

Recall of two ranitidine-containing products (with photos)

The Department of Health (DH) today (November 27) endorsed two licensed drug suppliers, Cera Medical Limited (Cera) and Sincerity (Asia) Company Limited (Sincerity), to recall two 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
Cera	Emtac 150 Tab 150mg	HK-59353
Sincerity	Ranitid 150 Tab 150mg	HK-59429

In view of the recent recall of ranitidine-containing products, the DH proactively collected samples of similar products from the market for analysis. Test results from the Government Laboratory revealed that the above products contain an impurity of N-nitrosodimethylamine (NDMA). NDMA is a probable human carcinogen based on results from laboratory tests. As a precautionary measure, the concerned suppliers are voluntarily recalling the affected products from the market.

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. Since September 24, the DH has endorsed the recalls of a total of 23 ranitidine-containing products. The DH 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 local private doctors, pharmacies and medicine companies.

The companies have set up hotlines to answer related enquiries: Cera (2695 8587), and Sincerity (2544 1401).

"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.

