Mr Karel de Gucht,
Commissioner for Trade
200 Rue de la Loi
B-1049 Brussels, Belgium

Brussels, the 26th of March 2013

Re: Safeguarding access to medicines in the last stage of free trade negotiations with India

Dear Commissioner De Gucht,

We are writing to you to express our concerns as regards the final stage of negotiations of a free trade agreement (FTA) between the EU and India, which are anticipated to conclude by April 2013.

For years, Oxfam and Health Action International (HAI) Europe have raised serious concerns with intellectual property barriers that prevent access to affordable medicines for patients in developing countries. Access to medicines is a core element of the human right to health, and affordable medicines are critical to build sustainable health care systems. Thus, we have consistently advocated that intellectual property rules (IPR) in trade agreements should not threaten public health and the production and circulation of affordable generic medicines.

India plays a critical role to provide millions of people in India and around the world with quality generic medicines. Nicknamed the "pharmacy of the developing world", Indian generics companies produce approximately two-thirds of generic medicines and 80% of medicines to treat HIV and AIDS used in low and middle-income countries. It is therefore of the utmost importance that the EC refrains from pushing for the introduction of harmful IP rules in the negotiating text that could threaten the vital role played by generics firms in India to supply low-cost medicines.

While we appreciate the decision of the EC to publicly announce that data exclusivity and patent term extensions will not be included in the FTA, we are worried, based upon a negotiating text leaked in March 2013, that other problematic provisions that would undermine access to medicines remain.

In particular, two problematic chapters remain on the negotiating table and have alarmed civil society organisations around the world:

1. **Enforcement of IPR**: We are concerned that this chapter contains TRIPS-Plus provisions that would disproportionately favour multinational drug companies defending their patents at the expense of generic competition. Under these provisions, right holders could claim their IPRs are being infringed and without prior judicial review allow for delay, seizure or even destruction of generic medicine shipments. The inclusion in this chapter of intermediary liability triggers great concerns for all actors involved in the generic supply chain, including suppliers of active pharmaceutical ingredients, retailers and those who provide treatment. A strict injunction system, third party liability provisions and stringent border measures are elements of this chapter that could create serious difficulties that undermine generic competition.

2. **Investment chapter**: Two key concerns are that the investment chapter includes an investor-state dispute resolution mechanism and a broad scope that allows IPR to be characterized as "investment". India, under its TRIPS obligations, has already put in place balanced IP laws that guarantee the promotion of public health while also providing adequate and effective intellectual property protection. In recent years, investor-state disputes involving intellectual property, such as Eli Lilly vs Canada, and Philip Morris vs. Uruguay and Australia, illustrate how investor-state disputes can be used to pressure or prevent governments from using IP flexibilities for public health purposes. These cases legitimize the concerns that the "investor-to-state" arbitration mechanism might be used with increasing frequency by drug companies in the name of protecting their investments. The mechanism may be used to challenge national IPR laws for pharmaceuticals, relevant legal decisions and national public health measures.

We urge the EC to bear in mind access to medicines considerations while concluding the last stage of the negotiation and to refrain from pressuring India to accept TRIPS-plus IPR enforcement provisions, as well as a dangerous investment chapter that would reduce its political space to take pro-public health policies. TRIPS-plus provisions should be excluded from the text in order to allow India to remain the "pharmacy of the developing world".

We hope that our concerns will be heard and taken into consideration. We remain available to discuss further these issues if you wish so.

Yours faithfully,

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Cc: Mr Andris Piebalgs
Commissioner for Development