

New Drugs (Prices Control) Order

352. SHRI SANJAY RAUT: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the new Drugs (Prices Control) Order notified recently has increased the number of essential drugs and capped their prices using simple average price formula, if so, the details thereof;

(b) whether according to Senior Director and Life Sciences leader at consulting firm, Deloitte Touche Tohmatsu's Indian arm, a string of issues, ranging from patents and drug safety to pricing and foreign direct investment norms have put the approximately ₹ 1 lakh crore Indian pharmaceutical industry in uncertainty; and

(c) if so, the response of Government thereto?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR): (a) The Government notified the National Pharmaceutical Pricing Policy-2012 and subsequently notified the new Drug (Prices Control) Order (DPCO), 2013 on 15.05.2013 to control and regulate the prices of medicines in the country. The medicines of dosages and strengths as specified under National List of Essential Medicines (NLEM)-2011 have been brought under price control based on a concept of Ceiling Price by having the Simple Average Price of all the branded and/or generic versions of such medicine having market share more than and equal to 1% of the total domestic market turnover of that medicine. The medicines not listed under NLEM-2011 are under monitoring and no manufacturer can increase the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months.

(b) Regarding patent regime, the amendment in the Patent Act, in 2005, extended grant of product patent to all technologies including pharmaceuticals. Since 2005 there have been no further amendments to the Act. As such India has a stable patent regime. Regarding drug safety, the Central Drugs Standard Control Organization (CDSCO) has not received any such information. The quality and safety of the drugs imported, manufactured and sold in the country is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under. Regarding pricing, the Government has notified Drug (Prices Control) Order (DPCO), 2013 on 15.05.2013 to control and regulate the prices of medicines in the country. The medicines of dosages and strengths as specified under National List of Essential Medicines (NLEM)-2011 have been brought under price control and the medicines not listed under NLEM-2011 are under monitoring and no manufacturer can increase the maximum retail price of a drug more than ten percent of maximum

retail price during preceding twelve months. Regarding Foreign Direct Investment (FDI), at present in pharma Sector FDI upto 100% is allowed under automatic route for greenfield investment. In order to safeguard the domestic generic industry, in case of brownfield investment FDI upto 100% is allowed through Government route (*i.e.* Foreign Investment Promotion Board) in the pharma sector.

(c) In view of reply (b) above, does not arise.

Redressal of grievances under Pharma Jan Samadhan

353. SHRI AVINASH PANDE: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) The number of complaints received under the Pharma Jan Samadhan grievance redressal system created by the National Pharmaceutical Pricing Authority (NPPA); and

(b) The detailed break-up of the nature of complaints received and redressed?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR): (a) and (b) The web portal Pharma Jan Samadhan (PJS) was launched on 12th March, 2015 for speedy and effective complaint redressal system regarding (i) availability of medicines, (ii) overpricing of medicines, (iii) sale of 'new drugs' without prior price approval, and (iv) refusal of supply or sale of medicines.

The details of complaints registered on PJS and redressal of such complaints since introduction of the PJS are as follows:

Particulars	Nos.
Overpricing	18
Shortage	134
Refusal to sell	147
Without price approval	2
TOTAL	301
Action taken/Disposed off	301

Shortage of subsidized fertilizers

354. SHRI MOHD. ALI KHAN: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the details of subsidy being provided to farmers in the country; and