

Recall of three ranitidine-containing products (with photos)

The Department of Health (DH) today (September 25) endorsed licensed drug wholesalers Hind Wing Co Ltd and Top Harvest Pharmaceuticals Co Ltd to recall three 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:

Wholesaler	Product	Hong Kong Registration Number
Hind Wing Co Ltd	APO-Ranitidine Tablets 150mg	HK-42273
	APO-Ranitidine Tablets 300mg	HK-41873
Top Harvest Pharmaceuticals Co Ltd	Zantidon Tablets 150mg	HK-64329

The DH received notifications from Hind Wing and Top Harvest today that the manufacturers of the products are concerned about the potential presence of an impurity, N-nitrosodimethylamine (NDMA), in the products. NDMA is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, both Hind Wing and Top Harvest have voluntarily recalled their affected products from the market.

The DH, via its surveillance system, was aware that certain ranitidine-containing products were found to contain NDMA in other countries. 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, and 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.

The above products are over-the-counter medicines used for the treatment of gastric diseases. According to Hind Wing, the affected products have been supplied to private hospitals, local private doctors and pharmacies. Some products were also re-exported to Macao. According to Top Harvest, the affected product has been supplied to local pharmacies.

The two wholesalers have set up hotlines to answer related enquiries: Hind Wing (2541 5731) and Top Harvest (2253 9112).

"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.

