Recall of six ranitidine-containing products (with photos)

The Department of Health (DH) today (November 1) endorsed a licensed drug wholesaler Welldone Pharmaceuticals Limited (Welldone) to recall six ranitidine-containing products from the market as a precautionary measure due to the potential presence of an impurity in the products.

The affected products are:

Product names	Hong Kong registration number
Epirant Tab 150mg	HK-56826
Welldone Ranitidine Tab 150mg	HK-57473
Kin Pak Tab 150mg	HK-56824
Wah Tat Tab 150mg	HK-56823
Super Pro Tab 150mg	HK-56825
Glo-Tac Tab 150mg	HK-57472

The DH received notification from the products' registration certificate holder Medexrom Limited that the manufacturer is voluntarily recalling the above products because they might contain N-nitrosodimethylamine (NDMA). NDMA is classified as a probable human carcinogen based on results from laboratory tests. Because the products are distributed by Welldone in Hong Kong, as a precautionary measure, Welldone is voluntarily recalling the affected products from the market.

The DH earlier 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 also has endorsed the recalls of a total of 11 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 any action deemed necessary.

The above products are over-the-counter medicines used for the treatment of gastric diseases. According to Welldone, the affected products have been supplied to local pharmacies and medicine companies, and some have been exported to Macao.

Welldone has set up a hotline (2467 1168) to answer related enquiries.

"So far, the DH has not received any adverse reaction reports 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.