

## **Press Release Issued by the Affordable Medicines and Treatment Campaign (India), Mediciens Sans Frontieres, Lawyers Collective HIV/AIDS Unit, Alternative Law Forum**

### **For Immediate Release**

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### **The Beginning of the End of Affordable Generics**

Under a new Bill approved today, India will start granting product patents for medicines – something they have not done since 1970 - without the necessary procedures in place to safeguard against wholesale hiking of medicine prices. India amended its 1970 Patent Act in order to be compliant with the requirements of the World Trade Organisation.

A key safeguard to assure availability of affordable medicines is the procedure of compulsory licenses – government grants patents but allows generic companies to make their versions of the patented medicines against a payment of a royalty to the patent holder. However, in the Bill that passed the Lower House (Lok Sabha) today procedures are still extremely complex and there is no control on levels of royalties to be paid, which will lead to endless litigation and delays.

The new Bill “grandfathers” products that are already on the market by allowing for automatic right to produce. The generic companies in such cases will pay royalties to be set by the government to the patent holder. International norms for royalties are in the range of 3-4%. This new law however does not set a fixed royalty rate. In South Africa, GlaxoSmithKline attempted to charge 40% royalty until activists and the courts intervened.

The worst-case scenario for people living with life-threatening diseases has been averted, but only in the short-term.

People who rely on low-cost medicines will have to wait three years before a generic company can even make an application for a right to produce the drug. Whereas people in wealthy countries will have access to new medicines immediately when they are proved safe and effective, people in poor countries will have to wait years.

In addition, with this Bill the government has crippled the critical right of the members of the public to oppose patent applications on medicines, the so-called “pre-grant opposition”. It has been rendered ineffective because the essential information on which to base the opposition will be withheld from the public.

The Bill will go before the Upper House (Rajya Sabha) for a final vote. It is expected that the Upper House will approve the Bill in its current form.

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