

Gilead licence expands access, but several countries left out

Excluded countries should be ready to issue compulsory licences to access needed drugs



An agreement announced recently by pharmaceutical company Gilead to licence several HIV/AIDS drugs to the Medicines Patent Pool could improve access to medicines for patients, but excludes several countries with large numbers of people living with HIV, the international medical humanitarian organisation Médecins Sans Frontières (MSF) has said.

"This agreement is an improvement over what other big pharma companies are doing to ensure access to their patented AIDS medicines in developing countries," said Michelle Childs, policy and advocacy director at MSF's Campaign for Access to Essential Medicines. "But some caution is needed because in several key areas, Gilead is not going beyond the status quo. More needs to be done to fulfil the vision of the Patent Pool to provide a solution to all people living with HIV, so this licence should not become the template for future agreements."

On the positive side, the licence covers two promising drugs in the pipeline, cobicistat and elvitegravir, one pipeline combination and the crucial drug tenofovir. This could help ensure that new treatment options are available in developing countries at the same time as in rich countries.

The licence also allows for new fixed-dose combinations and child-friendly medicines to be developed. Critically, the licence is the first of its kind to explicitly incorporate the potential use of public health safeguards: it allows medicines to be exported to countries excluded from the agreement when their governments choose to override the patent with a compulsory licence, and also allows producers to exit the agreement for any one of the drugs if Gilead loses a patent because of a legal challenge. The agreement has also been made public, which sets an important precedent for transparency.

Negative aspect

On the negative side, the agreement falls significantly short of what is needed to fully meet the public health needs for HIV/AIDS: it limits price-busting competition by confining manufacturing to one country (India) and includes narrow supply options for active pharmaceutical ingredients needed to make the drugs. Most critically, people living with HIV in certain middle-income countries are excluded. This contrasts sharply to the first Pool license granted by the US National Institutes of Health for all developing countries. If voluntary measures like the Patent Pool are unable to ensure people access to the medicines they need, countries that are left out will need to aggressively pursue non-voluntary paths like compulsory licences.

Several of the countries that are excluded under the Gilead licences are among the first in which MSF provided HIV/AIDS treatment ten years ago.

"We handed over many treatment programmes in Latin America and Asia to local authorities in the confidence that they would be able to provide people with the treatment they needed to stay alive," said Dr Tido von Schoen-Angerer, executive director of MSF's Access Campaign.

"If people in middle-income countries are left out of such deals, their governments still need to pursue compulsory licences to overcome patent barriers."

Some manufacturers left out

The initial idea of the Patent Pool was to allow access for all people in developing countries. Any producer meeting the right standards should be able to make use of licenses to produce and sell. However, in this agreement, manufacturers in Thailand and Brazil, which have capacity to produce, have been left out.

This agreement builds on existing contracts made in 2006 between Gilead and generic producers of tenofovir (TDF), a backbone of improved first-line treatment. The new deal will allow these producers to make new drugs coming from Gilead but has not overcome the issue of supply to countries facing patent barriers such as China.

"Companies currently negotiating with the Pool should agree to licenses that more fully meet public health needs," said Childs. "We expect all companies, including Johnson and Johnson, Abbott and Merck to also put their patents in the Pool, just as we hope that countries that don't benefit from this agreement will use all means including compulsory licenses to increase access to HIV medicines for their people."

Source: MSF

For more, visit: <https://www.bizcommunity.com>