

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO. 134  
TO BE ANSWERED ON 15<sup>TH</sup> DECEMBER, 2017**

**PATENTED DRUGS**

**134. SHRI RAJESH RANJAN:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether only 5 percent drugs are patented in the country at present and if so, the action plan of the Government to increase the number of patented drugs at local level;
- (b) whether the patients have to face a lot of trouble due to delay in approving new drugs by the Government at global level in view of the fact that presently there are 30 lakh cancer patients in the country;
- (c) the number of drugs provided by the Government at affordable rates in the country along with the criteria to select such drugs and whether the Government is considering to include more drugs in the list of affordable drugs; and
- (d) whether difficulties arises in controlling the prices of patented medicines due to its shortage in the country if so, the steps taken by the Government in this regard ?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): As per data made available by Indian Patent Office, the number of patents granted by Indian Patent Office in pharmaceutical field from 2005-06 onwards, is as below:

Year	Patents Granted
2005-06	457
2006-07	798
2007-08	905
2008-09	1207
2009-10	530
2010-11	596
2011-12	282
2012-13	344
2013-14	256
2014-15	389
2015-16	370
2016-17	551
2017-18 (Upto 31/10/2017)	398
<b>Total</b>	<b>7083</b>

(b): As and when the applications for grant of permission to import/ manufacture and marketing of any new drug including anticancer drugs are received by Central Drugs Standard Control Organisation (CDSCO), the applications are evaluated in consultation with the Subject Expert Committees (SECs) and permission is granted in accordance with the Drugs and Cosmetics Rules, 1945 and the applicable guidelines based on the recommendation of the Committee. There are provisions under the Drugs and Cosmetics Rules, 1945, under which permission to import/manufacture for marketing of new drugs can be granted without local clinical trial under certain conditions to make such drugs available early in the country in public interest.

(c): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed the ceiling price of 849 essential medicines to make them affordable. Further, affordable Medicines and Reliable Implants for Treatment (AMRIT) Deendayal Pharmacies are being opened by M/s HLL Lifecare Ltd., a PSU under the Ministry of Health and Family Welfare, with an objective to make available drugs and implants at discounted prices to the patients suffering from Cancer and Cardiovascular Diseases.

(d): In the Drug (Prices Control) Order 2013, only Indian patents based on the indigenous research and development are recognized for price control exemption.