GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:6907
ANSWERED ON:08.05.2015
BIO SIMILAR DRUGS
Galla Shri Jayadev

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

(a) the policy formulated by the Government with regard to manufacturing and sale of bio-similar drugs in the country along with the definition thereof;

(b) the number of pharmaceutical companies to whom permission has been given to manufacture bio-similar drugs in the country;

(c) whether the Government has drawn any action plan to promote manufacturing of bio-similar drugs in view of its growing demand in the world; and

(d) if so, the details thereof along with the various modalities worked out for the purpose?

Answer

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

(a): The manufacture and sale of drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules there under. The term bio-similar is not defined in the Drugs and Cosmetics Act and Rules there under. Presently, new drugs including Recombinant Deoxyribonucleic Acid (r-DNA) products that fall under the category of biosimilar drugs are regulated in accordance with the provisions of the Rules 122A, 122B, 122D and 122E and Schedule Y of Drugs and Cosmetics Rules to ensure their safety, efficacy and quality.

(b): Permission to manufacture r-DNA drugs which fall under the category of biosimilar drugs has been granted to 22 Indian pharmaceutical companies.

(c) & (d): While the Ministry of Health & Family Welfare is mandated to regulate the quality, safety and efficacy of drugs including r-DNA products, the Government is committed to ensure all round growth of the pharmaceutical sector including in the area of biosimilars through efforts such as 'Make in India'.