Macau: Recall of 6 medicines

In Hong Kong, there are 93 registered pharmaceutical products containing valsartan, and all products are prescription-only medicines.

A public announcement was issued on 6 Jul 2018 on the issue, and letters to inform local healthcare professionals of the latest development, including the affected products and recommendations on drug use, were issued by the Department of Health (DH) on 6 Jul 2018 and 9 Jul 2018. Related news was also previously issued by European Medicines Agency and the United Kingdom Medicines and Healthcare products Regulatory Agency, and was posted on the Drug Office website on 6 Jul 2018.

The DH contacted all certificate holders of registered valsartan products, among which Actavis Hong Kong Limited (Actavis) and Hong Kong Medical Supplies Ltd (HK Medical) confirmed that affected products have been marketed in Hong Kong.

The affected products are:-

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|----------------------------------|------------------------|--------------------------|
| Product | Hong Kong Registration | Registration certificate |
| | Number | holder |
| Valtensin 160mg tablets | HK-61786 | Actavis |
| Valtensin 80mg tablets | HK-61787 | Actavis |
| Valtensin HCT tablets 160/12.5mg | HK-61784 | Actavis |
| Valtensin HCT tablets 80/12.5mg | HK-61785 | Actavis |
| Valsartan Stada 80mg tablets | HK-60794 | HK Medical |

According to Actavis and HK Medical, the above products have been supplied to local doctors and pharmacies. The products Valtensin 80mg and 160mg tablets have also been supplied to the Hospital Authority. The DH instructed Actavis and HK Medical to recall all the above five products from the market as a precautionary measure on 6 Jul 2018, and will closely monitor the recall.

All other products containing valsartan available in local market are not affected.

So far, the DH has not received any adverse reactions related to the above products affected by the recall.

Patients who are taking the above products should not stop taking the medicines, but should seek advice from their healthcare professionals as soon as possible for proper arrangement.

Please refer to the following Chinese website for details:

 $\frac{http://www.drugoffice.gov.hk/eps/upload/eps_news/32041/ZH/1/NewsBulletin_09072}{018_Valsartan_Macau.pdf}$

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