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The Honourable Dr. Manmohan Singh
Prime Minister of India
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Geneva, 8 February 2012

Honourable Prime Minister,

Ahead of the India-Europe Summit on 10 February 2012, where a roadmap to conclude the EU-India free trade agreement (FTA) is set to be agreed, the international medical humanitarian organization Médecins Sans Frontières (MSF) would like to draw your attention to specific harmful provisions in the proposed intellectual property (IP) and investment chapters, that if included would have serious implications for access to affordable medicines in India and throughout the developing world.

MSF today relies overwhelmingly on affordable generic HIV/AIDS medicines produced in India to treat nearly 180,000 people in 20 countries, as well as using medicines from India to treat other diseases such as tuberculosis and malaria. India has played a pivotal role in supplying affordable generic versions of drugs used throughout the developing world. It is vital therefore that further barriers are not created that threaten the supply of affordable generic medicines from India.

As such, the March 2011 official statement by Minister Anand Sharma, against the introduction of 'data exclusivity' was welcomed by MSF and others given the harmful effect it would have on access to affordable medicines produced in India. We urge the Indian government to stand strong in this and in future free trade agreements, such as the one currently being negotiated with the European Free Trade Association countries of Switzerland, Iceland, Norway and Liechtenstein.

However the enforcement and investment provisions within the draft agreement are still a matter for serious concern as unchanged they will have significant negative implications for generic production critical for ensuring access to affordable medicines in India and throughout the developing world.

We therefore urge India to take a similarly strong stand in relation to the remaining harmful provisions, particularly:

Enforcement provisions: The European Commission's proposed text is broad in scope and goes well beyond what has already been agreed and implemented by India under the TRIPS Agreement. The EC had **reproduced some of the enforcement measures** contained in the Anti-counterfeiting Trade Agreement (ACTA) over which the Indian government has raised serious concerns at the WTO, stating that the agreement will "impede legitimate competition and shift the escalated costs of enforcing private commercial rights to governments, consumers and taxpayers"[1].

The EU is proposing an ambitious enforcement agenda that:

- **Widens the enforcement net so that life-saving legitimate medicines, under alleged trademark infringement, could be detained or destroyed at the border when being exported, simply because their label appears similar to the originator product.** Although this is often justified on the basis of protecting the public from fake medicines, this issue is entirely separate, and will do nothing to improve medicines' safety. It would in fact have a negative impact on access to treatment, as is evident from the recent seizures of Indian generic medicines in EU countries. The impact of any such detentions will be felt directly by patients awaiting the arrival of crucial generic medicines in the many countries that do not have manufacturing capacity to produce medicines, and therefore rely on importing more affordable generics from India;

- **Substantially increases the penalties** for alleged patent and trademark infringements. On a mere allegation - and not proof – including allegations brought by a competitor, generic suppliers allegedly infringing a patent or a trademark may face a ban on production, delay or destruction of goods, disproportionate damages, and potential bankruptcy;

- **Limits the Indian courts' ability to balance commercial and public health interests and the Indian Constitution's guarantee to the right to life**, by making use of a variety of alternative remedies rather than as the EU proposes, routinely granting provisional injunctions; and

- **Extends liability to third parties**, thereby putting at risk of injunctions and provisional measures a wide variety of public health stakeholders, including: suppliers of active pharmaceutical ingredients used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs such as MSF who provide treatment; funders who support health programmes; and drug regulatory authorities who examine medicines. This could act as a significant deterrent to anyone involved in the production, sale or distribution of affordable generic medicines.

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[1] http://arstechnica.com/tech-policy/news/2010/06/india-launches-offensive-against-acta-cites-due-process.ars

Investment Chapter: The European Commission is also pushing for the trade deal to be expanded in scope so that it covers investments, including intellectual property, and supports an "investor-to-state" mechanism.

This would allow multinational drug companies to bypass the Indian judiciary and take the Indian government to private arbitration courts over investment disputes in relation to intellectual property, in order to seek to reverse domestic health policies like tobacco warnings and measures to reduce prices of medicines. Pharmaceutical companies must be given no additional avenues to pressure India on policies and laws that promote access to medicines. India is already reeling from multiple litigations filed by companies like Novartis and Bayer against health safeguards enshrined in India's patent law.

In order to ensure that the EU-India FTA does not undermine access to medicines, the additional threats posed by the enforcement and investment provisions must be addressed. At a minimum, we would urge the Indian Government to request the following safeguards are contained in the roadmap to ensure that damage caused to people's access to medicines is minimised:

- The withdrawal of the IP enforcement measures, and as a minimum safeguard, the deletion of patents from the entire scope of the enforcement section;
- The withdrawal of third party liability from the enforcement provisions;
- The withdrawal of specific provisions dealing with injunctions from the enforcement provisions in order to preserve the existing flexibilities of the Indian judicial system;
- Border enforcement should be limited to the requirements of the TRIPS Agreement and as such exclude exports and trademark infringements; and
- The withdrawal of IP and the investor-to-state mechanisms from the scope of the investment chapter.

India has already shown that it's prepared to stand firm against harmful demands from the European Commission. As the negotiations are reaching their final stages we urge you to maintain your vigilance and commitment to preserving the space for continuation of the generic production of medicines that we and so many in India and beyond rely upon.

Yours sincerely,

Dr Unni Karunakara
International President
Médecins Sans Frontières

c.c. Honourable Minister of Commerce and Industry of India Shri Anand Sharma
c.c. Honourable Minister of External Affairs of India Shri S. M. Krishna