

Recall of five ranitidine-containing products (with photos)

The Department of Health (DH) today (November 7) endorsed three licensed drug wholesalers, Healthcare Pharmascience Limited (HP), Julius Chen & Co (HK) Limited (JC) and Atlantic Pharmaceutical Limited (Atlantic), to recall five ranitidine-containing products from the market as a precautionary measure due to the presence of an impurity in the products.

The affected products are:

Supplier	Product	Hong Kong Registration Number
HP	Raniplex 150 Tablet 150mg	HK-43456
	Tupast Tablet 150mg	HK-50378
JC	Wontac Tablet 150mg	HK-60085
	Jecefarma Ranitidine Tablet 150mg	HK-64041
Atlantic	Ratic Tablet 150mg	HK-61083

The DH received information from Macao Health Bureau that Raniplex, Tupast and Wontac were tested and found to contain N-nitrosodimethylamine (NDMA). NDMA is a probable human carcinogen based on results from laboratory tests. As a precautionary measure, the suppliers concerned are voluntarily recalling the affected products from the market. In addition, two other products, i.e. Jecefarma Ranitidine and Ratic, are also being recalled because the raw material ranitidine may contain NDMA.

The DH noted that certain ranitidine-containing products were found to contain NDMA in other countries, therefore a letter was sent to healthcare professionals on September 18 notifying them about the issue. The DH has endorsed the recalls of a total of 17 ranitidine-containing products since September 24. The DH also noted that overseas drug regulatory authorities have been reviewing the safety impact of the impurity found in the ranitidine-containing products. The DH will closely monitor the development of the issue and any safety updates of the drug issued by overseas drug regulatory authorities for consideration of action deemed necessary.

The above products are over-the-counter medicines used for the treatment of gastric diseases. According to the suppliers, the affected products have been supplied to the local healthcare sector including private doctors, pharmacies, medicine companies, a private hospital and an animal clinic.

The companies have set up hotlines to answer related enquiries: HP (3472 8128), JC (2487 1301), Atlantic (2563 4224).

"So far, the DH has not received any adverse reaction report in connection with the products. The DH will closely monitor the recall," a spokesman for the DH said.

"Patients who are taking the above products should seek advice from their healthcare professionals for appropriate arrangements. There are alternative medicines available on the market with similar indications," the spokesman added.

