

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

UNSTARRED QUESTION NO:1100
ANSWERED ON:28.11.2014
QUALITY OF GENERIC DRUGS
Chautala Shri Dushyant;Mahto Dr. Banshilal

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

- (a) whether the Government has permitted the small pharmaceutical companies to manufacture generic drugs to make them cheaper in the country, and if so, the details thereof;
- (b) the mechanism put in place by the Government to ensure the quality and efficacy of the generic life saving drugs manufactured by the small pharmaceutical companies;
- (c) the steps taken/proposed to be taken by the Government to ensure that the doctors prescribe generic drugs to the patients in the country; and
- (d) the measures being taken by the Government to popularise and promote the generic names of drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

- (a): The size of a pharmaceutical manufacturing company is not a consideration for issuing licenses to manufacture drugs.
 - (b): The manufacture for sale of drugs is regulated through a system of inspection and licensing. The manufacturer, whether large or small, is required to comply with the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that drugs manufactured by them are of standard quality.
 - (c) & (d): The Government has from time to time been issuing repeated circulars/ instructions to all Central Government hospitals, CGHS dispensaries and State Governments for encouraging/ motivating doctors to prescribe generic medicines. Instructions have also been issued that all Central Government hospitals provide only good quality generic medicines, and that whenever any branded medicine is prescribed, it shall invariably mention that any other equivalent generic medicines could also be provided.
- The Code of Medical Ethics under Indian Medical Council Regulations, 2002 also provides that every physician should, as far as possible, prescribe drugs with generic names and ensure that there is a rational prescription and use of drugs. Directions have also been issued to all the State/ UT Governments on 1.10.2012 to grant/ renew licenses to manufacture for sale or for distribution of drugs in proper/ generic names only.