Recall of Esmya Tablets 5mg (with photo)

The Department of Health (DH) today (March 20) endorsed a licensed wholesale dealer, Orient Europharma Co Ltd (OEP), to voluntarily recall a pharmaceutical product, Esmya 5mg Tablets (Hong Kong registration number: HK-62553) from patients due to the potential risk of liver injury.

The DH has been monitoring the safety of Esmya since December 2017, when the European Medicines Agency (EMA) started a review on Esmya following reports of serious liver injury, and healthcare professionals have been alerted to the risk. Following the EMA's further recommendation on March 13 this year that women taking Esmya and its generic products for uterine fibroids should stop taking it, the DH has also issued a letter to healthcare professionals informing them about the EMA's announcement.

Based on the latest EMA recommendation, OEP decided to recall the affected product from patients as a precautionary measure.

The product concerned, containing 5mg ulipristal acetate, is a prescription medicine used for the treatment of uterine fibroids. According to OEP, the product has been supplied to the Hospital Authority, private hospitals, local private doctors and pharmacies. Some products have also been exported to Macao.

OEP has set up a hotline (2578 7080) 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.

"People who are taking the above product should stop using the medicine and consult their healthcare professionals for appropriate arrangements," the spokesman added.