Médecins Sans Frontières Briefing Note
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ONE STEP FORWARD, TWO STEPS BACK?
ISSUES FOR THE 5TH WTO MINISTERIAL CONFERENCE (CANCÚN 2003)

In 2001 at the Ministerial Conference in Doha, Qatar, World Trade Organization (WTO) Members adopted the groundbreaking "Declaration on the TRIPS Agreement and Public Health," which unequivocally recognised the primacy of public health over commercial interests. The Declaration confirmed some of the key flexibilities in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and obligated countries to interpret the treaty in a manner that would protect public health and promote access to medicines for all. The core of the Declaration states:

> *"4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."*

On the eve of the next Ministerial in Cancún, what has been achieved? In this document, Médecins Sans Frontières (MSF) assesses both the major setbacks and accomplishments of the past two years, and outlines the key issues to be addressed at Cancún.

BROKEN PROMISES

Fairly quickly after the Doha Declaration was adopted, the optimistic "spirit of Doha" evaporated. There have been continuous attempts by wealthy nations – particularly those that are home to major pharmaceutical firms – to erode the reach and strength of the Declaration. These attacks have occurred in three main areas:

Paragraph 6 Negotiations: The United States, European Union, Canada, Switzerland, and Japan negotiated fiercely at the TRIPS Council discussions on Paragraph 6 to curtail the ability of developing countries to access generics. Paragraph 6 of the Doha Declaration had instructed the TRIPS Council to find an "expeditious solution" so that countries without drug production capacity could make use of compulsory licenses to import generics when necessary. However, countless attempts have been made to introduce unnecessary procedural complications and/or to limit the scope of the solution to a set list of diseases, eligible importing countries, or emergency situations. Such proposals seem to have been made in bad faith. For example, the proposed list of diseases had no public health rationale: almost all the listed diseases were ones for which there was no drug

treatment, or where existing treatment was already off patent—in other words, drugs for which there was no opportunity to issue a compulsory license.[1]

The solution that was nearly adopted (under tight time pressures), the so-called "December 16" or "Motta text," was also deeply flawed. It was so cumbersome that it would have made generic production almost economically unfeasible after 2005, when key manufacturing countries must fully implement TRIPS. At the end of the day, the supply of affordable versions of new medicines would have slowed to a trickle, with developing countries left with very few alternatives to the high prices and long-term monopolies of originator companies. The current prices of originator antiretrovirals (ARVs), which are discounted to developing countries but still usually far higher than generics, gives a preview of how drug prices could rise in a post-Motta world.

Bilateral and Regional Trade Negotiations: The US has been pursuing a number of regional or bilateral trade agreements that would, in effect, weaken or even completely annul the Doha Declaration. Negotiations to tighten patent protection are underway in regions heavily burdened by disease, such as the Southern African Customs Union and Central America, among others.[2] The most severe example is perhaps the Free Trade Area of the Americas (FTAA) Agreement, which includes 34 countries of the Western Hemisphere and covers 800 million people. Among the proposed measures are: limits on the circumstances in which compulsory licenses on pharmaceutical products may be issued; extension of patent terms beyond the 20 years required by TRIPS; a prohibition on the export of drugs produced under compulsory license; and exclusive rights on pharmaceutical test data, which would delay the introduction of generics even when there are no patents. The FTAA—intended to be a model for other agreements—would supersede both TRIPS and Doha, slamming the door shut on the key flexibilities that were designed to protect public health.

Technical Assistance: Some wealthy Members have been providing inappropriate and dangerous technical assistance to developing countries. While publicly supporting Doha on the one hand, they are quietly undermining it on the other through bilateral aid programs that advise countries to implement policies that are harmful to health, and yield little, if any, benefit to the country. For example, the US Agency for International Development (USAID) has been funding the US Commerce Department to provide technical assistance to Nigeria in re-writing its patent laws. The draft legislation demands far more than TRIPS requires, and includes measures such as the criminalisation of patent infringement, which sends a strong message discouraging Nigerians from trying to access affordable generic drugs.[3] In addition, the World Intellectual Property Organization (WIPO), charged with providing technical assistance on IP matters to countries worldwide, has been markedly slow in taking the Doha Declaration into account in its activities.[4]

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[1] For a full analysis of the list of diseases and drugs, see: Mary Moran. "Reneging on Doha: An MSF Analysis of recent attempts to restrict developing countries' use of compulsory licensing to a set list of diseases." May 2003. <www.accessmed-msf.org>

[2] In addition to the FTAA, free trade agreements are also currently being implemented or negotiated between the US and Singapore, Chile, Jordan, Morocco, five Central American countries (CAFTA), and the Southern African Customs Union (Botswana, Lesotho, Namibia, South Africa and Swaziland).

[3] Michael Schroeder. "Drug Patents Draw Scrutiny as Bush Makes African Visit." *The Wall Street Journal*. 9 July 2003.

[4] For more information on the shortcomings of WIPO technical assistance, see: MSF, Consumer Project on Technology, Oxfam International and Health Action International. "Conference Report: Implementation of the Doha Declaration on the TRIPS Agreement and Public Health. Technical Assistance—How to Get it Right." March 2002. <www.accessmed-msf.org>

FORGING AHEAD WITH THE DOHA DECLARATION

Despite multiple attempts to weaken the Declaration, the past two years have also seen certain countries moving forward to take advantage of the flexibilities afforded by Doha. For example, **Cambodia**'s new patent legislation excludes pharmaceutical products from patent protection until 2016, explicitly citing the Doha Declaration as justification.[5] In addition, **Cameroon** has been able to access the best international prices for ARVs because its Ministry of Health authorized the importation of generic versions of patented drugs when they were available at lower prices than the originator. As a result, the national procurement agency pays about US$277 for its first-line treatment combination–one of the lowest prices available internationally. Similarly, it is possible to buy a generic first-line ARV combination in **Malawi** for about US$288; as a Least Developed Country (LDC), Malawi does not have to enforce pharmaceutical patents until 2016. Finally, in a recent joint negotiation, **ten Latin American countries**[6] were able to reduce the prices of ARV triple-combinations from US$1000-$5000 down to US$350-$690 by setting a maximum reference price that only generic producers (except Abbott Laboratories) were willing to meet. While some of the drugs are patented in some of the countries, the governments did not allow this legal barrier to stand in the way of concluding these negotiations, and as a result, together they will save an estimated US$120 million a year. (While most of the examples above concern AIDS drugs, Doha applies to all public health problems and can certainly also be used to help access affordable drugs for other diseases.)

By finding ways to overcome patent barriers, Cambodia, Cameroon, Malawi, and the Latin American countries are acting in accordance with the core principle of Doha, that TRIPS should be "interpreted and implemented in a manner supportive of WTO Members right to protect public health."

In order to protect global public health at Cancún, MSF asks WTO Members to:

IMPLEMENT DOHA

- Developing countries should implement and seize the opportunities afforded by the Doha Declaration. The political space now exists so that patents should never be a barrier to purchasing or producing generic versions of medicines.
- LDCs should not enforce or provide patents on pharmaceutical products until *at least* 2016. LDCs have the maximum flexibility to disregard patents and data protection rules and are encouraged to do so to protect public health.
- Qualified WTO Members and international organizations should provide technical assistance for Doha implementation in developing countries that is "balanced, transparent, and unbiased," as the European Union recently affirmed.[7] Many developing countries cannot afford to have anything but the most effective implementation of Doha to address their pressing public health problems.

BOLSTER DOHA

- MSF calls on Members to reject the Motta text and any other unduly limited solutions to Paragraph 6. Rather, the solution should be simple, economically viable, and free of onerous conditions; it should not be limited to certain diseases, products, or countries, since the Declaration specifies that TRIPS should be interpreted in a manner that will "promote access to medicines for *all*"—not just for some. Therefore, MSF urges the WTO to allow production for export of new essential medicines as a limited exception to a patent right. All Members should take the time to negotiate a workable

[5] Article 136, Law on the Patents, Utility Model Certificates, and Industrial Designs, Cambodia. In preparation for its accession to the WTO at Cancún, Cambodia has been adapting its legislation to WTO requirements.

[6] The Andean Community (Peru, Bolivia, Colombia, Ecuador, Venezuela) and Chile, Argentina, Mexico, Paraguay and Uruguay.

[7] WTO. The Implementation of the Doha Declaration on the TRIPS Agreement and Public Health. Communication by the European Communities and their Member States. 24 June 2003. (IP/C/W/402)

solution, rather than succumbing to the pressure of artificial deadlines. Health specialists should be involved in the process, as their input is critical in trade negotiations that have such heavy health implications.

- MSF calls on Members to reject any TRIPS-plus provisions, and set the Doha Declaration as the ceiling on intellectual property protection for all bilateral and regional trade agreements. In particular, it calls for removing intellectual property provisions from the FTAA.

MSF also has broader concerns about the impact of TRIPS on access to medicines, which the WTO should begin to address at Cancún. In particular:

- How will production of affordable versions of new medicines be assured after 2005 when TRIPS is fully implemented?
- How will R&D that addresses the health needs of the poor be generated? Ample evidence indicates that TRIPS does not and will not spur R&D for the diseases that predominantly affect developing countries, as it had promised to do. Unless an alternative solution is found, this failure will undermine the very legitimacy of the treaty.

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