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Submission by Médecins Sans Frontières

**Doha Derailed: A Progress Report on TRIPS and Access to Medicines
Médecins Sans Frontières Briefing for the 5th WTO Ministerial Conference, Cancun 2003**

Paris, 20 October 2003

This paper has been submitted by Médecins Sans Frontières. The views expressed herein are those of the author and are not necessarily shared by Members of the OECD.

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DOHA DERAILED:



A Progress Report on TRIPS and Access to Medicines

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Introduction

At the 2001 Ministerial Conference in Doha, Qatar, Members of the World Trade Organization (WTO) adopted the groundbreaking “Declaration on the TRIPS Agreement and Public Health,” which unequivocally recognised that access to medicines should have primacy over commercial interests. The Doha Declaration confirmed some of the key flexibilities in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and encouraged 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.



Eric Miller

This group of people living with HIV/AIDS has been receiving generic antiretroviral therapy at the MSF clinic in Khayelitsha, South Africa. They are celebrating here the programme’s 2nd anniversary.

Since Doha, some Members have attacked both the spirit and intent of the Declaration, putting the interests of their pharmaceutical industries ahead of the health of the world’s poor. Meanwhile, other Members have been moving ahead to take measures that promote and protect the health of their populations, as supported by the Doha Declaration. In this progress report for the 5th Ministerial Conference at Cancún, Médecins Sans Frontières (MSF) assesses the progress and setbacks on the realisation of the Declaration, and outlines the next steps Members should take to meet their Doha obligations to “promote access to medicines for all.”

See back cover for recommendations.

Negotiating in Bad Faith: The Story of Paragraph 6

The past two years have clearly shown—most explicitly in the debates over the “Paragraph 6” issue—that the Doha Declaration must be actively implemented and defended if it is to have any force. Paragraph 6 of the Declaration had instructed the TRIPS Council to find an “expeditious solution” by the end of 2002 so that countries without drug production capacity could make use of compulsory licences to import generics when necessary. However, contrary to the spirit of Doha, the United States, European Union, Canada, Switzerland, and Japan negotiated fiercely at the TRIPS Council to handicap any proposed solution by introducing unnecessary procedural complications and/or limitations.

The solution that was nearly adopted under tight time pressures, the so-called “December 16” or “Motta text,” is extremely cumbersome, and economically both risky and nonsensical. For example, the Motta text requires both importing and exporting countries to issue compulsory licences (if there is a patent on the drug in both countries), and each country must declare whether or not it has sufficient manufacturing capacity; country

restrictions would curb economies of scale in production, and Members would have to notify the WTO TRIPS Council of each compulsory licence. Overall, the Motta text would make generic production much less feasible 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 slow to a trickle, with developing countries having few alternatives to the high prices and long-term monopolies of originator companies. Although the Motta text was not adopted in December 2002, it is still, unfortunately, the main candidate being advanced by Members as a solution.

A better answer would be to allow production for export as a limited exception to a patent right, which was the option forwarded by the WHO, and supported by intellectual property (IP) experts and MSF. This solution would enable greater competition so that prices could drop to more affordable levels. The experience with antiretrovirals (ARV) and other drugs has amply shown that as competition rises, prices fall.

Cambodia: A Backhanded Welcome to the WTO

The case of Cambodia provides a telling example of double-talking around the Doha Declaration by some wealthy Members. In early 2003 Cambodia’s legislature adopted a new law that excluded pharmaceutical products from patent protection until 2016, explicitly citing the Doha Declaration as justification.* While this legislation was initially considered an excellent example of Doha implementation, it has apparently since been compromised during closed-door negotiations in Geneva for Cambodia’s accession to the WTO. Under pressure from the US, Cambodia has evidently agreed to implement TRIPS in 2007, while immediately linking drug registration approval with patent status and granting 5 years of data exclusivity—measures that will hinder or delay generic availability, and that are not required by TRIPS (see more on these two legal provisions in “Extra Burdens” on page 4). Having recently emerged from years of civil war, Cambodia is one of the poorest nations in the world: it is a Least-Developed Country with a per capita gross national income (GNI) of US\$270, and a rank of 130 on the Human Development Index.

MSF has been working in Cambodia since 1989 and currently runs projects treating malaria and HIV/AIDS; on the ground, we know that the public health challenges that Cambodia already faces will only get worse with more stringent intellectual property protection on medicines.

The case of Cambodia’s accession not only demonstrates how some Members are completely disregarding their Doha commitments, but also sets a dangerous precedent for other developing countries wishing to join the WTO.

* Article 136, Law on the Patents, Utility Model Certificates, and Industrial Designs, Cambodia.



Mr Maum keeps vigil over his two sons: Ham, 12, suffering from typhoid fever and Hoy, 7, who has severe malaria. Health Centre, Anlong Veng, Cambodia.

Serge Sibert / Cosmos

Despite existing problems with the Motta text, wealthy WTO Members have been fighting to cripple it even further by pushing for additional limitations, including a **fixed list of diseases, limits on eligible importing countries**, and **restrictions to emergency situations**. Such moves have been made in extremely bad faith. For example, the proposed list of diseases had no public health rationale: almost all the included 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 licence.* In addition, efforts to restrict the list of eligible importing countries—if successful—would have excluded large (and disease-burdened) markets like Brazil, South Africa or the Philippines; in order to make drug production economically efficient and attractive to a generic firm, it is essential to include such large markets in the system. During the 2001 anthrax scare, even the US and Canada (who both have advanced drug production capacity)

were looking to import generic ciprofloxacin as an alternative to Bayer’s high prices. Finally, the proposal to restrict the solution to **emergency situations** was contrary both to the Motta text itself and to the Doha Declaration, which confirmed in paragraph 5(b) that “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” Emergency restrictions suggest that a country would have to sit on its hands until a public health problem had reached emergency proportions before taking action.

The Paragraph 6 story showcases how WTO Members with pharmaceutical industry interests have reneged on their Doha commitments, and demonstrates why the Declaration must be constantly defended if it is to impact the lives of the poor.**

* 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>
 ** At the time of going to press, Paragraph 6 had not yet been resolved.

Islands of Implementation: Forging Ahead with Doha

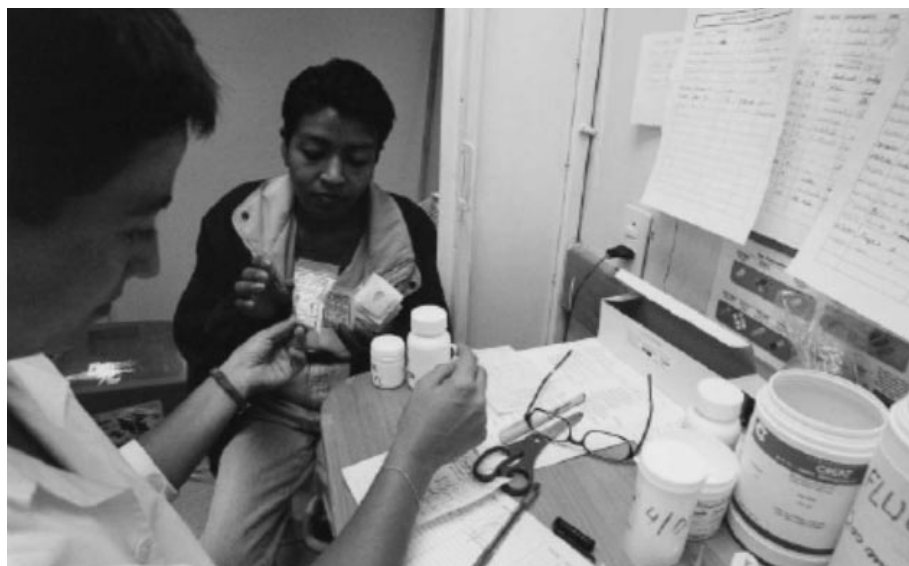
Despite multiple attempts to weaken the Doha Declaration, the past two years have also seen certain countries moving forward to take advantage of the flexibilities it has afforded. For example, **Cameroon** has been able to access the best international prices for antiretrovirals (ARVs) because its Ministry 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 per person/year (ppy) 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 ppy; as an LDC, Malawi does not have to enforce or grant pharmaceutical patents until 2016.

In addition, by including generic companies in the price negotiations, **ten Latin American countries*** were able to establish price ceilings for ARVs that are significantly lower than the existing prices in any of the countries. With the exception of Abbott Labs, no originator firm was willing to make regional offers for the requested products—they insisted instead that each country negotiate with each firm on a product-by-product basis within the framework of the Accelerating Access Initiative. Thus, offers from generic firms largely determined the regional reference prices. As a result, governments will save up to 93% on the price of a first-line triple combination (prices fell from as high as \$5000 down to \$365ppy). 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 could save an estimated US\$120 million a year. (See further details of this deal in “Voluntary Discounts from Big Pharma” on page 7.)

By finding ways to overcome patent barriers, 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.”

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



Marlene is a person living with HIV/AIDS who has access to ARV treatment. Roosevelt Hospital Pharmacy, Guatemala.

Jean Carlos Tomasi

Extra Burdens: IP Provisions Not Required by TRIPS

Many developing countries are granting protections on intellectual property that are not required by TRIPS—also known as “TRIPS-plus” provisions. Such measures, often implemented in the context of technical assistance, can be quite harmful to the population (see more in “Technical Assistance” on page 5). Below are explanations of three such provisions that have been appearing with increasing frequency around the globe, with explanations of why they are dangerous for public health.

a. Criminalisation of patent infringement

Counterfeiting and piracy are different from patent infringement. Fake or counterfeit medicines may contain no active ingredients at all, or even harmful ones. The TRIPS Agreement requires that counterfeiting and piracy be treated as a criminal offence, and generally, public authorities such as the police are responsible for enforcement.* In contrast, the TRIPS Agreement does not require that patent infringement be made a criminal offence—it only requires that the patent holder be able to take legal action against the infringement.** Where people cannot afford the patented version of a life-saving medicine they may try to import or use a less expensive generic version; the patent holder may then choose to sue to cut off the supply of generic medicines.

Unfortunately, legal provisions that criminalise patent infringement are being proposed in Nigeria and Uganda, and could result in sending doctors and patients to prison for trying to get access to affordable medicines. Such provisions are harsh, extreme, and certainly *not* required by TRIPS.

b. Exclusive rights to undisclosed data (or “data exclusivity”)

To register a new medicine with a Drug Regulatory Authority (DRA), an applicant has to show that their medicine is safe, effective, and of quality. The very first applicant will have to show clinical trial data to prove that the medicine is effective, among other things. Subsequent, generic versions of the medicine usually only have to show that they are equivalent to the original version.

The TRIPS Agreement requires some protection for the original undisclosed test data, for example against “unfair commercial use.”*** However, this protection against “unfair commercial use” can take many forms. The US and some European countries have decided to provide such protection by providing data exclusivity for 5 to 10 years. However, the TRIPS Agreement does not require giving such exclusive rights to the data. Nevertheless, Guatemala has recently provided data exclusivity for 5 years, and such measures are now being proposed in Uganda, Cambodia and the FTAA as well. If this is done, affordable generic versions of medicines will be prevented from being registered for this time period,

even if there is no patent. If a drug is not registered, it cannot legally be used in a country.

c. Linkage of patent status with drug regulatory authority (DRA) approval

There is nothing in TRIPS that requires a DRA to deny registration to a generic medicine because a third party has a patent on, or related to, the product. Questions about the validity of patents are totally separate from questions about drug regulatory approval, i.e. whether a medicine is safe, effective, and of quality. A drug regulatory agency generally does not have the expertise to decide if a patent is valid or has been infringed.

*TRIPS Agreement Art 61

**TRIPS Agreement Art 28, 41 et seq

***TRIPS Agreement Art 39.3

Outside the Gates of the WTO: Dangerous Bilateral and Regional Trade Deals

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, with perhaps the most severe example being 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 licences 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 licence; limits on parallel import regimes; and exclusive rights on pharmaceutical test data, which would delay the introduction of generics even when there are no patents. (See more on these measures in “Extra Burdens” above.) The FTAA—intended to be a model for other agreements—would add on to the IP commitments already required by TRIPS, and slam the door shut on some of the key flexibilities that were designed to protect public health.

In addition to the FTAA, the US is currently negotiating free trade agreements with five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua in CAFTA), the Dominican Republic, the Southern African Customs Union (Botswana, Lesotho, Namibia, South Africa and Swaziland), Morocco, Bahrain, and Australia. By exerting pressure on countries to adopt TRIPS-plus provisions, the US is going back on its word and breaching the commitments it made when it agreed to the Doha Declaration two years ago.

Technical ‘Assistance’: A Case of Malpractice?

Many developing countries cannot afford to have anything but the most effective implementation of TRIPS safeguards and Doha to address their pressing public health problems, and technical assistance is one important way to make this happen. Unfortunately, some countries have been receiving inappropriate and dangerous technical assistance from multilateral or bilateral sources, reflecting more the interests of the provider than the recipient.

One prominent example is the **World Intellectual Property Organization (WIPO)**, which is a UN agency that has an agreement with the WTO to provide legal and technical assistance to its Members. WIPO has been markedly slow in taking the Doha Declaration into account in its activities. This slowness is perhaps a reflection of the inherent contradiction between WIPO’s mandate to “*promote the protection of intellectual property throughout the world*,”* and its duty to provide technical assistance to least developed and developing Members on TRIPS implementation. Safeguarding public health requires a nuanced IP system that is fine-tuned to local conditions and levels of economic development—not simply stronger IP protection. As Cambodia was



This girl waits for medicines at an MSF malaria program that is focusing on testing and treatment of children under-five and pregnant women. Niger Delta, Nigeria.

preparing to join the WTO, MSF found in March 2002 that the draft patent law submitted by WIPO to the government did not take into account the flexibilities in TRIPS and Doha. In fact, MSF found that WIPO had not yet informed Cambodia of the Doha Declaration, nor was the government aware at the time that it was not required to grant or enforce patents on pharmaceutical products until 2016.** (In 2003, Cambodia adopted the 2016 deadline; however, this may now be under threat as a result of the country’s accession to the WTO. See more on Cambodia on page 2.)

In addition, while publicly supporting Doha on the one hand, some Members are quietly undermining it on the other through bilateral aid programs that advise countries to implement harmful policies that yield little, if any, benefit to the country. For example, the *Wall Street Journal* reported that 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.***

Similarly, in the process of revising its patent legislation, **Uganda** has been advised by a USAID-funded consultant to adopt provisions that are not required by TRIPS, but that will hinder generic competition. For example, the draft legislation would place extra limits on the uses of compulsory licensing, grant patent protection for new uses of previously patented products, and criminalise patent infringement. Such provisions are nothing short of bizarre, as they would protect the interests of US drug companies, but yield no benefits for the health of Ugandans. As an LDC, Uganda does not even have to provide or enforce patent protection on pharmaceutical products until at least 2016. (See more on criminalisation of patent infringement in “Extra Burdens” opposite.)

Contrary to its intent, technical assistance can often be a dangerous animal. Implementing Doha effectively in developing countries will require technical assistance that is “balanced, transparent, and unbiased,” as the European Union (EU) recently affirmed. MSF welcomes the EU’s public commitment “to fully take the Doha Declaration into account in their trade policy, and in particular as regards technical assistance for” TRIPS implementation, and supports the EU’s call on “all technical assistance providers, and in particular multilateral organizations, to join them in taking up this commitment.”****

* Article 3, Convention Establishing the World Intellectual Property Organization (1967).

** 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>

*** Michael Schroeder. “Drug Patents Draw Scrutiny as Bush Makes African Visit.” *The Wall Street Journal*. 9 July 2003.

**** 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)

TRIPS Fails to Deliver on R&D

The deal struck by TRIPS—extracting stronger IP protection from developing countries in exchange for increased R&D—has turned out to be hollow. TRIPS does not and will not spur R&D for the diseases that predominantly affect developing countries, because its underlying logic is essentially faulty. Ample evidence shows that private sector R&D is driven by the size of the potential market, not by levels of IP protection. Poor populations do not comprise a sufficient market to generate R&D responsive to their needs. Thus, we see that 90% of the world’s health R&D is devoted to conditions that affect just 10% of the world’s population. In addition, of the 1,393 new drugs approved between 1975 and 1999, only 16 (or just over 1%) were specifically developed for tropical diseases and tuberculosis. Finally, data from eleven major pharmaceutical firms that responded to a survey in 2001 indicate minimal investments into the diseases predominantly affecting the poor—in other words,



Serge Shevt / Cosmos

This boy is being checked for leishmaniasis infection by an MSF team. No new drug for leishmaniasis has been developed since the 1930s. Peru.

the drug pipeline is empty. If an alternative solution to the R&D problem is not found, it will undermine the very legitimacy of the TRIPS Agreement.

Enduring Myths

a. Myth: ARVs are not patented in Africa. There is a persistent myth that ARVs are not widely patented in Africa, and therefore, that patents do not impede access to medicines for AIDS. This myth stems from a controversial article published in 2001 in the *Journal of the American Medical Association*, and has lingered, in part because it is widely cited by drug industry lobbyists.* However, as scientists and NGOs involved in AIDS treatment have pointed out, the actual data presented in the article do not support the claim; on the contrary, the most popular antiretroviral combination in Africa was patented in 37 out of 53 countries at the time. Furthermore, many of the non-patented drugs are impractical for use in resource-poor settings. A survey conducted by an MSF legal team on patents in Kenya, Malawi, South Africa, Uganda, Zambia, Zimbabwe, and the 16 member states of the Organisation Africaine de la Propriété Intellectuelle (an organization of francophone African countries) found patents on antiretrovirals in *all* of them.** Furthermore, in South Africa, which has nearly 5 million people living with HIV/AIDS and represents half of the pharmaceutical market in Africa, 13 out of 15 antiretroviral treatments are patent protected. Every such patent in force is actually or potentially a barrier to access to an essential medicine, and should be both acknowledged and overcome.

b. Myth: Compulsory licensing is only for national emergencies.*** Compulsory licences may be issued by public authorities for a variety of reasons, including—but not limited to—addressing public health emergencies. For example, the US government frequently issues compulsory licences to counteract antitrust abuses. However, there is a widely-held misperception that compulsory licences are only for use in emergencies—a myth that was perpetuated by the efforts of some Members to restrict the Paragraph 6 solution to cases of “national emergency or other

circumstances of extreme urgency.” It may be easier to grant a compulsory licence in emergency situations, because there are fewer procedures required by TRIPS. However, the Doha Declaration clearly states that “Each Member has the right to grant compulsory licences and *the freedom to determine the grounds upon which such licences are granted.*” (paragraph 5b, emphasis added).

c. Myth: The crisis in access to medicines is only about ARVs. Unfortunately, the access crisis encompasses not only ARVs for AIDS, but also a wide range of medicines for the many diseases endemic to the developing world, such as acute respiratory infections, diarrhoea, sexually transmitted diseases and tuberculosis (TB). However, most of the available data on patents and prices concerns ARVs, in part, because of the political attention drawn to the staggering impact of the AIDS epidemic itself. A less-prominent virus is hepatitis C, which afflicts 170 million people worldwide and causes acute hepatitis and chronic liver disease, such as cirrhosis and liver cancer. However, the cost of treatment (a combination of interferon and ribavirin) is about US\$30,000 per patient/year. Such prices are unquestionably beyond the reach of developing countries. High prices of new drugs may also prevent useful research: for example, the high cost of the new quinolone class of antibiotics has prevented sufficient research into whether such drugs could be used to reduce the duration of treatment for TB, which currently lasts 6-8 months. Thus, ARVs are just the tip of the iceberg when it comes to the access crisis. But what the ARV case does demonstrate is that it will be increasingly important to take advantage of the flexibilities in TRIPS and Doha as other new drugs and new public health threats emerge.

* A. Attaran, L. Gillespie-White. “Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?” *JAMA*, 2001, vol. 286, No.15 pp1886-1892.

** Pascale Boulet, Christopher Garrison, Ellen t Hoen. “Drug patents under the spotlight : Sharing practical knowledge about pharmaceutical patents.” *Medecins Sans Frontieres*, May 2003.

*** Compulsory licensing allows the production or importation of a generic medicine without the consent of the patent holder (though they receive adequate compensation). A key TRIPS safeguard, it is also one of the most important policy tools to ensure generic competition.

Voluntary Discounts from Big Pharma: A Viable Alternative?

Is generic competition still necessary when originator firms are selling to developing countries at discounted prices? The experience of the past few years says, resoundingly, yes. There are three main areas in which the voluntary tiered pricing system has fallen short: price, middle-income countries, and non-AIDS related medicines:

Price: It has taken a tremendous amount of concerted social and political effort (not to mention competitive pressure from generics) to convince originator drug companies to adopt the principle of selling ARVs at lower prices to developing countries—a practice known as tiered or differential pricing. What has been the result? While a few firms sell their drugs at competitive prices, most originator prices are still significantly higher than generic alternatives. For example, the best international price of Boehringer Ingelheim’s nevirapine, a drug used in many first-line therapies, is \$438 ppy, while a generic version (whose quality has been pre-qualified by WHO) costs only \$166 ppy—or, 38% of the discounted originator price. Furthermore, the originator price comes with restrictions: Boehringer limits its offer to World Bank classified “low-income” countries and sub-Saharan Africa, and likely charges higher prices in other developing countries; in contrast, Ranbaxy, the generic manufacturer, has no country restrictions on its price. This price and restriction pattern holds for most of the other ARVs as well.

The single most powerful, systematic, and reliable factor reducing drug prices has been generic competition (see chart below), not voluntary discounts. This is why it is so critical that WTO Members find ways of preserving the dynamic of generic competition.

Middle-Income countries: While originator firms have earned praise for offering discounts on ARVs to least-

developed countries, most firms have no public pricing policy towards middle-income developing countries. As a result, prices can skyrocket beyond the affordable range for many disease-burdened nations. For example, Abbott offers an ARV combination (lopinavir/ritonavir) for \$500 ppy to all African countries and LDCs, but is charging \$4336 ppy for the same drug to ten Latin American countries with whom it recently concluded negotiations. Whether a country’s per capita GNI is \$200 or \$2000, it will be extremely difficult for the average person to afford a drug at this price. In Peru, where per capita GNI is \$2000, only about 2% of people living with HIV have access to ARV care.

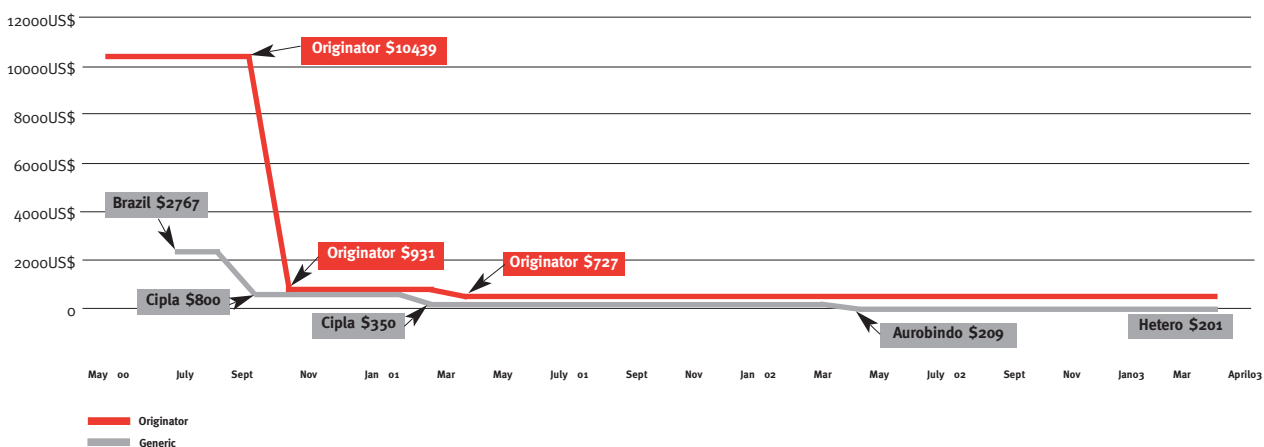
Merck and Roche are the only two major originator firms to have announced pricing policies for middle-income countries. However, their prices are still higher than those available from generic manufacturers. The Latin American countries mentioned above managed to get price offers from generic firms that were on average 38% lower than the prices for which they would have been eligible from Merck and Roche.

Non-AIDS related medicines: There is no tiered pricing for many drugs that are badly needed in the developing world. The case of interferon/ribavirin therapy for hepatitis C, which costs \$30,000 per patient/year, is just one example. (See further details on hepatitis in “Enduring Myths” on page 6.) The experience with voluntary discounts on ARVs suggests that diseases would have to reach epidemic proportions and capture global public attention before originator firms offer their patented drugs at differential prices. Voluntary discounts are an unacceptable and precarious way in which to respond to health needs.

The Effects of Generic Competition

Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year. During the last three years, originator companies have often responded to generic competition.

May 2000-April 2003



MSF Supports Developing Countries' Efforts To Implement The Doha Declaration

MSF supports developing countries' efforts to implement the Doha Declaration, and urges them to seize the opportunities now at hand. The political space now exists so that patents should never be a barrier to purchasing or producing generic versions of the medicines they need. However, while some countries have taken courageous steps to defend their populations' health despite pressure from wealthy countries, many more have yet to do so. Doha implementation is far from complete, and there is much that countries can still do to provide the strongest possible safeguards against unaffordable prices for much-needed drugs.

Therefore, MSF asks WTO Members to:

Implement the Doha Declaration

- Adapt national patent legislation, as necessary, to **take full advantage of the flexibilities** in TRIPS and the Doha Declaration.
- Least Developed Countries (LDC) 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.
- International organizations and WTO Members should provide **technical assistance** for Doha implementation in developing countries that is **"balanced, transparent, and unbiased,"** as the European Union recently affirmed.*

Bolster Doha

- MSF calls on Members to **reject the Motta text** and any other unduly limited solutions to Paragraph 6 (see page 2). MSF urges the WTO to allow production for export of new essential medicines as a **limited exception to a patent right**, as recommended by both the World Health Organization (WHO) and intellectual property (IP) experts.
- MSF calls on Members to **reject any IP provisions more stringent than TRIPS requires** (TRIPS-Plus), and to 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 Free Trade Area of the Americas (FTAA) Agreement**.
- MSF asks Members to include **health specialists** in any negotiations involving intellectual property protection, as their input is critical in talks with such heavy health implications.

Beyond Doha

MSF asks Members to address other TRIPS-related concerns about access to medicines, beyond those alluded to in the Doha Declaration. Specifically:

- How will production of **affordable versions of new medicines** be assured **after 2005** when TRIPS is fully implemented? The current challenge of overcoming high prices for antiretrovirals for AIDS offers a chilling preview of the access problems that lie ahead for all new medicines.
- 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.

* 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).



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Médecins Sans Frontières (MSF) is an independent humanitarian medical relief agency aiding victims of armed conflict, epidemics, and natural and man-made disasters. Founded in 1971, MSF currently works in more than 80 countries around the world. The organisation was awarded the Nobel Peace Prize in 1999.