

SINGAPORE, 10 JUNE 2011

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.
HSA UPDATES NO 2/2011

HSA UPDATES ON THE TEST RESULTS OF LOCALLY AVAILABLE AUGMENTIN ORAL SUSPENSION

The Health Sciences Authority (HSA) has on 7 June 2011, issued a press statement on the measures taken to test health products including medicinal products manufactured in Taiwan for Di(2-ethylhexyl)phthalate (DEHP) to ensure that they are safe for consumption. This follows reports of varying levels of DEHP that was found in Taiwan-manufactured health foods and products.

2 Since then, new information regarding the presence of Di-isododecyl phthalate (DIDP*) in Augmentin oral suspensions was reported by the media in Taiwan. HSA has been in contact with Glaxo Smithkline Pte Ltd (GSK) to further understand this matter and had clarified that the formulations of Augmentin available in Taiwan, namely Augmentin oral suspension (457mg/5ml) and Augmentin oral suspension (156mg/5ml), both strawberry flavoured, are not available in Singapore. Only Augmentin oral suspension 228mg/5ml (mixed fruit flavoured) is available locally which was sent promptly for testing. Based on the latest test results, DEHP and DIDP were not detected in this locally available product and it is safe for consumption.

About DIDP and Phthalates

3 DIDP belongs to a group of chemicals known as phthalates commonly used as plasticisers, which are used in the manufacturing of a large number of products and packaging materials to make them soft and flexible. As phthalates are commonly found in plastics, there is exposure to small levels of phthalates in everyday life.

4 It is unlikely that there will be side effects after exposure to low levels of phthalates. DIDP is rapidly broken down and readily excreted after it enters the human body. Harmful effects in animals such as liver toxicity have mainly been reported with high amounts of DIDP i.e. in doses that are more than 100 times higher than the amounts found in the affected Augmentin formulations in Taiwan. However, these toxic effects have not been established in humans.

Public Advisory

5 The latest test results indicate that DEHP and DIDP are not detected in Augmentin oral suspension 228mg/5ml (mixed fruit flavoured) and the product is therefore safe for consumption. Patients who were prescribed the medication should continue to use the product in accordance to the instructions provided by the doctor or pharmacist.

6 HSA continues to sample and test a range of health products manufactured in Taiwan for phthalates e.g. DEHP on a risk-based approach, and will alert members of the public of any significant safety findings.

HEALTH SCIENCES AUTHORITY

10 JUNE 2011

▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

▪ 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, click "News", and select "HSA Updates".

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