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## **PATENTS, INTERNATIONAL TRADE LAW AND ACCESS TO ESSENTIAL MEDICINES**

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### **What is the issue?**

More than 85% of the world's population live in developing countries, and the vast majority of them have no or limited access to drugs that have saved and extended the lives of people in richer, developed countries. In the developing world, where 95% of the 40 million people with HIV/AIDS live, 20 million people have already died from AIDS. Every day, over 8,000 more people die and another 15,000 are infected with HIV. The global epidemic is devastating entire countries and regions. Similarly, tuberculosis (TB) and malaria kill massively and mainly among the poorest and most vulnerable of the global population, given their extremely limited access to effective forms of treatment.

### **What does this document tell me?**

This document answers some frequently asked questions about patents and international trade laws. The rules on drug patents in domestic laws and international trade agreements affect the availability and affordability of medicines to treat diseases such as HIV/AIDS, TB and malaria. This document explains the connection between patent issues and access to affordable drugs, so that they can be informed advocates for the basic rights of people in developing countries.

### **What do patents have to do with access to medicines?**

Depending on the patent laws in place, conditions will be created to favour more or less competition between manufacturers of patented and generic drugs (definitions of these terms are offered below). Increased competition is proven to result in lower prices, which in turn contribute to improved access to medicines. Although access depends on numerous factors, high prices of drugs constitute a key obstacle that cannot be addressed in a comprehensive and sustainable manner through foreign aid and drug donations alone.

### **What is a patent?**

A patent is an "intellectual property right" in an invention. Intellectual property rights (IPRs) are rights given to a person or a corporation over mental creations, such as: an author's *copyright* in their book or the rights of musicians in their recordings; a company's distinctive *trademark* on its products; or a *patent* on a technological invention.

A patent gives its owner (the "patentee") the right to prevent others from making, using, importing, or selling an invention. In other words, patenting an invention gives the patent owner a monopoly over the invention. A patent is usually granted for a limited time, such as 20 years. A patent is granted under a country's domestic laws, which may be affected by international laws. A patent may come with conditions or exceptions, depending on what the law in a given country says.

## What is the World Trade Organization?

Established in 1995 after a decade of trade negotiations, the WTO has become the central institution in the world trading system, with a secretariat located in Geneva.

The WTO administers dozens of international trade agreements covering a wide range of areas, including intellectual property. These agreements set out "ground rules" for international trade that all WTO member countries must observe.

The WTO also monitors countries' national trade policies, and provides a forum for trade negotiations and for settling trade disputes.

144 countries are members of the WTO, accounting for over 97% of world trade. Several other countries are currently negotiating joining the WTO.

Being a WTO member gives a country:

- access, at least in theory, to the markets of other member countries on terms set out by the WTO agreements;
- the option of invoking a mechanism for settling trade disputes; and
- participation in future trade negotiations.

In order to be a member, a country must sign on to the whole package of WTO Agreements.

## What can be patented?

A patented invention can be either an actual *product* or a new *process* for making a product. In order to qualify for a patent, an invention must satisfy three criteria: it must be something new, it must not be obvious but actually involve some sort of "inventive step", and it must be usable. Medical drugs are inventions that can be patented.

## What is a patented drug? What is a generic drug?

A drug that is patented can only be made, used, imported/exported or sold by the patent holder. According to the World Health Organization's Action Programme on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention.

A generic drug is a pharmaceutical product usually intended to be interchangeable with the original patented drug ("bioequivalent") because it does the same thing. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the patentee. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

Generic drugs should not be confused with counterfeit drugs. "Counterfeit goods are generally defined as goods involving slavish copying of trademarks. According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging."<sup>1</sup>

## What is "TRIPS" or the "TRIPS Agreement"?

This is a shorthand way of referring to the *Agreement on Trade-Related Aspects of Intellectual Property Rights*. The TRIPS Agreement is one of a series of trade agreements administered by the World Trade Organization (WTO). It sets out rules for intellectual property rights that all countries belonging to the WTO members must reflect in their own domestic laws.

## What does the TRIPS Agreement require?

The TRIPS Agreement contains a number of requirements that WTO member countries must satisfy in their national laws.

Before the TRIPS Agreement, most industrialized countries granted patents on drugs, but many developing countries did not. In some cases, countries only granted patents for the *process* of producing an invention (e.g., the method of producing a drug) but not for the *product* (i.e., the drug itself). Because in some countries pharmaceutical products could not be patented, generic copies of these drugs could be made or imported into those countries without first getting

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<sup>1</sup> World Health Organization - Action Programme on Essential Drugs. *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, DAP Series No. 7, 1997 & 1999.

permission from a patent-holder. This meant prices of medicines were often lower because of generic competition against the patented drugs. The TRIPS Agreement ends this.

**Exclusive patent rights:** Under the TRIPS Agreement (Article 28), governments are required to recognize patents on products and processes in (almost) all fields of technology, and to give the patent holder the exclusive right to make, use, sell or import the product in their country for a given period of time. (During this time, a patent holder may choose to grant another individual or corporation the right to do these things. This authorization is called a “voluntary license”.)

**Minimum 20-year patent term:** All WTO member countries are now required to grant patents on pharmaceutical inventions for at least 20 years from the date of filing for the patent (Article 33). This prevents someone other than the patent-holder from making, using, selling or importing a drug during the period it is still under patent. The patent owner's monopoly often results in significantly higher prices for patented medicines than in a situation of market competition.

**“Non-discrimination”:** The TRIPS Agreement (Article 27) also says countries must make patents, and all patent rights, available “without discrimination” on certain grounds. Under TRIPS, countries are not allowed to treat national and foreign inventions differently. Some also claim countries are not allowed to discriminate between types of products (e.g. having special rules about pharmaceuticals as opposed to computers). Finally, TRIPS says countries’ patent laws cannot discriminate between imports and products made locally.

#### **Which countries are bound by TRIPS and when?**

All countries that belong to the WTO are bound by the TRIPS Agreement. All “developed” countries were required to bring their domestic laws into line with TRIPS rules no later than January 1, 1996. “Developing” countries had until January 1, 2000 to comply - although they have until 2005 for patents on pharmaceutical products if they did not previously recognize these. Those countries considered “least developed” have until January 1, 2006 to change their laws, and may ask for extensions of time.

#### **What if a country doesn’t meet its obligations under TRIPS?**

If a country doesn’t comply with an agreement such as TRIPS, other countries can take it before a trade tribunal. One function of the WTO is to provide a forum for countries to settle trade disputes. One of the WTO agreements, the Dispute Settlement Understanding (DSU), sets out a procedure to be followed when a country wishes to challenge the laws or practices of another country.

If a WTO tribunal rules that a country has breached a trade agreement, it “shall recommend” that the country bring its laws or policies into line and may suggest ways to do this. The country can comply with the “recommendations” by changing its laws or policies. Or, it can decide not to comply with the ruling, and pay “satisfactory compensation” to the country that brought the complaint, presumably on an ongoing basis. If it does not receive satisfactory compensation, the country with the complaint can request WTO authorization to impose trade sanctions in retaliation, including in other areas of trade. By default, the WTO

#### **How does the WTO work?**

In theory, the WTO is run by all its member countries. Every two years, the WTO has a Ministerial Conference, a gathering of government ministers, to discuss trade issues and set the agenda for future discussions.

In between these meetings, governments’ diplomatic missions in Geneva continue the day-to-day business.

While decisions are theoretically “taken by consensus” among all member countries, in practice decision-making tends to be concentrated with a handful of the wealthiest and most powerful countries – including the group of four referred to as the “Quad” (the United States, the European Union, Japan and Canada).

However, in recent months, developing countries have started to demand flexibility in the international trading system to allow them to respond to their health needs. This was evident at the most recent Ministerial Conference, in Doha, Qatar in November 2001, where the issue of TRIPS and access to medicines was a key issue.

## **The Generic Medicines case at the WTO (2000)**

In 1997, the European Union (EU) challenged a section of Canada's *Patent Act* intended to make it easier for cheaper, generic drugs to come to market as soon as possible. The section in no way limited an original drug company's market monopoly during its 20-year patent term, but simply allowed generic drug companies to stockpile their product for the last 6 months of the patent term, for sale as soon as the patent expired.

Among other things, Canada argued that the public interest in earlier access to more affordable drugs was a legitimate basis for this limited exception to exclusive patent rights.

Theoretically, these exceptions are allowed under Article 30 of TRIPS. The EU dismissed these arguments, complaining of "discrimination" against the pharmaceutical industry.

The WTO panel ignored Canada's public interest argument. It took a very narrow approach to deciding what were acceptable limitations on patent rights, looking only at the private patent owner's expectation of profits and not considering what other, social benefits were to be gained by limiting this monopoly.

will accept this request to authorize sanctions, unless every member country (other than the ones involved in the dispute) rejects it. Countries are not supposed to impose sanctions without going through this process. The country facing sanctions may have an arbitrator decide whether the sanctions are fair.

### **What does TRIPS say about protecting health?**

The TRIPS Agreement says the monopoly rights created by patents need to be balanced against other important interests. It says that protecting and enforcing intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology. Furthermore, TRIPS says that this should be to the benefit of both producers and users of technological knowledge, and should occur "in a manner conducive to social and economic welfare, and to a balance of rights and obligations" (Article 7).

The TRIPS Agreement also sets out some basic principles that should guide how it gets interpreted (Article 8). It says that, in shaping their own laws, countries "may take measures necessary to protect public health." It also recognizes that countries may need to take "appropriate measures" to prevent the "abuse" of patent rights by patent-holders or to prevent practices which "unreasonably" restrain trade or negatively affect the international transfer of technology. These measures, however, must be "consistent" with the provisions of TRIPS.

These provisions in TRIPS support the argument that countries are entitled to flexibility in how they meet their obligations to protect patent rights.

### **Does TRIPS leave options for increasing access to affordable medicines?**

Yes and no. There are some parts of TRIPS that countries can use to promote access to affordable medicines for people living with HIV/AIDS and other diseases (see below). And at the last WTO Ministerial Conference (Doha, November 2001), member countries issued a *Declaration on the TRIPS Agreement and Public Health* stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all."

However, there are still areas of uncertainty in the interpretation of the TRIPS Agreement. Whether the Doha Declaration will have any positive, concrete effect remains to be seen, and there are still problems in the TRIPS Agreement that have not been addressed (see below). Advocacy is still needed to ensure the maximum flexibility in interpreting and implementing the agreement. If the necessary flexibility cannot be found, it may be necessary to amend the Agreement to ensure that countries can protect the health and human rights of their people. But formally renegotiating the text of the agreement is a process that may take years before yielding unknown outcomes, while there is an urgent need for access to medicines now.

### **What are countries' options under TRIPS?**

There are four main aspects of TRIPS that may be useful for countries to promote access to affordable drugs.

**Exclusions from patent admissibility:** A country may prevent the commercial exploitation of some inventions if “necessary” in order to protect human life and health, by refusing to recognize their patent admissibility (Article 27). How to determine whether this is necessary, and who decides, are not clear.

**Exceptions to patent rights:** Under Article 30, a country may include in its patent laws “limited exceptions” to the rights of a patent owner to exclude others from making, using, importing or selling an invention, taking into account the legitimate interests of others. These exceptions must not “unreasonably conflict with the normal exploitation” of the patent, and may not “unreasonably prejudice” the patent owner’s legitimate interests. There has only been one WTO ruling interpreting this article, the *Generic Medicines* case involving Canada's patent laws. That case set a bad precedent for flexible interpretation of TRIPS favouring increased access to affordable generic medicines (see previous page).

**Parallel importing:** Manufacturers often charge lower prices for a drug in one country than in another. This means a country with limited resources can sometimes afford more of a patented drug by purchasing it abroad and importing it, rather than buying it directly at home from the manufacturer at a higher price.

Patent laws in most countries say that once a patent-holder sells its goods, it has no right to control the resale of those goods. In other words, the patent-holder has “exhausted” its property rights in that sold product. (The patent-holder still has the exclusive right to make the product in the first place, preserving its monopoly on the “know-how” behind the invention.) So an intermediary could buy a patented drug in one country at the lower price being charged by the manufacturer, and then resell that drug in another country at a price lower than what the manufacturer is charging for its product in that other country. This is called “parallel importing”. The TRIPS Agreement (Article 6) says that nothing in it prevents a country from allowing parallel imports.

**Compulsory licensing:** Under TRIPS, a country’s laws may allow the state or the courts to issue a “compulsory license,” which permits either the government, an individual or a company to use a drug (i.e. produce or import a generic drug) without the authorization of the patent owner. Compulsory licenses are usually granted on grounds of general interest such as public health, economic development, national defence and the absence of working (i.e. when the holder is not “exploiting” its patent). The TRIPS Agreement does not limit the grounds on which governments or courts may issue compulsory licences.

But there are restrictions on the use of compulsory licenses:

- Usually there must be an effort to negotiate a voluntary license with the patent owner “on reasonable commercial terms” within a “reasonable period of time.” Importantly however, this attempt at negotiation with the patent holder is not required if the drug is to be used for “public non-commercial use,” if there is a “national emergency” or other situation of “extreme urgency,” or if a legal process has determined that the patent owner has engaged in “anti-competitive” practices.

### **Parallel importing and price variations for HIV/AIDS drugs**

A recent survey by MSF, UNAIDS, UNICEF and WHO found worldwide variations in the price of fluconazole, an antifungal drug used to treat oral and vaginal candidiasis (yeast infection) and the deadly cryptococcal meningitis, ranging from a high of US \$7.25 to a low of US \$0.20 for a 200 mg tablet.

The anti-retroviral drug lamivudine (3TC) ranged from a maximum price of US \$0.43 to a low of US \$0.14 for a 150 mg tablet.

For poor countries with very limited health budgets and millions of people with HIV/AIDS, or for poor people with little income to spend on medicines, obtaining drugs at the lowest possible world price through parallel importing can make a significant difference.

Obtaining lower prices through parallel importing would also mean that any grants obtained from the new Global Fund to fight AIDS, TB & Malaria (established in June 2001) could be used to provide medicines to more people.

## Universal Declaration of Human Rights

*Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care.*  
- Article 25

*Everyone has the right... to share in scientific advancement and its benefits.*  
- Article 27

## States' Obligations

*The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties... to achieve the full realization of this right shall include those necessary for... the reduction of... infant mortality and for the healthy development of the child; ...and the prevention, treatment and control of epidemic diseases.*

- International Covenant on Economic, Social & Cultural Rights, Article 12

- If a compulsory license is issued, the patent owner is entitled to be paid "adequate remuneration" (e.g. either a symbolic fee acknowledging the inventor or a proper royalty in lieu of financial compensation for lost sales). The competent authority may also decide that the license should be granted free of charge. The TRIPS Agreement does not say how "adequate remuneration" should be determined.
- Furthermore, the license must be used "predominantly" for supplying the domestic market in the country issuing the license (unless the license is issued to remedy "anti-competitive" practices by the patent owner). This presents a likely barrier to accessing affordable drugs: many developing countries don't have the ability to produce their own generic drugs and would need to import them from other countries that do. But those countries that do have a generic drug industry are not permitted under TRIPS to issue a compulsory license authorizing someone to make a patent-protected drug primarily for export to other countries. The WTO is currently debating proposals for solving this restriction on exports of quality generic drugs to countries that need cheaper medicines but must import them because they cannot make their own. (This issue is discussed in more detail below).

### **Don't countries have an obligation to protect the health of their people?**

Yes. In addition to governments' ethical duty to act in the public interest, countries have an obligation under international human rights treaties to take steps, individually and collectively, to fully realize the universal human right to health. This includes making laws that will protect and promote this right.

According to the UN Committee on Economic, Social & Cultural Rights, in respecting the right to health, States should also ensure that this right is given consideration in international agreements (such as TRIPS) and should ensure that these agreements do not negatively affect the right to health. A separate body, the UN Commission on Human Rights, has also recognized that access to medication in the context of pandemics such as HIV/AIDS "is one fundamental element" for realizing everyone's right to health.

### **Aren't patent rights necessary for drug companies to recover their costs of researching and developing drugs?**

This argument is often used to justify a 20-year patent protection over innovative processes and products. But it is an inaccurate generalization and does not address the criticisms that overly strict international trade agreements on patents create barriers to poor countries accessing affordable medicines.

The pharmaceutical industry remains by far the most profitable in the world, well ahead of companies in all other sectors.<sup>2</sup> Current profits far exceed what is necessary for a "reasonable" return on their R&D. This is particularly the case if we consider that drugs commercialised by multinational companies have often been developed with significant public subsidies, both through tax breaks for R&D and by direct government investment in pharmaceutical research.

<sup>2</sup> "The 2002 Fortune 500". *Fortune Magazine*, April 2002.

Furthermore, the revenues they gain from poor countries are exceedingly small. For example, all of Africa accounts for about 1% of global pharmaceutical sales, even though millions of people need medicines for numerous conditions. Limiting or overriding patents in such countries will have no significant effect on drug company profits, which is their incentive for research and development (R&D).

In any event, a profit-driven system based on private patent rights provides an incentive only to develop drugs that will be most profitable. Diseases that affect predominantly poor people, who cannot pay high prices for medicines, will not be profitable areas for research, unless there is enough of a wealthy market to make the research investment worthwhile.

A global patent system with one set of rules does not work when countries are at different levels of development or choose different development paths. Most industrialized countries did not adopt their current patent laws until *after* reaching a certain stage of economic, social and technological development. Canada's own generic drug industry developed because of flexibility in drug patent laws (which were amended in the late 1987 and 1993 to almost completely abolish any sort of compulsory licensing). Imposing the industrialized world's rules on all countries will present an additional barrier to socio-economic development for poorer countries, which can ill afford the high costs of accessing technologies (including medicines) when multi-national corporations hold monopolies on that knowledge. The vast majority of patent-holders are in industrialized countries. World-wide monopolies on that knowledge will "lock in" the existing disparity.

According to Indian experts who spoke to MSF, "the Indian generic industry has been able to supply many developing countries with affordable medicines, largely because it has been able to develop to an advanced stage under protective legislation tailored to India's needs. India's 1970 patent law, which granted 'process' but not 'product' patents for pharmaceuticals, was the backbone that allowed the industry to mature to the point where it is today – a leading global producer of quality generic drugs and raw materials, that has the ability to invent new manufacturing processes of drugs through reverse-engineering, and can carry out original R&D [research and development]. Evidence from the Indian pharmaceutical industry indicated that since TRIPS was negotiated, the Indian drug industry has increased R&D but for *diseases of the West*, not for those endemic to India. As with all market-driven companies, Indian R&D priorities were driven by the size of potential markets rather than medical needs. The example is telling, as India is one of the few developing countries with domestic R&D capacity."

### **What can be done?**

TRIPS itself contains many ambiguities. Much remains unclear about just how much flexibility there is in interpreting and applying the TRIPS Agreement. Few cases have been brought to the WTO that offer clear interpretations, although the decision in the *Generic Medicines* case (see side box above) is cause for concern. But how the TRIPS Agreement is legally interpreted, and how it is used politically, will have a significant impact on whether and how countries can protect and promote access to affordable medicines. Despite some recent

*"People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off."*

- Kofi Annan, UN Secretary General, 26 April 2001

*"Discussions on access to medicines come at a time when even access to food is being questioned as a right. We must always remember that access to medicines is a right, not something that should be determined by charity or subsidies for the poorest of the poor."*

--Mira Shiva, *All India Drug Action Network*

encouraging developments, there is still a need for vigorous advocacy in support of maximum flexibility under TRIPS for countries to address health needs.

## **Doha Declaration**

*"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. .. 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."*

- Declaration on the TRIPS Agreement and Public Health, Fourth WTO Ministerial Conference, Doha (Qatar), 14 November 2001

### **What is the Doha Declaration and why is it important?**

In November 2001, at the WTO Ministerial Conference in Doha, Qatar, member countries issued a "Declaration on the TRIPS Agreement and Public Health." It states that the TRIPS Agreement "does not and should not" prevent countries from taking measures to protect public health, and "can and should" be interpreted in a way that supports countries' rights to protect public health and, in particular, to promote access to medicines for all.

The Doha Declaration represents an important step forward. The Ministerial Conference is the highest body with the authority to adopt interpretations of WTO treaties. Therefore, the Doha Declaration should, as a matter of law, guide the interpretation of the TRIPS Agreement in a more "health-friendly" direction in future disputes over patents. Those interpretations should also take into account countries' obligations under international law to protect and promote the right to health. The Doha Declaration may also help developing countries fend off pressure tactics by rich countries who invoke the TRIPS Agreement and threaten trade sanctions when developing countries limit exclusive patent rights in order to make medicines more affordable. It remains to be seen whether the promise of the Declaration will be realized.

The Doha Declaration also extended until 2016 the deadline for "least developed countries" to implement the sections of TRIPS that require them to grant exclusive, 20-year patent rights to pharmaceutical products.

### **What happens after the Doha Declaration?**

While asserting that a more pro-health interpretation of the TRIPS Agreement is in order, the Doha Declaration also acknowledged a further restriction imposed by the TRIPS Agreement.

As noted above, under Article 31(f), compulsory licenses authorizing the production of generic drugs must be limited to "predominantly" supplying that country's domestic market. During the 20-year patent term on a drug, this section restricts the freedom to grant a compulsory licence so that a company could produce generic medicines principally or solely for export to developing countries that don't have the capacity to make their own.

This represents a serious problem: without a source of supply, and without their own domestic manufacturing capacity, many developing countries are effectively unable to make use of safeguards such as compulsory licensing to access affordable generic medicines. The full effects may be felt soon if no solution is found. There is a handful of developing countries with a generic pharmaceutical industry who are not yet fully subject (until 2005) to the TRIPS requirement to grant exclusive patent rights on medicines, and so can still export cheaper, quality generic drugs.

But even if the political and industry leadership in these countries were willing, they cannot supply the entire need for drugs for HIV/AIDS and other illnesses



throughout the developing world. As of 2005, they will be subject to Article 31(f) of TRIPS, meaning that a compulsory license would need to be issued to produce generic versions of patented medicines. Even then, production of generic medicines would be limited to "predominantly" supplying their domestic market, rather than exporting to developing countries in need.

The WTO's Council for TRIPS, which oversees the agreement, has been instructed to find an "expeditious solution" to this problem and report back before the end of 2002. A coalition of non-governmental organizations has put forward proposals that would ensure maximum flexibility in ensuring developing countries' access to quality, affordable generic medicines.

But some rich countries (especially the US) are working hard to promote "solutions" that are very restrictive, merely temporary, and limited to addressing "pandemics" or public health "crises". So far, Canada is supporting these restrictive conditions on any solution.

These kinds of restrictions on compulsory licensing are not imposed by the TRIPS Agreement itself, so it would be unfair to impose them on developing countries who need to import medicines in order to make effective use of compulsory licensing, when other countries do not face this barrier. This violates the spirit of the Doha Declaration, which was to find a solution that would allow developing countries in need to make effective use of compulsory licensing. Rather than restricting the use by developing countries of the safeguards that do exist in the TRIPS Agreement, developed countries should be supporting practical options that would most benefit poor people living with HIV/AIDS and other serious health conditions in developing countries.

### **What needs to be done?**

The Doha Declaration affirmed the primacy of states' public health obligations, and the right to promote access to medicines for all, over intellectual property rights. Advocates should use this to push for the wider recognition that states' obligations to protect and promote human rights (including the realization of the highest attainable standard of health for all) take precedence over trade agreements.

People concerned about access to medicines in developing countries need to ensure that the promise of the Doha Declaration is realized in good faith. Advocates must work toward a solution that deals quickly and fairly with the issue of authorizing production of quality generic drugs for export to developing countries, and that does not impose restrictive conditions that will lead to more preventable deaths by denying access to more affordable medicines.

Advocates also need to ensure that the gains reflected in the Doha Declaration are not undermined by political pressure on developing countries if they pursue the measures allowed under the TRIPS Agreement to promote access to medicines. Other regional or bilateral trade agreements dealing with patents must also include these safeguards, and should not go beyond TRIPS in strengthening private patent rights at the expense of poor people who need medicines.

### **What about other trade agreements?**

TRIPS is one international trade agreement that affects access to affordable drugs, and affects the majority of the world's countries. But other regional trade agreements are being negotiated, and there is a real danger that these agreements could go even further than TRIPS in hindering access to essential medicines. For example, some countries negotiating the Free Trade Agreement of the Americas (FTAA) are pushing for sections in the final treaty that go even further than TRIPS in granting exclusive patent rights and limiting countries' options for balancing patents against promoting public health and human rights.

Similarly, MSF, the World Health Organization and the UN's Joint Programme on AIDS (UNAIDS) have warned that a treaty signed in February 1999 between several French-speaking countries in central and west Africa is more restrictive than necessary under TRIPS. The Bangui Agreement imposes even stricter conditions on the use of compulsory licences and prohibiting parallel imports from countries outside the bloc of countries that sign the agreement. Advocates have urged these countries not to ratify the Bangui Agreement, and certainly not before they are fully bound by TRIPS.

Governments must ensure that trade agreements do not hinder access to affordable medicines, especially in developing countries.

## Taking action

Canadian labour and non-governmental organizations concerned with HIV/AIDS, human rights, and international development have been working on the issue of global access to medicines and the right to health.

The **Global Treatment Action Group (GTAG)** came together in mid-2001. These organizations have taken a variety of initiatives to raise public awareness of the issue and to raise these concerns with the Canadian government. GTAG has also addressed the need for increased Canadian contributions to the Global Fund to fight AIDS, TB & Malaria, and to foreign aid to develop health infrastructures where these are under-funded or inadequate. The GTAG will take up other issues related to global access to health care in the future.

For more information about GTAG, contact:

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## WHERE CAN I GET MORE INFORMATION ABOUT GLOBAL ACCESS TO HIV/AIDS DRUGS AND OTHER ESSENTIAL DRUGS?

**Médecins Sans Frontières / Doctors Without Borders Canada** is the Canadian branch of the international medical relief organization. MSF is leading a global *Campaign for Access to Essential Medicines* ([www.accessmed-msf.org](http://www.accessmed-msf.org)) that includes action taken in Canada ([www.msf.ca/access/index.htm](http://www.msf.ca/access/index.htm)).

The **Canadian HIV/AIDS Legal Network** ([www.aidslaw.ca](http://www.aidslaw.ca)) focusses on legal and human rights issues related to HIV/AIDS. Its website includes a list of key resources on the issue of access to treatment for people living with HIV/AIDS in developing countries ([www.aidslaw.ca/Maincontent/issues/cts/selectedresources.htm](http://www.aidslaw.ca/Maincontent/issues/cts/selectedresources.htm)).

The **Interagency Coalition on AIDS and Development (ICAD)** brings ([www.icad-cisd.com](http://www.icad-cisd.com)) together HIV/AIDS and development organizations. ICAD has produced several factsheets on international development issues relating to HIV/AIDS, including "Access to HIV/AIDS Treatment in Developing Countries."

The **International Council of AIDS Service Organizations (ICASO)** ([www.icaso.org](http://www.icaso.org)) has produced a background paper on compulsory licensing and parallel importing.

**Oxfam** is a global NGO focussing on health and food security and democratic rights, and has been active in lobbying for global trade rules that put patients before profits. See their reports on-line ([www.oxfam.org.uk](http://www.oxfam.org.uk) and [www.oxfam.ca](http://www.oxfam.ca)).

The **Global Treatment Access Campaign (GTAC)** is a network for communication and advocacy efforts for access to essential medications. The website ([www.globaltreatmentaccess.org](http://www.globaltreatmentaccess.org)) is maintained by the Health GAP Coalition in the US, and provides action tools and updates, with a focus on the US government.

The **Consumer Project on Technology** ([www.cptech.org/ip/health](http://www.cptech.org/ip/health)) is a public interest advocacy organization in the US with a project on intellectual property and health issues. The website contains a wealth of materials, particularly detailed information about the pharmaceutical industry, and a listserv on pharmaceutical policy issues.

The **Joint UN Program on HIV/AIDS (UNAIDS)** website ([www.unaids.org](http://www.unaids.org)) includes numerous documents on global HIV/AIDS issues, including a report on the patent situation of HIV/AIDS-related drugs in 80 countries and an infosheet on "Pharmaceuticals and the WTO TRIPS Agreement: Questions & Answers."

The website of the **World Trade Organization** ([www.wto.org](http://www.wto.org)) provides access to the full text of the TRIPS Agreement (and other WTO treaties) and a searchable database of documents, including decisions of panels and the Appellate Body.

The **World Health Organization** ([www.who.int](http://www.who.int)) maintains an on-line catalogue of publications, some of which are themselves on-line, including its above-cited report on *Globalization and Access to Drugs* and a sheet on TRIPS and access to drugs.

The **International Centre for Trade & Sustainable Development (ICTSD)** ([www.ictsd.org](http://www.ictsd.org)) produces weekly and monthly reports on development issues in international trade law and maintains a web-page with resources on IP issues.

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