The United States: Updated: Torrent Pharmaceuticals Limited issues voluntary nationwide recall of all lots of unexpired valsartan-containing drug products, and FDA updates recall lists and releases method for the detection and quantification of NDMA in valsartan

The US Food and Drug Administration (FDA) announces that Torrent Pharmaceuticals Limited is expanding its voluntary recall to all lots of unexpired valsartan-containing drug products due to the detection of NDMA in the active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.

RemedyRepack, a repackager of Torrent's valsartan/amlodipine/hydrochlorothiazide (HCTZ) tablets, has also recalled.

FDA is releasing a gas chromatography-mass spectrometry (GC/MS) headspace method for manufacturers and regulators to detect and quantify NDMA in valsartan API and finished drug products. The agency is using this method to test potential NDMA-containing APIs and drug products. This method should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

FDA has also updated the list of valsartan products under recall and the list of valsartan products not under recall.

Please refer to the following website in FDA for details:
http://www.fda.gov/Drugs/DrugSafety/ucm613916.htm

In Hong Kong, there are 83 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, recommendations on drug use and possible risk, were issued by the Department of Health (DH) on 6 Jul 2018, 9 Jul 2018, 25 Jul 2018 and 3 Aug 2018. Related news was also previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 6 Jul 2018, with the latest update posted on 22 Aug 2018.

In summary, there are four manufacturers, namely Zhejiang Huahai, Zhejiang Tianyu and Zhuhai Rundu in China and Hetero Labs Limited in India, reported to have detection of trace amounts of NDMA in the valsartan Active Pharmaceutical Ingredient (API) by various overseas drug regulatory authorities.

The DH contacted the certificate holders of all registered valsartan products to follow up on the local impact regarding valsartan API produced by the above mentioned manufacturers.

For API produced by Zhejiang Huahai, there are 5 affected products marketed in Hong Kong. DH instructed the certificate holders to recall all the products from the market as a precautionary measure on 6 Jul 2018, and DH noted that all the recalls have been completed. The affected products are:

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

For API produced by Zhejiang Tianyu, amongst the registered pharmaceutical products containing valsartan, there is only one product namely Retoni Tablets 80mg (HK-65604) registered by Swiss Pharmaceutical Co Limited (Swiss Pharmaceutical) which has used API produced by Zhejiang Tianyu and is available in the local market. As confirmed with Swiss Pharmaceutical, the API was tested by the Taiwan Food and Drug Administration (TFDA) and the company has not received any notice from the TFDA for NDMA contamination. The DH collected samples of Retoni tablets for analysis and no NDMA was detected.

For API produced by Zhuhai Rundu and Hetero Labs Limited, the certificate holders confirmed that the valsartan products available in local market are not manufactured using API produced by Zhuhai Rundu or Hetero Labs Limited.

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.

Ends/Saturday, September 1, 2018
Issued at HKT 13.30