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Smt. Nirmala Sitharaman
Honourable Minister of State for Commerce & Industry (Independent Charge)
Room No. 45, Udyog Bhawan
New Delhi 110011

AC/IND/07/2014

22 August 2014

Re: Intellectual property negotiations in the Regional Comprehensive Economic Partnership

Dear Smt. Sitharaman,

Médecins Sans Frontières (MSF) is an independent international medical humanitarian organization that delivers medical care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries. In order to fulfil its mission, MSF requires access to affordable medicines.

We are writing to express our concern over the inclusion of intellectual property (IP) in the ongoing negotiations of the Regional Comprehensive Economic Partnership (RCEP)¹, a proposed free trade agreement of which India is now a negotiating member.

We know that at the third round of RCEP negotiations this year, an Intellectual Property Working Group (IPWG) was established. The Government of Japan speedily tabled a proposal—called the Elements paper—²with stringent IP text that exceeds WTO obligations.

Japan's negotiating text on IP is 'TRIPS Plus' and if accepted will roll back public health safeguards enshrined in international and Indian patent law. It will put in place far-reaching monopoly protections that restrict generic competition and keep medicine prices unaffordable for Médecins Sans Frontières' (MSF's) patients, for millions of others around Asia and across the developing world.

This is especially because the RCEP includes India. India, with a robust generics pharmaceutical industry manufactures two-thirds of all generic medicines, including over 80 per cent of all HIV medicines used in developing countries, is known as the 'pharmacy of the developing world'.

Generic competition has proven to be the most effective way to reduce prices of essential medicines and improve access to treatment. In 2001, the price of HIV medicines came down from \$10439 per patient per year to \$350 per person per year. Indian companies contributed to the price reduction by manufacturing generic versions of the medicines. This broke the market monopoly of a few multinational pharmaceutical companies. It has also translated into a reduction of the cost of some first-line HIV medicines—by 99 per cent—over the past decade. Since then health ministries, humanitarian medical treatment providers such as

¹ **Regional Comprehensive Economic Partnership (RCEP)** is a proposed free trade agreement (FTA) between the ten member states of the Association of South East Nations (ASEAN) and the six states with which ASEAN has existing FTAs – Australia, China, India, Japan, Korea and New Zealand. RCEP negotiations were formally launched in November 2012 at the ASEAN Summit in Cambodia. Till now there have been five rounds of negotiations.

² At the third round of the Regional Comprehensive Economic Partnership (RCEP) Negotiations, the Intellectual Property Working Group was established. In June 2014, Japan submitted a Elements paper to the Intellectual Property Working Group (IPWG) of the RCEP which includes a draft text on IP.

MSF, and donors have relied on affordable quality generic medicines to address global, regional and national public health challenges such as HIV, TB, Hepatitis and other diseases.

The freedom for Indian manufacturers to operate and produce affordable versions of new essential medicines is already severely curtailed. The reason is that in 2005, India, as part of its obligations under the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, was required to introduce a 20-year product patent regime. Stringent IP rules introduced under the RCEP would further undermine the ability of Indian generics companies to make, register and supply affordable versions of medicines required by treatment providers like MSF and health ministries.

India should reject all draft IP proposals that harm access to medicines and ensure that the final text is aligned with relevant global public health commitments, particularly the Doha Declaration on TRIPS and Public Health. Additionally, draft negotiating texts should be released at appropriate intervals for public review and input. Transparency can ensure that all viewpoints from concerned stakeholders are taken into account.

We acknowledge the Indian negotiating position in FTAs has been committed to systematically opposing attempts to impose greater restrictions on generic medicines production than required under international trade rules. This was first clearly reflected during the course of recent negotiations on the IP text in the India-Japan CEPA and in the EU-India FTA, with Indian negotiators standing firm against some of the most problematic IP provisions, such as data exclusivity and patent term extensions.

As negotiations on RCEP gain momentum in the coming year, we urge you to maintain your vigilance and commitment to monitor 'very closely' the continuing negotiations in the IPWG of the RCEP, to make sure the terms of any trade agreement reached 'do not impede free trade in generic medicines' that we and so many in the developing world rely upon.

MSF is preparing a detailed analysis of the 'Elements Paper' which we will share with you in the near future. We thank you for your attention and are available for further discussions and information.

Sincerely,



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