News

Deadlock on access to cheap drugs at global trade negotiations

At the end of 2002, the United States rejected a compromise proposal aimed at giving developing countries without local manufacturing capacities access to affordable life-saving drugs. At a December meeting at the World Trade Organization (WTO) in Geneva, negotiators of several of the 144 WTO members expressed their regret about the failure to reach an agreement by the intended deadline, which was the end of last year. Eduardo Perez Motta, Chairman of the WTO Trade-related Aspects of Intellectual Property Rights (TRIPS) Council and author of the compromise proposal, even apologized to sufferers from diseases in the developing world for the failure to come up with a viable solution. Meanwhile, in an attempt to reinvigorate the stalled negotiations, European Union (EU) Trade Commissioner Pascal Lamy put forward another compromise solution.

The bone of contention is the export of generic versions of drugs protected by patent to developing countries that lack manufacturing capacity to produce the generics themselves. At their fourth conference in Doha, Qatar, in November 2001, WTO ministers adopted a Declaration on TRIPS and public health. The agreement, usually referred to as the Doha Declaration, allowed poor countries to produce urgently needed drugs even if the drugs in question are under patent protection, a procedure known as compulsory licensing.

Even back then, however, WTO negotiators admitted there was a shortcoming in the Doha Declaration: the contentious paragraph 6 the Declaration bluntly states that "members with insufficient or no manufacturing capacity could face difficulties in making effective use of compulsory licensing ... We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002". This is because, according to TRIPS guidelines, drugs made under compulsory licence are intended predominantly for the domestic market, that is, not for export.

But the recent TRIPS Council meeting failed to deliver one, even though a compromise proposal, drafted and circulated by Perez Motta, was on the table. At the end of lengthy argument, the United States was the only country that refused to endorse the proposal. The US delegation considered the compromise — which did not restrict the range of diseases covered — to be too broad in scope, and insisted that instead the agreement should be limited to drugs for HIV/AIDS, malaria, tuberculosis and similarly infectious epidemics. According to a statement by the United States trade representative Robert Zoellick, issued on 20 December, such a focus on infectious diseases would reflect the original intentions of the Doha Declaration.

That is not the way Ellen T'Hoen of Médecins sans Frontières (MSF) sees it. "Already in Doha the United States tried to limit the scope of diseases," she pointed out. "None of those proposals of theirs made it through those negotiations. As a matter of fact, paragraph 4 of the Doha Declaration is very clear about this point: no limits [in terms of disease range]. In a way these attempts open up the whole Doha Declaration again." For T'Hoen the latest developments represent a "tragic U-turn in the health–trade debate."

T'Hoen is not alone in her critique. Celine Charveriat of Oxfam says: "The fact that the European Union and the United States argued that developing countries should not have access to affordable generic drugs for asthma and diabetes, which kill and debilitate millions in these countries, proves that profits still come before people's lives and that the WTO has powers totally beyond its competence."

The United States interpretation of the Doha Declaration also raised eyebrows at WHO. "Our understanding of the Doha Declaration is that it is fairly inclusive," says Jonathan Quick, head of Essential Medicines at WHO. "The idea of either the WTO or the WHO having a single global list [of diseases] is difficult to reconcile with the changing and diverse epidemiology of the world." That is why, in a statement on 17 Sep-

WHO supports EU proposal for cheap drugs

WHO would not like a fixed list of diseases to break the WTO deadlock [see adjacent story], as it is too inflexible, says Jonathan Quick, of WHO's Essential Drugs and Medicines Policy department. The Organization already publishes a priority list of its own — the Essential Medicines List, already in its tenth edition, but, Quick told the *Bulletin* ''It was never intended to be a global standard — it's a model that's meant to be adapted. It contains some 325 drugs, about the number least-developed countries can buy; middle-income countries typically use 600; high-income countries 1200. The bottom line has to be flexibility.''

''The way WHO operates, ultimately countries decide what is of importance to them; we provide advice, the best possible data, top-flight key data. Last April for example we said these are the best 12 antiretrovirals for HIV/AIDS, and these the first, second and third most effective combinations; but we would not say: 'Therefore these are the only drugs you can buy.'''

If a country considered it needed to import generics for some condition, according to the European Union (EU) proposal WHO's role would be to provide evidence and advice on the magnitude of the disease, and to recommend treatment — ''on or off patent''. The legal steps would then be up to WTO.

There had been discussions with the EU but ''some of the specific phrasing'' of the EU proposal ''can be read differently from what we'd intended. For example, we were not involved in that list of diseases. But we are completely behind this effort to bring this business to a harmonious closure.''

Speaking to *BioMed Central* (www.biomedcentral.com) Quick added ''We'd like a solution that's sufficiently robust to be good 10, 20, 30 years from now''. Disease patterns shift with time. No one was predicting AIDS 25 years ago. So ''from a public health point of view you'd like a flexible agreement.''

''It's important to step back and ask what's the dynamic'' of the [WTO] problem, said Quick. ''Basically the concern of some countries is that it is an open door to break all patents, and what's needed is an assurance that it won't be. And the European Union's hope is that WHO could provide enough reassurance that things can proceed.'' ■

RW

tember 2002, WHO described desirable solutions to the "paragraph 6 problem" as having a "broad coverage in terms of health problems and the range of medicines."

But according to MSF, Oxfam and other nongovernmental organizations (NGOs), even the Perez Motta proposal would have been insufficient to meet the real needs of the developing world. In an open letter to WTO delegates, the NGOs urged developing countries to reject the draft. "Nobody was happy with it," T'Hoen says. "The procedures it proposed are so complicated that it would have led to a paper solution, not a practical one."

So for T'Hoen the December failure is not entirely bad news. "This offers an opportunity to go back to the drawing board and hammer out something that is better." An ideal solution, T'Hoen adds, should be drafted like the Amendment 196 to the European Medicines Directive, which the European Parliament adopted last October and which states: "Manufacturing shall be allowed if the medical product is intended for export to a third country that has issued a compulsory licence for that product." T'Hoen says "That's it — a very nice and simple solution. No strings attached".

Another initiative to break the current deadlock was launched by EU Trade Commissioner Pascal Lamy in early January. Blaming a "lack of trust" between the United States and developing countries for the failure, Lamy suggested WHO should be actively involved in the process. "When there is too much mistrust in the game you have to call on a third party, and the WHO is a trusted party," Lamy said at a press conference in Brussels.

Lamy presented a list of infectious epidemics, covering more than 20 diseases "generally recognized as those which have the most damaging impact on developing countries". Lamy stressed, however, that this was not intended to be a restrictive list; with any other disease or health issue, affected countries should ask WHO to assess the severity of the situation and make recommendations as to how to respond to the problem. Lamy said he was convinced that his proposal "will be able to break the deadlock and rapidly achieve a final agreement".

WHO's Jonathan Quick considers the Lamy initiative "reasonable" [see Box].

The next deadline is approaching fast. WTO Director-General Supachai Panitchpakdi recently said the aim would be to reach an agreement by the first meeting of WTO's governing General Council scheduled for 10 February in Geneva. Jonathan Quick is hopeful that a solution will be achieved before too long. "The 'spirit of Doha' has been tested, that is for sure; people are looking at the part of the glass that isn't full yet. But in fact much of the key content [of the Doha Declaration] is there and has been very helpful," he says. ■

Michael Hagmann, Zurich

Donors are distorting India's health priorities, say protestors

International donors are driving India's national health agenda in the wrong directions, says a growing movement of Indian health policy experts and nongovernmental organizations (NGOs). For example, although AIDS mortality is still low in the country, there is an excessive focus on HIV/AIDS prevention, with little linkage to primary treatment, they say. Meanwhile, grassroots concerns and larger immediate public health needs are being ignored, they claim.

The recent visit of the Microsoft tycoon Bill Gates, with his US$ 100 million grant for AIDS prevention in India, sparked the debate. At that time, the view of the Government of India and part of the Indian media was that they should not "look a gift horse in the mouth". Public health experts, however, argued that this was a myopic approach that failed to recognize grassroots reality.

Alka Gogate, director of the Mumbai AIDS Society, says that those who have direct contact with this reality recognize the importance of ensuring that AIDS funds are used to strengthen general health services, even while ensuring care and support for AIDS patients. There have been several meetings on this issue with the deans of public hospitals in the city, she said. She claimed that it was "well recognized" that if primary health services were neglected, the huge load of infectious disease patients would be pushed onto the city's tertiary services — which cannot cope with this pressure.

The top killers in India were classified in the 1994 survey of the Indian Registrar General as: "senility or old age" 21.2% (1.8 million); "cough" 19.3% (1.6 million); "circulatory disease" 11.2% (940 000), and "causes peculiar to infancy" 9.6% (810 000).

The epidemiology of HIV/AIDS in India has recently generated heated controversy between the Government of India and international agencies. India urgently needs a new system of disease surveillance, according to Anish Mahajan, AIDS researcher with a Chennai-based AIDS support group and Brown Medical School in the US. The present system extrapolates data from high-risk groups, and has no community-based information from the private sector — which is the country's largest health provider.

The National AIDS Control Organization (NACO) estimates that four million people suffer from HIV infection in India. AIDS is not reported as a cause of death in the death registers, but NACO states that between 1986 and November 2002 there were 42 411 cases of full blown AIDS in the country. NACO also claimed that the epidemic is now plateauing because of its efforts. Others are sceptical, and reliable data, that all sides can agree, are urgently needed.

As for finance, according to the Central Government's Expenditure Budget for 2000–01, India's health and welfare budget was some US$ 1.2 billion. The disease control programme received some US$ 170 million, around 14% of this. AIDS and sexually transmitted diseases got some US$ 30 million, 2.5% of the health and welfare budget.

But the current donor interest in HIV/AIDS in India is boosting HIV/AIDS spending by approximately an additional US$ 80 million a year, causing spending on this one disease to reach US$ 110 million a year, thus making HIV/AIDS the main target of India's spending on disease control.

Moreover all AIDS funding is routed through NACO and state AIDS Societies, bypassing state health departments, so contributing little to improving the country's struggling health system.

Meanwhile, says Ravi Duggal, a health policy researcher at the Centre for Health and Allied Themes, Mumbai, treatment budgets are barely adequate to