

## 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](http://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.” ■

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