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Karel de Gucht
European Commissioner for Trade
European Commission
Directorate General for Trade
Rue de la Loi, 200
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Geneva, April 6 2010

Dear Commissioner,

I write to you on behalf of Médecins Sans Frontières (MSF), an international aid organisation that provides emergency medical assistance to populations in distress in more than 80 countries. MSF has been providing antiretroviral therapy (ART) to people living with HIV/AIDS (PLHAs) since 2000.

We understand that both informal and formal negotiations between India and the European Union towards the signing of a Free Trade Agreement (FTA) are about to conclude. MSF would like to draw your attention to the harmful effects on access to medicines of proposals likely to be contained in the FTA.

India has played a pivotal role in supplying affordable generic versions of drugs used throughout the developing world. MSF for example sources over 80% of its antiretroviral medicines used in its AIDS projects around the world from India. The availability of fixed-dose combination therapy (or three-in-one pills) has revolutionised AIDS treatment, a fact we have witnessed first hand in our own programmes. Providing this form of treatment adapted to resource-poor settings in developing countries has only been possible because there were no patent constraints in India on putting these medicines together in one tablet. Currently 92% of people living with HIV on treatment in low- and middle-income countries use generic antiretrovirals manufactured in India.

Since 2005, India has developed a patent law that balances the need of patients to access life-saving medicines at affordable prices with pharmaceutical company profits. Specifically, India's Patents Act allows patient groups and other interested parties to oppose frivolous or abusive patenting through pre- or post-grant oppositions, and by defining stricter patentability criteria has prevented a practice known as evergreening where company monopolies can be endlessly extended.

Yet we are concerned that the EU-India FTA may contain provisions that dismantle this progress and represent a considerable step backwards, with dire consequences for access to medicines in India and the rest of the developing world. Restrictive provisions will have one major consequence with regard to access to medicines: they will

strengthen and extend the monopoly rights of multinational pharmaceutical manufacturers at the expense of patients in India and beyond. More specifically, these provisions all seek to limit, and in some cases completely block, generic competition. Generic competition has proven to be key in lowering the prices of medicines, thereby improving access to medicines.

We would like specifically to call your attention to the following concerns in FTAs negotiated by the European Union:

- **Data Exclusivity:** Data exclusivity provisions being pushed by the EU in FTA negotiations will delay, and could even prevent, the registration of generic versions of medicines - even when there is no patent on a medicine. The only alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would be medically unethical as it would involve replicating tests in humans to demonstrate what is already known to be effective. Further, data exclusivity could effectively block compulsory licenses.
- **Patent term extensions:** At present, patents on drugs in most countries last for 20 years from the date of filing. The EU seeks to extend the life of the patent by the length of time the drug regulatory authority takes to examine an application for registration, or a patent office takes to examine a patent application. The life of the patent would be extended beyond 20 years, extending the patent holder's monopoly position and preventing generic competition.
- **Enforcement and border measures:** Border measures that seek to detain imports or exports of good suspected of infringing intellectual property rights are of great concern to other developing countries as well as international agencies like MSF that procure their medicines from India. In 2009, Indian generic medicines, including crucial AIDS drugs, transiting through the EU en route to Africa and Latin America were detained by the European Union. The EU is now seeking to export the provisions of its customs regulations that allow such detentions to developing countries which could hinder the flow of lifesaving generic medicines.

The impact of such detentions is felt directly by patients awaiting the arrival of crucial generic medicines. Many countries do not have manufacturing capacity to produce medicines, or rely on importing more affordable generic medicines from India in order to treat their population. As such, the trade in legitimate medicines between countries is fundamental to ensuring access to medicines for millions.

None of these restrictive provisions are required under the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), and this is reaffirmed by the November 2001 Doha Declaration on TRIPS and Public Health.

Both the EU and India committed to the Doha Declaration and the Global Strategy and Plan of Action on Intellectual Property (GSPA), Innovation and Public Health adopted by the World Health Assembly in May 2008.

The GSPA adopts the principle of placing public health protection over commercial interests, and calls upon member states to *"take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights."*

In addition, the European Parliament, during its previous legislature, passed a Resolution on 12 July 2007 calling on the European Council "to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related

TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the (...) future bilateral and regional agreements with developing countries.”

During the hearing for your investiture, as new Commissioner for Trade, at the European Parliament on 12 January 2010, responding to concerns raised by MEP David Martin, chair of the European Parliament Working Group on Innovation, Access to Medicines and Poverty-related diseases, you promised to monitor “very closely” the continuing negotiations with India, to make sure the terms of any trade agreement reached “do not impede free trade in generic medicines” and said “I will take care of that”. Nevertheless, the policy currently being implemented by the Direction General for Trade, through this negotiation, does not reflect the political direction and commitment you made, either the EU commitment to the Doha Declaration, to the GSPA and to the European Parliament’s position, as cited above.

For patients living in India and all over the developing world, these provisions could mean the difference between life or death. It is crucial that generic competition remains possible in India. So many lives depend on it worldwide.

We therefore urge you to ensure that the negotiations lead by the European Commission’s representatives, on behalf of the European Union, do not contain intellectual property proposals that go beyond the requirements of the TRIPS Agreement.

Yours sincerely,



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Jerzy Buzek
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Mr Vital Moreira
President of INTA Committee, European Parliament