

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

STARRED QUESTION NO:316

ANSWERED ON:17.08.2004

GENERIC DRUGS

Mishra Dr. Rajesh Kumar;Thummar Shri Virjibhai

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

- (a) whether any policy decision for altering the norms of value ceiling for monitoring the prices of medicines in the country has been taken;
- (b) if so, the details thereof;
- (c) whether Operation Research Group (ORG) does not monitor sale of generic drugs;
- (d) whether some big generic drugs companies from the western countries are likely to start manufacturing these brands in India;
- (e) if so, the impact thereof on Indian Pharmaceutical Companies manufacturing the same formulation; and
- (f) the remedial steps to be taken by the Government in this regard?

Answer

THE MINISTER OF CHEMICALS , FERTILIZERS & MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

(a) to (e) : A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARTS (a) to (f) OF THE LOK SABHA STARRED QUESTION NO. 316 (15th position) FOR ANSWER ON 17-8-2004 REGARDING ' GENERIC DRUGS'

The Government, vide a resolution dated 29.8.1997, have constituted the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts with powers, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, from time to time under the Drugs (Prices Control) Order, 1995 (DPCO, 1995). According to the resolution, the NPPA shall have the power to regulate its own procedure for performing the functions entrusted to it. The procedures and systems for monitoring of the prices of non-Scheduled formulations have been decided in the Authority from time to time. These guidelines are uniformly followed for monitoring the whole Pharma market as per monthly Retail Audit Reports of ORG-IMS Research Pvt. Ltd. Quite a few generic products are covered in the monthly audit. This Ministry has no specific information regarding any big generic drug company from western countries likely to start manufacturing in India.