NGOs, patient groups alert PMO not to act on behest of OPPI on patent issues

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A large number of patient groups, groups working on public health and HIV, public interest organizations, experts and concerned citizens have demanded to the Prime Minister's Office (PMO) to immediately withdraw the biased and one-sided notes which the PMO had reportedly circulated to the union ministries of commerce, health, legal affairs and chemicals at the urging of OPPI to amend key public health safeguards in the Patents Act including Section 3(d), and asking for patent linkages and data exclusivity.

The NGOs and experts in a letter to the PMO said that the OPPIs' demands are contrary to the Indian Constitution and Indian law, and will severely undermine access and availability of affordable quality generic medicines. "We regret that the PMO circulated this biased note without any prior investigation into the legitimacy of the claims or the fact that several demands made by OPPI and US and European Pharmaceutical companies are either sub-judice or have been rejected by Indian Courts keeping in mind the Government's constitutional obligations of life & health", the letter said.

Arguing against the OPPI's demand for weakening Section 3(d), the NGOs said that this Section has been crucial in keeping several life-saving drugs off patent. For instance, Novartis' patent application for a life-saving anti-cancer drug, imatinib mesylate, was rejected under section 3(d). If not, patients suffering from chronic myeloid leukaemia would have had to pay Novartis' price of Rs. 1,20,000 per month to continue to live. Due to section 3(d), they can purchase generic versions of the medicine at less than one-tenth the price.
It would be unfortunate and also against the interests of Indian public and Indian industry if the government negates this seminal provision, they said.

On the OPPI's demand for introduction of data exclusivity, the NGOs argued that data exclusivity is not a TRIPS requirement. The claim by MNC pharmaceutical companies that they require exclusivity to account for the period of time taken by clinical trials ignores the fact that TRIPS already extended patent protection from 14 years in most countries of the world to 20 years. At that time, it was admitted by every country that the 20 year period would take care of all expenses related to innovation & marketing of new drugs. Several developing countries have been pressured into adopting data exclusivity over the years, usually through pressure of free trade agreements.

Evidence of the impact of data exclusivity on prices & availability of medicines is now available. A recently released study of medicine prices in Guatemala has shown price differences in the same therapeutic class ranging up to 845000% because of data exclusivity.

In India the impact of data exclusivity would be far more severe as this measure not only undermines key public health safeguards like compulsory licencing as explained below but allows MNC pharma to completely bypass the impact of Section 3(d), the NGOs and experts warned the government, the letter said.

The NGOs and other groups further said that it is unclear as to the basis on which the PMO is taking these actions. The takeover of Indian companies and the high prices of patented medicines should prompt the PMO in another direction and certainly to unambiguously reject all TRIPS-plus measures regardless of which avenue they are being pushed through. The PMO's note comes at a particularly sensitive time for Indian generics, when they are being attacked as being "counterfeit", when there is an Anti-Counterfeiting Trade Agreement (ACTA) being negotiated and when developed countries like the EU and Japan are demanding TRIPS-plus measures in free trade agreement negotiations with India.