

# The Medicines Patent Pool: improving access to ARVs and stimulating innovation for new medicines

Antiretrovirals are currently keeping 6 million people alive. In a competitive but necessarily low-profit sector of the pharma market, a mechanism was needed to maximise momentum. The Patent Pool is it. Kaitlin Mara reports

Treating people living with HIV comes with many challenges in resource-poor settings. One of the most difficult is the lack of availability of treatments: medicines needed for the effective treatment of HIV are not always available, or are not available at prices people living with HIV can afford, in particular when they are patented. Newer drugs often see years of delay between when they are available in developed countries and when they finally become available in developing countries.

The Medicines Patent Pool is a new mechanism seeking to improve the availability of quality, affordable, HIV medicines in developing countries. It does this by negotiating with major pharmaceutical companies for the patent rights to HIV drugs, including new medicines in the pipeline, so that generic versions can be produced and made available in developing countries.

When the first generic antiretroviral medicines came to market ten years ago – in conjunction with new financing provided by the Global Fund, PEPFAR in the United States, and UNITAID to roll out treatment programmes – it was a revolution for people living with HIV in developing countries.

The price of first generation HIV medicines fell by more than 99% thanks to generic competition – from the unattainable US\$10 000 per person per year to as low as US\$60 per person a year in some countries today. This for the first time put tools to treat the HIV epidemic in the hands of medical practitioners in developing countries. These cheaper first-generation medicines are now keeping over 6 million people alive and healthy (see Figure 1).

But the conditions that allowed for the scale-up of treatment in the last decade are coming under threat. The global financial crisis has stymied funding for HIV-

related interventions, notably the Global Fund, which in November announced it would cancel its latest round of funding due to budget shortages. This is happening

even as the need for HIV medicines continues to grow, and as new scientific research has revealed that timely treatment can not only save lives but also prevent new HIV infections.

The need for cheap drugs, and lots of them, has never been more acute. At the same time, increased patenting of

medicines in developing countries due to changing international trade rules is limiting generic competition on newer generations of HIV medicines just as the need for these new medicines is on the rise. Second-line drugs such as atazanavir, lopinavir, and ritonavir and third-line drugs like darunavir, etravirine, and raltegravir, or even more recent drugs that are yet to receive regulatory approval, are increasingly likely to be patented in key generics producing countries (see Figure 2).

Generic competition in early years was facilitated by countries that did not grant patents on medicines, or countries such as India that did not grant patents on medical products. In these places, generic companies were able to produce and supply HIV medicines at low cost. Today the vast majority of HIV medicines used for treatment of people in the developing world are generic medicines. A study in the *Journal of the International AIDS Society* found that Indian generic manufacturers alone were supplying over 80% of donor-funded HIV medicines available in generic countries since 2006.

But the new trend in medicines patenting means that even where people have access to treatment it may not be to the newer HIV medicines. Many people today on HIV treatment will build resistance to the drugs they have, and will need continued access to new medicines to survive in the long run. These second- and third-line therapies – newer, and more likely to be patented – may not be available at affordable prices.

Patent barriers can also prove problematic for the



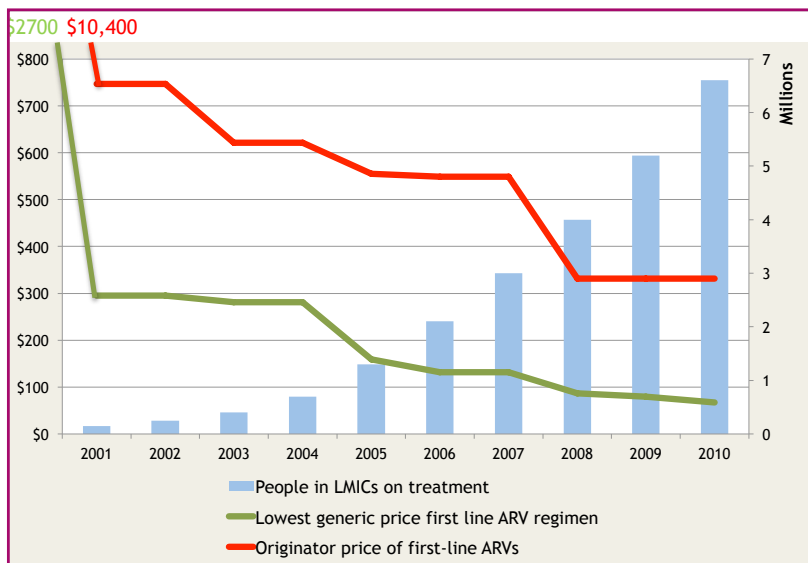


Figure 1 Generic competition and treatment scale-up

Product	+/- Expiry date
Atazanavir (BMS)	2017
Cobicistat (Gilead)	2027
Darunavir (J&J/Tibotec)	2023
Etravirine (J&J/Tibotec)	2019
Lopinavir (Abbott)	2017
GSK 572 -Dolutegravir (ViiV)	2026
Raltegravir (MSD)	2025
Rilpivirine (J&J/Tibotec)	2022
Ritonavir hs (Abbott)	2024
Tenofovir DF (Gilead)	2018
Maraviroc (Pfizer)	2019

Figure 2 Newer ARVs widely patented in developing countries

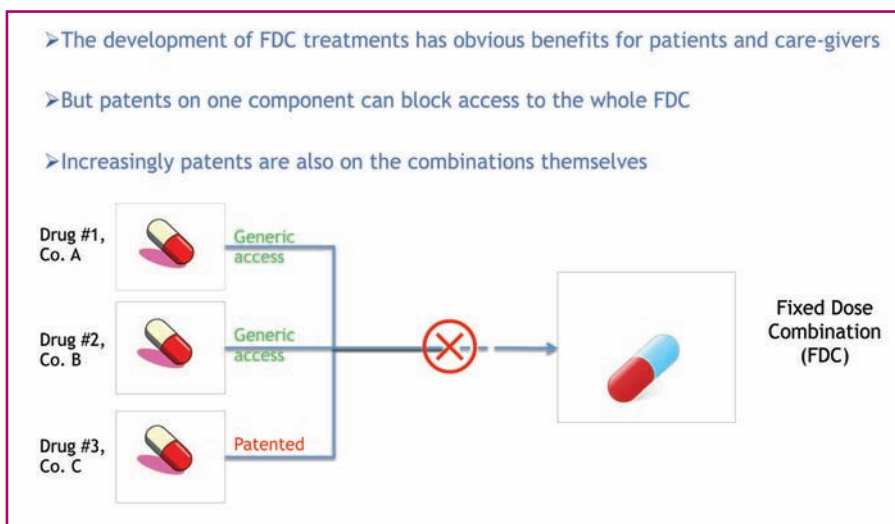


Figure 3 Problems with fixed-dose combinations

development of new formulations, such as fixed-dose combinations useful for treatment scale-up in developing countries or medicines specifically formulated for children. Fixed-dose combinations provide a particular patent challenge, as patents on even one component of the drug can block access to the whole FDC (see Figure 3).

And paediatric HIV has become a neglected disease: Children living with HIV live almost exclusively in developing countries, where few market incentives exist for larger companies to develop and produce the adapted formulations required to treat them.

### How the medicines patent pool can help

In July 2010, the Medicines Patent Pool was set up with the help of innovative financing mechanism UNITAID in order to help find solutions for these problems that work for everybody.

The Medicines Patent Pool functions as follows: patent holders voluntarily offer, under certain conditions, licences to the patents related to their HIV medicines for use in developing countries. These licences are then 'pooled', creating a one-stop shop for HIV medicines patents. Any company that wants to use the intellectual property to produce the drugs competitively can do so in exchange for a royalty payment to the patent holder.

This saves generic companies the uncertainty of having to negotiate with several patent holders for the right to produce a particular medicine. The Pool mechanism reduces transaction costs, making it easier for potential generic manufacturers or new innovators to enter the market (see Figure 4).

Patent-holding companies are assured a fair royalty for joining the Pool, and are given a concrete, visual way to contribute to global health.

Most importantly, it works for people living with HIV and their care providers by bringing prices to affordable levels and helping to provide the missing medicines needed to prolong lives.

In its first year of existence, the Pool has had promising success: it signed its first licences in September 2011 with the US National Institutes of Health for several patents related to darunavir.

In July 2011, the Pool signed its first licences with a major pharmaceutical company, Gilead Sciences, that allow for the manufacture of



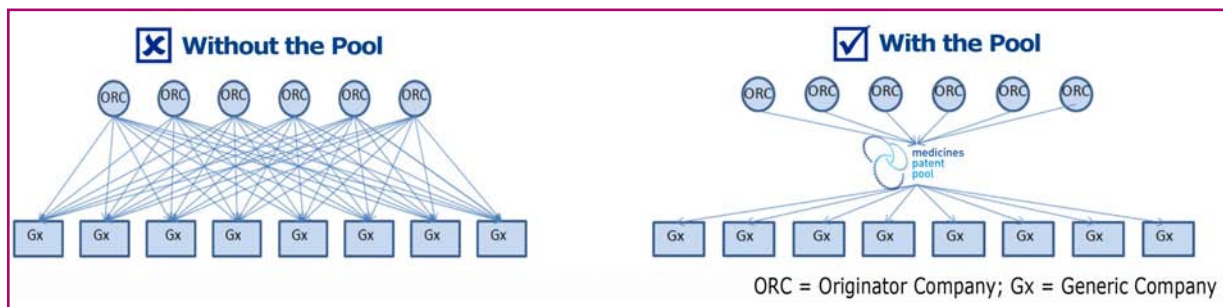


Figure 4 The Pool mechanism reduces transaction costs

emtricitabine as well as the pipeline products cobicistat, elvitegravir, and the Quad, a fixed-dose combination of tenofovir, emtricitabine, cobicistat, and elvitegravir.

The Pool also is in ongoing negotiations with Boehringer Ingelheim, Bristol-Myers Squibb, F Hoffman-La Roche, Sequoia Pharmaceuticals, and ViiV Healthcare (a joint venture of GlaxoSmithKline and Pfizer).

The work of the Pool has received support from the World Health Organization, UNAIDS, the Global Fund to Fight HIV, TB, and Malaria, and the Group of 8 countries, as well as NGOs.

The very success of the Pool depends on these and

other stakeholders' support, and in particular pharmaceutical patent holders' willingness to collaborate.

The Medicines Patent Pool has the potential to help increase access to medicines, improving the lives of millions of people living with HIV. But it can only do so if all stakeholders collaborate, in particular patent holders and pharmaceutical manufacturers. The need is urgent – and growing. Spiraling treatment costs if left unaddressed risk threatening even those currently receiving treatment. Now is the time to avert the treatment access crisis – before it is too late.

### Erratum

On page 18 of the November issue of *Africa Health* we published an article 'Scaling-up TB screening and isoniazid preventive therapy among children and adults living with HIV: new WHO guidelines', written by Delphine Sculier and Haileyesus Getahun.

Unfortunately, due to a production error the last two paragraphs of the article did not appear. We publish them here with apologies to the authors. A full PDF version of the article can be downloaded from our website: [http://www.africa-health.com/latest\\_issues.html#nov\\_2011](http://www.africa-health.com/latest_issues.html#nov_2011).

The Editor



Adherence rates for IPT reported in observational studies and randomised trials varied widely from 34% to 98%. Although it is important for good individual and programme outcomes treatment is completed, the primary objective is to ensure that people do not continue to take IPT in the rare event of active TB. Regular screening using the clinical algorithm at every contact with a healthcare provider is thus important to identify people who may develop active TB on IPT and to stop the prophylaxis. IPT should also be discontinued in cases of toxicity. However, adverse events due to IPT, especially hepatotoxicity, are rare, as observed in a cohort of over 24 000 patients in South Africa (0.54% and 0.07% respectively for adverse events and hepatotoxicity) and can be monitored based on clinical symptoms only.<sup>20</sup>

### Conclusions

IPT is a beneficial intervention to prevent active TB disease among people living with HIV. However, implementation has been slow so far. The WHO 'Guidelines for intensified TB case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings' aims to provide simplified, evidence-based guidance for TB screening and provision of IPT. Success in implementing IPT and reducing the burden of TB among people living with HIV will depend on the leadership of HIV programmes and service providers to take-up these guidelines and appropriately address perceived barriers to providing IPT. Many countries – such as Ethiopia, Mozambique, and South Africa – have already adopted and implemented the WHO guidelines and demonstrated that rapid scale-up in the provision of IPT to people living with HIV is feasible.<sup>1</sup>