

# Recall of Aprovel Tablets and CoAprovel Tablets (with photos)

The Department of Health (DH) today (October 21) endorsed a licensed drug wholesaler, Sanofi Hong Kong Limited, to recall five batches of the following four products from the market as a precautionary measure due to the presence of an impurity in the products.

Name of product	Hong Kong registration number	Batch number
Aprovel Tablets 150mg	HK-42891	AA365
Aprovel Tablets 300mg	HK-42892	AA691
CoAprovel Tablets 150/12.5mg	HK-49777	AA557
CoAprovel Tablets 300/12.5mg	HK-49778	AA510, AA549

The DH today received notification from Sanofi of the finding by the overseas manufacturers that the active pharmaceutical ingredient of the above batches of products contains a higher than accepted level of azido impurity. As a precautionary measure, Sanofi is voluntarily recalling the above batches of the products 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 of causing 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 necessary action.

The above products are prescription medicines used to lower blood pressure. According to Sanofi, the products have been imported to Hong Kong and supplied to Hospital Authority hospitals, clinics of the DH, private hospitals, private doctors and community pharmacies as well as re-exported to Macao.

Sanofi has set up a hotline (2506 8333) 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 products should not stop taking them, but should seek advice from their healthcare professionals as soon as possible for appropriate arrangements," the spokesman added.

