

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

UNSTARRED QUESTION NO:395
ANSWERED ON:06.08.2013
PRICES CONTROL ON PATENTED DRUGS
Karwariya Shri Kapil Muni

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the National Pharmaceutical Pricing Authority (NPPA) had informed that it cannot fix the prices of patented drugs and most imported medicines used for treatment of diseases such as cancer and requested the Government to make necessary law to control the prices of imported drugs;
- (b) if so, the details thereof and the reaction of the Government thereto;
- (c) whether the Government is considering amendments to the drug pricing law to authorise NPPA to seek the details of landed cost of medicines and fix the prices accordingly;
- (d) if so, the details thereof; and
- (e) the comprehensive measures being taken by the Government to control the prices of imported drugs?

Answer

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

(a) to (e): Government has notified the Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May 2013 in supersession of DPCO, 1995. There are 33 anti-cancer drugs included in the first schedule of DPCO, 2013 and as such presently brought under price control. As per the provisions of DPCO, 2013 the ceiling prices notified by the Government are applicable to Scheduled imported formulations also.

Provisions of DPCO, 2013 do not apply to

- i. a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country; and
- ii. a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of commencement of its commercial production in the country.