

Batch recall of two products of Apo-Amitriptyline tablets due to presence of impurity (with photos)

The Department of Health (DH) today (October 18) endorsed a licensed drug wholesaler, Hind Wing Co Ltd, to recall a total of 14 batches of the following two products from the market as a precautionary measure due to the presence of impurity in the products.

| Name of product | Hong Kong registration number | Batch number |
|--------------------------------|-------------------------------|--------------|
| Apo-Amitriptyline Tablets 10mg | HK-09273 | RN6384 |
| | | RR0266 |
| | | RV1644 |
| | | RW8597 |
| | | TA6008 |
| | | TF8585 |
| | | TF8587 |
| | | TF8589 |
| Apo-Amitriptyline Tablets 25mg | HK-09274 | RM8130 |
| | | RR0781 |
| | | RV1656 |
| | | RW8691 |
| | | TA6062 |
| | | TF8602 |

The DH received notification from Hind Wing that the overseas manufacturer of the products is recalling the above batches of Apo-amitriptyline tablets as they exceed or may exceed the accepted level of an impurity, N-Nitrosonortriptyline (NNORT). NNORT is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Hind Wing is voluntarily recalling the affected batches of products from the market.

The above products, containing amitriptyline, are prescription medicines used for the treatment of depression. According to Hind Wing, the above batches of products had been imported into Hong Kong. The affected batches of products had been supplied to the DH clinics, pharmacies, private doctors, and private hospitals, and re-exported to Macao.

Hind Wing has set up a hotline (2541 5731) 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 not stop taking the medicine, but should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.

