Batch recall of two products of Pms-Fluoxetine capsules due to presence of impurity

The Department of Health (DH) today (Apr 29) endorsed a licensed drug wholesaler, Trenton-Boma Limited (Trenton-Boma), to recall a total of eight 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
Pms-Fluoxetine Capsules 10mg	HK-61931	643518
		644912
		647317
		648682
		653478
		655449
Pms-Fluoxetine Capsules 20mg	HK-59714	641413
		645412

The DH received notification from Trenton-Boma that the overseas manufacturer of the products is recalling the above batches of Pms- Fluoxetine capsules as they exceed the accepted level of an impurity, N-nitroso-fluoxetine. N-nitroso-fluoxetine is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Trenton-Boma is voluntarily recalling the affected batches of products from the market.

The above products, containing fluoxetine, are prescription medicines used for the treatment of depression. According to Trenton-Boma, the affected batches of products have been imported into Hong Kong and supplied to the private doctors, veterinary surgeon, private hospitals and pharmacies, and re-exported to Macao.

Trenton-Boma has set up a hotline 8101 2716 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.

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.

Ends/ Tuesday, April 29, 2025