

Recall of pms-Irbesartan Tablet 150mg and pms-Irbesartan Tablet 300mg

The Department of Health (DH) today (May 31) endorsed a licensed drug wholesaler, Trenton-boma Ltd (T-Boma), to recall two batches of the following products from the market as a precautionary measure due to the presence of an impurity in the product.

Name of Product	Hong Kong Registration Number	Batch Number
pms-Irbesartan Tablet 150mg	HK-61098	617492
pms-Irbesartan Tablet 300mg	HK-61097	624193

The DH received notification from T-Boma today that the overseas manufacturer of the product is initiating a voluntary recall of certain batches of products due to the presence of a higher than accepted level of azido impurity in the affected batches. According to T-Boma, the two affected batches of tablets have been imported and supplied in Hong Kong. As a precautionary measure, T-Boma is voluntarily recalling those batches from the market.

Azido impurity is considered a mutagen that can cause a change in the DNA of a cell and may increase the risk of cancer, but the risk for the azido impurity to cause cancer in humans is unknown. Overseas drug regulatory authorities have been reviewing the safety impact of azido impurity found in medicinal products. 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 products are prescription medicines used to lower blood pressure. According to T-Boma, the affected batches have been supplied to private doctors and hospital, as well as pharmacies.

T-Boma has set up a hotline (2370 2092) to handle 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 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.

