US watch list may hit affordable drug biz

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Mumbai: The United States Trade Representative's (USTR's) 2016 edition of a 'Special 301 Report' targeting countries including India by putting these on a 'priority watch list' has been criticised by health activists, saying any change in India's patent laws will restrict the country's ability to produce affordable medicines.

India remains on the priority watch list and continues to be singled out for what the USTR considers to be inadequate protection of intellectual property (IP) for its pharmaceutical industry. They say, India is the world's principal producer and supplier of quality generic medicines, including for US-funded treatment programmes like PEPFAR that support anti-retroviral treatment in developing countries. Also, two-thirds of all drugs procured for international medical aid to treat HIV, TB and malaria come from India.

The 301 report clearly attacks section 3(d) of the Indian Patent Act and the fact that, through the application of a stricter patentability standard, a number of evergreening claims have been denied patent protection. The 301 report states that "the United States also continues to monitor India's application of its compulsory licensing law".

Yet, India's laws and policies promote generic competition and limit abusive pharmaceutical industry practices, including patent 'evergreening', and are entirely consistent with the established norms of the WTO. India is a compliant with WTO trade rules, the international medical humanitarian agency Médecins Sans Frontières (MSF) said in a statement.

Indian Pharmaceutical Alliance director general D G Shah had told TOI earlier, "India's stance is that the current patent regime is fully TRIPS compliant and strikes the appropriate balance between the grant of monopoly patent rights and public health imperatives."

In response to a parliamentary question, Union minister for commerce and industry Nirmala Sitharaman, made a statement recently regarding the USTR report, "The Special 301 Report is a unilateral measure to create pressure on countries to enhance IPR protection beyond the TRIPS agreement. Under the WTO regime, any dispute between two countries needs to be referred to the Dispute Settlement Body of the WTO and unilateral actions are not tenable under this regime. Special 301, which is an extra-territorial application of domestic law of a country, is inconsistent with the established norms of the WTO. The government is committed to fully utilizing all the flexibilities provided under the TRIPS agreement to protect domestic pharmaceutical sector from pressure warrants by the foreign countries."

In June 2015, MSF launched a campaign 'Hands Off Our Meds' to urge PM Narendra Modi to stand strong in the face of intensifying pressure from the US to change India's laws in ways that would severely restrict the country's ability to produce affordable medicines.