Recall of two ranitidine-containing products (with photos)

The Department of Health (DH) today (September 27) endorsed licensed drug manufacturer APT Pharma Limited and licensed drug wholesaler Eugenpharm International Limited to recall their 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
APT Pharma Limited	Amratidine tablets 150mg	HK-53143
Eugenpharm International Limited	Peptil H 150 tablets 150mg	HK-65103

The DH, via its surveillance system, was aware that certain ranitidine-containing products were found to contain N-nitrosodimethylamine (NDMA) in other countries and had been collecting samples of ranitidine-containing products from the market for analysis. The DH also noted that overseas drug regulatory authorities including the United States Food and Drug Administration and the European Medicines Agency 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 update of the drug issued by overseas drug regulatory authorities for consideration of any action deemed necessary. A letter was also sent to healthcare professionals on September 18 notifying them about the issue.

Based on the DH's follow-up actions, samples of the above Amratidine tablets 150mg were collected for analysis and test results from the Government Laboratory confirmed that the samples contain low levels of NDMA. NDMA is classified as a probable human carcinogen based on results from laboratory tests. The potential risks are only associated with long-term exposure. In addition, Eugenpharm suspected that its Peptil H 150 tablets 150mg may also contain NDMA due to recent recalls of ranitidine-containing products. As a precautionary measure, both APT and Eugenpharm voluntarily recalled the affected products from the market.

The above products are over-the-counter medicines used for the treatment of gastric diseases. According to APT, the affected product has been supplied to the Hospital Authority, DH clinics, local private doctors, dentists, pharmacies and medicine companies, and some has been exported to Macao. On the other hand, Eugenpharm indicated that the affected product has been supplied to local pharmacies and medicine companies.

Both companies have set up hotlines to answer related enquiries: APT (2389 6279) and Eugenpharm (3647 3781).

"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.