

EU-India negotiations on FTA pose a serious threat to access to affordable medicines in the developing world

Negotiations on the intellectual property (IP) provisions in the EU-India free trade agreement, of which a round is taking place this week in Brussels, are cause for real concern as they could have a huge impact on Access to Medicines in India and across the developing world.

The EU's ambitions for IP include provisions on data exclusivity and supplementary protection certificates that would significantly extend the length of the market monopoly for brand pharmaceutical products. These provisions inhibit generic production and competition; maintain high prices and impeding access to medicines for many. The extensive chapter on enforcement of IP goes beyond current World Trade Organization (WTO) obligations and would generate additional implementation costs that could put a chill on generic competition, as the seizures of generic medicines in EU Member States have shown.

Prospective impact studies² by the EU-Latin American and Caribbean Alliance for Access to medicines on these same IP provisions during the EU's negotiations with the Andean region show that there are good reasons to be concerned.³ The forecast for the 'extension of patents' proposals revealed a dramatic increase in medicines' spending in Peru and Colombia due to the lack of generic competition, resulting in an increase in spending of 250 million USD in Peru. In addition, the extension of protection of trial data (data exclusivity) from 5 to 11 years would trigger an increase in medicines' spending of 217 million USD in Colombia and 136 million USD in Peru by 2025. As ever, the victims of the rising cost of healthcare are the poorest families and those without healthcare insurance. Though the provisions on data exclusivity and data protection were fortunately removed in the case of the Andean countries, they could have even further reaching consequences in the EU-India Agreement because of India's role in generic manufacturing.

In response to these concerns the European Commission continues to insist that the trade agreement will not limit the use of TRIPS flexibilities and that the text will contain a reference to the Doha Declaration on TRIPS and Public Health. But, it is hard to believe that the EU is suggesting for India's to systematically issue compulsory licenses and break the monopolies of brand pharmaceuticals. To ensure access to medicines for India's citizens and for the rest of the developing world, the EU's IP negotiations must be watched closely.

1 For information on seizures see 'Dutch seizures on generic medicines in transit'

http://www.haiweb.org/02_focus_b.htm

2 Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru. 11 November 2009. For more info see

[http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru\(EN\).pdf](http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru(EN).pdf) The methodology was developed by a consortium of organisations including WHO, PAHO, the World Bank Institute and the International Centre Trade and Sustainable Development (ICTSD).

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www.iprsonline.org/ictsd/Dialogues/2007-05-27/Documents/IPR%20IMPACT%20MODEL.ppt