CIVIL SOCIETY RESPONSE TO THE DRAFT PLAN OF ACTION

This is a response to the draft Plan of Action from a global coalition of 24 civil society groups, which is concerned at the direction and assumptions of the IGWG.

The Draft Global Strategy is underpinned by three basic premises:

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

Several Member States commented on these issues, but were apparently ignored in the July 31 draft global strategy:

- **Australia**: "it is not clear that a new forum is necessary … existing arrangements should be assessed before making any decisions to establish a new forum."[1]
- **Japan**: "it is important to promote research and development efficiently, utilizing existing mechanisms such as TDR at WHO / Geneva."[2]
- **Germany**, speaking on behalf of the EU: "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."[3]
- The **United States**: "does not support the establishment of any new funding mechanisms, as there are several existing funding mechanisms, including public and private entities."[4]

WHO failed to provide Member States with a collective assessment of non-supportive comments, leaving Member States to sort this out for themselves.

Neglected diseases

According to WHO, there are ten "neglected" diseases:[5]

Tropical diseases

- Trypanosomiasis
- Chagas disease
- Schistosomiasis
- Leishmaniasis
- Onchocerciases

Other diseases

- HIV/AIDS
- Tuberculosis
- Malaria
- Diarrhoeal diseases

These diseases currently constitute a tiny and declining fraction of the disease burden in less developed countries. 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.[6] The burden of tropical diseases is set out in Table 1 overleaf.

While the "other diseases" have higher mortality rates, there are treatments available for each of them, often at very low prices. Neither is there a funding shortage for the other "diseases of poverty". World expenditure on AIDS alone was $8 billion in 2004,[8] $8.3 billion in 2005, $9 billion in 2006, and is expected to exceed $10 billion in 2007. Expenditure on TB and malaria is estimated at $6–7 billion over the same period.

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

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

In 2001, the *Journal of the American Medical Association* published a study which found that patents on antiretroviral (ARV) medicines are rarely registered or enforced in the poorest WTO member states. It is wrong, the authors argued, to assume that patents constitute a barrier to AIDS treatment, because the relationship between patents and access is complex. It depends on factors such as the medical guidelines for ARV treatment, offers by pharmaceutical firms to discount or donate medicines, and on the availability of international aid finance to purchase drugs.[9]

In fact, the quality of health infrastructure is the most crucial determinant of rates of access to medicines. In July 2006, the director of WHO's HIV division 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."[10]

As well as these problems, there are other serious barriers

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: WHO[7]

to access to medicines that are largely ignored by the Secretariat:

- **Taxes and tariffs.** A 2006 WHO report on drug pricing stated that "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."[11]
- **Non-tariff barriers.** Manufacturers wishing to export to overseas markets often face significant hurdles in registering their products. A German government study found that pharmaceutical manufacturers face difficulty in accessing African markets as regulator frequently "offer a preferential treatment to national suppliers."[12] This increases the cost and complexity of supplying the markets of less developed countries.
- **Inadequate risk-pooling mechanisms**. A lack of functioning insurance systems means that the majority of people in developing countries pay for medicines out-of-pocket, which results in lower access to medicines.

R&D investments in neglected diseases

Judging from the country responses to the IGWG, many Member States have incorrectly appraised the current R&D landscape for neglected diseases. In August 2007, the *British Medical Journal* stated that "The long-held belief that it is not economically feasible to develop drugs … specifically for tropical diseases has been shattered … We can expect to see eight or nine new drugs for neglected tropical diseases within the next five years."[13]

Only two of the 15 country responses mentioned WHO's Tropical Disease Research Programme (TDR), which already does much of what the Commission is recommending. It has been in operation since 1974, expending to date some $1.3 billion, and has collaborated on projects such as developing a new treatment for visceral leishmaniasis, which could save most of the 60 000 who die from the disease every year.[14] Brazil, the tenth largest economy in the world and an outspoken proponent of the proposed Action Plan, has made a contribution "of $100 000 in support of TDR's research efforts" over the past 13 years."[15]

In 2005, a London School of Economics and Political Science report said that "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."[16]

In addition to the collaborations made between governments, international organisations and the private sector outlined in the LSE paper, a significant amount of pure private sector activity is being devoted to addressing diseases predominantly suffered by the world's poor. Several global R&D firms have had major research efforts underway on malaria, TB, AIDS, and dengue fever for decades, devoting billions to product development for diseases which have limited commercial markets. These efforts also include substantial investments in research facilities located in some of the world's poorest countries, providing financial and technical support for clinics devoted to the treatment of specific diseases in some of the most affected areas, and opening up large patent libraries to facilitate additional research.

An absence of evidence

There is clearly little evidence that supports WHO's justification for this Plan of Action.

None of the Member State responses cited any statistics on disease incidence rates, and all discussed price in subjective terms, such as "too high". Only Spain alluded to its extensive private investment in R&D on diseases identified by WHO as affecting the poor – despite the fact that such activity is taking place in many OECD countries.

None mentioned that the governments of less developed countries often neglect the health of their own populations. The government of Nigeria recently accepted a $4 million initiative from the Carter Center, which had offered to treat every case of schistosomiasis in the country for this sum. No-one mentioned that a country that exports 2.4 million barrels of oil a day could easily finance this itself.

According to the submission of the USG, in 1990 the WHO "Commission on health research and development 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."[17] At a 2002 conference in Nigeria, developing countries pledged to allocate 15% of their national budgets to public health, a pledge renewed at the 2005 G8 summit. None have yet complied.

Evidence as a basis for policy

Since patents aren't the issue in access to medicines, "neglected" diseases make up only a tiny fraction of total disease rates, and there is no lack of R&D on these diseases, one must question the real objective of those promoting the Commission's work.

It appears to be to strike at the heart of the pharmaceutical industry's global franchise: chronic disease therapies. They plan to have these therapies listed on WHO's Essential Drugs and Medicines Programme, so that developing countries can issue compulsory licences and produce these drugs with the imprimatur of WHO and UN agencies.

Thailand's recent issuance of a compulsory licence for Plavix, a heart medication, and India's threat to issue a compulsory licence for Glivec, a cancer therapy, are the opening salvos in this upcoming campaign.

MSF, 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. But even Thailand is considering the revocation of its compulsory licence for Efavirenz. As the Minister of Health recently stated: "Who wants to buy generic drugs for treating patients if the original drug is more affordable?"[18]

The Commission and the IGWG are forcing the R&D industry to expend its resources on self-defence, rather than focusing on its key strength, which is developing new medicines. Equally importantly, the Commission's work would be an expensive duplication of both private and public initiatives long underway, such as WHO's TDR.

Canada is a good example of what can happen if WHO tries to "force-fit" a square peg into a round 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 UN's Special Envoy for AIDS to Africa called it a "stunning breakthrough".[19]

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.[20] Canadian generic manufacturers complained that even with the $100 million subsidy from the government, and a Compulsory Licence, they were unable to produce these drugs at a profit.

Yet pharmaceutical companies in Africa are able to produce them at a profit. Although 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."[21]

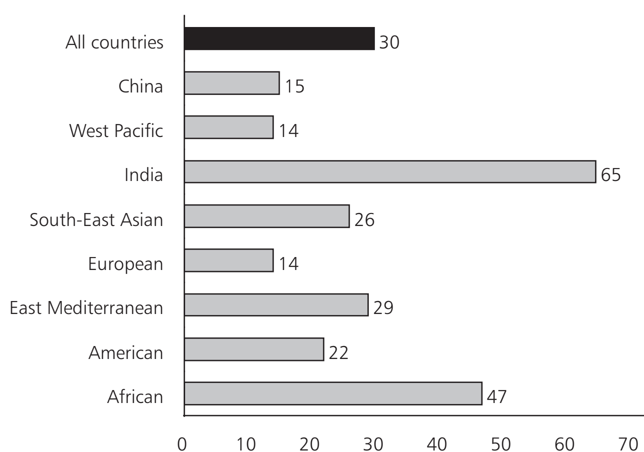
WHO's own track record on research and product development is also worth reviewing. In WHO's Financial Performance for 2002–2003, it budgeted $88.9

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."[22] A footnote also explained that its TDR programme had expended more on research than did the WHO itself.

If WHO and the activist community really prioritised the needs of the poor, they would press the industry to develop new products for emerging strains of drug-resistant TB and AIDS, and the oncoming tsunami of chronic disease, instead of forcing it to expend valuable resources defending itself from the Commission. These diseases, if inadequately treated, will cause massive macroeconomic distortions in the form of early retirements, disabilities and huge amounts of expensive medical infrastructure. The cost of medicines will only represent a small fraction of these costs.

It is time to leave rhetoric and ideology aside and address the pressing global problem of very low rates of access to essential medicines (Figure 1).The draft Plan of Action contains almost nothing which addresses the fundamental causes of this problem.

Figure 1 **Percentage of WHO regions lacking access to essential medicines**



Source: WHO Medicines strategy report, 2003

Conclusion

The evidence is that price, patents and "neglected" diseases do no justify the creation of this Commission by WHO. What, then, is its purpose?

The Global Strategy and Action Plan represents the special interests of some countries and non-state actors, and disregards others. The Secretariat set aside the facts to reach a pre-determined outcome. It ignored authoritative documentation on the current state of play with regard to "neglected" tropical diseases. For instance, the Journal of Clinical Infectious Diseases reported in 2004 that "over the past two decades there have been significant achievements in the control of a handful of important tropical infections could be eventually controlled to the point of eliminating some areas of endemicity."[23]

As several Members stated, though their views were not represented in the Secretariat's presentation, intellectual property and innovation are issues which are too serious to be left to WHO alone. Japan commented that "it is necessary to consult with other international organizations with specialized expertise in the area of intellectual property … and we think it is appropriate to discuss matters of building innovative capacity in WIPO."[24]

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 WHO and ensure that it addresses the real issues affecting the provision of healthcare in less-developed countries;
2. An inventory be undertaken to catalogue extant R&D activities, both public and private, targeted on "neglected" diseases, to ensure that work is not duplicated;
3. WHO sponsor a cost-benefit analysis to determine if its Plan of Action would dampen incentives for local and foreign investment in the rapidly developing Sub-Saharan African pharmaceutical industry, as well as current investment into R&D for the diseases of poverty.

Supporting Organisations

Alternate Solutions Institute, Pakistan
Asociación de Consumidores Libres, Costa Rica
Cediquifa, Argentina
Center for Science in Public Policy, Hudson Institute, USA
Centro de Investigaciones y Económicas Nacionales, Guatemala
Congress of Racial Equality, USA
Free Market Foundation, South Africa
Fundación Atlas 1953, 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
Insituto Liberdade, Brazil
Instituto Libertad y Progreso, Colombia
Instituto Libre Empresa, Peru
International Policy Network, UK
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

Notes

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

2. Comments on "Elements of a global strategy and plan of action", by the government of Japan, no date.

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

4. US government comments on Annexes I and II of the "Elements of a global strategy and plan of action".

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

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

7. "Projections of mortality and burden of disease 2006", WHO, Department of Measurement and Health Information, Geneva, November 2006.

8. IMF, Peter Heller *et al.* "Sizeable boost in HIV/AIDS assistance will challenge low income countries", *IMF survey*, July 12, 2004, p. 202.

9. Amir Attaran and Lee Gillespie-White. "Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?", *Journal of the American Medical Association*, 2001.

10. Patricia Reaney. "Interview: Creaking Health systems hampering AIDS battle – WHO". *Reuters News Media*, July 21, 2006.

11. WHO. *Price, availability and affordability: an international comparison of chronic disease medicines*, Geneva, May 2006.

12. Federal Ministry for Economic Cooperation and Development. "The viability of pharmaceutical production in Tanzania", 2007. Available at:

http://www2.gtz.de/dokumente/bib/07–0300.pdf

13. Gavin Yamey and Peter Hotez. "Neglected tropical diseases", *British Medical Journal*, vol. 335, August 11, 2007.

14. WHO press release. "New therapy for 'Black fever' is 95% effective", Geneva, June 17, 2002.

15. WHO. "About TDR, Financial Contributions to TDR, up to December 31, 2004." TDR homepage, December 2004.

16. Wellcome Trust press release. "Attention for neglected diseases", website, 2005.

17. WHO. *Access to HIV/AIDS drugs and diagnostics of acceptable quality, procurement quality and sourcing project*, Geneva, all editions through 2006.

18. "Gov't considers revoking compulsory license for Efavirenz", *The Bangkok Post*, May 24, 2007.

19. "Canada breaks AIDS pledge", *Toronto Star*, August 3, 2006.

20. "Canada breaks AIDS pledge", *Toronto Star*, August 3, 2006.

21. "Big Pharma's cash", The East African, August 15, 2007. Available at: http://allafrica.com/stories/200708140670.html

22. WHO, General Management Office of the Comptroller. "Financial Performance 2002–2003", WHO, Geneva.

23. P.J. Hotez, H. Remme, P. Buss, G. Alleyne, C. Morel, *et al*. "Combating tropical communicable diseases, workshop report of the disease control priorities project", *Journal of Clinical Infectious Diseases*, 38, 2004, pp.871–878.

24. Comments on "Elements of a global strategy and plan of action", by the government of Japan, no date.