines. This includes the promotion of tools available to governments, such as compulsory licences, to help secure access to medicines for their populations. The WHO's role to assist countries in making this happen must be explicated here;
- Concerted review and amendment of the mechanisms in place today that are failing and have shown to not contribute to solving the access to medicines problem. This includes submitting recommendations to the World Trade Organization (WTO) for amendment to its rules governing the exportation of medicines under compulsory licence, known as the August 30th Decision. [16]

Over and above these two tracks, the plan must be global. It must involve a strategic direction for the WHO, and address recommendations to a number of different players, including WHO, Members States, other international agencies such as the World Intellectual Property Organization (WIPO) and WTO, and other players such as research institutes, pharmaceutical companies, regulatory authorities, and others.

Finally, it is crucial that a monitoring mechanism be put in place, for these different actors to report on their progress, and so that experience may be shared as the plan is progressively implemented.

3. How do you see your organisation contributing to the proposed plan?

Médecins Sans Frontières is eager to participate actively in the IGWG. We believe ourselves to be in a strong position to offer input to the IGWG, on both questions related to innovation and those concerning access.

For questions concerning innovation, MSF can help the Group in identifying what health needs are currently neglected and need prioritisation, through the experience of our field projects in over 70 countries. We can share our analysis of the needs of patients, and the gaps we see in today's R&D efforts. We can examine the feasibility of new proposed funding mechanisms for R&D.

For issues related to access to medicines, MSF can help identify barriers to access, and propose solutions for overcoming them. We can assist in examining the feasibility of new mechanisms, and can share our expertise on existing mechanisms that facilitate the reduction of prices, and the increased production and exportation of essential medicines.

MSF would like to note however its disappointment that no accreditation process to participate in the IGWG has been established for NGOs that are not in official relations with WHO, and would like to suggest one be established, modelled for example on the process used for the Tobacco Convention or WIPO meetings.

4. Is your organisation already implementing components of resolution WHA 59.24 at the moment? What have been the outcomes?

It is important to note that the Resolution is a call on WHO and its Member States. Nevertheless, as a part of its mandate, Médecins Sans Frontières has been active on both fronts at the heart of the Resolution – innovation and access - and indeed actively brought its expertise to the discussions held by the CIPIH.

For questions related to innovation, MSF has sought to challenge and respond to the lack of R&D for neglected diseases. Following considerable gathering of evidence and expertise through the Neglected Diseases Working Group [17], MSF co-founded with a number of governmental research institutions the Drugs for Neglected Diseases Intiative (DNDi). Since its creation, DNDi has focussed on product development for neglected diseases and is expected to release a new malaria treatment before the end of 2006. In parallel, MSF is currently working with different academic and private actors to respond to market failures and develop a tool for diagnosis of HIV in infants, and for monitoring of HIV treatment failure, that is adapted to the settings in which we work.

For matters related to access to medicines, MSF has engaged in the on-going Campaign for Access to Essential Medicines. The drive for the Campaign stems from the frustration felt by field doctors at the commercial and political barriers that stand in the way of getting safe, efficacious and adapted medical tools to patients in MSF clinics. Part of the Campaign's remit is to build and disseminate knowledge on the relationship between intellectual property, innovation and public health, for example through research on the impact of patents, of competition between manufacturers, of the TRIPS Agreement, and of WTO mechanisms on the prices of drugs and access to medicines, as well as analyses of the R&D environment [5, 6, 14, 16, 17, 18, 19].

We look forward to sharing our expertise and perspectives with the IGWG.

5. What other suggestions do you have for the IGWG and WHO, as we take forward this important and challenging task?

It is important that the WHO maintain its focus *both* on innovation *and* on access to medicines, all the while giving primacy to public health concerns.

In matters related to innovation, the IGWG should not limit itself to calling for new funding mechanisms. Although securing the sustainable financing of R&D is of crucial importance, it is not enough. Recent years have seen repeated promises that R&D into neglected diseases would be stimulated, if only IP were strengthened in developing countries. [20] This has now happened, but promises of greater investment into R&D driven by health needs have not been fulfilled. [5, 6, 7, 21] Similarly, the need for greater financing must not distract the IGWG from addressing the wider issues.

Product development partnerships (PDPs) respond to part of the problem but are by no means enough: viewing the response to tuberculosis, for which PDPs exist, and the response to cancer or cardiovascular disease, by comparing the number of potential drugs under development for example, illustrates the shortcomings of relying solely on PDPs. There is increasing documentation that new philanthropic efforts are far from enough to address the crisis. [5, 6, 7, 21] Indeed, PDPs themselves acknowledge that more governmental responsibility is needed, [22] just as pharmaceutical companies have stated that they cannot respond, without an overhaul of the system. [23] The IGWG must explore these and additional concerns, and not limit itself to the financial angle.

Regarding access to medicines, the IGWG must address the consequences on the price of drugs of the absence of competition amongst manufacturers, and explore solutions to overcome these obstacles. We recommend the Group does not accept a reduction in the scope of its mandate to cover neglected diseases only. Indeed, major diseases including HIV/AIDS and non-communicable diseases are also affected, and should not be ignored.

More generally, we are particularly encouraged that WHO appears to be emerging from its relative silence on crucial questions related to innovation and intellectual property protection. We regret to note that this silence has left the field open to other agencies such as the WTO and WIPO that are not apt to give proper consideration to health issues. As such, the IGWG process is an unprecedented opportunity, both for WHO and beyond, for these issues to be examined with the consideration of health above all other concerns. WHO should seize this opportunity to re-establish its leadership on health, and make active recommendations to WIPO and WTO.

The Intergovernmental Working Group is an historic opportunity that WHO must not squander. Médecins Sans Frontières urges Member States to take up this challenge, and fulfil what the CIPIH report was right in calling a "moral imperative". [24]

References:

[1] UK Commission on Intellectual Property Rights www.iprcommission.org
[2] UN Millennium Project: Taskforce on HIV/AIDS, Malaria, TB and Access to Essential Medicines
[3] Commission on Intellectual Property Innovation and Public Health Report, p28-9, p34
[4] Chirac P, Torreele E, Global framework on essential health R&D, Lancet 2006; 367:1560-61
[5] Tuberculosis diagnosis and drug sensitivity testing, an overview of the current diagnostic pipeline, Médecins Sans Frontières, Paris, October 2006, available from www.accessmed-msf.org
[6] Development of new drugs for TB chemotherapy, overview and critical analysis of the current drug pipeline, Médecins Sans Frontières, Paris, October 2006, available from www.accessmed-msf.org
[7] Tuberculosis research and development: a critical assessment, Treatment Action Group, available from www.aidsfornyc.org
[8] Open letter from scientists in support of World Health Organisation resolution proposed by Brazil and Kenya, January 2006, available from www.whoscientistsletter.org
[9] CIPIH report p81, p149
[10] From bench to bedside – could a new business model revive drug discovery, The Economist, 2nd November 2006, London
[11] A review of new drugs in 2004: Floundering innovation and increased risk-taking, Prescrire International 2005 14:76 pp68-73
[12] Barer M, Caetano P, Black C, Morgan S, Bassett K, Wright J, Evans R, Breakthrough drugs and growth in expenditure on prescription drugs in Canada, British Medical Journal, 2005 331:815-16
[13] Research and development in the pharmaceutical industry, Congress of the United States, Congressional Budget Office, October 2006
[14] Untangling the Web of Antiretroviral Prices, 9th edition (revised), Médecins Sans Frontières, Geneva, 2006, available from www.accessmed-msf.org
[15] CIPIH report, p196
[16] Neither expeditious, nor a solution – the WTO August 30Th Decision is unworkable; Médecins Sans Frontières, Geneva/Montréal, 2006, available from www.accessmed-msf.org
[17] Fatal imbalance – the crisis in research and development for drugs for neglected diseases, Médecins Sans Frontières and Drugs for Neglected Diseases Working Group, Geneva, 2001
[18] Drug patents under the spotlight, Médecins Sans Frontières, May 2003, available from http://www.accessmed-msf.org
[19] Determining the patent status of essential medicines in developing countries, Health Economics and Drugs, EDM No 17, UNAIDS, WHO & MSF, available at http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.6.pdf
[20] Pecoul B, Chirac P, Trouiller P, Pinel J, Access to essential drugs: a lost battle? JAMA 1999; 281:361-67
[21] Moran M, The new landscape of neglected disease drug development, London School of Economics/Wellcome Trust, September 2005
[22] Boosting Innovation for neglected diseases – a call to governments; DNDi Research Appeal, available from www.researchappeal.org
[23] Novartis chief in warning on cheap drugs, Financial Times, 30th September 2006, London
[24] CIPIH report, p21.