

Medicines are a luxury for too many people in Latin America and the Caribbean. This fact is starting to change for AIDS drugs in some Latin American and Caribbean countries because generic competition is bringing down prices dramatically. However, this positive dynamic is now threatened by draft intellectual property provisions contained in the Free Trade Area of the Americas (FTAA) agreement, a proposed regional trade agreement covering all of the Americas, except Cuba. To avoid destroying the competition that is reducing drug prices and making treatment more accessible, Médecins Sans Frontières/ Doctors Without Borders (MSF) calls on countries of the Americas to exclude intellectual property provisions from the FTAA agreement altogether. New tougher intellectual property rules proposed in the FTAA agreement will be bad for the health of people in the Americas.



The international debate over the last four years about the impact of global trade rules on public health and access to medicines has raised concerns about the effects of intellectual property (IP) protection—particularly patents—on prices and access to medicines. Patents are tools of public policy that are supposed to guarantee that society as a whole benefits from any innovation. But, in the case of medicines, when patent protection is too strict in a developing country, it can limit the ability of governments and the private sector to produce or import more affordable products. However, governments of the Americas are not powerless. They can help counter the negative effects of patents by including safeguards to protect public health in their national laws.

This right is enshrined in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and was reinforced at the 4th WTO ministerial meeting in Doha, Qatar, in November 2001 in an historic declaration—the Ministerial Declaration on the TRIPS Agreement and Public Health—which has become known as the "Doha Declaration." The Doha Declaration placed the protection of public health above the protection of private commercial interests, and in particular, affirmed the right of countries to take measures to override patents when necessary in order to protect public health and promote access to medicines for all.

The Doha Declaration reaffirmed many key flexibilities in the TRIPS Agreement, including:

- The right of countries to issue a compulsory license (see glossary on page 11) at their discretion, not only in cases of emergency.
- The right of countries to determine for themselves what constitutes a national emergency or situation of extreme urgency in which case the procedure for issuing a compulsory license becomes easier and faster.

Some countries are starting to make use of the flexibilities reaffirmed in Doha. However, wealthy countries are putting pressure on developing countries to accept proposals in multilateral, regional, and bilateral trade negotiations that would limit their ability to implement the Doha Declaration and safeguard public health. Countries in the Americas are bearing the brunt of this pressure. For example, the United States has negotiated a bilateral agreement with Chile and is negotiating a regional agreement with five Central American countries (Costa Rica, El Salvador, Honduras, Guatemala, and Nicaragua) known as the Central American Free Trade Agreement or CAFTA, likely to be completed by the end of 2003. These agreements are being touted as models for the hemisphere-wide Free Trade Areas of the Americas (FTAA) agreement. Worldwide, the FTAA is the most far-reaching and extreme attempt to weaken the Doha Declaration.

The Effects of Generic Competition

A first-line antiretroviral (ARV) triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year (in US\$).



Because of a lack of transparency in CAFTA negotiations, the draft text of CAFTA has not been made public, and it is therefore impossible to provide an informed analysis of the IP provisions being proposed in the agreements. However, IP provisions in other bilateral free trade agreements (e.g. the US-Singapore agreement) are clearly TRIPS-plus, and these are consistent with proposed provisions in the FTAA agreement. It is safe to assume that the same provisions are being proposed in CAFTA. Even if IP provisions were to be excluded from FTAA, Central American countries could be locked into more stringent IP rules than is required in TRIPS as early as December 2003 if negotiations are concluded within the proposed timeframe.

The Free Trade Area of the Americas (FTAA)

The Free Trade Area of the Americas (FTAA) is a proposed regional trade agreement between 34 countries in North, Central and South America and the Caribbean, except Cuba. If implemented, it will be the largest "free trade zone" in the world, a US\$13 trillion market covering more than 800 million people. FTAA negotiations were launched officially in 1998, and are scheduled for completion by 2005.

The draft FTAA agreement is a set of proposals that includes provisions on IP, services, investments, agriculture, and market access, among others. There are nine FTAA Negotiating Groups, including one on IP, that are negotiating text for the chapters in the agreement.²

Throughout the negotiations on IP, the United States has been pushing to increase the IP protection provided to pharmaceutical products held by the originator (sometimes called "brand-name") pharmaceutical industry and to reduce the rights of countries in the region to take measures necessary to protect public health. In other words, the US is trying to impose standards on pharmaceuticals that go much further than what is required in the WTO TRIPS Agreement,³ for instance:

Dramatic limitations on the circumstances under which compulsory licenses on pharmaceuticals may be issued, whereas the TRIPS Agreement includes no such limitations and the Doha Declaration, which was adopted by all WTO member states, confirmed that countries have "the freedom to determine the grounds upon which such licenses are granted." Proposals in the draft FTAA text would, for example, limit compulsory licensing to declared "national emergencies" or other situations of extreme urgency and to the public sector only, meaning that countries would no longer have the right to issue a compulsory license to remedy high prices that restrict access to medicines, or to foster competition in the private sector to increase access to patented essential medicines.

** The extension of patent terms beyond the 20 years required in TRIPS. This would prolong the monopoly enjoyed by patent holders and further delay introduction of generic products.

A new role for drug regulatory authorities (DRAs), which are normally responsible for guaranteeing drug safety and efficacy and have no mandate regarding patents. These proposed rules would require DRAs to consider the patent status of drugs before granting marketing authorization to generic makers. This could, in effect, lead to enforcement of invalid patents since DRAs do not have the expertise or means to verify whether a patent has merit or not.



An MSF volunteer screens children for malaria in Colombia.

Exclusive rights on pharmaceutical test data that have been provided to DRAs. Since generic companies rely on these data to demonstrate that their product is safe and effective, this exclusivity will significantly delay the introduction of generics even when there are no patent barriers.

Another concern with the current draft text is that the agreement may restrict parallel importation to within the FTAA region only, contrary to the Doha Declaration. As a result, FTAA countries will not be able to shop around on the international market to import the best-priced medicines. In addition, the draft text includes a proposal to prohibit the export of drugs produced under compulsory license, which is currently permissible under the TRIPS Agreement to a certain extent.

These proposals, described by many experts as "TRIPS-plus,"⁴ would subject countries in the Americas to the most stringent and burdensome IP regimes in the world. Haiti, a least-developed country (LDC), would be forced into having stringent patent rules even though the Doha Declaration allows LDCs to have no patents on medicines until 2016. Once signed, the agreement would be binding for all 34 FTAA countries, and could take primacy over the TRIPS Agreement and the Doha Declaration.

⁴ Note that 'TRIPS-plus' is a non-technical term, which refers to any IP provision that is more stringent than the TRIPS Agreement requires. According to the WHO, "[5]ince the public health impact of TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements." (WHO Policy Perspectives on Medicines, No. 3, March 2001)



²These Negotiating Groups meet every month in Puebla, Mexico. In addition to the Negotiating Group meetings, there are regular meetings of the Trade Negotiating Committee (for vice-ministers of trade), currently co-chaired by Brazil and the US, as well as annual FTAA Ministerial Meetings (for ministers of trade). The most important upcoming meetings include the VIII Ministerial Meeting, which will be held November 20-21, 2003, in Miami, Florida, and the IX Ministerial Meeting, which will be held in Brazil in 2004, and which is scheduled to be the final FTAA meeting.

³ US negotiating objectives on IP rights have been made public and are available at http://www.ustr.gov/regions/whemisphere/intel.pdf.

What is at Stake for People in the Americas?

The HIV/AIDS crisis and the significant disparities in access to AIDS treatment between rich and poor countries provide a striking example of what is at stake in FTAA negotiations for people in the Americas. It helps illustrate what the situation will be for new medicines for a whole host of diseases

prevalent in the region, such as Chagas disease, malaria, and leishmaniasis, beginning in 2005.

At that time, all new innovative products could be patent protected because of TRIPS Agreement rules (in the Americas, Haiti should be an exception because it is classified as an LDC).





These two Honduran children are both infected with the parasite that causes Chagas disease. In Latin America, 100 million people are at risk of infection.

According to the World Health Organization (WHO), there are currently 1.9 million people living with HIV/AIDS in Latin America and the Caribbean. The Caribbean is the second-most affected region in the world after sub-Saharan Africa. The AIDS epidemic is also exacerbating other infectious diseases in the region, such as tuberculosis.

In wealthy countries such as the US and Canada, antiretroviral (ARV) drugs have dramatically extended and improved the lives of people living with HIV/AIDS, reducing AIDS-related deaths by more than 70%.⁵ But in developing countries in the Americas, hundreds of thousands of people living with HIV/AIDS do not have access to these life-saving drugs, because they are not affordable.

Latin American countries are already at a disadvantage when it comes to accessing affordable medicines. In the last few years, most originator companies have responded to generic competition and public pressure by adopting differential pricing policies for ARVs in developing countries through the "Accelerating Access Initiative" (AAI).⁶ But for the most part, Latin American countries have been left out in the cold.

While all the originator companies have steeply reduced prices for LDCs and sub-Saharan Africa, only Merck and Roche have established differential prices for middle-income developing countries.⁷

However, recently, access to generics is starting to bring down prices in Latin America. In June 2003, the Pan American Health Organization (PAHO) announced the completion of price negotiations with 10 Latin American countries—Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay, and Venezuela—which included the generic industry. Generic competition caused a drop in the cost of first-line treatment from US\$1,000-5,000 to US\$350-690 per person per year. All originator companies that produce ARVs

except Abbott Laboratories were unwilling to propose a common regional price and withdrew from these negotiations.⁸ 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 negotiations, and as a result, together they could save an estimated US\$120 million a year, provided flexible conditions for granting compulsory licenses are in place.

Generic competition has been one of the most important, reliable, and powerful forces to reduce drug prices systematically. If the FTAA strengthens patent protection, it will destroy the dynamic of competition that has caused ARV prices to plummet in some low- and mid-dle-income countries in the Americas. An FTAA agreement that has TRIPS-plus provisions threatens to have a catastrophic impact on the lives of millions of people living with HIV/AIDS and other diseases.

⁸ Negotiations also included key HIV-related diagnostics. See http://www.paho.org/English/DD/PIN/pr030612.htm.



⁵ Centers for Disease Control and Prevention (CDC). HIV/AIDS Surveillance Report 2001; 13 (no. 1):1-41.

⁶The Accelerating Access Initiative (AAI) was established in May 2000 by Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, and Roche along with UNAIDS, WHO, the World Bank, UNICEF, and UNFPA. Abbott Laboratories later joined. See http://www.unaids.org/acc_access/index.html.

⁷ Merck has a specific pricing policy for medium Human Development Index (HDI) countries with adult HIV prevalence of 1% or greater, and medium HDI countries with adult HIV prevalence of less than 1%. Roche has a specific pricing policy established in March 2003 for lower-middle-income countries, as classified by the World Bank. All other companies negotiate prices with non-LDC and non-sub-Saharan African countries on a "case-by-case basis." See "Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries," Fourth edition, April 24, 2003, Médecins Sans Frontières (MSF). Available in English, French and Spanish at http://www.accessmed-msf.org/prod/publications.asp?scntid=9520031050482&contenttype=PARA&.

Guatemala

"The situation for access to medicines in Guatemala is awful, it is terrible. Regarding HIV/AIDS, there are approximately 1,500 people receiving antiretroviral treatment in Guatemala at present, MSF is treating almost one-third of them. We buy quality generics. If there is any compromise on the possibility of buying such generics, then it will become almost impossible to treat HIV/AIDS patients in Guatemala. If only 'brand-name' drugs are available to treat HIV/AIDS, virtually no patients will receive treatment."

Luis Villa Head of Mission MSF in Guatemala In Guatemala, 67,000 people—of which 4,800 are children—are living with HIV/AIDS.9 Not much attention is given to HIV/AIDS in the country. ARVs are available, but unaffordable: treatment from originator companies costs from \$320-\$800 per month, and the average income is about US\$160 a month. MSF treats nearly 400 patients with ARV therapy in hospitals in Guatemala City and Coatepeque, and plans to double the number of patients under treatment next year.

Since ARVs are not protected by patents in Guatemala, MSF uses generic ARVs in its programs. Just one year ago, this meant the price differential between what MSF paid for generics and the price the Guatemalan government paid for originator drugs was between 75-99% (see table). Although the prices of originator ARVs have fallen dramatically in the past year due to generic competition, they are still on average two to five times as expensive as quality generic alternatives. Should the government decide to launch a national treatment program and use generic medicines, under today's laws it would have the right to buy the affordable medicines that MSF is purchasing. But if FTAA introduces new, more stringent rules, access to affordable medicines will be much more difficult and already strained health budgets will not stretch nearly as far.

This woman is a candidate to receive ARV therapy in an MSF program in Guatemala. Her name has been on the waiting list for 11 months.



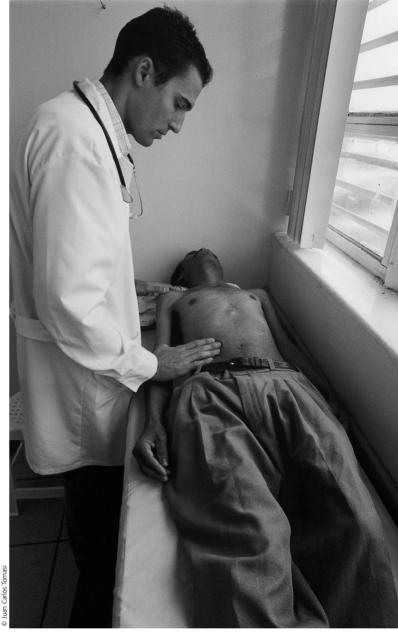
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Sample Prices of Generic versus Originator ARV Drugs in Guatemala

in US\$ Per Patient Per Year

Drug name	AZT+3TC	d4T (40 mg)
Price from Originator Companies July 2002	4,198	5,271
Price from Originator Companies July 2003	686 ¹⁰	270 ¹¹
Price from Generic Companies July 2003	352	53

Patents are not the only way that the FTAA could restrict access. In April 2003, under pressure to adopt US standards for protection of pharmaceutical test data, the Guatemalan government modified its national IP bill by passing a decree. This decree gives originator pharmaceutical companies five years of exclusivity on the test data they must provide to get a drug approved by the DRA. This means an automatic five-year delay in the availability of generic drugs even if they are not under patent. For thousands of Guatemalans living with HIV, five years without access to affordable ARVs can be the difference between life and death. MSF, in conjunction with Guatemalan civil society groups, is urging the government to repeal the decree and abolish data exclusivity, in order to promote generic competition and improve access to quality medicines. As it stands, Guatemala is the only country in Central America that gives five years of exclusive protection for test data, but the FTAA threatens to extend such a provision to all countries of the Americas.



An MSF doctor examines a man living with HIV in Guatemala.

⁹ UNAIDS 2002

GlaxoSmithKline offers the same combination at US\$329/year to LDCs (UN index), sub-Saharan Africa and countries eligible in the AAI. Although Honduras and Guatemala are on the list of AAI countries (according to the UNAIDS web site) they are not getting this price.

Bristol-Myers Squibb offers the same drug at US\$55/year to sub-Saharan African countries, but requires all other developing countries to negotiate prices on a case-by-case basis through the AAI.

Brazil

"My country needs to be able to issue compulsory licenses whenever it needs to increase access to medicines for its population, and no international agreement, including the FTAA, should prevent it from doing so. Our National AIDS Program is now supplying antiretrovirals free of charge for 115,000 people with HIV/AIDS. The new medicines that some of us need to use are very expensive already, and compulsory licensing will definitely be part of the only solution to keep the Brazilian AIDS Program functioning. The right to health is fundamental for all human beings and no trade agreement should be above this right."

Jorge Beloqui AIDS activist Grupo de Incentivo a Vida (GIV) São Paulo



On World AIDS Day, Brazilian AIDS activists celebrate the 90,000 deaths avoided through the country's ARV program.

The wide availability of affordable medicines can help countries achieve dramatic results with HIV/AIDS treatment programs. By using local generic production and competition to procure low-price quality drugs, the Brazilian National AIDS Program guarantees universal access to treatment for all Brazilians living with HIV/AIDS. If FTAA had been in place when a presidential decree mandated universal access, it is doubtful that the program would ever have been possible, and Brazil may not have been able to achieve its spectacular success: 90,000 AIDS deaths averted, 60,000 AIDS cases prevented, and 358,000 AIDS-related hospitalizations avoided between 1996 and 2002, leading to government savings of more than US\$2 billion during the same period.¹²

AIDS activists in Brazil are concerned about the negative impact of the US proposals on IP in the FTAA.

¹² Paulo R. Teixeira, Marco Antonio Vitoria, Jhoney Barcarolo. "The Brazilian Experience in Providing Universal Access to Antiretroviral Therapy." In eds. J.P. Moati et. al., *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges.* Paris: ANRS/National Agency for AIDS Research, 2003. 80.

Peru

"I want to see my son grow, I want to see him go to school, I want to see him at his first communion, dance with him when he turns 18. These infants, they don't know what they have [HIV/AIDS], they have the right to keep living, they want to live. I want the best medicines but antiretrovirals are not within my reach."

Veronica 30-year-old MSF patient from Lima, Peru, whose husband and son are also living with HIV/AIDS Approximately 76,000 people are living with HIV/AIDS in Peru,¹³ but only around 2% of people living with HIV/AIDS have access to ARVs. The cost of the cheapest available treatment has been US\$1,100 per person per year, about the average annual income.

MSF has two HIV/AIDS prevention and care programs in Peru, one in the south of Lima in an urban slum area and another in Lurigancho Prison. To help people with HIV/AIDS get access to life-prolonging ARVs, MSF also supports "Colectivo Para la Vida" (Collective for Life), a group of Peruvian NGOs and self-help groups working to increase access to essential drugs, including ARVs. MSF aims to introduce ARV therapy in its projects in 2004.

Generic ARVs are progressively entering the Peruvian market and competing with originator drugs, but this is only possible because very few medicines are patented in Peru. Since the revision of the Andean regional legislation to comply with TRIPS, patent applications are now being filed for new medicines entering the market, such as the AZT+3TC combination, marketed by GlaxoSmithKline (GSK) as Combivir® in 1998. Under current legislation in all Andean countries, Peru has recourse if GSK charges a price that is too high. Current rules stipulate that they only need to make a public interest declaration instructing the patent office to grant a compulsory license to other producers that can make the drug at lower prices. Such a simple compulsory licensing system will be impossible under the current FTAA draft.

13 Ministry of Health 2001



A mother brings her daughter who has leishmaniasis for treatment at an MSF health facility in Peru.



Isn't Strong Patent Protection Essential to Ensure Development of New Medicines?

Some argue that granting patents to protect pharmaceutical innovations is the best way to stimulate research and development (R&D) for new medicines and other health technologies. Patents are part of a complex system that *can* motivate investment in R&D under certain circumstances, such as when a profitable return on investment can be expected. But what about diseases like dengue, leishmaniasis, trachoma, or Chagas disease that affect people in the Americas with little or no purchasing power?

American trypanosomiasis, or Chagas disease, kills an estimated 50,000 people annually on the American continent. An estimated 18 million people are living with the parasite in their blood and about 100 million people are at risk of infection in 21 Central and South American countries. This is about 25% of the population of Latin America. In Bolivia, for example, 3.5 million people—nearly half of the population—are at risk of contracting the disease, and Chagas is the fourth leading cause of death among people 15 to 75 years old.

The disease is caused by *Trypanosoma cruzi*, a protozoan parasite transmitted to humans by blood-sucking insects that live in the walls and roofs of mud and straw housing commonly found in the poor rural areas and urban slums of Latin America. The disease can also be transmitted by blood transfusion and from mother to child during pregnancy.

There is no treatment for the chronic stage of Chagas, which continues to disable and kill people at the peak of their lives. And in a 2001 survey of the leading pharmaceutical companies, only one out of 11 was developing a drug against Chagas disease, and not one had brought a Chagas drug to market in the past five years.

Some FTAA negotiators want to strengthen IP protection claiming that it will create incentives to develop new drugs. But there is ample evidence that without a lucrative market, stronger IP protection will raise prices without stimulating needed research for diseases like Chagas. MSF currently runs three Chagas projects in Bolivia, Guatemala and Nicaragua.

Conclusions and Recommendations

As a medical humanitarian organization, Médecins Sans Frontières/Doctors Without Borders (MSF) has seen first hand the detrimental effects of strong intellectual property protection in developing countries—high prices mean people do not get the medicines they need. Safeguards in TRIPS, reaffirmed in the Doha Declaration, provide countries with the safety valve they need, and FTAA threatens to shut this valve.

MSF calls upon countries in the Americas to uphold their obligation to put the health needs of people before commercial and trade interests by implementing the Doha Declaration and making full use of the flexibilities in the TRIPS Agreement.

MSF calls upon countries of the Americas to exclude IP provisions from the FTAA agreement altogether in order to protect public health and promote access to medicines.

MSF calls upon the World Health Organization (WHO)/ Pan American Health Organization (PAHO) and UNAIDS to publicly support an "IP out of FTAA" position.



In Brazil, an MSF lab technician examines slides for the parasite that causes malaria.

What is a generic drug?

According to the World Health Organization (WHO), a generic drug is a pharmaceutical product intended to be interchangeable with the originator product, and which is generally manufactured without a license from the originator company. Generic products may be marketed either under a non-proprietary or approved name rather than a proprietary name. Generic does not mean counterfeit, fake, or substandard. Recently, WHO, in collaboration with other United Nations agencies, launched a project to "pre-qualify" producers of ARVs and other AIDS drugs, including generic manufacturers. Many generic ARV producers have been "pre-qualified" by the WHO as meeting international standards for quality, and the list is updated regularly.

What is the TRIPS Agreement?

The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which came into being in 1995, is an international agreement on the protection of various IP rights, including patents, copyrights and trademarks. It sets out guidelines for minimum standards for IP protection that must be met by all WTO Members within specific timeframes. The deadline has been extended to 2016 for least developed countries, as per paragraph 7 of the WTO Ministerial Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").

What is compulsory licensing?

Compulsory licensing allows the production or importation of a generic medicine without the consent of the patent holder (though they receive adequate compensation). Compulsory licenses may be issued by public authorities for various reasons, including, but not limited to, addressing public health or emergencies. They are permitted under the TRIPS Agreement, and are considered a regular feature of any good IP legislation. They are commonly used by industrialized countries such as the US. Compulsory licensing of pharmaceuticals is one of the most important policy tools for ensuring generic competition.

What is parallel importation?

Parallel importation allows a country to "shop around" for the best price of a branded drug on the global market, without the permission of the patent holder. It is an attractive option for developing countries when the same branded medicine is being sold for different prices in different markets. Many European countries, such as the UK, benefit from significant parallel trade to reduce the overall cost of medicines. Parallel importing does not involve the purchase of generics.

What are "strategies to accelerate the introduction of generics"?

To sell a generic version of a drug, a manufacturer has to put its product through various tests to obtain regulatory approval. A "Bolar provision" is a strategy to accelerate the introduction of generics by allowing the manufacturer to conduct these tests while the product is still under patent. The producer can then put the generic product onto the market as soon as the patent expires. Without this provision, the introduction of a generic could be delayed by two to four years after the patent expires.



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Medicines shouldn't be a luxury! Don't trade away health in the FTAA!

MSF currently has projects in 11 countries in the Americas—Argentina, Bolivia, Brazil, Colombia, Ecuador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, and Peru. MSF teams provide primary care, maternal/child health care, and other complementary attention for displaced and homeless populations and for indigenous people, as well as medical care for people with HIV/AIDS, malaria, Chaqas disease, and other infectious diseases.

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Cover photo: © Serge Sibert 2001 An MSF doctor examines children in Peru for signs of leishmaniasis.

MSF is an independent, international medical humanitarian organization that delivers emergency aid to victims of armed conflict, epidemics, natural and man-made disasters, and to others who lack health care due to social or geographic marginalization in nearly 80 countries throughout the world. MSF was awarded the 1999 Nobel Peace Prize, and that same year launched an international Campaign for Access to Essential Medicines, which grew directly out of the frustration of MSF medical teams that were increasingly unable to treat their patients because the medicines they needed were too expensive, no longer produced, increasingly ineffective, or simply did not exist.

For more information about the FTAA and MSF's Campaign for Access to Essential Medicines, please visit:

www.accessmed-msf.org www.msf.es www.msf.org

