**F. No. DC-DT-15011(11)/59/2025-eoffice (E 22970)**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(DCC-DTAB Division)**

Dated:

**To**

24 JUL 2025

**All State/ UT Drug Controllers**

**Subject: Issues related to safety of Ranitidine drug due to presence of NDMA impurity –regarding**

**Sir/Madam,**

The issue related to safety of Ranitidine drug due to presence of NDMA impurity has been under consideration for quite some time now and this office has taken various measures from time to time.

In this regard, an expert-committee was constituted vide O.M. dated 16.12.2024. The report of the expert committee was placed before the 92nd Drugs Technical Advisory Board (DTAB) meeting held on 28.04.2025. The minutes of DTAB meeting are **enclosed**.

The DTAB after detailed deliberation recommended that:

1. A larger committee is required to be constituted which will look into the all the aspects including the storage conditions of the ranitidine drug.
2. ICMR may conduct a study for assessing the safety of ranitidine drug considering the presence of NDMA impurity.
3. The manufacturers should monitor the NDMA levels in the API/formulation and also take risk based measurers such as reducing the shelf life etc.

In view of above, as recommended by DTAB, you are requested to direct the manufacturers under your jurisdiction to monitor the NDMA levels in the API/formulation of Ranitidine and also take risk-based measurers such as reducing the shelf life, etc.

**Yours faithfully**

**(Dr. Rajeev Singh Raghuvanshi)**
**Drugs Controller General (India)**

**Enclosures: As above**

**Copy for necessary action to: -**

1. All Zonal/ Sub-zonal offices of CDSCO
2. CDSCO website