

**GOVERNMENT OF INDIA  
CHEMICALS AND FERTILIZERS  
LOK SABHA**

UNSTARRED QUESTION NO:1955  
ANSWERED ON:23.08.2012  
OFF-PATENT OF BLOCKBUSTER DRUGS  
Das Shri Khagen

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

- (a) Whether the `blockbuster drugs` have gone off-Patent and US Drug Administration has also cleared their generic versions during the last four months;
- (b) If so, the details of such drugs;
- (c) Whether the Indian pharmaceutical companies have a huge opportunity in its production and sale;
- (d) if so, the details thereof; and

**Answer**

THE MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) and (b) A block buster drug is one which has at least drug sale of US\$ 1 bn and such drugs becoming off-patent in US market is a continuous process. US drug Authority (USFDA) regularly approves generic versions of such off-patented drugs. As informed by Pharmaceutical Export Promotion Council, generic version approvals have been given to Indian Companies by USFDA during 2010 and 2011 for the following block buster drugs :

S.No. Name of Molecule

1. Lipitor (Atorvastatin)
2. Plavix (clopidogrel)
3. Seroquel (Quetiapine fumarate)
4. Zyprexa (olanzapine)

(c) and (d) Though the price value of block buster drugs significantly decreases as a generic version, there is good opportunity for all generic companies who obtain product approvals and market the product in the US.