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SAFETY ALERT OF DETECTION OF NDMA IN RANITIDINE MEDICINES

On 13th September, 2019, the United States Food and Drug Administration (US-FDA) issued a press release about detection of very low levels of nitrosamine impurity called N-nitrosodimethylamine (NDMA) in ranitidine medicines (Zantac). The European Medicine Agency (EMA) vides a press release on 13th September, 2019 also started review of ranitidine medicines after tests showed that some of these products contained NDMA. Neither the source of material nor the quantity of NDMA found was mentioned by both the agencies in their press release. Both the agencies are evaluating any possible risk to patients due low level of NDMA. The new updates on the issue came from Canada, wherein Health Canada on 17th September, 2019 requested companies to stop distributing Ranitidine drugs in Canada, while it assesses the NDMA. A company namely Novartis AG's Sandoz is also voluntarily recalling its product containing Ranitidine in Canada and has stopped its worldwide distribution. In addition, multiple recalls and halt on distribution of generic version of ranitidine is happening around the world including United States.

Last year, in July, 2018, EMA detected NDMA in valsartan active substance manufactured by Zhejiang Huahai Pharmaceuticals China. Subsequently, valsartan medicines were recalled in the European Union. Accordingly, the Drug Regulatory Authority of Pakistan in July, 2018, triggered a recall of all valsartan containing medicines having the same source of active substance as of EMA and also issued a list of manufacturers who have purchased valsartan raw material from the same source/

Drug Regulatory Authority is aware of the international reports of contamination of Ranitidine medicines with NDMA and is at present coordinating with international regulators for further investigation.

Ranitidine is a H2 (histamine-2) blocker which decreases the amount of acid created by the stomach. It is used to treat heartburn, gastric and intestinal ulcers and treatment of gastro-esophageal reflux disease.

NDMA is classified as a probable human carcinogen, based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables and is not expected to cause harm when ingested in very low levels.

In greater public interest and in order to protect patients from risk associated with detection of low levels of NDMA in ranitidine containing products as per alert of FDA and EMA, the DRAP at first advised to halt the distribution/sale/utilization of ranitidine containing medicines in Pakistan followed by its recall and suspension of production of all dosage forms. DRAP will continue to keep the public updated on the issue.

There are multiple medicines in the market that are approved for same or similar uses as ranitidine. Individuals wishing to seek other treatment options should speak to their doctor or pharmacist.