

Policy briefing: Access to Essential Medicines for HIV May 2006

Summary

If universal access to treatment by 2010 is to be achieved, production and distribution of affordable medicines in developing countries must be rapidly expanded.

We have identified **three key areas for action** by the UK government.

- 1. Ensuring new generic versions of key drugs become rapidly available**
- 2. Supporting developing countries in ensuring access to essential medicines**
- 3. Following through on existing commitments**

Context: the global treatment gap

Under the current system, many HIV drugs are priced out of reach of those in low and middle-income countries. While access has been rising steadily over the last two years only 1.3 million people in the developing world are receiving antiretrovirals (ARVs), out of a total of 6.5 million who need them urgently. Less than 5 per cent of the 700,000 HIV-positive children in need of paediatric AIDS treatment are receiving it – and nearly all those who do are in developed countries.

Furthermore, key drugs needed to treat opportunistic and other infections are also in short supply. As treatment for HIV and AIDS is a life-long medical intervention, a system must be found that guarantees that patients all over the world will profit from medical progress equally. The task ahead is clearly huge.

A crisis of supply

The Stop AIDS Campaign has identified the price and supply of essential medicines as a key area where significant barriers currently stand in the way of achieving universal access. Dr Jim Kim, former WHO director of HIV/AIDS has warned that, in scaling up towards 2010, “a crisis in terms of supply” will be reached “very, very soon” because of the rapid expansion of HIV treatment programmes.¹

As the WHO Commission on Innovation and Intellectual Property Rights concluded, the whole area of drug patents and pricing, intellectual property rules and rights, and the production and distribution of generic drugs needs urgent attention. There is a pressing need for vision and determined leadership in order for the necessary progress to be made, and we urge the UK government to take on this challenge.

Generics hold the key

At the heart of a comprehensive, sustainable approach must be generic competition, and the UK government must proactively uphold this principle. Approximately half of the people in the developing world who are already on antiretroviral therapy rely on generic versions of more expensive patented drugs. In order to scale up supplies to the required level, Dr Kim argues that a “*humanitarian corridor*” must be created, involving countries with the capability to produce low cost generic ARVs supplying them to Africa.

Generics are the only hope for introducing key ‘second-line’ treatments, needed for patients when they develop resistance to their first combination of medicines. This is a particularly pressing issue, as essential second-line treatments are currently under patent and priced out of reach – as will be any new, more effective drugs that come onto the market in the future.

Generics also help overcome the problems encountered in producing fixed-dose combinations when the different components are patented by different companies unwilling to co-operate. Such combination drugs have had a major impact in helping scale up global AIDS treatment by simplifying it. There is a particular problem with accessing appropriate and affordable paediatric formulations on the scale required. Differential pricing is part of the solution but can only be truly effective as part of a functioning market that includes generic competition.

Proponents of the patent system argue against the need for generic production, pointing out that companies now make low-cost versions of their drugs available in developing countries. However, MSF recently highlighted the example of New Kaletra, a highly potent HIV drug, with specific benefits for people in resource-poor settings, which is not available in Africa. Abbott Laboratories – the company owning the rights over this drug - has delayed supplying it in low and middle income countries, despite repeated calls from activists, health providers and people living with HIV. It’s therefore clear that generic competition has a key role to play in scaling up towards 2010.

TRIPS isn’t working, TRIPS-plus is worse

Unfortunately barriers currently stand in the way of the easy accessibility of generic medicines in poor countries. The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has been at the heart of debates around drug pricing for some years.

Recent amendments to the TRIPS agreement, hailed by Northern governments as a huge step forward for access to medicines, have failed to facilitate the distribution of low cost generics required for public health. The new flexibilities contained in TRIPS are unnecessarily complex and in the three years since these procedures were agreed, no country has yet used them to import generic versions of essential medicines.ⁱⁱ

Of additional concern is the fact that many countries are being, or have already been, encouraged to sign regional and bilateral free trade agreements which ensure a higher level of patent protection or other forms of de-facto monopolies - such as protection of pharmaceutical test data and prohibition of parallel importation - than even TRIPS requires. These so-called ‘TRIPS-plus’ policies, favoured by the US, remove any possibility of placing public health above commercial interests such as patent rights.

Call to action: what the UK must do

The UK government has already done important work in the area of access to medicines, and has made promising statements about its future plans. But evidence of its commitment to follow these through is hard to come by.

We have identified **three key areas for action**. We would like to see the UK government clarify its commitment to each one, and outline the action it is taking.

We would welcome **six-monthly reports** updating us on the UK's involvement in each of the three areas, and showing evidence of its impact.

1. Ensuring new generic versions of key drugs become rapidly available

A range of legal, technical and procedural barriers currently stand in the way of access to ARVs, from registration to prequalification to licensing to export. While politicians, patent lawyers and bureaucrats discuss these barriers thousands continue to die. The UK government has a major role to play in helping remove and minimise the harm caused by these barriers. Evidence of UK political will and concrete precedents in promoting health over patents are desperately needed.

Valuable precedents could be set through the examples of **tenofovir disoproxil fumarate** (marketed by Gilead as Viread) and **heat-stable lopinavir/ritonavir** (marketed by Abbott as Kaletra). These two ARV drugs, both currently patented or seeking patents in WTO member countries, would have a hugely beneficial impact in the developing world if generic versions were to be produced and made widely available.

Both drugs are recommended for use in resource poor settings by WHO:

- Tenofovir disoproxil fumarate is used as an alternative first-line drug to reduce long-term toxicity and as a second-line drug in certain patients.
- Lopinavir/ritonavir is the backbone of most second-line treatment regimens in resource poor settings. Lopinavir/ritonavir is currently the only co-formulated heat-stable boosted protease inhibitor on the world market. Its importance for use in tropical countries cannot be overestimated.

Both drugs therefore have a key role to play in achieving the 2010 target.

We would like to see the UK government take a lead and, working with other countries and the WHO, focus its efforts on ensuring that **generic versions of these two drugs become available to developing countries within a year**.

2. Supporting developing countries in ensuring access to essential medicines

The task of making intellectual property rules work in a way that ensures access to generics in developing countries is legally and politically extremely challenging. The UK government should provide **substantial financial and technical assistance** in order to support developing countries to achieve access to generics despite the barriers that may stand in their way. This will involve the following.

- making sure countries are **fully aware of, and able to use, the flexibilities** that are available to them to import ARVs and other essential medicines that are under patent
- aiding countries to **implement TRIPS flexibilities into domestic legislation** when they are required to do so
- aiding countries to enact patent laws allowing **pre-grant opposition**, and supporting individuals and groups in challenging the validity of patents where appropriate
- supporting the African Union's call to encourage **local and regional production of generics** and providing technical assistance to promote and supervise internationally recognized quality standards such as WHO prequalification
- providing whatever support is necessary – including political support - to countries negotiating **free trade agreements**, to withstand any pressure on them to agree to provisions that have the potential to go beyond TRIPS and undermine countries' abilities to use its flexibilities.
- influencing the US **not to go beyond TRIPS** in the regional and bilateral FTAs they are negotiating

3. Following through on existing commitments

We would like to see **transparent monitoring and reporting of all existing initiatives**, in order to be kept informed of their progress and effectiveness, including:

- The Chancellor's initiatives for: tax credits on R&D for poverty-related diseases; advance purchasing commitments
- EC regulation allowing differential pricing for selected ARVsⁱⁱⁱ
- WHO's monitoring of the impact of trade agreements on access to medicines and public health^{iv}
- Commitment that bilateral and other trade agreements should not oblige countries to adopt intellectual property standards or timetables that go beyond TRIPS, and to ensure that EU agreements with developing countries avoid imposing obligations beyond TRIPS.^v

We are also concerned that the Department for International Development lacks internal technical capacity to back the UK's leadership on crucial international health policies; to ensure coherence among UK government departments; or to link with NGOs working on access to medicines, such as ourselves. It has dramatically reduced the number of staff working on this area in recent years, from a full team to, currently, none.

An access to medicines team with appropriate expertise needs to be in place in order to follow through on existing commitments and guide the UK government's ongoing, high profile work in this area.

ⁱ <http://www.aidsmap.com/en/news/B2F31072-8CBF-4538-B4D6-A4F0E2D33B7A.asp>

ⁱⁱ There are no notifications of intent to use the system on the dedicated WTO website:
http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

ⁱⁱⁱ Council Regulation 953/2003 to avoid Trade Diversion into the European Union of certain key Medicines,
<http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl>

^{iv} World Health Assembly Resolution 56.27 on intellectual property rights, innovation and public health, 28 May 2003.

^v UK Government response to Commission on Intellectual Property Rights
http://www.iprcommission.org/graphic/uk_government_response.htm

www.stopaidscampaign.org.uk

The Stop AIDS Campaign is a campaigning initiative of the UK Consortium on AIDS and International Development, a group of more than 80 UK based organisations which work together to understand and develop effective approaches to the problems created by the HIV epidemic in developing countries. Reg charity 1113204.

UK Consortium on AIDS and International Development

