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

RAJYA SABHA
UNSTARRED QUESTION NO.1708
TO BE ANSWERED ON 10TH DECEMBER, 2024

SUBSTANDARD DRUGS MANUFACTURED BY KARNATAKA ANTIBIOTIC AND PHARMACEUTICALS LIMITED AND THE HINDUSTAN ANTIBIOTIC LIMITED

1708: SHRI A. D. SINGH:

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

(a) whether samples of some drugs manufactured by Karnataka Antibiotic and Pharmaceuticals Limited and the Hindustan Antibiotic Limited were found to be of low standard on testing recently;

(b) the details of the drugs that were found as substandard and the reasons therefor; and

(c) the actions taken by Government to sustain the standard of drugs manufactured by these public sector companies?

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

(a) to (c): As informed by Department of Pharmaceuticals, Tablet Metronidazole 400 mg (Batch No. HMAA04) manufactured by Hindustan Antibiotic Limited (HAL) and Tablet Paracetamol 500 mg (Batch No. 2508323) manufactured by Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) have been found to be "Not of Standard Quality" (NSQ) during testing. The drug samples did not conform to test for Dissolution and Description, respectively as per Indian Pharmacopoeia 2022.

List of such drugs alongwith their details, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in).

As informed by Department of Pharmaceuticals, both HAL and KAPL have withdrawn/replaced the requisite NSQ stocks to the consignee's with fresh stocks.

As per the Drugs Rules, 1945 all manufacturers are required to comply with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. Further, Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products.

In the cases concerning quality or safety of drugs as and when reported, actions are taken by the licensing authorities concerned under the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

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