

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:4339  
ANSWERED ON:08.08.2014  
ACTION AGAINST DRUG MANUFACTURERS  
De(Nag) Dr. (Smt.) Ratna;Singh Shri Pashupati Nath

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

- (a) whether the Drugs Controller General of India (DCGI) has issued any circular according to which manufacturers are required to launch the new drug within six months from the date of the grant of the permission and, if so, the details thereof;
- (b) whether many drug manufacturers have been found guilty of the noncompliance of the said condition, if so, the details thereof along with the action taken/ proposed to be taken by the DCGI against them;
- (c) whether the DCGI has ordered certain drug manufacturers to get prior approval for sale of their new drugs being marketed in the country, if so, the details thereof; and
- (d) the action taken/proposed to be taken by the Government against the drug companies for not complying with the said order?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

- (a): A letter addressed to All State Drugs Controllers was issued on 10.01.2013 requesting to instruct all the manufacturers that in case the applicants/ manufacturers fail to launch their new drugs within six months after getting approval from CDSCO, the permission/ License obtained from CDSCO will be treated as cancelled.
- (b): No case of non-compliance with the aforesaid condition has been reported.
- (c): No such order has been issued by the DCG(I) in the recent past.
- (d): Does not arise.