GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 152
TO BE ANSWERED ON 02ND FEBRUARY, 2024

QUALITY OF PHARMACEUTICAL PRODUCTS

152: DR. PON GAUTHAM SIGAMANI:

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

(a) whether it is a fact that the Government has notified revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945 in the country and if so the details thereof;

(b) whether it is a fact that the Government has set a six-month deadline for small manufacturers and a twelve-month deadline for large units to get the World Health Organisation Good Manufacturing Practices certification in the country;

(c) if so, the details thereof;

(d) whether it is a fact that the revised rules emphasize that manufacturers must assume responsibility for the quality of pharmaceutical products to ensure that they are fit for their intended use, comply with the license requirements license, and do not place patients at risk due to inadequate safety, quality or efficacy; and

(e) if so the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): 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 shall come into force for manufacturers for implementation 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 these rules.
Small and Medium manufacturers (Turnover ≤ 250 crores)	Twelve months from the date of publication of these rules.

(d) & (e): As part of Pharmaceutical Quality System (PQS) mentioned in the above notification, the manufacturer must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the licence and do not place patients at risk due to inadequate safety, quality or efficacy.

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