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NGOs caution govt on designs of EU through on-going FTA negotiations

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Even as closed-door negotiations are going on between European and Indian negotiators on a Free Trade Agreement (FTA) between India and the European Union (EU), the public interest groups have warned the Indian government that through the FTA the European countries are aiming to achieve data exclusivity, extending the patent life and are also trying to prevent trade in medicines between developing countries.

Warning the government about the impact of data exclusivity, these groups said that if data exclusivity is introduced, it will create a new patent-like monopoly by blocking the registration of generic medicines. The drug companies are required to generate their own test data to register any generic medicine, this will impose huge costs on them. Given that the generic manufacturing model relies on low profit margins, this may even have the effect of killing off competition altogether.

Data exclusivity refers to a certain length of time during which a country's drug regulatory authority is prohibited from relying on available clinical trial data in order to register a generic medicine.

Generic drug can currently be registered if the manufacturer shows that its drug is therapeutically equivalent to an existing drug. There is no requirement for the generic company to conclude lengthy clinical trials to establish that it is safe and effective - relying on the original product data is sufficient for the drug authority to grant marketing approval.

In addition, the requirement to re-test a drug already proven to be safe and effective is medically unethical, because it forces a number of patients to take part in clinical trials which are not necessary, and requires some to take placebos in order to compare outcomes with the actual drug and therefore forego a proven treatment.

The public interest groups also warned that through the FTA, the EU wanted to extend the patent life. At present, patents on drugs in most countries last for 20 years from the date of filing. What the EU wants is that the life of the patent be extended 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 extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.

Warning the government that the EU is bent upon to prevent trade in medicines between developing countries, these groups said that recent cases of seizures of generic medicines from India on their way to developing countries in Latin America and Africa, detained by customs officials in Europe, highlight the danger of border protection

regimes based on intellectual property (IP).

IP customs enforcement rules which allow patent owners to petition customs officials to act "when goods are suspected of infringing an intellectual property right", hinder the flow of life-saving generic medicines.

The impact of such border measures is evident from the seizure of Indian generic medicines by the EU in 2008 and 2009. A total of 18 such seizures were made under the European Commission's Customs Regulation No. 1383/2003.

The EU customs regulations go beyond the obligations required under the TRIPS Agreement in relation to customs authorities. Yet of late, the EU has been attempting to export provisions of its own laws related to greater intellectual property enforcement and in particular on increased border measures through FTA negotiations, the public interest groups said.

The impact of such seizures 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.