Civil Society commentary on the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Elements of a global strategy and draft plan of action

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Alternate Solutions Institute, Pakistan
Asociación de Consumidores Libres, Costa Rica
Cediquifa, Argentina
Center for Science in Public Policy, Hudson Institute, USA
Centro de Investigaciones de Instituciones y Mercados de Argentina
Centro de Investigaciones Económicas Nacionales, Guatemala
Congress of Racial Equality, USA
Free Market Foundation, South Africa
Fundación Atlas 1853, Argentina
IMANI Center for Policy and Education, Ghana
Initiative for Public Policy Analysis, Nigeria
Institut Constant de Rebeque, Switzerland
Institut für Unternehmerische Freiheit, Germany
Instituto Ecuatoriano de Economía y Política, Ecuador
Instituto Liberdade, Brazil
Instituto Libertad y Progreso, Colombia
Instituto Libre Empresa, Peru
International Policy Network, United Kingdom
Institute of Public Affairs, Australia
Instituto Veritas, Honduras
Istituto Bruno Leoni, Italy
Jerusalem Institute for Market Studies, Israel
Liberty Institute, India
Lion Rock Institute, Hong Kong
Minimal Government, Philippines

Introduction

On January 12, 2007 Member States were asked to provide additional comments on the document prepared by the Intergovernmental Working Group (IGWG), entitled "Elements of a global strategy and plan of action – progress to date in the Intergovernmental Working Group". This was prepared by World Health Organization's (WHO) Commission on Intellectual Property Rights, Innovation and Public Health. On July 31, using comments submitted by 15 Member States, WHO then issued "Draft global strategy and plan of action on public health, innovation and intellectual property, report by the Secretariat." Subsequently, the IGWG will submit to the Sixty-first World Health Assembly, through the Executive Board, a global strategy and plan of action to provide a medium-term framework based on the recommendations of the Commission.[1]

This report is a response from a global coalition of concerned civil society groups, which builds on our previous submission to the WHO – the Civil Society Report on Intellectual Property, Innovation and Health.[2] It will examine resolution WHA 59.24 – the origins of the Commission's institutional legitimacy – in which the World Health Assembly established its terms of reference.

Mission statement, focus of the strategy and thematic presentations

The Secretariat set out a clear mission statement in the first line of its Draft Global Strategy. The Health Assembly recognized "the growing burden of diseases and conditions disproportionately affecting developing countries … and reducing them is an overriding priority." Subsequently, the Secretariat fixed its primary focus on "disease conditions of significant public health importance in developing countries for which an adequate treatment … is not available – either because no treatment exists or because, where treatment exist [sic], they are inappropriate for use in countries with poor delivery systems, or unaffordable." [4]

The mission statement and the focus of a strategy around which a Plan of Action has been proposed are intertwined with three themes throughout the Secretariat's texts. These themes form the basis for the delegated authorities to the Commission by the Health Assembly:

1 neglected diseases disproportionately affect poorer countries;
2 the international patent system – and concomitantly price – is a barrier to access of medicines by the poor;
3 there is a dearth of R&D for these diseases.

However, the substance of the non-supportive comments offered by key Member States on these elements as a result of WHO's invitation of January 12 were ignored by the Secretariat in the July 31 draft global strategy:

- **Australia** commented that "it is not clear that a new forum is necessary to implement the WHA Resolution on WHO's role and responsibilities in health research, and that existing arrangements should be assessed before making any decisions to establish a new forum."[5]
- **Japan** commented that "it is important to promote research and development efficiently, utilizing existing mechanisms such as TDR at WHO/ Geneva."[6]
- **Germany**, speaking on behalf of 27 Member States of the **EU** said: "it is of the utmost importance for the plan of action to stick to the WHO mandate and respect the work carried out in other international organizations, such as WIPO and WTO."[7]
- The **United States** "commends the IWGW to review how the WHO Secretariat is already actively engaged in many of the activities suggested through programs such as its Special Programme for Research in Tropical Diseases (TDR) in Geneva." It went on to comment that "the IGWG should not consider the Recommendation on Type 1 diseases", and that the U. S. "does not support the establishment of any new funding mechanisms, as there are several existing funding mechanisms, including public and private entities", and that the IGWG "should estimate funding needs for implementation of the plan of action."[8]
- WHO failed to provide to Member States a collective assessment of non-supportive comments in its July 31 draft, leaving this task to individual Members to sort out for themselves.

Neglected diseases

According to WHO, there are ten 'neglected' diseases:[9]

Tropical diseases
- Trypanosomiasis
- Chagas disease
- Schistosomiasis
- Leishmaniasis
- Lymphatic filiariasis
- Onchocerciasis

Other diseases
- HIV/AIDS
- Tuberculosis
- Malaria
- Diarrhoeal diseases

In 2007, *The Lancet* reported that in the year 2000 the number of disability-adjusted life years for tropical diseases was 0.9% of the total, and global mortality was 0.3%. By 2002, WHO recorded a 0.1% mortality rate for trypanosomiasis and leishmaniasis and zero for the remaining tropical diseases. There was a striking decrease in mortality from schistosomiasis, which WHO recorded at 200,000 in 1995.[10]

> "The long held belief that it is not economically feasible to develop drugs … specifically for tropical diseases has been shattered."
>
> *British Medical Journal*, 2007

The burden of neglected and other communicable diseases in countries is set out in Table 1.

While the Other Diseases record higher rates of mortality, there are available treatments, often at zero prices, for each of them – particularly those that are most burdensome, such as respiratory infections and diarrhoeal diseases. The International Monetary Fund (IMF) reports that expenditures for AIDS alone were $8 billion in 2004[12]; WHO reports that they were $8.3 billion in 2005, and UNAIDS says they reached at least $9 billion in 2006, while estimates for 2007 are reasonably expected to exceed $10 billion. Expenditures on TB and malaria, while lower than on AIDS, nonetheless are estimated at $6-7 billion over this same time frame. In total, then, since 2004 some $41.8 billion have been expended on three disease entities.

If these are diseases are 'neglected', then the Commission and the IGWG will have to redefine the term for the global health community.

The WHO Commission has not kept track of the pace and pattern of contemporary developments in neglected diseases. In 2002, the British Medical Journal published an editorial entitled: "The world's most neglected diseases." On August 11, 2007 the BMJ published an update, written by one of the same authors of the 2002 editorial. The update stated that "The long held belief that it is not economically feasible to develop drugs … specifically for tropical diseases has been shattered. Product development partnerships have been established for at least six neglected diseases in the past seven years without commercial markets or conventional business models, and several new drugs and vaccines are in the pipeline. We can expect to see eight or nine new drugs for neglected tropical diseases within the next five years."[13]

Table 1 **Deaths from tropical diseases as percentage of total deaths, by country income level, 2005 (WHO projection)**

Country income level	*Trypanosomiasis*	*Chagas disease*	*Schistosomiasis*	*Leishmaniasis*	*Lymphatic filariasis*	*Onchocerciasis*	***Total***
Low	0.2%	0.0008%	0.1%	0.2%	0.001%	0%	**0.4%**
Lower-middle	0.004%	0.02%	0.06%	0.003%	0.0004%	0%	**0.09%**
Upper-middle	0.002%	0.3%	0.03%	0.01%	0.0001%	0.00006%	**0.31%**
High	0.00001%	0.00004%	0.0002%	0.0003%	0%	0%	**0%**

Source: World Heath Organization[11]

Do patents and drug prices harm the health of the poor?

In 2001, the *Journal of the American Medical Association* published a landmark study on patents in the developing world. It found that patents on antiretroviral medicines for HIV/AIDS in Africa are either rarely registered or enforced in the poorest WTO member states. It is wrong, the authors stated, to categorically equate the mere existence of patents with a barrier to accessing AIDS treatment, because the relationship between patents and access is a complex and nuanced one. For instance, it depends on non-market factors such as the medically accepted guidelines for ARV treatment; offers by pharmaceutical firms to discount or donate medicines, notwithstanding patent status; and – above all, the availability of international aid finance to purchase drugs.[14]

In May 2004, the U. S. FDA offered to Fast Track any ARV from any country, in order to test and certify it as a true generic that conforms to rigorous bioequivalence testing and international manufacturing standards. In conformity with US laws and requirements, the FDA was compelled to invite comment from the patent holders who could challenge the applications from abroad. None did so. Today, several copy ARVs manufactured in India and South Africa have been designated by the FDA as true generics and are now listed on WHO's prequalification program. PEPFAR states that 70% of all ARV use among its programs is from either of these two countries, and they are being procured with US foreign aid monies.[15]

In July 2006, the director for WHO's HIV division publicly stated: "Africa has been hardest hit by the AIDS epidemic … it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, and supply chains that don't exist."[16]

> "… it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems …"
>
> Kevin de Cock, director of WHO's HIV Division, 2006

These factors notwithstanding, there are several other major barriers to access to medicines that have been largely ignored by the Secretariat:

Table 2 **Percentage of gross domestic product (GDP) for medical expenditures paid out of pocket in selected countries, 2002**

Country	*Percent paid out of pocket**
Bangladesh	64
Cameroon	69
Côte d'Ivoire	73
Cyprus	57
Democratic Republic of Congo	70
Ecuador	57
Egypt	58
Georgia	80
Ghana	59
Guinea	84
India	78
Indonesia	48
Kenya	45
Malaysia	50
Nigeria	67
Pakistan	65
Philippines	47
Sri Lanka	49
United Republic of Tanzania	38
Venezuela	46
Vietnam	62

Source: World Health Organization, *The World Health Report 2005: Make Every Mother and Child Count* (Geneva: WHO Press, 2005)
*Includes out-of-pocket payments for people covered by both public and private insurance.

- **Taxes and tariffs.** During the World Health Assembly in 2006, WHO released a report on the pricing of drugs. A major finding: "taxes and duties levied on medicines, as well as the mark-up applied, frequently contribute more to the final price than the actual manufacturers' price." WHO went on to comment: "There is evidence that some governments procure medicines efficiently, but charge markedly higher prices to patients, e.g., in Indonesia's public

sector, patients paid 11 times the procurement price."[17]

- **Non-tariff barriers.** Manufacturers wishing to export to overseas markets often face significant hurdles and complexity in registering their products. A study conducted by the German Economic Development Ministry on the Tanzanian Drug Regulatory Authority concluded that pharmaceutical manufacturers face difficulty in exploiting African markets as regulators frequently "offer a preferential treatment to national suppliers," often without any scientific justification.[18] These can include such things as arbitrarily requiring importers to attain standards higher than those required by relevant trade bodies; failing to provide adequate information regarding the regulations and procedural norms concerning methods of sampling, inspection and testing of drugs; or excessive delay and bureaucracy at customs clearing points. South Africa's Medicines Control Council (MCC), requires that all new medicines must attain its own regulatory approval before they can be marketed in the country – even if they have already been approved by reputable foreign regulatory bodies such as the US FDA. This means that already approved drugs take an average of 39 months to be registered in South Africa.

- **Inadequate risk pooling mechanisms.** A lack of functioning health insurance or social insurance means that many people in less developed countries pay for medicines out of pocket, which in turn translates into lower access to medicines. The levels of out of pocket payments in a range of less developed countries are illustrated in table 2.

R&D investments on neglected diseases

Judging by the country responses to the IGWG, many Member states have incorrectly appraised the current R&D landscape for neglected diseases. Of the 15 responses sent in by Members, only two mentioned the existence of WHO's Tropical Disease Research Programme (TDR), though it has been in operation since 1974, expending to date some $1.3 billion. Many of the respondents called for public-private collaboration on R&D for neglected diseases without recognizing that TDR was established for this purpose. Brazil, the 10th largest economy in the world, and an outspoken proponent for implementation of the proposed Action Plan, has made a single contribution "of $100,000 in support of TDR's research efforts" over the past 33 years.[19]

TDR already does – and has been doing – much of what the Commission is recommending. On June 17, 2002 a WHO press release announced that through collaboration with the Government of India, a German biopharmaceutical company and TDR, "scientists have developed a new treatment for the 500,000 people who develop visceral leishmaniasis each year." In clinical trials it cured 95% of treated patients. The new drug, miltefosine, could save most of the 60,000 who die from the disease every year, according to WHO.[20]

> "TDR already does much of what the Commission is recommending."

In 2005, the London School of Economics and Political Science released a report on "a dramatic sea-change in research into ten so-called neglected diseases … could result in at least eight new drugs being developed by 2010 [through] Public – Private Partnerships (PPPs). PPPs now conduct the majority of neglected disease drug projects, have the majority of drugs in clinical trials and are likely to have registered several products within the next few years."[21]

GlaxoSmithKline has built a new research facility in Spain, dedicated to diseases identified by WHO "as neglected". Novartis developed a Tropical Disease Research Institute in Singapore, targeting dengue, malaria and tuberculosis. For any product subsequently developed in this facility, Novartis will sell to UN agencies at 'no profit'.

In October 2006, Pfizer announced a collaborative effort with TDR. This will give TDR access to Pfizer's library of medical compounds – the world's largest.[22] Although this

was announced last year, the Secretariat has failed to take notice of it, though several Member States requested it to review the current situation with libraries for medical compounds.

Pfizer built the first Infectious Disease Institute in Uganda, now producing well-trained physicians and other healthcare cadres in the treatment of HIV/AIDS. Bristol Myer-Squibb (BMS) and the Baylor Medical College built the first Pediatric AIDS Hospital in all of Africa, located in Botswana. Through Baylor, they now sponsor a Pediatric AIDS Corps, sending volunteer physicians to specialty centers of excellence in ten Southern African countries. And BMS built an AIDS Laboratory in Botswana, the first on the continent, now operated by Harvard University.[23]

> "In 1990 the WHO set a target for developing countries to spend two per cent of their health budgets on research. To date only Brazil and Argentina have complied."

Several of the global R&D firms have had major bench research efforts underway on malaria, TB, AIDS, and dengue fever for the past few decades, with billions being devoted to product development for diseases which have no commercial markets to justify a return on investment.

An absence of evidence

Any self-respecting panel of independent experts would have to conclude that there is an absence of evidence, empirical and otherwise, that can support WHO's justification for this Commission, either in terms of its mission, its focus, or the three themes embedded in both. If diseases which disproportionately affect the poor, or price/patents, or a dearth of R&D on these diseases isn't the issue, then what is?

None of the respondents cited any statistics on disease incidence rates, though all quickly stated the problem. The subject of price was discussed in subjective terms, such as "too high", without relating it to a more possibly advantageous economic value relative to clinical outcome. Only Spain alluded to its extensive, private investment on R&D on diseases identified by WHO as those affecting the poor – despite the fact that such activity is taking place in many OECD countries.

None mentioned that many tropical diseases (such as schistosomiasis) can be treated very cheaply with existing medications, nor is there mention of the dozens of private philanthropic programmes specifically directed at the diseases of poverty.

None offered to explain why governments of the affected countries were neglecting the diseases that were causing so much suffering among their own people. In March 2007, the Carter Center informed the president of Nigeria that it could treat all of his nation's schistosomiasis cases, mainly among children, for a total of $4 million. The president gave the Center permission to raise the required funds from private foundations and corporations outside of Nigeria – but no-one mentioned that a country that exports 2.4 million barrels of oil per day could easily finance this itself.

Yet, even when they supported the Commission, IWGW respondents stated that their recommendations could only be implemented with the active collaboration of WIPO or WTO. Some went so far as to comment that such issues as intellectual property and patents were outside the remit of WHO.

Almost all respondents to the IGWG placed the responsibility for funding R&D into the diseases of poverty onto developed countries, while Brazil, Thailand and Kenya advocated the expropriation of intellectual property. Only one, the USG, raised the issue of past international commitments through the WHO on the funding of research activities. For instance, in 1990 the WHO "Commission on Health Research and Development set a target for developing countries to spend two percent of their health budgets on health research. To date, only Brazil and Argentina have complied."[24]

More recently, at the 2002 Abuja Conference in Nigeria,

developing countries signed on to a commitment in which they pledge to allocate 15% of their national budgets for public health activities. This pledge was renewed at the G8 Summit in Gleneagles, Scotland in 2005. None have complied thus far.

WHO has launched several new initiatives in the past, such as Health for All by the Year 2000; Roll Back Malaria; the Commission on the Social Determinants of Health; the Commission on Macroeconomics and Health; and in 2003, its '3 by 5' plan on AIDS treatment. It takes on impossible goals and, as was the case with Health for All, has failed to report on donor expenditure of $99 billion between 1977–2000.

WHO promotes new initiatives as if it had extraterritorial legal powers. For instance, in June, the Globalization Knowledge Network released its final report to the WHO Commission on the Social Determinants of Health. In order to meet the Millennium Development Goals and provide debt relief, the Report recommends that "based on a per capita income of $3 per day … and no taxes on those within this 'ethical poverty line' and a 25 percent tax on all people above it", then social justice can be accomplished on a global basis.[25]

> "… when developing evidence-based guidelines, the World Health Organization routinely forgets one key ingredient: evidence."
>
> *The Lancet*, 2007

In the respondents' recommendations that developed countries assume the financial responsibility for funding health R&D, there is the assumption that foreign aid has a significant impact on the most critical indicator of a nation's health: infant mortality. In May 2007, the IMF released a report on Health Aid and Infant Mortality. It found that "despite the vast empirical literature considering the effects of foreign aid on growth, there is little systematic empirical evidence on how overall aid affects health, and none on how health aid affects health."[26] Indeed, there is compelling evidence that suggests that corruption within developing country health systems seriously undermines the effectiveness of donor funding.[27]

Evidence as a basis for policy

Research and development in medicine is a complex technological endeavor in any society. Its fundamental basis is uncompromising evidence drawn from rigorous research. In the May issue of *The Lancet*, researchers found that "when developing evidence-based guidelines, the World Health Organization routinely forgets one key ingredient: evidence."[28]

In an interview with a Canadian newspaper after publication of this article in *The Lancet*, its editor commented: "This is a pretty seismic event … it undermines the very purpose of WHO." In response to his comment, a WHO official noted "that, in many cases, evidence simply did not exist."[29]

Nor does it exist, as this analysis demonstrates, to support an institutional rationale for the Commission on Intellectual Property Rights.

Along with a lack of evidence, WHO contradicts itself – within the same report. In April 2006, a draft Report of the WHO's Commission on Intellectual Property Rights was released. On page 16, WHO stated: "deaths from communicable diseases are projected to fall 13% by 2015." By the time a reader reaches page 193, a vast change has occurred: "the burden of infectious diseases that disproportionately affect developing countries continues to increase." [30]

Since 'neglected' diseases constitute a tiny fraction of total disease rates, and patents aren't an issue, nor is there a lack of R&D on these diseases, one must question the downstream objective of those who are promoting the Commission's work. It appears to be to strike at the heart of the pharmaceutical industry's global franchise: chronic disease therapies, or Type 1 diseases. Through WHO, they plan to have these therapies listed on its Essential Drugs and Medicines Programme, thus declaring them as "essential medicines" for the poor. Developing countries can then issue compulsory licenses and produce these drugs with the imprimatur of WHO and UN agencies.

The recent Compulsory License by Thailand for Plavix, a heart medication, and the threat by India for Glivec, a therapy for a rare cancer disease, are the opening salvos in this upcoming campaign. Médecins Sans Frontières, the Clinton Foundation, WHO, UNAIDS, the World Bank, and the media were all quick to endorse Thailand and India's claim that price is the main barrier to access to medicines by the poor.

Yet, price is no barrier if it is one that has been negotiated by the activist community. On May 18, *Drug Week* praised the Clinton Foundation for its landmark price negotiations with Indian firms. The foundation's published price for lopinavir/r is $695 per person per year. However, for the past five years, the right holder has been offering this same drug with assured quality, safety and efficacy to 69 poor countries at $500 per person per year.[31] In the press release, the foundation doesn't explain why it is paying 28% more in order to provide the poor with access to a drug of indeterminate quality. The mere source of the drug imputes a therapeutic benefit to patients, notwithstanding its questionable quality.

The Minister of Health in Thailand has an interesting perspective on patented vs. copy drugs. His government is now considering the revocation of its compulsory license for Efavirenz. In a May 24 article in *The Bangkok Post*, he said: Who wants to buy generic drugs for treating patients if the original drug is more affordable."[32]

The work of the Commission and the IGWG is a costly distraction for the research based industry, forcing it to expend ever-increasing amounts of human and fiscal resources to defend themselves. These resources could be better spent on what industry does best: new product development. Equally important, the Commission's work would be an expensive duplication of initiatives long underway, both by industry and by the donor community, e.g., the Tropical Disease Research Institute in Singapore and WHO's TDR Programme.

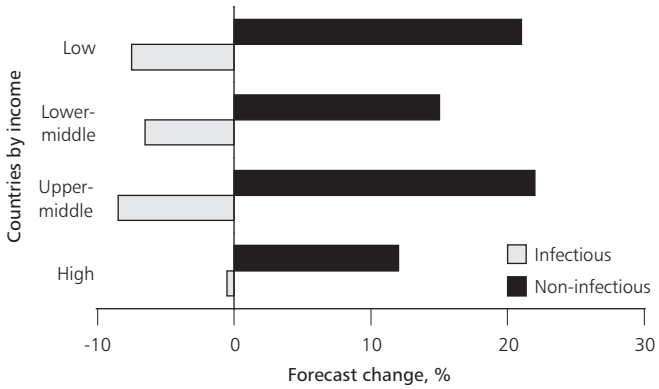
The WHO Commission can only succeed if five variables are operationally harmonised with the active collaboration of WIPO and the WTO. When any one variable fails, the Commission's work would be rendered moot. Thus, WHO can only succeed with this Commission if:

1 The research based industries can be encouraged to continue the development of new products for expropriation;
2 Donor countries assume the responsibility for sustainable financing of R&D capacity building in developing countries, and support involuntary tax systems, such as UNITAID and the 25 percent tax on all incomes above $3 a day as proposed to WHO's Commission on the Social Determinants of Health;
3 Governments in the developing world provide subsidies to maintain the production and pricing structure of expropriated drugs against competitive drugs of the same strength and dosage forms in the market;
4 Countries which execute compulsory licenses actually produce drugs to equivalent standards as the right holders, and can control pricing from manufactures to patients;
5 The poor continue to be denied the principles of consumer choice and Informed Consent, as guaranteed in the UN's Universal Declaration on Human Rights.

A voluntary membership organization has no authorities to control these variables, save the fifth item – which WHO has so far ignored in AIDS treatment. But it can act as a 'Trojan Horse' for the activist community and lend it the Organisation's institutional legitimacy to erect non-tariff barriers to the free flow of health and medical goods in international commerce. Yet, the intervention by activists is no guarantee for lower prices. It only guarantees that the price is from one of its approved producers, e.g. India through such organizations as the Clinton Foundation.

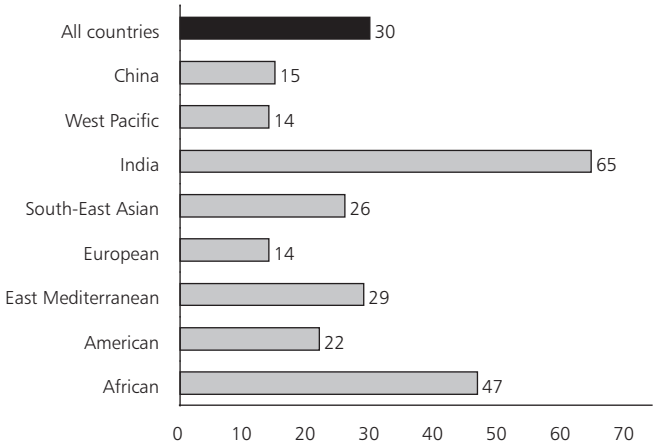
If the WHO Commission and the activist community were interested in the needs of the poor, then they would press the research based industries to get on with the heavy lifting and develop new products, especially those which will be in demand for multi-drug resistant TB, AIDS – and the oncoming tsunami of chronic diseases. These, if left inadequately treated, will cause massive

Figure 1 **The global rise of chronic disease**



Source: World Health Organization[33]

Figure 2 **Percentage of WHO regions lacking access to essential medicines**



Source: WHO Medicines strategy report, 2003

macroeconomic distortions in the developing world, e.g., early retirements, disabilities, and long term care in expensive medical facilities. The gravity of this changing disease burden is illustrated in Figure 1.

It is time to leave rhetoric and ideology aside and recognize and deal with the actual causes of poor rates of access to medicines for the most disadvantaged. As Figure 2 shows, rates of access to essential medicines – the majority of which are off-patent – are unacceptably low in many parts of the world.

No UN membership organisation built on the guaranteed equality of all can long sustain its institutional authorities by providing commercial advantage to some, through the disenfranchisement of others, and still expect to secure the respect of the wider community of nations. WHO's sponsorship of this Commission out-sources Constitutional authorities to supporters in the activist community who serve their own interests; it is now time for both to serve those they have long purported to represent.

What can a commission do that isn't being done?

As has been discussed, there is already unprecedented R&D activity in both the public and private sectors. The question then becomes, what more value can the Commission add?

Canada is a good example of what can happen if WHO tries to 'force-fit' a round peg into a square hole with this Commission. In May 2004, the government gave a grant of $100 million to its generic industry to produce ARV and malaria products for Africa. It even passed a law that would force pharmaceutical companies to offer some patented drugs to generic producers if impoverished countries requested them. The law was intended to take advantage of an agreement signed by Canadian officials at a WTO meeting in Doha in 2001: the issuance of a Compulsory License in cases of national health emergencies. Canada became the first country to implement that international generics agreement through legislation. The UN's Special Envoy for AIDS to Africa called it a "stunning breakthrough".[34]

In August 2006, the head of Canada's Access to Medicines regime observed that "not a single drug has gone out of Canada under the legislation." "That's an undeniable fact", he added.[35]

Canadian generic manufacturers complained that even with the $100 million subsidy from the government, and a Compulsory License, they were unable to produce

these drugs at a profit. An update by Canada's *Globe & Mail* newspaper on August 9, 2007, commented that [still] "not one pill has been exported".[36]

Yet, pharmaceutical firms in Sub-Saharan Africa are producing them at a profit. Though Africa has long been considered a charity case by donors, in 2006 its pharmaceutical industry "earned $4 billion in revenues … with estimates of reaching $6.9 billion by 2012." In four countries alone (Kenya, South Africa, Nigeria and Tanzania) their medical equipment market was an additional $1.87 billion. In each of these countries, analysis showed a high potential for growth opportunities within the healthcare industry.[37]

If research and product development for communicable diseases is of great interest to the WHO Commission, it may be useful to review data on this issue. In WHO's Financial Performance for 2002-2003, it budgeted $88.9 million for these activities against an income of $75.8 million. Yet, WHO expended only $66.8 million. In a budget note, WHO explained that "expenditures were below budget due to lower than planned spending in research in developing countries on the burden of communicable diseases upon poor or marginalised populations."[38] A footnote also explained that its TDR Programme had expended more on research than did the WHO itself.

> "… there is the possibility that some neglected tropical infections could be eventually controlled to the point of eliminating some areas of endemicity."
>
> *Journal of Clinical Infectious Diseases*, 2004

Conclusion

Since there is a lack of evidence to support neglected diseases, price and patents as the principles underlying the formation of this Commission by WHO, what, then, is its purpose?

The Secretariat's current presentation of a Global Strategy and Action Plan represents the special interests of some Members and Non-members, while disregarding all others. In terms of its three themes, the Secretariat set aside known facts to reach an outcome which was predetermined. It ignored authoritative documentation on the current state of play with regards to 'neglected' tropical diseases. For instance, "over the past two decades there have been significant achievements in the control of a handful of important tropical infections … as a result of aggressive regional vertical interventions, there is the possibility that some neglected tropical infections could be eventually controlled to the point of eliminating some areas of endemicity."[39]

The presentation is therefore unworthy of an organisation that is the "legally mandated inter-governmental agency responsible for global health".

As several Members stated, though their views were not represented in the Secretariat's presentation, intellectual property and innovation are societal issues which are too serious to be left in the hands of WHO alone. Japan commented that "it is necessary to consult with other international organisations with specialised expertise in the area of intellectual property … and we think it is appropriate to discuss matters of building innovative capacity in WIPO."[40]

We recommend, therefore, that:

1 the Secretariat withdraw the Global Strategy and Action Plan until such time that it can be re-written in a fair and objective manner which represents the interests of the community of Member States comprising the Organisation;
2 an inventory be undertaken to catalogue extant activities, both public and private, in R&D activities targeted on neglected diseases, e.g., TDR, and the private research facilities in Spain and Singapore;
3 WHO sponsor a benefit-cost analysis to determine if its implemented Plan of Action would dampen incentives for local and foreign investment in the Sub-Saharan African pharmaceutical industry, now in its ascendancy;
4 and, upon completion of the above, that any subsequent action taken to fund the Commission's ongoing work will direct expenditures only through WHO's Regular Budget.

Notes

1. Draft global strategy and plan of action on public health, innovation and intellectual property, WHO, Geneva, July 31, 2007.

2. Available at www.policynetwork.net/uploaded/pdf/civil_society_text_web.pdf

3. Refer to end note #1

4. Refer to end note #1.

5. Australian submission on Elements of a global strategy and plan of action, no date.

6. Comments on Elements of a global strategy and plan of action, by the Government of Japan, no date.

7. Consultation on "Elements of a global strategy and plan of action", Comments by the European Union, via Germany in the role of the EU presidency, February 2, 2007.

8. U. S. Government Comments on Annexes I and II of the World Health Organizatgion Secretariat's Elements of a Global Strategy and Plan of Action for the purpose of the WHO Secretariat preparing a working document for the Intergovernmental Working Group (IGWG).

9. WHO. *The World Health Report 2002, Reducing Risks, Promoting Healthy Life*, Geneva, 2002.

10. WHO. *The World Health Report 2002, Reducing Risks, Promoting Healthy Life*, Geneva, 2002.

11. "Projections of mortality and burden of disease 2006", World Health Organisation, Department of Measurement and Health Information, Geneva, November 2006

12. IMF. Peter Heller et al. "Sizeable Boost in HIV/AIDS Assistance Will Challenge Low Income Countries" *IMF Survey*, July 12, 2004, pg. 202.

13. Gavin Yamey, Peter Hotez, Neglected Tropical Diseases, British Medical Journal, August 11, 2007, Vol. 335.

14. Amir Attaran & Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", *Journal of the American Medical Association*, 2001.

15. WHO. *Access to HIV/AIDS Drugs and Diagostics of Acceptable Quality, Procurement Quality and Sourcing Project*, Geneva, all editions through 2006.

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Civil Society commentary on the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

This is an analysis of the WHO Intergovernmental Working Group on Intellectual Property, Innovation and Public Health's draft Plan of Action by a global coalition of independent, non-partisan civil society groups. We are concerned about the direction of the plan and its apparent disregard of widely available and contrary evidence.

The focus of the draft Plan of Action is predicated on three basic assumptions:

1 'neglected' diseases disproportionately affect poor countries and are a significant contributor to the disease burden;
2 there is little research & development (R&D) conducted for these diseases;
3 the international patent system is a barrier to access of medicines by the poor.

However, the documented evidence is contrary to these assumptions.

First, WHO data shows 'neglected' tropical diseases to be decreasing in prevalence in developing countries, and that they constitute only a fraction of mortality even in the poorest countries. The other 'diseases of poverty' – for instance AIDS, tuberculosis and malaria – have received donor financing to the order $41.8bn since 2004. Meanwhile, many Member States, particularly from developing countries, have failed to honour their past spending commitments on both public health and R&D.

Second, it is inaccurate to claim that there is a dearth of R&D for these so-called 'neglected' diseases. These diseases and other diseases of poverty are currently the focus of unprecedented levels of research and development, often through Product Development Partnerships between the private and public sectors. Additionally, there are many cheap, existing treatments that could be readily employed to address these diseases.

Third, there is no clear evidence to suggest the international patent system is a barrier to access of medicines by the poor. Patents are rarely registered and enforced in the poorest countries. Uptake of medicines is more a determinant of factors such as infrastructure and health risk pooling schemes. If patents were a problem, India would never have become the world's leading supplier of ARVs to Africa.

The IGWG's draft Plan of Action, therefore, arrives at conclusions that are not supported by evidence. The fact that many Member States' non-supportive comments were omitted from the draft suggests the conclusions were predetermined from the outset. Moreover, the Plan of Action represents costly duplications of activities already underway, specifically as several Members mention, through WHO's TDR Programme. Most importantly, WHO provided no cost estimates for the 8 Elements as requested.

We recommend that the Secretariat withdraw the Global Strategy and Action plan until it can be re-written in a fair and objective manner. We also recommend the Secretariat create an inventory which catalogues current R&D activities targeted at 'neglected' tropical diseases. Finally, WHO should sponsor a cost-benefit analysis to determine if its implemented plan of action would undermine local and foreign investment in the Sub-Saharan private pharmaceutical industry.