



**SINGAPORE, 7 MARCH 2019**

## **HSA UPDATES**

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

**HSA UPDATES NO 2/2019**

### **HSA UPDATES ON OVERSEAS RECALL OF ANGIOTENSIN II RECEPTOR BLOCKERS**

The Health Sciences Authority (HSA) has been closely monitoring the presence of nitrosamine impurities in angiotensin II receptor blockers (ARBs)<sup>1</sup> that are marketed in Singapore for the control of high blood pressure.

2 The nitrosamine impurities are by-products that are produced in trace amounts during the manufacturing process of certain of these medicines. Following the detection of the impurities N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in certain overseas products last year, HSA conducted testing of the products in Singapore for the presence of these impurities. We also worked with the companies to review their manufacturing processes and to conduct testing on their products before supply to the Singapore market. To-date, none of the products found locally have been detected to contain unacceptable levels of these 2 impurities.

3 Trace amounts of another nitrosamine impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) has recently been detected by overseas regulatory agencies in the losartan medicines manufactured by Hetero Labs. HSA is working with the companies to check if the local batches are affected and has started testing all the losartan medicines for this new contaminant. The products will be recalled should we detect impurities at unacceptable levels. HSA will keep members of the public informed of any significant findings.

#### **Patient advisory**

4 Patients should continue to take their ARB medicines as prescribed by their doctors. As these medicines are used for the control of high blood pressure, stopping the medicine without consulting the doctor may lead to heart attacks and stroke.

---

<sup>1</sup> The ARB class of medicines is used for the control of high blood pressure and include valsartan, losartan, candesartan, fimasartan, irbesartan and olmesartan. Overseas recalls were conducted as the affected ARBs contained unacceptable levels of these impurities.

**HEALTH SCIENCES AUTHORITY  
SINGAPORE  
7 MARCH 2019**

---

▪ **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/>.

For more updates on public health and safety matters, follow us on Twitter at [www.twitter.com/HSAsq](http://www.twitter.com/HSAsq).

▪ **About HSA Updates**

The “HSA Updates” seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit [www.hsa.gov.sg](http://www.hsa.gov.sg) click “News & Events”, and select “HSA Updates”.

**Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.**