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

RAJYA SABHA
UNSTARRED QUESTION NO.269
TO BE ANSWERED ON 04TH FEBRUARY, 2025

REGULATORY FRAMEWORK FOR BIOSIMILAR DRUGS

269: SHRI M. MOHAMED ABDULLA:

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

(a) whether it is a fact that there are inadequate regulatory laws to evaluate the safety and efficacy of biosimilar drugs manufactured by Indian competitors and if so, the steps taken thereon;

(b) whether Government has any plans to implement a new regulatory pathway for biosimilar drugs;

(c) if so, the details thereof and If not, the reasons therefor; and

(d) the measures being taken to ensure international compliance and competitiveness of Indian-manufactured biosimilar drugs in global markets?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (d): New drugs including similar biologics are regulated under the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940.

Detailed requirements and guidelines for grant of permission to import or manufacture of new drug including similar biologics are prescribed under Second Schedule of New Drugs and Clinical Trials Rules, 2019.

Further, the Guidelines on similar biologics, adopted in 2012, revised in 2016, specifies regulatory pathway regarding manufacturing process, safety, efficacy and quality aspects for similar biologics. These processes remain harmonious to International approaches.

Schedule M (Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products) has been revised vide Notification dated 28.12.2023 in-line with global requirements to ensure the quality of drugs manufactured in India including similar biologics.

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