# Recall of three batches of Metformin-Teva 500mg Tablets (with photo)

The Department of Health (DH) today (March 11) endorsed a licensed wholesale dealer, the International Medical Company Ltd, to recall three batches of Metformin-Teva 500mg Tablets (Hong Kong registration number: HK-60334) from the market due to the potential presence of an impurity in the product. The affected batches are 16532717, 16532817 and 16532917.

The DH received notification from the wholesale dealer that the manufacturer suspected that the above product might contain the impurity N-nitrosodimethylamine (NDMA) based on laboratory testing. The DH then collected samples of the product for analysis. Results from the Government Laboratory confirmed that the samples contained NDMA. As a precautionary measure, the wholesale dealer is voluntarily recalling all available batches of the above product from the market.

The DH noted that NDMA is classified as a probable human carcinogen based on results from laboratory tests and overseas drug regulatory authorities have been reviewing the safety impact of NDMA found in some medicinal products including metformin. The DH will closely monitor the development of the issue and any safety updates regarding the drug issued by overseas drug regulatory authorities for consideration of action deemed necessary.

The above product containing metformin is a prescription medicine used for the treatment of diabetes mellitus. According to the wholesale dealer, the product has been supplied to local private doctors and pharmacies.

The International Medical Company Ltd has set up a hotline (3904 3799) to answer related enquiries.

"So far, the DH has not received any adverse reaction report 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.

**TEVA**

**Metformin-Teva 500 mg Tablets**
(Metformin Hydrochloride)

90 tablets

500 mg

For oral administration