衞生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
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DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Recall of five valsartan-containing products

Your attention is drawn to the public announcement made by the Department of Health (DH) today regarding the recall of five valsartan-containing products as a precautionary measure due to an impurity detected in the raw material.

The DH instructed two licensed medicine wholesalers, namely Actavis Hong Kong Limited (Actavis) and Hong Kong Medical Supplies Ltd (HK Medical), to recall the following products:-

Product	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

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 N-nitrosodimethylamine (NDMA). NDMA is classified as a probable human carcinogen based on results from laboratory tests.

In Hong Kong, there are a total of 93 registered pharmaceutical products containing valsartan. So far, the above 5 products registered in Hong Kong are confirmed by the wholesalers to contain the affected raw material. The DH is still pending for the confirmation from suppliers on several valsartan products. If any of these products are affected, the DH will issue immediate public announcement. You are advised to take note of the latest development.

The European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) also made similar announcements last night. Please refer to the following EMA and MHRA websites for details.

EMA:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/07/news_detail_002984.jsp&mid=WC0b01ac058004d5c1

MHRA:
https://www.gov.uk/government/news/blood-pressure-and-heart-medication-recalled-from-pharmacies

According to the preliminary investigation of the Mainland manufacturer, the presence of NDMA is unexpected and believed to be related to its production method of the valsartan raw material.

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.

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.

Being a healthcare professional, you may need to give health advice to your patients and consider prescribing alternative treatment if necessary. According to the information provided by local suppliers, there are stocks of valsartan products that are not affected by the recall 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,

(Daniel CHEUNG)
for Assistant Director (Drug)