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

RAJYA SABHA
UNSTARRED QUESTION NO. 2500
TO BE ANSWERED ON 17TH DECEMBER, 2024

REGULATORY OVERSIGHT ON RANITIDINE IN THE COUNTRY

2500: SHRI MOHAMMED NADIMUL HAQUE:

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

(a) whether Government has reviewed the findings of international regulatory bodies, USFDA and EMA, on the presence of N-nitrosodimethylamine (NDMA) in Ranitidine and its health implications if so, the details thereof;

(b) whether the Indian Pharmacopeia Commission has updated the Indian Pharmacopeia to include permissible standards for NDMA in Ranitidine, if not, the reasons for the delay; and

(c) whether Government plans to issue an order under Section 26A of the Drugs and Cosmetics Act, 1940, to prohibit the manufacture and sale of Ranitidine in the country, if not, the reasons thereof?

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

(a) to (c): Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare has taken various actions including testing of Ranitidine samples for the impurity and communication with the State Drugs Controllers to instruct the manufacturer of Ranitidine API and formulations to verify/ test their products and take appropriate measures to ensure patient safety. CDSCO had also instructed zonal offices for drawing of samples for testing the level of N-nitrosodimethylamine (NDMA) impurity in ranitidine. At present, there is no proposal to prohibit the manufacture, distribution and sale of Ranitidine in the country.

Indian Pharmacopoeia Commission has published a General chapter on Nitrosamine Impurities in the 9th edition of Indian Pharmacopoeia (IP) 2022. This chapter provides the methods of analysis of the nitrosamine impurities including the NDMA along with their acceptable intake (AI) limits.

****