Campaign for access to essential medicines
Médecins sans Frontières

Frequently Asked Questions

General:

1. What is the MSF Campaign for Access to Essential Medicines?

One-third of the world's population lacks access to essential medicines; in the poorest parts of Africa and Asia this figure rises to one-half. Too often in the countries where MSF works, we cannot treat our patients because the medicines are too expensive or they are no longer produced. Sometimes, the only drugs we have are highly-toxic or ineffective, and nobody is looking for a better treatment. Launched in November 1999, the MSF campaign has been working internationally to find long-term, sustainable solutions to this crisis. The Campaign is pushing to lower the prices of existing medicines in developing countries, to bring abandoned drugs back into production, to stimulate research and development for neglected diseases that primarily affect the poor, and to overcome other barriers to access.

2. Why don't people have access to life-saving medicines?

Many factors influence access to effective medicines, including: quality of diagnosis; accurate prescribing, selection, distribution and dispensing of medicines; drug quality; capacities of health systems and budgets; lack of research and development (R&D); and price. Through its field projects, MSF is working on the local and national levels to address many of these issues. Internationally, the Campaign is focusing on addressing the lack of R&D, and affordability and availability of existing medicines.

3. What solutions is MSF proposing?

Essential medicines should be accessible and affordable to people in developing countries. Therefore, MSF is advocating for a combination of policies to lower drug prices on a sustainable basis; these strategies include encouraging generic competition, voluntary discounts on branded drugs, global procurement, and local production. MSF is also pushing for increased research into neglected diseases – such as tuberculosis, malaria, sleeping sickness, and leishmaniasis – through increased funding, investing in R&D capability in developing countries, and supporting alternative models for R&D. To address the issue of abandoned drugs, MSF is calling on companies and governments to find solutions to bring unprofitable but medically necessary drugs back into production. MSF is also supporting developing countries in codifying into law the "safeguards" that are allowed under international trade rules in order to protect access to medicines.

4. Who is responsible?

MSF believes many actors have a role to play in addressing the access crisis. On the ground, healthcare providers have the responsibility to demand the best possible level of care for their patients. At the local and national level, governments have the responsibility to give priority to public health through strong, pro-health legislation. At the international level, organisations such as the World Health Organisation, World Bank, UNAIDS, UNICEF, and other UN agencies, should adopt and advocate for policies that give the highest level of protection for public health. In the private sector, pharmaceutical companies should contribute to long-term solutions, such as cutting their prices for developing countries in a transparent and predictable way, and committing to R&D for neglected diseases. International donors should fund drug purchase and treatment programmes, in addition to funding disease prevention. Finally, civil society has the responsibility to monitor and hold accountable all of these actors, and to expose failure and demand change when necessary.

5. Does MSF believe that treatment should take precedence over prevention activities?

MSF operates its projects on the basic principle that prevention and treatment are BOTH essential and complementary components of combating disease. Our field experience has shown us that prevention efforts are boosted when treatment is also made available. (see #12)

Tuberculosis:

6. How can access to TB medicines be improved?

MSF implements the Directly Observed Treatment Short Course (DOTS) protocol for the treatment of TB throughout its projects. However, treatment with DOTS lasts 6-8 months, is difficult to implement and inadequately addresses the growing problem of multi-drug resistant TB. DOTS can be a heavy burden on already struggling health services, and can often be too expensive to implement for developing countries. For these reasons it is not surprising that only one in every four persons with active TB worldwide has access to the treatment. Therefore, MSF is calling for research to shorten and simplify DOTS, and for intensified R&D efforts to find better drugs for the disease. MSF is also advocating for improved and expanded treatment programmes for people with multi-drug resistant TB.

Malaria:

7. How can access to malaria medicines be improved?

The rapid development of drug resistance has rendered many existing malaria medicines ineffective. At the same time, some of the newer medicines have severe side-effects, and are 10-100 times more expensive than older treatments, often putting them out of the reach of poor patients. Furthermore, a lack of ongoing research and development makes the prospects for better medicines very dim. The result is that malaria in developing countries is often treated with drugs that are no longer effective, and people with resistant malaria cannot access the treatment that could save their lives. MSF is advocating for new treatments and new treatment strategies, including the greater use of combination therapies, which have been shown to be effective and can slow the spread of drug-resistance.

HIV/AIDS:

8. Is antiretroviral treatment necessary to combat HIV/AIDS?

Yes. A few years after infection with HIV, the virus weakens the patient's immune system to the point where the first "opportunistic infections" appear. HIV itself does not kill, it is opportunistic infections – such as tuberculosis and pneumonia – that do. Medicines to treat most opportunistic infections are available (though they are often too expensive for the majority of patients). But treating opportunistic infections is only a temporary solution, since HIV continues to attack the immune system. After one infection is cured, others inevitably follow. Antiretroviral (ARV) drugs are needed in order to combat HIV directly and are an important part of a comprehensive approach to addressing the epidemic. They do not cure AIDS, but can improve a patient's quality of life and prolong survival when taken consistently. Over the last six years, the introduction of ARVs in Europe and the US has cut AIDS deaths by over 70%. In Brazil, the use of ARVs has cut AIDS mortality by 51% from 1996-1999. Treatment is also a powerful incentive to get tested, providing a strong boost to prevention efforts. (See #12) While ARV treatment cannot be implemented immediately everywhere, we cannot afford to wait to extend treatment where possible.

9. What are the barriers to access to medicines for AIDS in developing countries?

The high price of medicines is one of many barriers to providing ARV treatment for people living with AIDS in developing countries. Other barriers include political will, social stigma, health infrastructure, and insufficient funding. But until recently, the prices of ARVs were so high that wide scale treatment programmes were unthinkable. Since September 2000, the injection of generic competition into the global ARV market has catalysed a dramatic drop in drug prices. As a result, medical, academic, and political leaders are now beginning to tackle other barriers to treatment. With the prices of drugs tumbling, there is no longer any excuse to deny medical treatment to the millions who are already ill.

10. How much does treatment for AIDS cost today? How low could the prices go?

A triple-combination of ARVs costs $10,000 - $15,000 per patient per year in the US and Europe. However, generic drug producers have offered to sell the equivalent medicines for as low as $300 per patient/year. Competitive pressure from the generic producers, combined with public pressure

on drug companies, has also pushed down the prices of branded drugs to around $700-$1000. MSF believes that with expanded production, prices could fall to as low as $200. At these levels, ARVs will be brought within reach of many more patients, and with international donor support, can be delivered to even more.

11. Surely the main obstacles to access to medicines are not patents but poverty and inadequate health services?

In many developing countries, particularly in urban centers, the necessary infrastructure exists to provide antiretroviral therapy today. Small pilot programmes in Uganda, Côte d'Ivoire, and Senegal, and widescale treatment programmes in Brazil and other Latin American countries, have demonstrated that it is possible. It is possible to start treatment programmes today, while simultaneously conducting operational research to learn the best ways of delivering care in resource-poor settings. Simpler drug regimens and diagnostic methods, coupled with medical training and infrastructure investment, will be necessary to expand treatment quickly to other areas with limited resources. But we cannot afford to wait any longer. Infrastructure challenges are not a valid excuse to continue denying medical treatment to those in need.

12. Will focusing on treatment for people who are already HIV-positive detract from prevention efforts?

MSF's field experience has shown that treatment and prevention efforts are both necessary and complementary strategies for combating the HIV epidemic. People have little incentive to get tested to find out their HIV status without the possibility of treatment. Once people know their status, they can modify their behavior to reduce transmission. New efforts to combat the HIV pandemic must include treatment in order to be effective.

13. Will providing antiretroviral drugs in developing countries cause the emergence of super-drug-resistant strains of HIV?

It is believed that patients who do not closely adhere with their drug regimens run a higher chance of developing drug-resistant strains of HIV. Patients may find adherence difficult due to a number of factors, including complicated drug dosing regimens or interruptions in drug supply due to high prices. The complexity of AIDS treatment makes patient adherence a challenge in BOTH wealthy and poor settings. However, results from the few existing programmes are encouraging. With limited health infrastructure, Brazil has dramatically reduced illnesses and deaths from AIDS, and enjoys treatment adherence rates that match those in the US (around 70% of patients taking their medicines properly 80% of the time). In much poorer Uganda and Côte d'Ivoire, well-run pilot projects have also demonstrated that adherence rates can match those of Europe and the US. The priority now is to boost research into simplifying treatment protocols, especially for resource-poor settings. A combination of three drugs in one pill, to be taken twice a day, already exists, and another is currently being developed -- these are steps in the right direction. In wealthier countries, fear of non-adherence has never been an acceptable reason to deny a patient life-saving treatment. It should not be acceptable in poorer ones.

14. What is included in the declaration on TRIPS and Public Health and what impact will it have on access to medicines, e.g. HIV/AIDS drugs?

The one hundred and forty two countries who came together at the 4th WTO ministerial conference in Doha clearly affirmed that governments are free to take all necessary measures to protect public health. The declaration gave primacy to public health over intellectual property rights.

"The TRIPS agreement does not and should not prevent members from taking measures to protect public health", the declaration says, adding that it 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". Now, if drug companies price medicines beyond the reach of people who need them, governments can override patents without the threat of retribution.

The declaration gives an unambiguous road map to all the key flexibilities the TRIPS offers:

- compulsory licensing not only in cases of emergency
- leaves countries free to determine what is a national emergency or urgency in which case the procedure for issuing a compulsory license becomes easier and faster.

- a clear statement that countries can have the parallel import regimes they want. Parallel importation enables countries to obtain patented medicines at the lowest price available on the market.
- least developed countries were granted a 10 year extension. This means that these countries need to be TRIPS compliant by the year 2016 instead of 2006.

15. Isn't anti-retroviral therapy much too complicated to be used successfully in resource-poor settings?

MSF and others are currently providing triple therapy in a number of pilot projects in developing countries around the world, including least developed countries such as Malawi and Cameroon. Our experiences so far are very encouraging, but it is clear that in order to expand such programmes dramatically, it will be necessary to introduce simpler treatment protocols, and cheaper and less complicated monitoring tools.

To date, few of the clinical trials conducted in low and middle income countries have directly addressed the specific clinical questions that must be answered to provide adequate and effective medical care for people living with HIV/AIDS in these countries.

Based on our field experiences, we have seen that there is an urgent need to reduce the total amount of pills needed and the frequency of doses, while maintaining the efficacy of the treatment. Also, the need for monitoring toxicity and immunological and virological responses to therapy must be reduced. The currently available tests to measure viral load and CD4+ T-lymphocyte levels are too expensive and complex for widespread use in resource-poor settings. Education and guidance aimed at ensuring the patients' adherence to treatment are a vital part of any successful care programmes.

16. What is MSF's position regarding the Global Fund?

As a medical humanitarian organization, MSF believes that the Global Fund must provide financing for treatment programmes for HIV/AIDS, TB, and malaria. This is an ethical imperative. In its statement of underlying principles for the Global Fund, the TWG commits to "pursu[ing] an integrated and balanced approach covering prevention, treatment, and care and support in dealing with the three diseases." MSF fully supports an integrated approach to AIDS, TB, malaria and other infectious diseases - in fact MSF implements disease control programmes in a comprehensive, integrated manner in the field. But we are deeply concerned that because donors and some in the international health community traditionally favour prevention at the expense of treatment, patients already infected could be written off as not sufficiently "cost-effective" to treat.

It is of vital importance that the Global Fund be used to support improvement of treatment interventions, and that it does not inadvertently facilitate the expanded use of ineffective treatments. For instance, in the case of malaria treatment, it would be wrong to support programmes which continue to use inexpensive treatments in areas where they have lost their effectiveness due to resistance.

Operational research also desperately needs to be accelerated to increase knowledge on best practices for implementing new combination treatments and diagnostic strategies in resource-poor settings. Newer, more effective, field-relevant medicines and medical technologies must be made available to poor countries at affordable prices as soon as they are developed.

To ensure that international funding mechanisms, including the Global Fund, offer treatment to the highest number of people possible, it is essential that funds be available for bulk purchases of medicines and medical technologies at the lowest possible cost, through international tender.

Prices, Patents, and Alternatives:

17. Do patents block access to medicines?

When medicines are under patent in a country, the patent-holder has a monopoly on the drug for a minimum of 20 years and can charge whatever price will maximise profit. Too often in developing countries, this translates into prices that are not affordable for the patient. When generic competition is introduced, prices will fall. For example, after the Brazilian government began producing AIDS drugs generically, prices dropped by 82%. In contrast, the prices of drugs with no generic competitor dropped by only 9%. Likewise, generic competition reduced the price of a triple-combination of antiretrovirals from $10,000 to $300 in one year. When patent protection is

too strict in a developing country, and does not balance the rights of the patent holder with the public interest, patents can block access to medicines. Governments can help counter the negative effects of patents by building legal safeguards into their national legislation.

18. Aren't 95% of essential drugs off-patent and therefore affordable?

That depends on how you define "essential." 95% of medicines on the WHO Model List of Essential Drugs are indeed off-patent. However, many drugs that are medically essential – including life-saving medicines – are not included on the list because they are too expensive. Most of these drugs have been developed more recently and are still under patent. These drugs include some anti-fungals, some anti-biotics, and nearly all anti-retrovirals. WHO is currently working to revise the list to include drugs that are medically necessary, even if they are currently unaffordable in developing countries.

19. Will lowering drug prices for poor countries hurt research and development (R&D) for new medicines?

No. Developing countries make up such a small part of drug industry revenue, that it is unlikely that lowering prices for developing countries will hurt R&D. 77% of the $406 billion worldwide drug market projected for 2002 will be in North America, Europe, and Japan. All of Africa accounts for just over 1%. When asked if a price cut for Merck's AIDS drugs would take away some of the incentive for R&D, Guy Macdonald, Vice President for Anti-Infectives, replied "It absolutely does not. We are totally committed to our research and development in the area of HIV and AIDS." Furthermore, the industry is one of the most profitable in the world. In 1998, the top ten companies enjoyed $108.1 billion in sales, of which $34.7 billion was profit — at 32.1%, this is one of the highest average profit margins of any industry worldwide. Finally, it is notable that companies consistently spend more on marketing and administration than on R&D. (See more on R&D below.)

20. Why not ask companies simply to donate the drugs?

MSF does not believe that drug donations are a long-term solution to the access crisis. Therefore, MSF is studying and advocating for more sustainable, long-term solutions (see #3). Drug donation programmes can also have other drawbacks, including: donations usually do not cover global need and are limited in time and place; they often come with burdensome restrictions on recipient health ministries; they often require extra administrative work, diverting scarce resources from health systems; they can distort rational drug use; tax deductions given for donations may cost donor countries more than other options. Considering the weaknesses, donations should neither be relied-upon, portrayed, nor promoted as the best way to improve access to medicines.

21. Is MSF opposed to all drug donation programmes?

No. Depending on many factors, including the epidemiology of the disease, details of the donation, availability of treatment, availability of alternative sources of drugs, and urgency of short-term need, drug donation programmes can be a short-term solution in some situations. However, donations cannot be a systematic or long-term solution. (See #20)

22. Aren't generic manufacturers stealing intellectual property and breaking the law?

No. Patents are granted on a national basis -- there is no such thing as an international patent. Therefore, if a drug is not patented in a country, it is perfectly legal for a generic company to produce or import a version of that drug in that country. Companies can also export generics to other countries where that drug is not under patent. A concrete example is the AIDS drug zidovudine (AZT). GlaxoSmithKline holds the patent for AZT in the US and Europe, but it does not have a patent for AZT in Ghana. This means that Ghana can legally produce or import a generic version of AZT, and is not in any way infringing on the patent rights of GlaxoSmithKline. In India, there is no product patent for AZT. This means that a generic company like Cipla, based in Bombay, can legally produce and export AZT to a country like Ghana.

23. How do international trade policies impact access to medicines? What is TRIPS and why does it matter?

Globalisation and the international regulation of trade are becoming increasingly linked to health. The World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), is the most important international agreement on protection of patents,

copyrights, and trademarks. TRIPS does not establish a uniform international law, but sets out minimum guidelines for intellectual property protection that must be met by all WTO Members by 2006 at the latest. TRIPS treats medicines in the same way as any other patented product – such as compact discs or video games. It is a threat to public health in poor countries because it gives patents on medicines for a minimum of 20 years, which grants a monopoly to patent-holders during that time. This will lead to further increases in drug prices and negatively impact the developing world's ability to produce affordable generic alternatives to branded drugs. Nonetheless, there are safeguards within TRIPS that developing countries can write into their national laws in order to protect public health. These safeguards include compulsory licences, parallel imports, and strategies to accelerate the introduction of generics (discussed below).

24. What is compulsory licencing?

Compulsory licences allow the production or import of a generic medicine, without the consent of the patent holder. Patent-holders receive adequate compensation. Compulsory licences may be issued by public authorities for various reasons, including public health or emergency. They are neither a form of pirating, a legal loophole, nor a way of stealing intellectual property. Compulsory licences are legal under the TRIPS Agreement, are considered a regular feature of any good intellectual property legislation, and are commonly used by industrialised countries such as the US. France authorizes compulsory licences when patented drugs "are only made available to the public in insufficient quantities or quality or at abnormally high prices." Both private entities and governments can typically apply for a compulsory licence. Countries should design fast, simple procedures for granting compulsory licences to make full use of this safeguard.

25. What is parallel importing?

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. For example, it would allow a country like Mozambique, where 100 units of Bayer's ciprofloxacin (500mg) costs $740, to import the same product from India where Bayer sells it for the much lower price of $15, due to vigorous generic competition. Many European countries, such as the United Kingdom, benefit from significant parallel trade to reduce the overall cost of medicines. Parallel importing does not involve the purchase of generics.

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

In order to sell a generic version of a drug, a manufacturer has to put its product through various tests to get 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. It allows the producer to put a generic product on the market as soon as the patent expires. Without a Bolar provision, the introduction of a generic could be delayed by 2-4 years after the patent expires. Because generic drugs are often much less expensive than their patented equivalents, it is beneficial to introduce them as quickly as possible.

27. What is "equity pricing"?

MSF uses the term "equity pricing" to describe pricing policies that ensure that, from the point of view of the community and the individual, the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them. Equity pricing is based on the principle that the poor should pay less for, and have access to, products such as essential medicines.

The terms "differential pricing," "preferential pricing" and "tiered pricing" are also often used to describe lower prices for low-income populations, but they do not necessarily result in affordability or equitable access to a product. Rather, they are commercial terms for pricing practices aimed at maximising the income of the seller. While differential, preferential or tiered pricing may lead to equitable access to medicines, they do not necessarily mean that even the lowest prices charged will be affordable. For some countries, even the lowest possible prices will not be affordable; international funding should then be considered to ensure that people have access to the medicines they need.

Research and Development:

28. How much does it cost to research and develop a new drug?

An accurate answer is impossible, since companies do not divulge R&D costs per drug, and methods for calculating this figure are highly controversial. The industry estimates that R&D for each new drug ranges from $350-$500 million. These estimates cover many costs, including compounds that have failed, overhead, and opportunity cost. In contrast, independent estimates range from $30-$160 million. In addition, R&D is often funded by the public sector. According to the World Bank, half of the current R&D expenditure worldwide, estimated at $70-$90 billion, is funded publicly. Many of the drugs marketed by private companies were originally discovered with public funding, including the AIDS drugs stavudine (d4T), zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), abacavir, and ritonavir.

29. Isn't strong patent protection necessary to stimulate R&D for new drugs?

While the patent system has proven successful for some diseases – notably, those with a lucrative potential market in the industrialised world -- the market has failed and will continue to fail to stimulate sufficient R&D for diseases that primarily affect poor countries. While pharmaceutical companies argue that their patents must be sacrosanct in poor countries for the sake of R&D, private sector R&D has long neglected the major killers of the developing world. Of the 1393 new chemical entities developed between 1975-1999, only 11 were for the treatment of tropical diseases, 5 of which were the result of veterinary research. It has been over 30 years since the last major new TB drug was developed. And, for lack of a market, drugs are simply not developed for the most neglected diseases.

30. Why is there so little R&D for illnesses endemic to developing countries?

Different diseases are neglected for different reasons, including lack of interest from the private sector, as well as insufficient investment from the public sector. Consequently, disease-specific solutions may be required. Furthermore, there is limited capacity in developing countries to develop new drugs independently; as a direct result, few medicines exist for diseases that primarily affect poor countries. Instead, developing countries rely on drugs produced in wealthy countries, which are often inappropriate in terms of target disease, price, and dosage. Therefore, investing in developing countries' capacity to research, develop, and produce their own medicines will be a key part of a sustainable solution. This will require involving scientists from endemic countries in the R&D process, as well as promoting transfer of technology and knowledge.

31. Is MSF against patents?

MSF does not oppose patents. Nor does MSF advocate for abolishing the patent system. But protecting human life must take precedence over protecting intellectual property. The imbalance that exists between the sanctity of patents and the health of people today must be corrected.

MSF supports measures such as compulsory licensing, parallel imports, and mechanisms to accelerate the introduction of generics, to help counter the adverse effects of patent protection on public health in developing countries. MSF believes that these measures are possible under current international WTO rules. However, should continued practise demonstrate that the so-called safeguards of current trade rules don't work, MSF will advocate for a full revision of the TRIPS agreement.

32. Aren't generic drugs always of lower quality than branded products? Wouldn't that be setting a double-standard for developing countries?

No. In many countries, such as India, Mexico, Thailand, Brazil, Colombia, Canada, South Korea, Argentina, Spain and the US there are strong generic pharmaceutical industries that produce quality drugs. Many of these generic drugmakers produce and export drugs under sub-contract for drug companies in North America, Europe and Japan. Generic companies in developing countries often have manufacturing plants that have been certified by foreign governments as well as their own national authorities.

Generic drugmakers, like proprietary manufacturers (that make brand name drugs should always be examined for quality and good manufacturing practices. This is the primary responsibility of national drug regulatory authorities. MSF supports testing of drugs to meet standards for quality and is advocating for UN agencies to provide support to developing countries by pre-qualifying generic producers of medicines where appropriate, as in the case of anti-retrovirals and other drugs needed in HIV/AIDS.