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Nearly 250 NGOs across world urge PM to reject IP provisions in FTA with EU

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Hundreds of public interest groups across the world have jointly urged prime minister Manmohan Singh not to sign the proposed free trade agreement (FTA) with European Union as the Centre's role in medicines supply is under threat due to the intellectual property provisions included in the pact.

The joint appeal signed by around 250 NGOs worldwide and prominent personalities came even as India and EU launched the crucial round of negotiations in Delhi to finalise the FTA which is expected to be signed by the end of this year. The letter had signatories representing patient groups, people living with HIV (PLHIV) networks, HIV & public health organisations, medical organisations, public interest groups and individuals.

Quoting from the recent studies, the letter said that India's generic production plays key role in AIDS treatment and about four million people started treatment between 2003 and 2008, largely due to India's ability to produce low cost quality medicines. Indian generic producers supplied the majority of ARVs in developing countries. Indian-produced generic antiretrovirals (AIDS drugs) comprised 87 per cent of ARV purchase volumes and accounted for 91 per cent of paediatric ARV volumes in 2008.

"We are therefore concerned that the Indian government may accept intellectual property (IP) provisions that will undermine the production, registration and worldwide availability of essential generic medicines. This is not the first time. India through a series of legal amendments in the last decade has already enforced the requirements for intellectual property protection under international law. The TRIPS agreement – which has bound India to introduce a product patent regime in 2005 - has already begun to curtail the country's ability to produce low-cost generic versions of newer HIV, hepatitis and cancer medicines," the letter said.

Because India signed the TRIPS Agreement, some new essential medicines already patented in India and cannot be domestically produced, have made patients in India and across the developing world without access to affordable versions of these medicines. Trade agreements being currently discussed - particularly the one with the European Union (EU) – will further restrict this access. If India signs up to the IP clauses demanded by the EU, which go significantly beyond TRIPS standards (TRIPS Plus), it will further reduce the country's ability to provide affordable essential medicines, the groups said.

“Patent term extension known as 'Supplementary Protection Certificates' in the negotiations, is a straightforward way to extend a pharmaceutical company’s monopoly by extending the patent life on a medicine beyond 20 years. If India accepts this clause, the years added to the patent in India are extra years in which the company can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition,” the letter said.

“The current text of the IP chapter on pharmaceutical test data as proposed by the EU to India essentially requires that India amend its drug regulatory legislation in a manner that will not permit the placing of a generic pharmaceutical product on the market if the originator has submitted any clinical trial data relating to the medicine to the Indian drug regulatory authority (Drug Controller General of India). If India accepts this clause, India’s drug regulator will be legally prohibited from registering a generic medicine as long as the exclusivity lasts over the trial data (usually several years). Generic producers will have to submit their own safety and efficacy data to register the generic. This will oblige generic companies to repeat clinical and pre-clinical trials. The repetition of trials raises grave ethical issues, as it would require withholding safe and effective medicines from some patients (the control group), solely for the purpose of proving something that is already known. This may not pass the scrutiny of ethical committees, making it difficult for generic companies to repeat the clinical trials. In addition, repetition of clinical trials will take time and involve costs that the generic producers usually cannot afford,” it said.

'The Indian government will be trading away our lives by agreeing to the EU’s demands on intellectual property and enforcement in FTA negotiations. We request India to not to trade away our lives and right to health in the name of another trade agreement. We request you to ensure that generic competition remains possible in India. So many lives depend on it worldwide,' the groups said.