

Continued use of ranitidine in Pakistan despite global withdrawal: A call for regulatory action

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Dear Editor, We wish to draw attention to a critical drug safety issue: the continued use of ranitidine in Pakistan, despite its withdrawal from major international markets due to safety risks.

In April 2020, the U.S. Food and Drug Administration (FDA) requested the withdrawal of all ranitidine products after detecting unacceptable levels of N-Nitrosodimethylamine (NDMA), a probable human carcinogen.^{1,2} NDMA formation in ranitidine increases significantly over time and when stored at elevated temperatures, conditions that are common in Pakistan's supply chain.³ The European Medicines Agency (EMA) also recommended suspension of ranitidine-containing products due to similar concerns.⁴

Despite these global actions, ranitidine remains widely available in Pakistani pharmacies and continues to be prescribed in both outpatient and inpatient settings. Many clinicians and patients appear unaware of its potential carcinogenic risks. While the Drug Regulatory Authority of Pakistan (DRAP) has issued recalls for specific batches, a comprehensive nationwide ban or public awareness campaign is lacking.

Alternative therapies, such as proton pump inhibitors (PPIs) including omeprazole and lansoprazole, or other H₂-receptor antagonists not associated with NDMA formation (e.g., famotidine), are available.⁵ The continued use of ranitidine undermines global pharmacovigilance efforts and potentially puts patients at avoidable risk.

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We urge the relevant health authorities, including DRAP and professional medical bodies, to formally suspend the sale of ranitidine in Pakistan and to issue updated guidelines. National medical journals have a pivotal role in promoting awareness and advocating for responsible prescribing to safeguard public health.

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