

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:1878
ANSWERED ON:17.12.2013
GENERIC VERSION OF CANCER DRUG
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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the Supreme Court has directed the Government not to change the present pricing policy for life-saving drugs;
- (b) if so, the details thereof along with the reaction of the Government thereto and the progress achieved in the implementation of the National Pharmaceutical Pricing Policy, 2012;
- (c) whether the Supreme Court has allowed the manufacturers to continue making generic version of Glivec cancer drug in a recent judgement;
- (d) if so, the extent to which this judgement is likely to help the large number of cancer patients in the country and also the Indian pharmaceutical companies to introduce modernized version of generic drugs; and
- (e) the extent to which this judgement is likely to affect the new inventions and investment by foreign companies and availability/scarcity of good quality of drugs to the patients?

Answer

MINISTER OF THE STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF THE STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION (SHRI SRIKANT KUMAR JENA)

- (a) No such final order has been given by the Hon'ble Supreme Court.
- (b) In view of reply to (a) above, does not arise.
- (c) to (e) The judgment of the Supreme Court in the case of M/s Novartis AG vs Union of India deliberates upon the patentability of the invention claimed by M/s Novartis in its application filed in the patent office, Chennai on 17th July, 1998. The Supreme Court has decided that

the said invention fails in the test of invention and patentability as provided under Sections 2(1)(j), 2(1)(ja) and 3(d) of the Patents Act, 1970. Accordingly, the SLP filed by M/s Novartis was dismissed. The said judgment does not contain any orders in respect of manufacturing of generic version of cancer drug Glivec. In light of the said judgment, the cancer drug Glivec as the beta crystalline form of Imatinib Mesylate is not a patented product and hence there is no restriction on the generic drug manufacturing companies for manufacturing the said drug. The Indian's IPR regime is fully compliant with TRIPS Agreement. As such, there is no reason for any foreign company to be apprehensive about protection of IPRs and effect on the new inventions and investment by foreign companies and availability of good quality of drugs to the patients in India.