



SINGAPORE, 29 AUGUST 2018

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.

HSA UPDATES NO 5/2018

HSA UPDATES ON OVERSEAS RECALL OF VALSARTAN MEDICINES

The Health Sciences Authority (HSA) has investigated the recent overseas recalls on valsartan medicines. The medicines sold in Singapore are not affected by the recalls reported in the media.

Background

2 In June 2018, several valsartan-containing medicines were recalled globally due to the presence of N-nitrosodimethylamine (NDMA). This is a carcinogenic impurity, detected in the valsartan manufactured by Zhejiang Huahai Pharmaceuticals in China. Following this event, several other valsartan-containing medicines manufactured by a few other manufacturers were also recalled due to the presence of NDMA. NDMA is an impurity related to the manufacturing process used by these companies in the manufacture of the valsartan active ingredient.

Local situation

3 HSA has been closely monitoring the international developments and also following up closely with the companies that market valsartan-containing medicines in Singapore.

4 Based on our investigations and the available information to date, the valsartan-containing medicines that are sold in Singapore are not affected. These products do not use the valsartan produced by the affected manufacturers and they are manufactured in a way that should not generate NDMA as an impurity.

5 HSA will continue to monitor the developments and will communicate any relevant updates on the local situation to healthcare professionals. We will take prompt actions to ensure public safety if there are any new findings.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
29 AUGUST 2018**

- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

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