Recall of Zantac products (with photos)

The Department of Health (DH) today (September 24) endorsed a licensed drug wholesaler, GlaxoSmithKline Ltd (GSK), to recall all Zantac products from the market as a precautionary measure due to the presence of an impurity in the products.

The affected products are:

Product	Hong Kong Registration Number
Zantac Tablet 150mg	HK-42792
Zantac Tablet 300mg	HK-42793
Zantac Syrup 150mg/10ml	HK-30459
Zantac Injection 25mg/ml	HK-42045

The DH received notification from GSK today that an impurity, N-nitrosodimethylamine (NDMA), was found in Zantac products by overseas regulatory authorities. NDMA is classified as a probable human carcinogen based on results from laboratory tests. GSK reported that the products' active ingredient, ranitidine, produced by an Indian manufacturer was found to contain low levels of NDMA. As a precautionary measure, GSK voluntarily has recalled all Zantac products with the affected active ingredient 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 notes 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 medicines used for the treatment of gastric diseases. Oral preparations are over-the-counter medicines. According to GSK, the affected products have been supplied to the Hospital Authority, DH clinics, private hospitals, local private doctors and pharmacies. Some products were also re-exported to Macao.

GSK has set up a hotline (3189 8765) to answer related enquiries.

"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.