

Availability of Cheaper Medicines

3290. SHRI GOVINDRAO ADIK :

SHRI SANJAY RAUT :

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

(a) whether Government is considering to a long standing demand of public disclosure of every medicine patented in the country to bring more transparency and availability of cheaper medicine, particularly expensive cancer and HIV drugs in the market; and

(b) if so, the details of steps taken or proposed to be taken to prevent generic drug maker from launching a cheaper version of drug by patent holders?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT JENA): (a) The details of patents granted in India can be obtained from the website www.ipindia.nic.in of Controller General of Patents Designs and Trademarks.

At present, the prices of medicines including Cancer and HIV Drugs in the country is regulated as per the provision of Drugs (Prices Control) Order, 1995. All the manufacturers are required to follow the price fixed by NPPA for the scheduled drugs. As for non-scheduled drug no person can sell any formulation (medicines) of price controlled category to a consumer at a price exceeding the price notified/approved by the NPPA/Government. In respect of drugs - not covered under the Drugs (Prices Control) Order, 1995 i.e. nonscheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government/NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities/packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc.

As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG IMS(now renamed as IMS Health) and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, subject to prescribed conditions, the manufacturers is asked to bring down the price voluntarily failing which

action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process.

(b) As per Section 48 of the Indian Patent Act, 1970 (as amended from time to time), it confers upon the patentee:

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

Control on prices of drugs

3291. SHRI RAJIV PRATAP RUDY: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that several pharmaceutical products in the market are priced exorbitantly and are out of the reach of common man;

(b) the steps taken by Government to ensure that pharmaceutical companies are stopped from charging from patients beyond a limit;

(c) whether there is lack of regulation and checks to control the prices of drugs in the country; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT JENA): (a) and (b) Under the provisions of the Drugs (Prices Control) Order, 1995 (DPCO, 95) prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled. National Pharmaceutical Pricing Authority (NPPA) fixes or revises prices of scheduled drugs / formulations as per the provisions of the DPCO, 95. The NPPA monitors the prices of all formulations including imported scheduled formulations under price control. Under the provisions of DPCO, 95, no person can sell any scheduled formulation (medicine) to a consumer at a price exceeding the price notified/approved by the NPPA/Government.