these reactions were rarely treatment-limiting events.[7] In a combined safety analysis[4] of TORO 1 and 2, hypersensitivity reactions were reported in two patients. Bacterial pneumonia was more common in enfuvirtide recipients (5·6% *vs* 0·3%) and requires careful monitoring and additional study.

The addition of enfuvirtide to a new optimised regimen of antiretroviral agents has been convincingly shown to improve virological and immunological responses in patients who are highly experienced with previous treatment. Therapy for these individuals, however, remains far from satisfactory. Only 19·6% of patients who received enfuvirtide achieved less than 50 copies of HIV RNA per mL after 24 weeks of therapy (7·3% with the optimised background regimen). The durability of response is unknown, as is any effect on progression of clinical disease. The addition of enfuvirtide to a regimen comes at a staggering increase in cost. The yearly cost of a zidovudine, lamivudine, tenofovir, plus lopinavir/ritonavir regimen is US$21 500 (average wholesale price); the yearly cost of enfuvirtide is about $20 000. These considerations dampen enthusiasm for enfuvirtide, and cost in particular will restrict its use. Still, enfuvirtide illustrates the science of drug discovery that has advanced the pharmacotherapy of HIV infection and improved the lives of those infected. And these are reasons to welcome its availability.

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The G8 and access to medicines: no more broken promises

On June 1, the G8 leaders will gather in Evian, France, where access to medicines is again at the top of the their agenda. (The G8 countries are: Canada, France, Germany, Italy, Japan, Russia, UK, USA.) That same day, according to far too familiar disease statistics, 19 000 people will die from AIDS, tuberculosis, malaria, African trypanosomiasis, and visceral leishmaniasis. These five diseases represent the failure of the pharmaceutical industry to deliver medicines for the developing world, and the non-response from governments to this market failure.[1,2] The G8 has an enormous political and financial potential to curb this death toll. However, while several important commitments have been made to improve access to medicines in the past 3 years, few have been achieved, and many have been forgotten (panel).

In 2000, G8 leaders in Okinawa committed to setting up a "new" partnership with governments, international organisations, industry, academia, and non-governmental organisations aimed at reducing disease burden for HIV, tuberculosis, and malaria—also noting the impact of pneumonia, diarrhoea, measles, and other

G-8: the road to Evian

Okinawa, 2000
- Co-ordinate existing public and private initiatives to reduce disease burden of HIV, tuberculosis, and malaria according to UN goals
- Set up an infectious diseases conference to determine priorities for action

Okinawa Conference gave support for:
- Purchase funds or bulk procurement to stimulate research and development
- Fiscal and regulatory measures to stimulate research and development; medicines should be seen as public goods
- Fostering research and development capacity in Southern hemisphere
- Increased public funding for research and development into neglected diseases
- Operational research to adapt new therapies to resource-poor settings
- Internationally defined and prioritised agenda for infectious diseases, including research and development

Genoa, 2001
- Make GFATM operational by end of 2001 (announced at UNGASS, June, 2000)
- Strengthen intellectual property protection in developing countries through bilateral assistance and international organisations such as WTO and WIPO
- Work with pharmaceutical industry to facilitate drug provision in affordable and effective manner

Kananaskis, 2002
- Financial commitment to wipe out poliomyelitis in Africa by 2005 (dedicated funding announced)
- Support African efforts to build sustainable health systems
- Help Africa combat HIV/AIDS through preventive measures
- Accelerate elimination in Africa of poliomyelitis, river blindness, and other diseases and deficiencies; commitment to provide sufficient resources to eliminate poliomyelitis in Africa by 2005; and funding for immunisation of children and elimination of micronutrient deficiencies in Africa
- Support health research on diseases prevalent in Africa, including expanding health-research networks to focus on African health issues and making more extensive use of researchers based in Africa

GFATM=Global Fund to Fight AIDS, Tuberculosis and Malaria, UNGASS=UN General Assembly Special Session on HIV/AIDS, WTO=World Trade Organisation, WIPO=World Intellectual Property Organization.

childhood infectious diseases. The focus was on three main themes: improving health systems, improving access in developing countries to medicines and preventive measures, and strengthening the research and development of new drugs, vaccines, and other tools for diseases common in developing countries.[3] The adjunct Okinawa Infectious Disease Conference led to support for a range of much-needed policies to increase drug access and research and development, including a commitment to "increasing our support . . . for the R&D of international public goods" through mechanisms such as purchase funds or bulk procurement; and to "make key drugs, vaccines, treatments and preventive measures more universally available and affordable in developing countries".

The G8 meeting the following year in Genoa took place in the context of growing international pressure on increasing access to medicines, particularly for HIV/AIDS. The South African legal case had been dropped by the pharmaceutical industry in February, 2001[4] (South Africa wanted to import more affordable anti-AIDS drugs, and was sued by 39 pharmaceutical companies). The TRIPS Council (Trade-related Aspects of Intellectual Property Rights) had started to discuss access to medicines.[5] And the UN General Assembly Special Session on HIV/AIDS in June resulted in the launch of the GFATM (Global Fund to Fight Aids, Tuberculosis and Malaria).[6] However, amid mounting evidence that patents result in high prices for drugs while doing little to stimulate research and development into the diseases of the developing world, the G8 chose to emphasise the importance of strengthening intellectual property rights. The disease focus at Genoa had narrowed to AIDS, tuberculosis, and malaria while research and development for tropical diseases had fallen completely off the agenda.[7]

At Kananaskis in 2002, under the shadow of terrorism and security, the G8 reached for the lowest hanging fruit. A needed commitment was made towards the elimination of poliomyelitis, but ambitions at Okinawa to increase research and development in areas that are completely failed by market forces and public policies were ignored.[8] On AIDS the focus was almost exclusively on preventive measures, at a time when the need to ensure treatment for the 6 million people who currently need it was gaining international acceptance.[9]

Since Okinawa, the number of HIV-infected children has nearly tripled from 1·3 million to 3·2 million; 6 million more people have died from tuberculosis; and malaria mortality in children under 5 has increased up to 5-fold in some parts of Africa. And yet, under the guise of doing good, the G8 in fact appears most concerned about protecting their own interests. Strong commitments to stimulate research and development into new health tools for the diseases of the developing world as international public goods have dissolved; proposals to promote research and development by private industry have not been adequately laid down; and the crisis in research and development remains as acute as ever.[2] The GFATM now risks becoming bankrupt, largely because G8 countries have not contributed enough, while even the basic right of developing countries to access generic medicines for infectious diseases risks being swept away by efforts from G8 members to limit the scope of compulsory licensing.[10]

The G8 have the financial and pharmaceutical resources to do an enormous amount of good. They should do this by: making existing medicines affordable through promoting equity pricing (fair, affordable, and equitable drug pricing achieved through such mechanisms as generic competition, global procurement and comprehensive tiered pricing) and the Doha Declaration on TRIPS and public health (which affirms the right of countries to protect public health and ensure access to medicine for all); increasing funding to help purchase existing medicines; and establishing needs-driven research and development through public funding and the enhancement of north-south and south-south collaboration and technology transfer,[11] guaranteed through an international convention.

In other words, the G8 should move towards meeting past commitments rather than away from them, and to demonstrate to the developing world that it can put global health above the interests of industry in the developed world. No more broken promises.

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The dangerous rise of American exceptionalism

A series of decisions by the current US Administration, in widely differing sectors, are causing increasing concern among the global public-health community. Together, these decisions can perhaps best be thought of as manifestations of American exceptionalism,[1] in which international laws and standards of behaviour apply only to other countries.

Some of these decisions were stimulated by the attacks in the USA on Sept 11, 2001. In the USA, large numbers of people of Arab descent have spent long periods in custody without being charged or having access to a lawyer. And blunt acts of discrimination, in which airline passengers who arouse suspicion for appearing to be Arabs are refused boarding, have given way to more sophisticated, but secret, profiling systems that may preclude completely innocent people from boarding an aircraft.[2]