

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 864
TO BE ANSWERED ON THE 29TH NOVEMBER 2024

Fresh GMP norms for Small Drug Firms

864. Shri Bhartruhari Mahtab:

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

- (a) whether the Government will shortly notify a revised version of Good Manufacturing Practices (GMP) at par with the WHO standards, for small pharmaceutical companies with an annual turnover of less than Rs. 250 crore; and
(b) if so, the details thereof?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SMT. ANUPRIYA PATEL)**

(a) & (b): Manufacturers of drugs for sale in the country are required to comply with the requirements as prescribed under Schedule M of the Drugs Rules, 1945.

The Government of India has published Gazette notification vide G.S.R. 922(E) dated 28.12.2023 to amend the Drugs Rules, 1945 for revising the Schedule M regarding Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.

As per the amendment, the revised Good Manufacturing Practices and Requirements are as under:

Category of manufacturers [Based on turnover (INR)]	Time line for implementation
Large manufacturers (Turnover > 250 crores)	Six months from the date of publication of the notification
Small and Medium manufacturers (Turnover < 250 crores)	Twelve months from the date of publication of the notification.
