GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1239
TO BE ANSWERED ON THE 27th July, 2021

Manufacture of Fake Medicine

1239. SHRI MANOJ TIWARI:

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

(a) whether the Government has any proposal to make strict laws regarding the manufacture of fake medicines which was very evident during the second wave of the COVID-19 pandemic in the country;
(b) if so, the details thereof;
(c) if not, the reasons therefor; and
(d) the details of its impact on the pharma sector?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI MANSUKH MANDAVIYA)

(a) to (d): As per Central Drugs Standard Control Organisation (CDSCO), manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 made there under through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Manufacturer/Licensees are required to comply with all the condition of license and follow Good Manufacturing Practices (GMP) as prescribed in Schedule M to Drugs Rules to ensure that the drugs manufactured by them are safe and of standard quality. The State Licensing Authorities are empowered to take action against any violation of the conditions of licenses.

Further, in order to harmonize the good manufacturing Practices (GMP) in line with WHO guidelines, Draft Rules have been published vide GSR No 999 (E) Dated 05.10.2018 for amendment in Schedule M of the Rules for ensuring quality of drugs manufactured in the Country.

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