Ranitidine Oral Solution and Tablets recall

The MHRA has issued an <u>alert to healthcare professionals</u>, as Creo Pharma Limited and Tillomed Laboratories Limited are recalling all unexpired stock of certain batches of prescription-only Ranitidine medicines used to treat conditions such as heartburn and stomach ulcers.

The recall affects Ranitidine Oral Solution 30mg/ml produced, by Creo Pharma Limited, and Ranitidine 150mg Tablets, produced by Tillomed Laboratories Limited.

Healthcare professionals have been told to stop supplying the products immediately. All remaining stock should be quarantined and returned without delay to the supplier.

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

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

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. On <u>8 October</u>, <u>17 October</u> and <u>25 October</u>, MHRA drug alerts were also issued regarding the withdrawal of other ranitidine medicines.

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 Note to editors:

- 1. <u>Medicines and Healthcare products Regulatory Agency</u> 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 <u>National Institute for Biological</u> <u>Standards and Control (NIBSC)</u> and the <u>Clinical Practice Research</u> <u>Datalink (CPRD)</u>. MHRA is an executive agency of the Department of Health and Social Care.