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

RAJYA SABHA
STARRED QUESTION NO. 239
TO BE ANSWERED ON THE 17TH DECEMBER, 2024

GUIDELINES OF DCGI ON RECALL OF DRUGS, GOOD DISTRIBUTION PRACTICE AND AGAINST CONFUSING BRANDS

239 SHRI A. D. SINGH:

Will the Minister of Health and Family Welfare be pleased to state:

(a) whether guidelines issued by Drug Controller General of India (DCGI) on recall of drugs, good distribution practice and against confusing brands are having no force of law;

(b) if so, the details thereof;

(c) whether these guidelines have not been incorporated in the rules;

(d) if so, the reasons therefor;

(e) whether Government will incorporate these guidelines in the rules, so that their enforceability can be ensured; and

(f) if not, the reasons therefor?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (f) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 239 * FOR 17 TH DECEMBER, 2024

(a) to (f) Central Drugs Standard Control Organization (CDSCO) has issued guidelines on ″Recall and Rapid Alert System for Drugs″ (including Biologicals & Vaccines). Further, Draft Guidelines on Good Distribution Practices for Pharmaceutical Products is also published for ensuring quality of Drugs in the supply chain. These guidelines are available on website of CDSCO (www.cdsco.gov.in).

On 06.11.2019, the Drugs and Cosmetics Rules, 1945 were amended vide G.S.R 828 (E) making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

Further, Central Government has also amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. These contain specific reference for product recalls.

In case of drug samples declared as Not of Standard Quality by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the Not of standard quality Drugs in the market.

Under the Drugs and Cosmetics Act, 1940 and Rules thereunder, manufacturers of drugs are required to comply with conditions of manufacturing licence and the requirements of Good Manufacturing Practices (GMP). As per the Drugs Rules, 1945, the manufacturing, testing, labelling, packaging, storage and distribution are required to be carried out in compliance with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. In case of violation, the Licensing Authority is empowered to take the action as per the said Act and Rules.

Further on need basis, various guidelines/regulatory procedures are considered and incorporated in the Rules through amendment as per the procedures prescribed in the Drugs and Cosmetic Act, 1940.

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