衞生署藥物辦公室
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**DRUG OFFICE**
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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

**Updates on the recall of valsartan-containing products**

Following the public announcement made by the Department of Health (DH) and the previous letters to Healthcare Professionals on 6 July, 9 July and 25 July 2018 regarding the recall of five valsartan-containing products, this letter serves to update you the latest situation.

The European Medicines Agency (EMA) has just issued its preliminary assessment of possible risk to patients due to the present of N-nitrosodimethylamine (NDMA) in valsartan products. Based on extrapolation from animal studies, EMA estimates that there could be one extra case of cancer for every 5,000 patients taking the affected medicines at the highest valsartan dose (320mg) every day for 7 years. For details, please refer to http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1.

The DH through its surveillance system noted that the raw material valsartan produced by a manufacturer in the Mainland and used in certain pharmaceutical products as active ingredient, was found to contain an impurity NDMA. NDMA is classified as a probable human carcinogen based on results from laboratory tests.

In Hong Kong, there are currently a total of 84 registered pharmaceutical products containing valsartan. Having confirmed with all registration certificate holders of these products, it is noted that apart from the five valsartan products recalled on 6 July (see table below), all other products available in local market are not affected.

| Products recalled | Hong Kong Registration Number | Registration certificate 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 the investigation of the EMA, the presence of NDMA is unexpected and believed to be related to the change of production method of the valsartan raw material since July 2012. Many countries around the world have recalled the affected products from their market.

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. Both companies have set up hotlines (Actavis: 3188 4288; HK Medical: 2806 3112) to answer related enquiries. So far, the DH has not received any adverse reactions related to the above products affected by the recall.

It is expected that the NDMA in the affected products will not cause acute toxicity or immediate health risks. 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.

Being a healthcare professional, you may need to give health advice to your patients about the potential risk of the affected products with NDMA and consider prescribing other unaffected valsartan products or alternative treatments to patients. According to the information provided by local suppliers, there are stocks of unaffected valsartan products available in Hong Kong. For the full list of registered valsartan products, please access at Drug Office's website (http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/search_drug_database.html).

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Edwin LAM)
for Assistant Director (Drug)