HIV/AIDS PROGRESS UNDER SIEGE:

Double Blow of Reduced Funding and High Drug Prices Blocks Impact of Latest Science and Treatment Recommendations for People Living With HIV/AIDS

Médecins Sans Frontières (MSF) has been providing antiretroviral therapy (ART) to people living with HIV/AIDS for ten years, and today more than 160,000 people across the developing world receive ART through MSF. ART prolongs lives and dramatically improves people's health, taking them from near-death back to health, family and employment. Across the developing world, more than five million people receive ART, which represents important progress. But a further nearly ten million people are in urgent need of treatment and will die without it within the next few years.

Encouraging recent data, including from MSF projects, shows that we can make progress against the epidemic – by decentralizing treatment; putting people on better treatment, earlier; and by shifting tasks from doctors to other healthcare workers. But just as these important gains are beginning to show their promise for patients, a stagnation in donor funding, coupled with trade policies that will create serious additional barriers to accessing affordable generic medicines, are dealing HIV/AIDS treatment a double blow. We know the tools we need to expand the initial progress on HIV/AIDS, but they are being taken away.

Scientific advances and the need for continued bold treatment initiatives

The 2010 WHO HIV treatment guideline revisions support recent evidence showing that starting treatment earlier (when people's CD4 cell count drops to 350 instead of 200 cells/mm^3), improves survival and reduces illness, in particular tuberculosis (TB) – the number one killer of people living with HIV/AIDS. Data just published from MSF's project in Lesotho shows that providing people with treatment earlier (at a CD4 cell count above 200) led to reductions in deaths (by 68%), reductions in new diseases (by 27%), reductions in hospitalization (by 63%), and reductions in defaulting from care (by 39%).[1]

Further, the WHO guidelines reinforced the importance of moving towards the use of better-tolerated medicines such as tenofovir, and away from older, more toxic medicines such as stavudine.

MSF is currently working to implement these new recommendations in all its programmes, but with caution that some countries are not able to get adequate donor support to implement expanded treatment criteria.

Further, several recent studies have highlighted the importance of treatment as prevention, both in terms of preventing transmission of the virus from mother-to-child, as well as through sexual transmission. A 92% reduction in heterosexual transmission of HIV was demonstrated in serodiscordant couples (where one person is HIV-positive and the other is not) treated with ART as compared to those not on ART.[2]

Taken together, these developments underscore the importance of expanding access to earlier treatment, both to prevent illness and deaths, and to prevent HIV transmission. However, wealthy nations are retreating from funding HIV/AIDS, and at the same time are implementing policies that will severely restrict access to affordable AIDS medicines. It's a double blow that may mean the difference between turning back the tide of HIV and watching the pandemic grow.

THE FIRST BLOW: DRAMATIC FUNDING SHORTAGE FOR HIV/AIDS

Donors on all sides continue to retreat from adequately funding the fight against HIV/AIDS. In October 2010, the Global Fund to Fight AIDS, TB and Malaria (GFATM) held its third replenishment conference. While the Global Fund had requested donors to meet the goal of US$ 20 billion over three years (2011 – 2013) in order to provide funds to scale up programs, only approximately $11.7 billion were contributed. This is below the bare minimum of $13 billion the Global Fund has stated it needs just to keep existing programs running. To date, Italy, Spain, the Netherlands, Sweden, Belgium and the UK have not contributed to the third replenishment conference, although Belgium and the UK are expected to pledge soon.

The decision of wealthy countries to severely underfund the Global Fund will almost certainly mean that quality grant applications will be rejected, restricting countries' ability to meet the new WHO treatment recommendations or scale up treatment and prevention programs.

The US-government-funded AIDS treatment program, PEPFAR, is also being underfunded. While the US Congress has authorized up to $48 billion to be pledged over five years for PEPFAR alone, the US is nowhere near on track to meet that goal and has essentially flat-lined funding to this crucial program for the past three years.

Without increased financial support, important gains already made in the fight against HIV/AIDS are under threat and countries are unlikely to be able to implement significant treatment scale up, realize the full benefits of treatment as prevention or execute the new WHO guidelines.

THE SECOND BLOW: POLICIES THAT THREATEN ACCESS TO AFFORDABLE HIV DRUGS

Worrying prospects for access to newer medicines

India plays a critical role in supplying the developing world with affordable quality generic medicines, and has been called the 'pharmacy of the developing world.' MSF purchases more than 80% of the AIDS medicines it uses to treat 160,000 people with HIV/AIDS from producers in India. We're not the only ones - a recent study found that more than 80% of donor-funded purchases of HIV medicines from 2003-2008 were sourced from producers of affordable generics in India.[3] Generic medicines have played a crucial role in scaling up treatment to more than five million people on ART in developing countries, as more affordable medicines means more people on treatment: PEPFAR estimates to have saved more than $300 million between 2005 and 2008.[3] But this source of affordable medicines is under threat.

India became a key source of affordable medicines because until 2005, the country did not grant patents on medicines. This meant that affordable generic versions could be produced freely by multiple producers, bringing prices for the most-commonly-used AIDS treatment combination down by more than 99% since 2000. Since 2005, however, the World Trade Organization's (WTO) TRIPS agreement has obligated India to begin patenting medicines. This has a particular impact on access to newer medicines.

Newer medicines are particularly important for treating HIV/AIDS as it is a life-long disease. As people become resistant to their medicine combinations over time, they must be switched to alternatives. A 'second-line' combination for someone who is failing their first–line medication costs between more than two and more than three times the WHO-recommended first-line regimen.[4] And the need for second-line combinations is growing fast: in MSF's longest-running AIDS program, in Khayelitsha, South Africa, 14% of patients were failing their

treatment and needed to be switched to a second line after five years on treatment. In another recent study, 8% of patients on second-line therapy in MSF-supported programs had failed at two years and required a regimen that would ideally include a newer medication.[5]

But several newer HIV/AIDS medicines, including etravirine ($913 per patient per year) and raltegravir ($1,113 per patient per year) have already been patented in India, blocking the production of more affordable generic versions. So for patients who fail their second-line regimen, switching to a third-line regimen implies a further steep price increase – a third-line regimen costs nearly 25 times as much as the WHO-recommended first-line regimen.[6] Additionally, promising new medications in the pipeline that have excellent effectiveness, good side effect profiles and low cost of production may be the first-line medications of the future. But these are likely to be patented, so the dramatic price drops that were seen for the first generation of AIDS medicines can not be expected for newer drugs.

Tightening the screw by undermining India's patent law

Although the prospects for ensuring access to medicines – and to newer medicines in particular – is already worrying, rich countries are now seeking to turn the screw even tighter. When India devised its patent law, it did so in a way that puts people above profits. The strict law deems that only those medicines that show an improved therapeutic effect over existing ones deserve a patent. Additionally, India rejects many 'evergreening' techniques that allow drug manufacturers to extend patents for years because of minor changes in formulation that are not novel inventions. When Roche, for example, attempted to patent valganciclovir, a new form of ganciclovir, a drug that was invented in the 1980s to treat cytomegalovirus (a blinding opportunistic infection in HIV patients), its application for a patent was rejected in India.

The pharmaceutical industry has long worked to undermine these public-health protections within India's patent law. In 2006, Novartis took the Indian government to court over its patent law, but lost its case in 2007. The company has appealed and the case is ongoing. Now rich countries are stepping in to empty the law of its substance.

The European Commission (EC) is currently negotiating a free trade agreement (FTA) with India that includes a number of harmful provisions that could seriously hamper access to medicines across the developing world. The **EU-India FTA** would include provisions such as so-called 'data exclusivity' that would extend monopolies on medicines and would delay production of affordable, quality generic versions for up to a decade. Data exclusivity prevents generic manufacturers from relying on existing clinical trial data to register generic versions of medicines. It would require generic producers to generate their own clinical trial data, which would not only be expensive, but also unethical, as it would mean repeating trials for drugs already proven effective, and withholding life-saving medicine from the 'control group.'

Data exclusivity is particularly dangerous because it could even apply to drugs that do not merit a patent under India's law – if India accepts data exclusivity, even if a drug was not found to merit a patent, only the originator company would be allowed to produce for a period of up to ten years, thereby completely undermining the public-health flexibilities in India's patent law.

Longer monopolies mean more expensive drugs: a study on the effects of data exclusivity in another free trade agreement negotiated by Europe showed that in Colombia alone, the introduction of a ten-year period of test data exclusivity would lead to an increase in medicines expenditure of $340 million by 2030.[7] Data exclusivity has been shown to raise the price of medicines wherever it has been adopted (e.g. Jordan, Guatemala).

The EU is not the only actor pressuring India to adopt policies that would undermine the production of generic medicines. The US is also demanding that India implement more restrictive intellectual property policies that would hinder generic production and restrict use of public health safeguards. The US has even gone so far as to put India on the "Priority Watch List" in its "Special 301 Report," which lists countries that the US Trade Representative claims are not doing enough to protect intellectual property – an accusation that the US levels against India, in part because the country has put in place an entirely legal limit on what does and does not deserve a patent.

The EU and US are also pushing policies that will undermine access to affordable generics through the so-called '**Anti-Counterfeiting Trade Agreement' (ACTA)**. ACTA greatly extends the ability of customs officials to detain and destroy medicines based on suspected trademark infringements – even before a judicial review is performed or the producer is notified. This agreement also greatly increases punishment for alleged intellectual property infringement, including making it possible to bring criminal charges against all parties, from the producer to recipients and third parties, such as suppliers of active pharmaceutical ingredients, funders of legitimate medicines, or even healthcare providers like MSF that use medicines to treat people. The big pharmaceutical companies will be able to use ACTA to punish generic producers. This provides a simple path for them to deter and discourage competitors. Again, the end result would be restrictions on generic competition, which will lead to higher drug prices and diminished access to medicines people need to stay alive.[8]

The negotiations between the ACTA countries have now finished but the agreement now needs to be ratified in each country.

Restrictions on the Indian generic market will directly translate into a decreased pipeline of affordable versions of important HIV medicines for people in developing countries. The number of patients switching to second-line medicines is increasing, but unless attacks by the European Commission and others on the future of generic production in India are stopped, costs to donors and national programs will rise, antiretroviral access will be rationed, and patients will die.

To take action against the EU's attacks on affordable generics, visit action.msf.org and help MSF tell Europe to keep their HANDS OFF OUR MEDICINE!

MSF Demands:

I. Funding for HIV/AIDS

- The global community must meet its responsibilities and fully fund the Global Fund, with a goal of at least US $20 billion for the next three years;
- President Obama should meet his pledge to fully fund PEPFAR and significantly increase funding to get back on track to meet the authorized US $48 billion by 2013; and; and
- African country governments should keep their own commitments made with the Abuja Declaration and increase internal HIV/AIDS and health funding to 15% of their national budgets.

II. Policies that threaten access to affordable medicines

- EU Trade Commissioner Karel De Gucht must refrain from pushing policies that will decrease access to affordable medicines.
- US Trade Representative Ron Kirk and President Obama should remove India from the Special 301 Report and immediately cease pressuring India to adopt

ever more restrictive intellectual property policies that damage access to medicines.

- ACTA should be revised to eliminate measures that will have a negative impact on the production and flow of legitimate generic medicines to people in developing countries.

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[1] Ford N, Kranzer K, Hildebrand K *et al*. Early initiation of antiretroviral therapy and associated reduction in mortality, morbidity and defaulting in a nurse-managed, community cohort in Lesotho. *AIDS* 2010, 24: 2645-2650

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[3] Waning B, Diedrichsen E, Moon S. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS Society* 2010, 13: 35

[4] Untangling the Web of Antiretroviral Price Reductions, 13th edition. Médecins Sans Frontières. July 2010.

[5] Pujades-Rodriguez M, Balkan S, Arnould L et al. 2010. Treatment failure and mortality factors in patients receiving second line therapy in resource-limited countries. JAMA. 304(3): 303-312.

[6] Untangling the Web of Antiretroviral Price Reductions, 13th edition. Médecins Sans Frontières. July 2010.

[7] Oxfam and Health Action International, (2009), 'Trading away access to medicines. How the European Union's trade agenda has taken the wrong turn.'

[8] The Secret Treaty – Anti-Counterfeiting Trade Agreement and its Impact on Access to Medicines. http://www.msfaccess.org/main/access-patents/hands-off-our-medicine-campaign/