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SME, NGOs urge for policy measures to ensure issue of compulsory licences

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With the debate on the compulsory licensing (CL) gathering momentum after the Department of Industry Policy and Promotion (DIPP) brought out a concept paper, small scale pharma sector and the NGOs reiterated their demand for policy measures to introduce the same.

"India followed a strategy of incorporation of TRIPS flexibilities into domestic laws to address the concerns coming out of the product patent monopoly. Thus compulsory license constitutes an important TRIPS flexibility incorporated in the Indian Patents Act to use as a safeguard against the abuse of patent monopoly. Domestic manufacturing capacity is an important constituent element for the actual use of flexibilities in the country. India possesses this capability and placed itself in a strong wicket to use this flexibility," Federation of Pharmaceutical Entrepreneurs (FOPE) said in a representation to the DIPP.

"As far as SME sector is concerned we would like to develop a business model based on CL provisions of Indian Patents Act. However, certain bottlenecks hinder such efforts. These bottlenecks can be grouped into three: legal, institutional and policy," said the detailed note sent in response to DIPP paper calling for feedbacks from the stakeholders.

According to FOPE, the legal bottlenecks included the three year mandatory cooling period for granting CL and prior condition of obtaining commercial licence before applying for CL. Besides, Patents Act does not provide any time limit for the disposal of a CL application. Hence, there is no predictability with regard to the time frame wherein which one can obtain a CL. There is no ceiling on royalty as a result one may demand extreme royalty as a condition for granting for CL. There are a lot of procedural requirements which needs to be fulfilled to obtain a CL, the organisation said.

"SME sector obtaining a CL under Section 84 is complicated if not impossible. Amendment of statute and rules are the only effective long lasting remedy in this context. But it is a time consuming process. Therefore Government should invoke Section 92A to declare at least certain diseases as a condition of national emergency or extreme urgency," it said.

The Federation also pointed out there are a number of institutional hurdles like the absence of institutional mechanism to invoke stipulated provisions. It called for positive policy directions like excise duty exemption for a product which is produced under CL on public health grounds. The FOPE wanted that the government should give some form of subsidy or grant for the expenses incurred for the product development and regulatory

clearance for a product under CL.

Médecins Sans Frontières (MSF) campaigner Leena Menghaney who represented the NGO in the recent meetings with the Department of Pharmaceuticals on the issue also reiterated that the stand of the NGOs was clear and open that India should go for the compulsory licensing as the best way to ensure access to medicines.