



**FOR IMMEDIATE RELEASE**

**HEALTH SCIENCES AUTHORITY  
PRESS RELEASE**

**7 June 2011**

## **HSA TAKES PRO-ACTIVE MEASURES TO TEST DEHP IN HEALTH PRODUCTS MANUFACTURED IN TAIWAN**

The Health Sciences Authority (HSA) has taken pro-active measures to test health 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 To safeguard public health and safety, HSA is working on a risk-based approach to sample and test Taiwan-made health products for DEHP content which includes the following: affected products reported by other countries/regions, products used in children, products with high sales volumes and oral preparations that may have used DEHP as an adulterant. The ongoing analytical tests by HSA have shown that over 100 sampled health products have passed HSA's quality requirement for DEHP content, with only two brands of health products, namely "Brand's Alpha Tank Chewable Multi Vitamins & Minerals" and "Naturex Immune+ Probiotic 50B" that have failed to meet the requirement.

3 "Brand's Alpha Tank Chewable Multi Vitamins & Minerals" and "Naturex Immune+ Probiotic 50B", manufactured by Prince Pharmaceutical Co. Ltd and Geneferm Biotechnology Co. Ltd respectively, have been voluntarily withdrawn from the market by their respective distributors. On the two affected products which were withdrawn, Ms Chan Cheng Leng<sup>1</sup>, Division Director of Vigilance, Compliance and Enforcement Division says, "Although the levels of DEHP found in these health products are not known to cause harm to health, they did not meet regulatory requirements for DEHP content. Their recall from the market is a precautionary measure."

### **About DEHP and phthalates**

4 Phthalates including DEHP are a group of chemicals commonly used as plasticisers in a large number of products and packaging material to make them soft and flexible. There is exposure to small levels of phthalates such as DEHP in everyday life. DEHP is found in low levels in the environment and is not expected to cause harmful health effects in humans at that level. DEHP is rapidly broken down and readily excreted after it enters the human body. Skin contact with products containing DEHP is not likely to cause harmful effects because it cannot be easily absorbed through the skin. Harmful effects in animals such as male reproductive toxicity have mainly been reported with high amounts of DEHP i.e. in doses that are 100 times higher than the amounts found in the affected products.

## **Risk assessment of DEHP detected in health products**

5 It is not acceptable for DEHP to be used as an ingredient in the manufacture of health products and the deliberate contamination of health products with DEHP is considered an adulteration of the product. HSA has consulted toxicology experts on the regulatory limit of DEHP allowable in health products and the tolerable daily intake (TDI\*) of DEHP in humans. The TDI is an estimate of the amount of DEHP that humans can be exposed to on a daily basis over a lifetime without significant health risks.

6 HSA, together with the experts, has assessed that based on the amount of DEHP found in the two affected products, they are considered unlikely to cause harmful effects if taken according to the recommended dosage as their DEHP content is much lower than the TDI. Says Professor Ong Choon Nam<sup>2</sup>, Department of Epidemiology and Public Health, National University of Singapore Yong Loo Lin School of Medicine: "Exposure of individuals to DEHP at levels below the TDI of 0.05 mg/kg body weight per day is unlikely to result in significant health risk."

## **HSA's advisory**

7 Consumers who have consumed "Brand's Alpha Tank Chewable Multi Vitamins & Minerals" and "Naturext Immune+ Probiotic 50B" are advised that the low content of DEHP found in each product is unlikely to cause harm to their health. They are nevertheless, advised to stop consuming the products as a precautionary measure.

8 Consumers may wish to contact the following companies for more information on the product recall or refund and exchange procedures:

Name of Product	Name of Company	Contact (Tel No.)
"Brand's Alpha Tank Chewable Multi Vitamins & Minerals"	Cerebos Pacific Limited	1800-7324748
"Naturext Immune+ Probiotic 50B"	International Advanced Bio-Pharmaceutical Industries (IAPBI) Pte. Ltd.	6873-8693

9 HSA will continue to monitor and test the health products from Taiwan and will alert members of the public of any new significant safety findings. For other enquiries related to this Press Release, members of the public can call HSA's Vigilance Branch at 6866 3538/3548 (Monday- Friday) or email: [HSA\\_Productsafety@hsa.gov.sg](mailto:HSA_Productsafety@hsa.gov.sg)

*\* The Tolerable Daily Intake (TDI) of DEHP, as established by the European Union, is 0.05mg/kg body weight/day and has incorporated a safety margin of 100 times.*

<sup>1</sup> *Ms Chan Cheng Leng's name & title in Chinese :*

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## HEALTH SCIENCES AUTHORITY

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### ▪ **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, 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. 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 <http://www.hsa.gov.sg/>.

### ▪ **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

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Photo of “Naturext Immune+ Probiotic 50B”



Photo of “Brand’s Alpha Tank Chewable Multi Vitamins & Minerals”

