Batch recall of Metformin Denk 850 Tablets 850mg (with photo)

The Department of Health (DH) today (October 9) endorsed a licensed drug wholesaler, Star Medical Supplies Ltd, to recall one batch (Batch Number: 21334) of Metformin Denk 850 Tablets 850mg (Hong Kong Registration Number: HK-49776) from the market as a precautionary measure due to the possible presence of an impurity in the product.

The DH received notification from an overseas drug regulatory authority that the aforementioned batch of Metformin Denk 850 Tablets 850mg was found to contain an impurity, N-nitrosodimethylamine (NDMA). As a precautionary measure, Star Medical voluntarily recalled the affected batch from the market.

NDMA is classified as a probable human carcinogen based on results from laboratory tests. 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 any action deemed necessary.

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

Star Medical has set up a hotline (2370 1183) 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, and should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.

