

## The Medicines Patent Pool initiative

UNITAID is working to establish an international system to boost the availability of new and more patient-friendly medicines for people in developing countries.

Through a collective management structure for medicines patents, known as a patent pool, UNITAID seeks to improve access to patents and foster the development and production of life-saving, more affordable, and more suitable medicines.

Although such a 'pool' structure has shown its worth in many areas – agriculture and information technology, for example - the UNITAID initiative will lead to the first patent pool for medicines.

### Why we need a medicines patent pool

The principle of a patent pool is to facilitate the availability of new technologies by making patents and other forms of intellectual property more readily available to entities other than the patent holder.

For health, the impact of such a mechanism could be considerable.

A medicines patent pool could for instance facilitate the production of new essential medicines that combine several pharmaceutical compounds patented by different companies into a single pill. Known as fixed-dose combinations (FDCs), these medicines have shown their worth in AIDS treatment, where they have been proven to be more user friendly for children and adults, promote treatment compliance and boost treatment outcomes.

In addition, the patent pool could make newer medicines more affordable for populations in developing countries. While some older medicines for the treatment of AIDS have become increasingly affordable, newer, less toxic products are still too expensive. For example, treating a patient for one year with the most affordable improved first-line regimen for HIV, as recommended by the World Health Organization (WHO), today costs between US\$ 613 and 1 033, using originator products. This represents at least an eight-fold increase from the price of the older regimen, which stands at US\$ 87.

With increasing numbers of AIDS patients failing on their first-line therapy, there is also an urgent need to find affordable second-line treatments.

Additionally, children's needs are still largely overlooked by pharmaceutical research – of the 22 antiretrovirals approved by the US FDA and currently available, six are not approved for paediatric use and seven are not available in paediatric formulations.

Improving access to IP will thus both help improve access to medicines and boost innovation that responds to patients' needs.

## What the pool will look like

The Medicines Patent Pool will:

- Be a **voluntary mechanism**, meaning its success will largely depend on the willingness of pharmaceutical companies to participate and allow their intellectual property to be managed by the pool. Other entities, including generic producers, will be able to make use of the patents in exchange for the payment of royalties;
- Be a **win-win deal**. Pharmaceutical companies are rewarded for their investments into research and development; generic companies are able to access the intellectual property more easily and faster; patients in developing countries get access to better, more affordable treatments, faster;
- Have as its geographical target **developing countries**;
- Focus on **HIV medicines initially**, concentrating on those products that are needed but are not yet developed (such as second-line medicines and paediatric formulations) and on those existing products for which the number of suppliers is insufficient to create economies of scale. Once up and running, the pool could expand to serve other disease areas of need;
- Aim to ensure that producers that make use of the patents in the pool meet agreed **quality standards**.

## How the Pool would work

- **Collective management of patents:**  
The idea behind a patent pool is that patent holders - companies, researchers or universities - voluntarily offer, under certain conditions, the intellectual property related to their inventions to the Medicines Patent Pool. Any company that wants to use the intellectual property to produce or develop medicines can seek a license from the Pool against the payment of royalties to produce the medicines for use in developing countries.
- **Stimulus to innovation:**  
Without a patent pool that facilitates access to patents, a company wishing to develop a fixed-dose combination for the treatment of HIV/AIDS might need to obtain licenses from at least three different patent holders to be able to develop, produce, export and sell the product. With a patent pool holding the relevant IP however, the license 'user' or licensee will only have to deal with the pool. The patent pool is in fact a one-stop-shop for all parties involved - it therefore facilitates legal and bureaucratic processes involved in obtaining licenses, it reduces expenses and increases access to intellectual property essential to make important medicines.
- **Making medicines more affordable, faster:**  
The pool will help to speed up the availability of lower-priced, newer medicines because there will be no need to wait out the patent term (usually about 20 years - time patients can ill-afford to lose). In exchange for the payment of royalties to the patent owners, any producer can manufacture the patented medicines and sell them in countries well before the expiration of the patent term. With licenses covering a wide geographical area - developing and emerging economies - the scope of the market would be attractively large, thereby encouraging multiple producers to come forward

and access the patents. The greater the competition between producers, the more one can expect the price of medicines to fall.

## **UNITAID's role**

UNITAID was established in September 2006 to support existing efforts to tackle HIV/AIDS, malaria and tuberculosis. These diseases are responsible for approximately 3.7 million deaths annually and take a huge toll on families and communities. Yet the diagnostics and medicines required to test, treat and prevent them are inaccessible to most of the people who need them.

UNITAID's specific contribution is to provide sustainable funding for the purchase and supply of needed diagnostics and medicines. UNITAID also seeks to have a lasting impact on markets - essentially, by reducing prices, increasing production and driving the development of new medicines and tests.

The patent pool initiative will be a crucial tool in addressing this mandate.

UNITAID has so far spent US\$ 407 million on the purchase of AIDS treatments. By acting as a catalyst for reductions in the price of such medicines, the patent pool will mean that for the same amount of money, UNITAID will be able to change the lives of many more people.

## **UNITAID takes the plunge**

UNITAID was given the go-ahead to create a patent pool on 3 July 2008, when its Executive Board approved the plan in principle.

The next steps undertaken by UNITAID will be to develop an operational plan for the creation of the patent pool.