Acidity Medication Ranitidine Under Renewed Vigilance by CDSCO

The Central Drugs Standard Control Organisation (CDSCO), India's national regulatory body for pharmaceuticals and medical devices, has issued a directive to all state and Union Territory drug regulators. The directive, dated July 24, 2025, mandates that manufacturers of ranitidine, a widely prescribed medication for acidity and heartburn, rigorously monitor the levels of N-nitrosodimethylamine (NDMA), a substance classified as a probable human carcinogen. This move underscores an ongoing commitment to public health and drug safety standards.

The scrutiny over ranitidine's safety, particularly concerning NDMA impurity, has been a focus for Indian drug authorities for some time. An expert committee was established in December 2024 to delve into various aspects of this issue. The committee's report was subsequently presented to the 92nd meeting of the Drugs Technical Advisory Board (DTAB) on April 28, 2025. Following detailed deliberations, the DTAB recommended several key actions, including the need for manufacturers to monitor NDMA levels closely.

NDMA is a chemical impurity that can form in ranitidine over time, especially under specific storage conditions, or through the degradation of the active pharmaceutical ingredient. While NDMA can also be found in common foods and water, its presence at elevated levels in medication poses a potential health risk. The international concern regarding NDMA in ranitidine led to significant market withdrawals in various countries, including the United States, in 2020. However, India's approach has focused on mitigation rather than a blanket ban, emphasizing stringent monitoring and risk-based measures.

As part of the recent directive, the CDSCO has also advised manufacturers to consider risk-based measures such as reducing the shelf life of ranitidine products to minimize potential patient exposure to NDMA. Furthermore, the DTAB recommended the constitution of a larger committee to investigate all aspects of ranitidine’s safety, including optimal storage conditions. The Indian Council of Medical Research (ICMR) has also been urged to conduct a comprehensive study assessing ranitidine's safety profile in light of NDMA presence. This multi-pronged approach aims to ensure that commonly used medications remain safe and effective for consumers. The focus now shifts to how manufacturers will implement these heightened monitoring and risk mitigation protocols.