CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

MSF Briefing Document for G8
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Introduction

Today, 19,000 people will die from HIV/AIDS, tuberculosis, malaria, sleeping sickness and kala-azar. These and other infectious diseases will kill a total of 14 million people this year, despite the countless promises and political commitments made by Group of Eight (G8) countries since the July 2000 G8 Summit in Okinawa, Japan, and the December 2000 Okinawa Conference on Infectious Diseases, where a major initiative to tackle infectious diseases was launched.

In Okinawa, the G8 endorsed the following goals:

- Reducing the number of HIV/AIDS-infected young people by 25% by 2010
- Reducing tuberculosis deaths and prevalence of the disease by 50% by 2010
- Reducing the burden of disease associated with malaria by 50% by 2010.

We are now one third of the way towards 2010, but no nearer these targets. Indeed, in some cases we are further away than ever:

- The number of **HIV-**infected children under the age of 15 has nearly *tripled*, from 1.3 million in 2000 to 3.2 million in 2002. The total number of people living with HIV overall increased from 34 million to 42 million during the same time. More than 3 million people died of HIV/AIDS in 2002 alone.
- Global **TB** prevalence increased slightly (by 1.5%) with TB prevalence in Africa increasing at four times this rate .
- **Malaria** incidence remained unchanged, but mortality in children under the age of five has increased 2 to 5 times in parts of Africa in parallel with growing drug resistance.

Each year, on the occasion of the annual G8 summits, Médecins Sans Frontières (MSF) urges G8 countries to uphold the commitments they have made and to mobilise the political will and financial resources necessary to mount a credible response to the death, destruction, and human suffering caused by infectious diseases in developing countries. Each year, we remind G8 leaders that their annual summits offer an unparalleled opportunity for the world's wealthiest nations to boldly transform the goals and commitments that have been made on paper or in lofty speeches into real, life-saving interventions. And each year, we bear witness to yet more unnecessary deaths as a result of political failure to act on these commitments. The time for serious political action is long overdue.

Access to life-saving drugs still limited in developing countries

HIV/AIDS

AIDS is the world's most disastrous pandemic. It is a medical, social, economic, and political crisis. There are more than 42 million people worldwide currently living with HIV/AIDS, over 95% of whom live in the developing world.

An estimated 6 million people in developing countries are in immediate need of life-sustaining antiretroviral therapy (ART), and only around 300,000 are receiving it. Although there has been a 50% increase in access to ARVs in all developing countries over the last year. The numbers of patients under treatment have stayed low despite the overwhelming evidence of the economic and social benefits of treatment.

Médecins Sans Frontières (MSF) activities on AIDS include prevention efforts (including interventions to block mother to child transmission), voluntary counselling and testing, psychosocial support, prophylaxis and treatment of opportunistic infections and antiretroviral treatment. MSF currently provides antiretroviral treatment to patients with HIV/AIDS in Burkina Faso, Cambodia, Cameroon, Guatemala, Honduras, Kenya, Malawi, South Africa, Thailand, Uganda and Ukraine. We now treat more than 2,600 patients in these countries, including over 100 children. In the next year, MSF will double the number patients under treatment in existing projects, and will open new projects in Burma, Ethiopia, Indonesia, Laos, Mozambique, Peru, Rwanda, Zambia and Zimbabwe.

Our experience has demonstrated that providing effective treatment is not only feasible in resource-poor settings, but has concrete clinical benefits and dramatic effects on the lives of individuals and their communities. The provision of treatment has also strengthened prevention efforts by, for example, providing an incentive for people to come forward for voluntary counselling and testing, promoting openness about HIV and reducing stigma. In the MSF project in Khayelitsha township in South Africa, ART increase the voluntary HIV testing and counselling less than 1,000 in 1998 to over 12,000 in 2002.

This experience can only be scaled up if G8 leaders deliver the promised resources and support equity pricing to ensure that resources cover needs.

Although free and expanded access to ARV treatment is being provided in Botswana, Costa Rica, Cuba, Nigeria, Senegal Thailand and Brazil, Brazil is the only developing country that has achieved universal access. Its national programme has cut AIDS mortality by half and reduced common opportunistic infections by 60-80%. The resulting reduction in hospitalisation and medical care costs generated savings of US$422 million in 1997-1999 (a figure which almost entirely offset the cost of providing the ARVs). Key factors in Brazil's success have been **political will** and an **active civil society movement of people living with HIV/AIDS**, as well as competitive pricing due to **local production of generics and** the **willingness to use compulsory licensing.**

In other developing countries, increased access to ARVs has been largely due to price drops of common ARV triple therapies from US$10,400 per patient per year in early 2001 to current prices of around $250-300 for the equivalent therapy. The prices dropped because of **generic competition** and international **public pressure** to bring medicines within reach of the people who need them.

But the price of medicines is not the only obstacle to expanding ARV programmes. There is an urgent need to simplify treatment and monitoring protocols for resource-poor settings. This entails the quick introduction of affordable diagnostics and once-a-day formulations, as well as operational research to adapt treatment to clinical reality.

Malaria

Malaria is Africa's leading cause of under-five mortality (20%) and constitutes 10% of the continent's overall disease burden. It accounts for 40% of public health expenditures, 30-50% of inpatient admissions and up to 50% of outpatient visits in areas with high malaria transmission. The parasite's growing resistance to existing anti-malarials and the paucity and expense of new treatments is reducing the effectiveness of malaria control efforts in Africa. Better treatments do exist: artemisinin-based combination therapies (ACTs), not only treat the patient rapidly and effectively but also significantly reduce transmission of the disease.

Médecins Sans Frontières (MSF) current experience: prevention and treatment for malaria has always been a component of our projects in Africa, Asia and Latin America. We currently manage specific malaria interventions in 24 African countries, eight Asian countries and five Latin American countries. MSF has conducted numerous drug resistance studies in collaboration with national health ministries.

To attempt to reduce mortality, MSF has decided to implement artemisinin-based combination therapy in all its malaria projects. At this point, ACT has been introduced in 12 projects (Afghanistan, Cambodia, Congo Brazzaville, Kenya, Liberia, Myanmar, Pakistan, DRC, Sierra Leone, Sudan, Thailand and Zambia) and the organisation is reaching out to assist governments in the process of making the change to ACTs.

Some communities are already managing to control and even reverse malaria epidemics. KwaZulu Natal province, in South Africa, implemented ACT as first-line therapy in February 2001 together with improved vector control measures. In the first year alone, malaria cases dropped by 78% (from over 40,000 in 2000 to 9,400 in 2001). Admissions to hospital were reduced by 82%, while malaria deaths decreased by a dramatic 87%.

What were the factors in this success? **Political commitment**, sufficient **funding** to allow a change in protocol and the involvement of WHO and NGOs in negotiating **a 75% cut in the price** of the ACT (from US$10 to US$2.40), bringing it within reach of the government's capacity to pay.

Implementing effective artemisinin-based combination therapy for the treatment of drug-resistant malaria will initially entail increased cost for the countries involved Without significant financial help from the G8, African countries will not be able to implement this more effective treatment.

Visceral leishmaniasis

Visceral leishmaniasis, known in India as kala-azar, is endemic in 62 countries but the majority of cases occur in India, Bangladesh, Sudan, Brazil, and Nepal. An estimated 500 000 people are infected every year, and a total of 200 million people are at risk. If left untreated, kala-azar is fatal.

MSF started treating patients with kala-azar in 1988 and has since cared for over
60,000 patients in Sudan, Ethiopia, Uganda, Kenya and Somalia. The most recent epidemic started in Sudan in late 2002. MSF responded by increasing the number of treatment centres and stepping up its support to Sudanese health authorities and other NGOs.

But efforts by MSF and others have been handicapped by a lack of affordable, available treatments, particularly in Africa. The most commonly used drug against in kala-azar, sodium stibogluconate, was discovered more than 70 years ago. It has to be injected into the muscle or given intravenously. It is so toxic that it causes side-effects in 10% of the patients, killing some.

There are more modern treatments, but they are not available to most patients in Africa. AmBisome ®, dubbed as a "miracle drug", revives patients within hours of the first shot and has virtually no

side-effects. However, it is astronomically expensive at US$ 850-1400 per treatment. The gross national income per capita in Sudan is US$ 330 per year. So far the producer has not offered significant discounts for developing countries and no generic formulations are available.

Access to kala-azar drugs has been improved by the **registration of a new oral drug, miltefosine,** in India and by the **use of generic sodium stibogluconate** in some African countries. But real progress in tackling the disease will require **additional sources of generic drugs and a substantial increase in public funding for R&D to discover or finish development of new, affordable drugs and diagnostics**.

MSF's Recommendations

Our patients, and millions of others who confront the devastation caused by infectious diseases every day, will not be satisfied with yet another G8 summit that results in yet another declaration.

MSF therefore demands that G8 countries announce in Evian concrete actions to accomplish the following:

1. **make existing essential medicines affordable to those who need them through equity pricing**

2. **increase funding for the fight against major infectious diseases so that objectives become achievable**

3. **ensure that public health needs are protected over commercial interests in international trade negotiations**

4. **increase research and development (R&D) into new health technologies for neglected diseases.**

Equity Pricing: the key to making existing essential medicines affordable to those who need them

As pointed out by the "UK Working Group on Increasing Access to Essential Medicines in the Developing World" in their November 2002 report to Prime Minister Tony Blair, "the price of medicines is one of the key obstacles keeping people from the drugs they need". This Group noted that differential pricing should become the "operational norm" but that "differential pricing alone would not be a panacea", adding that truly affordable prices would require the use of additional mechanisms, including increased generic competition, bulk purchasing and top-up financing by donor governments and institutions.

Experience confirms the UK Working Group's conclusions that differential (or tiered) pricing alone is insufficient to improve access to essential medicines. After three years of operation, the most prominent voluntary tiered-pricing scheme, the UN-sponsored Accelerating Access Initiative (AAI), has delivered AIDS drugs to only a fraction of those who need them, and at prices at least four times higher than those of commercially available generic equivalents. In a significant number of cases, the announced AAI drugs have not been available (for instance, because the drug is not registered, or does not have a distributor in, the recipient country), or are not available at the announced low price. By contrast, Brazil's AIDS treatment programme, using a combination of strategies (see above), delivered cost-effective treatment to over 115,000 patients in 2001 alone.

MSF is concerned that the current UK, French and European Commission proposals on tiered pricing are voluntary and, in some cases, are not based on a systematic approach to providing lower-priced drugs to developing countries.

In order to secure lowest possible prices for all essential medicines, G8 Members need to go beyond voluntary differential pricing to a system that will deliver "equity pricing", defined as prices that are fair, equitable and affordable from the point of view of individuals and health systems in poor countries. Equity pricing is the only way genuinely to deliver lowest prices to those who need them. An "equity pricing system" requires:

- Stimulating generic competition;
- Fully implementing the Doha Declaration on TRIPS and Public Health, including agreeing to allow production and export of generic medicines to countries in need (Paragraph 6);

- Ensuring systematic, transparent differential (tiered) pricing;
- Promoting regional and local production through voluntary licensing and technology transfer; and
- Aggregating demand by pooling drug procurement.

We therefore demand that the G8:

1. Formally announce support for an equity pricing system, as described above.
2. Provide political and financial support for the WHO pre-qualification project, to ensure the widest possible availability of affordable, quality drugs.
3. Ensure that any tiered/differential pricing system, which forms part of an overall equity pricing approach, will:
   - be a comprehensive system;
   - cover all essential medicines – not only those for high-profile diseases such as AIDS, TB and malaria;
   - offer the lowest possible price using marginal cost of production as a guideline for least-developed country prices;
   - not be restricted to the public or NGO-sector;
   - address the needs of all developing countries;
   - ensure lower priced medicines do not flow back to high-income markets.

Funding the fight against infectious diseases

At the July 2000 G8 Summit in Okinawa, Japan, and the December 2000 Okinawa Conference on Infectious Diseases, an initiative was proposed to tackle major infectious diseases worldwide. The result has been the creation of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM). Despite the constant calls for increased international funding to address the devastation caused by major infectious diseases, donor governments, namely G8 countries, have failed to mobilise the financial resources necessary to mount a credible response. This failure is best illustrated in the current situation of the GFATM.

The GFATM holds a promise—as yet unfulfilled—for the millions of people in Africa, Asia, Latin America, Eastern Europe, and other high-burden countries living with and dying from AIDS, TB and malaria. Although the UN Secretary General has made repeated calls for an *annual* fund of US$7-10 billion dollars alone to fight HIV/AIDS,[1] *total* pledges from governments to the GFATM from 2001-2008 are just over US$3.3 billion,[2] and the GFATM is in danger of being unable to fulfil funding requests in its third round of funding.

In order to guarantee sustainable financing for needed health interventions, including massive scale-up of treatment programmes for HIV/AIDS, TB, and malaria, we demand that the G8:

4. Significantly increase their funding of international financing mechanisms such as the GFATM to meet stated targets. The proposed July Donor Conference offers an excellent opportunity for G8 governments to replenish the GFATM through additional financial contributions that are commensurate with financial needs.
5. Actively support the adoption by all financing mechanisms of procurement policies that promote purchases of lowest priced quality drugs, diagnostics, and vaccines, which will guarantee treatment for the largest number of people possible.
6. Unequivocally support the right of recipients of donor funds to make full use of TRIPS safeguards when pharmaceutical patents constitute a barrier to access to essential medicines.

[1] See, for example, Schwartlander B., Stover J., Walker N et al. AIDS: resource needs for HIV/AIDS, *Science 2001*; 292: 2434-36
[2] http://www.globalfundatm.org/files/Pledges&Contributions030325.rtf - accessed March 26, 2003.

Protecting public health needs over commercial interests: TRIPS and the Doha Declaration

At the World Trade Organization (WTO) 4th Ministerial Conference in Doha, Qatar, in November 2001, all WTO members endorsed the right of developing countries to make full use of TRIPS safeguards in order to protect the public health of their citizens. The historic WTO Ministerial Declaration on the TRIPS Agreement and Public Health firmly placed public health needs above commercial interest. However, it left one key issue unresolved: Paragraph 6 of the Doha Declaration states that "we recognize that the WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."

Some G8 members have been supporting a solution which would make non-producing countries second-class WTO members by restricting their rights to use safeguards. The proposals limit the number of diseases for which generic medicines can be exported effectively drying up potential sources for affordable medicines. They also remove the right of a non-producing country to determine its own health needs.

Until now the G8 as a group has been largely silent on the issue of intellectual property rights relating to essential medicines. WTO Members as a whole have failed to come up with a viable solution to ensure that developing countries without production capacity can access affordable versions of newer, more effective medicines that may help them manage their public health problems.

It is time for the G8 to speak out. If individual governments and international institutions cannot keep their promises, and if international trade rules can so clearly be structured to protect the interests of the few over the interests of the many, the viability of the current system will be put into question.

We therefore demand that the G8:

7. Support a solution to Paragraph 6 of the Doha Declaration that is simple, workable and economically viable. MSF supports the WHO's September 17 proposal, which recommends a solution based on Article 30 of the TRIPS Agreement. Under this article, WTO members may override patent rights to permit production and export of generic versions of patented products if it is needed to address the health needs of a third country.
8. Make a clear commitment to the Doha Declaration as the ceiling for all bilateral and regional trade agreements, and reaffirm their statements that they will not pursue retribution against countries that implement TRIPS-consistent safeguards.
9. Provide political and technical support for implementation of the Doha Declaration at the national level in developing and least developed countries.

Increasing research and development (R&D) for neglected diseases

Despite the unprecedented advances in science and biotechnology of the past three decades—and the significant morbidity and mortality associated with communicable diseases—tropical diseases have been all but forgotten by drug developers. Ninety percent of the world's health R&D is devoted to conditions that affect just 10% of the world's population. Of the 1,393 new drugs approved between 1975 and 1999, only 16 (or just over 1%) were specifically developed for tropical diseases and tuberculosis – diseases that account for 11.4% of the global disease burden. The handful of new medicines produced for tropical diseases tend to be unaffordable and poorly adapted to those who need them.

This fatal imbalance is the result of both market failure – market forces skew drug development investments toward diseases, including conditions such as male pattern baldness, that guarantee

the highest financial returns — and a compounding failure of public policy to ensure the development of drugs based on global health needs.

New public-private partnerships (PPPs) partially address this lack of R&D, but PPPs only work when there is at least some market potential to generate pharmaceutical industry interest or activity, as is the case with TB, malaria and AIDS. For the most neglected diseases that only occur in developing countries, new approaches will be needed, including early definition of a shared, needs-driven R&D agenda, as well as a substantial increase in public funding. An example of an innovative, independent approach requiring such support is the Dugs for Neglected Diseases Initiative (DNDi), a virtual drug development organisation being set up by various partners including public and private research institutes, WHO and MSF.

At the Okinawa Infectious Diseases Conference, the G8 committed to "increasing our support at the global level for the R&D of international public goods such as AIDS vaccines; treatment drugs for AIDS, TB and malaria; microbicides and other health commodities" and to "increasing incentives for the development of international public goods according to the priorities for vaccines, drugs and diagnostics set out in the Chairman's Summary". G8 Members also strongly committed to the principle that new tools stemming from R&D into diseases affecting developing countries should be considered as international public goods (and listed vaccines, drugs, methods of treatment and health commodities as examples).

MSF welcomes these commitments, and urges the G8 to turn them into reality by:

10. Calling on and supporting the WHO to start discussions on an international Convention on essential health research and development. This convention should:
    - define a needs-driven international R&D priority agenda;
    - commit all countries to contribute to R&D for health;
    - outline an agreement and clear rationale for sharing the burden of the cost of this R&D;
    - define appropriate funding and incentive mechanisms for governments to fulfil their commitments to public sector involvement in R&D;
    - establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology;
    - ensure that developing country involvement in public R&D is central, including through North-South and South-South collaboration, and through the conduct of such R&D in disease-endemic countries.