Batch recall of Apo-Amitriptyline Tablets 10 mg (with photo)

The Department of Health (DH) today (April 15) endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall one batch (batch number: RF0410) of Apo-Amitriptyline Tablets 10 mg (Hong Kong registration number: HK-09273) from the market as a precautionary measure due to the presence of an impurity in the product.

The DH received notification from Hind Wing today that the overseas manufacturer of the product is initiating a voluntary recall of the batch concerned due to the presence of a higher than accepted level of an impurity, N-nitrosodimethylamine (NDMA), in the affected batch. NDMA is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Hind Wing is voluntarily recalling the affected product from the market.

The above product is a prescription medicine used for the treatment of depression. According to Hind Wing, the product has been supplied to DH clinics, private hospitals, local doctors and pharmacies as well as 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 product. The DH will closely monitor the recall," a spokesman for the DH said.

"Patients who are taking the above product should not stop taking the medicine, but should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.