GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4547
ANSWERED ON:19.12.2014
QUALITY AND SAFETY OF GENERIC DRUGS
Gavit Dr. Heena Vijaykumar;Mahadik Shri Dhananjay Bhimrao;Mahto Dr. Banshilal;Patil Shri Vijaysinh Mohite;Satav Shri Rajeev Shankarrao;Sule Smt. Supriya Sadanand

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

(a) whether certain pharmaceutical companies are reported to be manufacturing and marketing untested generic drugs in the country, and if so, the details thereof;

(b) whether the Indian Council of Medical Research have taken up the matter with the Drug Controller General of India (DCGI) for action against such erring companies, and if so, the details thereof;

(c) the action taken/proposed to be taken by DCGI against such pharmaceutical companies; and

(d) the measures being taken by the Government to ensure the safety, quality and efficacy of generic drugs in the country?

Answer

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

(a): The Government is aware of the reports appearing in the media regarding manufacturing of generic versions of some drugs without proper testing.

(b): Yes.

(c): Action as permissible under the Drugs & Cosmetics Act, 1940 and the rules made thereunder, will be taken by Drugs Controller General (India) after verification of facts.

(d): The manufacture for sale of drugs is regulated through a system of inspection and licensing under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. The manufacturer is required to comply with the conditions of license and follow the Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are of standard quality. One of the conditions of the license is that the licensee shall either in his own laboratory, or in any other laboratory approved by the Licensing Authority, test each batch of the raw material used by him for manufacturing products as also each batch of the final product and shall maintain records showing the particulars of such tests.