GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1857
TO BE ANSWERED ON THE 14th March, 2017

Licence to Pharma Companies

†1857. SHRIMATI KAMLA DEVI PAATLE:

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

(a) whether India is the biggest manufacturer and exporter of generic medicines in the world and if so, the details thereof;
(b) whether the Government has formulated any uniform procedure to award licence to the generic drugs pharmaceutical companies;
(c) if so, the details of the companies to which licence has been awarded, Statewise; and
(d) the steps taken/proposed to be taken by the Government to provide protection to the indigenous generic drugs manufacturers from the multinational pharmaceutical companies?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): As per the report of Working Group on Drugs and Pharmaceutical Industry 12th Five Year Plan (2012-2017), the Indian Pharmaceutical Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production.
(b): Central Drugs Standard Control Organization (CDSCO) regulates safety, efficacy and quality of the drugs under the provisions of Drugs & Cosmetic Act, 1940 & Rules, 1945 made there under. Under the provision of Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under State Licensing Authorities (SLAs) appointed by State Governments are empowered to grant license for manufacture for sale, sale or distribution of drugs in the country in accordance with the provisions of the Act and Rules. However, for manufacture of a new drug in the country prior permission/ approval is required to be obtained from CDSCO. The new drugs are approved in proper name/ generic name.
(c): The details of the companies to which manufacturing licences has been granted by State Licensing Authorities are not maintained at Central level.
(d): Requirements for grant of licence to manufacture drugs for sale are prescribed in Drugs and Cosmetics Act, 1940 and Rules, 1945, which are same for indigenous drugs manufacturers and multinational pharmaceutical companies.

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