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Agreement Reached for Generic Drugs

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In the preparatory meeting for the Fifth World Trade Organization (WTO) Ministerial Conference in Cancun, Mexico, Sept. 10-14, a last-minute deal was reached to allow poor countries to import generic drugs to respond to health crises. Critics, however, said the Aug. 30 deal at the Geneva meeting contained so many requirements that it would do little to improve availability of muchneeded drugs.

Access to medications is dealt with under the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Poor countries want the right to produce or purchase low-cost or generic drugs to treat HIV-Aids, malaria, tuberculosis, and other diseases. But the big multinational and USbased pharmaceutical firms hold the patents on many of these medications. WTO member countries had agreed in principle in 2001 that the patent regime should be waived in certain circumstances, allowing developing countries to buy low-cost generic drugs.

The matter was close to being resolved last December, when the chair of the TRIPS council at the WTO, Mexican negotiator Eduardo Perez Motta, obtained majority backing for a declaration that the developing countries found acceptable. But the US delegation blocked the agreement at the WTO.

The US stand on the issue has gradually weakened since Sept. 11, 2001. In the wake of the anthrax scare, the US used the "anti-terrorist" card to pressure the manufacturer of the anthrax vaccine to lower the price, making it harder to argue in favor of denying that possibility to other countries. In addition, new health problems, such as SARS, convinced the US to drop efforts to restrict any exceptions on drug patents to treatments for HIV-Aids, tuberculosis, and malaria.

Geneva meeting falters

The latest effort on the drug-access issue was crafted by negotiators from Brazil, India, Kenya, South Africa, and the US. It included requirements for a "compulsory license" or permission to ignore patent restrictions in exceptional circumstances. But hope for a success dimmed when several countries led by the Philippines threatened to block the deal. They objected to an accompanying statement aimed at reassuring the pharmaceuticals lobby.

The statement said that rules allowing countries to override patents "should be used in good faith to protect public health...not as an instrument to pursue industrial or commercial policy objectives." It called for special measures to prevent drugs being smuggled back to rich country markets, including special packaging or different colored tablets. When the Philippines balked, dissent spread among developing countries, with 20 others indicating they had problems with the draft deal.

"You have rich white people telling African countries what is good for them," said one senior trade source. Agreement came the following morning after an appeal from several African delegates.

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They said that more than 8,000 Africans likely died of HIV-Aids and other treatable diseases in the hours since the deadlock, and more than 2 million have likely died since the US blocked the draft of the deal in December 2002. The agreement was one of the few successes, for those who saw it as a success, at the Geneva meeting.

Uruguayan Ambassador Carlos Perez del Castillo, current chair of the WTO's General Council, and WTO director-general Supachai Panitchpakdi submitted their draft declaration to ministers on Aug. 31. But the cover letter said the draft had not been agreed to "in any part" and did not include many of the member governments' proposals. They said, however, that "it remains our best judgment of what could constitute a workable framework for action by Ministers at Cancun."

In Cancun, the trade ministers of the WTO's 146 member countries will assess the state of trade negotiations of the Doha Round, launched in the Qatar capital in November 2001. The Doha Round is facing contentious debate between the developing South and the industrialized North, particularly regarding agricultural subsidies.

Agreement broadens access to generic drugs

International agreements have always allowed countries to break patents during national health emergencies, but that was little help for countries with no pharmaceutical industry to make the medicines. The Geneva deal, for the first time, allows India, Brazil and other countries with drug-manufacturing capability to produce drugs patented by US and other pharmaceuticals companies as long as they export them only to needy nations.

Panitchpakdi called the decision historic. "The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual-property rules to deal with the diseases that ravage their people," he said.

The New York Times said the pact would "enhance the Bush administration's international standing." But critics saw it differently. They said the agreement's fatal flaw was the export process itself, by which the manufacturing country issues a license to the producing company overriding foreign patents a cumbersome process that leaves exporting countries susceptible to pressure to not grant the licenses. Many international nongovernmental groups including Medecins Sans Frontieres criticized the deal.

On Aug. 28, Oxfam International and Swiss humanitarian organization Berne Declaration said the compromise imposes conditions on developing countries that will be difficult if not impossible to fulfill and will only perpetuate existing inequality between rich and poor nations. They said the "annoying" and onerous conditions and restrictions were included to satisfy pharmaceuticals companies.

"The proposed deal is largely cosmetic and will not make a significant difference to the millions of sick people who die unnecessarily in the Third World every year," said Celine Charveriat, Oxfam representative in Geneva. "If confirmed, the deal would be a betrayal of the pledge made in the Doha Declaration to put public health before patent rights."



Brazil, India ready to provide drugs

On Aug. 30, Brazil and India, two key negotiators in the drug-access agreement, said they planned to use the new accord both as importers and exporters of medicines. "Brazil does not discount any possibility. We have a limited manufacturing capacity, until now mostly for internal uses, but we do not discount other uses," said Brazil's WTO Ambassador Luiz Felipe de Seixas Correa.

The Brazilian ambassador said the Doha Declaration recognized "fully and unequivocally" the right of member countries to grant obligatory licenses. Member countries that want to import a generic medicine for a health crisis only need to notify the TRIPS council of their decision, he said. In a related announcement, Brazil also threatened to break patents and start producing anti-AIDS drugs if the three pharmaceutical companies selling them do not slash prices.

"The cost has to go down so we can treat the patients," said Marcia Lage, a spokesperson for the Brazilian Health Ministry's AIDS division. "If the price remains high, we'll start producing or importing the drugs." Negotiations to lower the price of the AIDS drugs sold to the Brazilian government by Abbott Laboratories, Roche, and Merck & Co. have so far failed to produce any meaningful price reductions, she said. The government wants a 50% price cut.

Brazilian Health Minister Humberto Costa told the companies that if no acceptable plan was forthcoming, Brazil would start making generic versions of the drugs and explore the possibility of importing them. A similar threat by Costa's predecessor two years ago convinced Roche to reduce the price of an AIDS drug by 40%.

Brazil can make its own drugs and its 1997 intellectual-property law allows patents to be broken when companies employ abusive pricing policies. Brazil has one of the most successful anti-AIDS programs in the world, providing free anti-AIDS drugs to anyone who needs them. About 143,000 Brazilians have AIDS, and about 70,000 receive antiretrovial drugs (see NotiSur, 2001-05-25).

The issue of access of generic drugs illustrates one of the major problems with the process of trade negotiations, say critics, since a public-health matter affecting millions of people is decided not by the World Health Organization (WHO) or a similar international public-health agency, but by an institution devoted to protecting commercial interests. They say that until global health decisions are made on the basis of keeping the afflicted alive, not on keeping stockholders happy, people will keep dying needlessly.

More trouble ahead at Cancun

Some trade experts said rich countries had made the mistake of thinking they could neutralize developing-country grievances on many other issues with an agreement on drugs. But Washington and Brussels have seriously misjudged the level of frustration among developing countries in the run-up to Cancun, said Alejandra Alvarez, a trade expert at consultants APCO. "The WTO is a different animal now," she said. "The larger members need to take into account the views of developing countries."





With the pharmaceuticals issue apparently taken care of, the potentially more difficult matter of agriculture will take center stage at Cancun. "Without an accord on medicines, everything would have been very difficult in Cancun," said Seixas Correa. "But that does not mean that with an accord everything will now be easy. If we don't find a solution to the agricultural question, we won't negotiate on any others."

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