MHRA drug alert: recalls for 13 over-the-counter Ranitidine medicines

OTC Concepts Ltd, Relconchem Ltd and Noumed Life Sciences Ltd are recalling all unexpired batches of the products listed in the alert from pharmacies and retail stores. Medreich PLC is recalling specific batches from pharmacies and retail stores.

The recall affects 13, separate Ranitidine products listed in the MHRA drug alert here. Retailers have been advised to stop supplying the recalled products immediately and for all remaining stock to be quarantined and returned without delay to the supplier.

The recall is a precautionary measure due to possible contamination with an impurity, N- nitrosodimethylamine (NDMA), which has been identified as a potential risk factor in the development of certain cancers.

Patients should not stop taking their medication, and a treatment review is not necessary until the next routine appointment.

This recall follows 4 previous recalls on 8 October, 17 October, 25 October and 19 November regarding the withdrawal of other ranitidine products, also recalled as a precautionary measure. The MHRA is actively involved with the European Medicines Agency and other medicines' regulators to determine the impact of what is an ongoing, global issue.

Dr Andrew Gray, MHRA Deputy Director of Inspections, Enforcement & Standards, comments:

"Whilst this action is precautionary, the MHRA takes patient safety very seriously.

"Patients should keep taking their current medicines but should speak to their doctor or pharmacist if they are concerned and should seek their doctor's advice before stopping any prescribed medicines.

"We have asked companies to quarantine batches of potentially affected medicines whilst we investigate and we will take action as necessary, including product recalls where appropriate.

"We have also requested risk assessments from the relevant companies which will include the testing of potentially affected batches.

"Currently, there is no evidence that medicines containing nitrosamines have caused any harm to patients, but the Agency is closely monitoring the situation, and working with other Regulatory Agencies around the world."

Ends

Notes to Editor

1. Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

2. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). MHRA is an executive agency of the Department of Health and Social Care.