

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

UNSTARRED QUESTION NO:4915
ANSWERED ON:25.04.2013
CAPITALISATION OF OFF PATENTED DRUGS IN US
Das Shri Khagen

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

- (a) Whether many drugs are likely to fall-off the patent cliff in US during the next few year;
- (b) if so, the details of such drugs;
- (c) whether the Government is planning to facilitate the Indian generic companies to capitalize on the opportunity; and
- (d) if so, the details thereof?

Answer

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

(a) & (b) As per Mckinsey & company study "Capturing the India Advantage" quoted in the Report of Working Group on Drugs & Pharmaceuticals Industry constituted for the XII Five Year Plan (2012-2017), US\$ 300 billion are expected to go off patent by 2015 for conventional molecules and Biopharma. Factoring for the reduction in price and the consequent market value from patent to generics this is estimated to be at least 30-35% which translates to some US\$ 100 Billion.

(c) & (d) Department of Biotechnology has intimated that they in collaboration with Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, New Delhi developed "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India- 2012" through consultative process with the involvement of various stakeholders including industry representatives. These Guidelines streamline the regulatory process and provide guidance & documentary support to develop safe, efficacious, affordable, and quality similar biologics (biogeneric drugs) and also facilitate Indian generic pharmaceutical companies to capitalize on the opportunity on account of fall-off the patent cliff in the US during the next few years.