(*The Lancet*)[Red]: a missed opportunity

The past 5 years have been essential to increasing access to antiretroviral treatment in resource-poor countries, and this experience has raised many challenges. The first was simply to start treating patients in the face of criticism and doubts expressed by the scientific community[1] and major donors,[2] with little support from UN agencies. Although we welcome *The Lancet*'s initiative to devote an issue to HIV/AIDS, we are disappointed that so much space was devoted to uncontroversial and apolitical statements by UN agencies.

Behind the self-congratulation of multilateral agencies lies the fact that universal access is far from within reach, and strategies to ensure long-term quality care in resource-limited settings hardly exist. Ensuring free, long-term treatment access will require more than goodwill, and affordable medicines do not suddenly appear with the publication of new formularies.

WHO's public-health approach to antiretroviral therapy focuses on the "Fours Ss": when to Start, when to Substitute, when to Switch, and when to Stop.[3] But who will pay the price of this strategy? Most countries are barely managing with the first and last S (starting and stopping). Although basic first-line therapy costs are as low as US$132 per patient per year, the main substitution for toxicity requires tenofovir, which is rarely registered, at least 2·5 times more costly, and not available as a triple fixed-dose combination. Basic second-line regimens currently cost at least ten times more (figure).[4] At these prices, 10% of patients on second-line therapy would represent over 60% of the national drug budget. What is WHO doing to address this issue?

Price is only a part of the problem. Of the 13 drugs recommended by WHO, only six have been prequalified. There are no generic prequalified versions of any of the five antiretrovirals specifically recommended for second-line treatment (didanosine, atazanavir, lopinavir/ritonavir, saquinavir, and ritonavir), and only two originator companies offer a differential price for these products.

With the World Trade Organization's TRIPS Agreement now in full force in major generic-producing countries such as India—on whose generic medicines around half of those receiving antiretroviral treatment in the developing world currently depend—it is unlikely that generic versions of these and other new drugs will be produced without a serious political struggle. The recent removal of the WHO representative in Thailand for suggesting that compulsory licensing should be considered an option for securing affordable second-line medicines shows how little progress has been made to confront these major political barriers.[5] That none of these issues were addressed by the major multilateral agencies who dominated *The Lancet*'s special issue provides further confirmation of the lack of political courage where it is needed most.

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1 Marseille E, Hofmann P, Kahn J. HIV prevention before HAART in sub-Saharan Africa. *Lancet* 2002; **359:** 1851–56.
2 Donnelly J. Natsios called racist; firing sought. *Boston Globe* Sept 6, 2001.
3 Gilks C, Crowley S, Ekpini R, et al. The WHO public health approach to antiretroviral treatment against HIV in resource-limited settings. *Lancet* 2006; **268:** 505–10.
4 Campaign for Access to Essential Medicines. Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries, 9th edn. Geneva: Médecins sans Frontières, 2006. http://www.accessmed-msf.org/documents/untanglingtheweb%209.pdf (accessed Sept 12, 2006).
5 Williams D. World health: a lethal dose of US politics. *Asia Times* June 17, 2006. http://www.atimes.com/atimes/Southeast_Asia/HF17Ae01.html (accessed Aug 31, 2006).

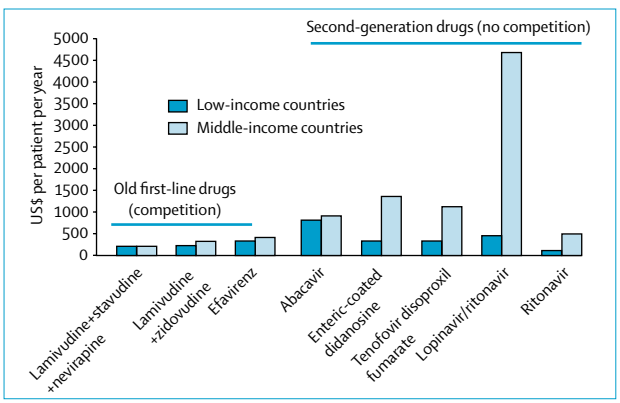

Figure: **Average prices paid for first-line and second-line antiretroviral drugs in low-income and middle-income countries in 2005**
Data from WHO Global Price Reporting Mechanism on Antiretroviral Drugs.

Exceptional responses or TRIPS over red tape?

Peter Piot's Viewpoint (Aug 5, p 526)[1] was commendable in its recognition of HIV/AIDS as an "exceptional" challenge and its call for action. Such a challenge undoubtedly requires an exceptional response, yet despite Piot's emphasis on "momentum and achievement", it is clear that the global response remains ordinarily lacking.

It is right to celebrate the genuine successes so far—because they have saved lives and restored hope—but if universal access to treatment by 2010 is to be more than rhetoric, we must shake off any hint of complacency. The facts are stark. Only 20% of those in urgent need of treatment are receiving it.[2] More than 4 million additional health workers are needed.[3] On current trends, we will spend only half the US$20–23 billion needed annually by 2010.[1] Clearly momentum is not enough: a change in pace is necessary.

In these areas, Piot outlines many positive steps, but like others, does not mention one crucial piece of the puzzle: increasing the manufacture and distribution of affordable generic drugs, particularly expensive patented second-line and third-line treatments. Compulsory licensing again remains the mechanism so sorely needed yet so rarely spoken of. The fundamental importance of generic competition to

For the website of the **Prequalification Programme** managed by WHO see http://mednet3.who.int/prequal/