GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

STARRED QUESTION NO:199
ANSWERED ON:11.12.2008
SALE OF UNAPPROVED BRAND OF MEDICINES
Gaikwad Shri Eknath Mahadeo;Mane Smt. Nivedita

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

(a) Whether the National Pharmaceutical Pricing Authority (NPPA) had recently announced that drug makers altering the strength or changing the ingredients of their brands to skirt price control and increase retail price of their formulations would face action;

(b) if so,the details thereof;

(c) whether the announcement was made after receipt of some complaints in this regard

(d) if so,the details thereof;and

(e)the action taken by the Government thereon against the manufacturers involved?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

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

STATEMENT REFERRED IN REPLY TO PARTS (a) to (e) OF THE LOK SABHA STARRED QUESTION NO.199 FOR ANSWER ON 11.12,2008 REGARDING SALE OF UNAPPROVED BRAND OF MEDICINES

NPPA does not have powers for approving the strengths or the ingredients or the dosage of medicines for sale in the market. These powers are vested under the Drugs & Cosmetics Act, 1940 and Rules,1945 to the Drugs Controller General of India (DCGI).However, Para 8(6) of Drug Price Control Order, 1995 provides that no manufacturer/importer shall market a new drug not covered by a price order issued by NPPA or a new dosage form of any existing scheduled formulation without obtaining the prior approval of its price from the Government/NPPA.The responsibility of taking the requisite price approval from NPPA under the DPCO`1995, therefore, is on the manufacturer or importer and also on the DCGI to inform NPPA of such approvals.

The matter has repeatedly come to the notice of Government/NPPA. During the past few months the Department has taken up the matter with the DCGI under intimation to NPPA. Given the aforesaid circumstances in which NPPA does not have powers and having regard to the fact that the responsibility of approving such products of the changed composition, dosage form, etc.is vested in the DCGI; NPPA take recourse to fixing prices of scheduled formulations as and when this information comes to its notice. In addition, NPPA takes action for detection of such scheduled formulations selling in the market without the required approval of price for NPPA by a variety of measures. Such measures include monitoring the prices of all scheduled formulations to the extent information is available in the ORG IMS monthly report to NPPA,information provided by different State Drug Controllers (since NPPA does not have any separate field organization), information from NGOs and other sources as also through market surveillance such as procurement of samples from the open market and analysis of their prices etc.

Whenever it comes to the knowledge of NPPA that any company is manufacturing/marketing scheduled medicines in new dosages/composition (other than the doses/composition for which ceiling price exist) which have not been notified by the NPPA (i.e.selling without price approval); NPPA regularly issues Show Cause Notice to the defaulting companies and take appropriate action as per the provisions of DPCO`95 including fixing celling price of the Formulation.