



29 December 2010

Health Products Regulation Group
Health Sciences Authority
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Dear Healthcare Professional

VOLUNTARY RECALL OF “CARE WIPES”, “TRIHEXID CHLORHEXIDINE 0.2% MOUTH RINSE” AND “PEARLIE WHITE FLUORINZE FLUORIDE MOUTH RINSE”

The Health Sciences Authority (HSA) would like to alert healthcare professionals on the voluntary consumer level recall by the companies distributing the following products:

- “Care Wipes” by Tai Sun Paper Products Pte Ltd (Singapore)
- “Trihexid Chlorhexidine 0.2% Mouth Rinse” by Trident Pharm Pte Ltd
- “Pearlie White Fluorinze Fluoride Mouth Rinse” by Corlison Pte Ltd

2 These products were found to be contaminated with the bacteria, *Burkholderia cepacia* (*B. cepacia*).

Background Information

3 Following the detection of *B. cepacia* in “Oral Guard Antiseptic-Antiplaque Mouthwash” on 19 November 2010, HSA stepped up its quality compliance testing of health products that are marketed in Singapore. A risk-based approach towards product sampling was taken, which took into consideration the products most likely to be contaminated by *B. cepacia*. The products tested include those used in hospitals and the more commonly used mass-market brands of consumer health products. The results of these tests revealed that the above three products are similarly contaminated with *B. cepacia*.

4 “Care Wipes” is a disposable skin cleansing wipe. “Trihexid Chlorhexidine 0.2% Mouth Rinse” is labelled for use in the prevention of bad breath, tooth and gum diseases, reduction of plaque build-up, mouth ulcers and oral care following surgery. “Pearlie White Fluorinze Fluoride Mouth Rinse” is labelled to help kill bacteria that cause bad breath, plaque and gum problems, relieve tooth sensitivity, prevent tooth decay, strengthen tooth enamel and freshen breath.

***Burkholderia cepacia* (*B. cepacia*)**

5 *B. cepacia* is a bacterium that can be found in water, soil and other moist environmental sources. *B. cepacia* poses little medical risk to healthy people. However, people who have certain health problems such as weakened immune systems or chronic lung diseases may be more susceptible to infections caused by *B. cepacia*. There have been reported cases of *B. cepacia* detected in products such as mouth rinses and cleansing wipes in other parts of the world.

HSA's actions and advisory

6 HSA is currently overseeing the voluntary recall of the affected products and is also working with the companies to identify the root cause of *B. cepacia* contamination in the affected products. In the meantime, HSA will continue to sample and test other similar health products marketed locally to ensure that they comply with the quality requirements. HSA will keep healthcare professionals informed of any significant findings arising from its surveillance and tests.

7 Should you or your patients require further information or clarification on the recall of the affected products, please call the following telephone numbers for the respective products:

- "Care Wipes"; Tel: 6442 0212
- "Trihexid Chlorhexidine 0.2% Mouth Rinse"; Tel: 6288 7723
- "Pearlie White Fluorinze Fluoride Mouth Rinse"; Tel: 6288 2277

8 For further enquiries on this matter, please contact the Vigilance Branch at Tel: 6866 3538 / 3539, fax: 6478 9069 or email: HSA_productsafety@hsa.gov.sg

Thank you.

Yours sincerely



MS CHAN CHENG LENG
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HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

cc Director of Medical Services, Ministry of Health
Chief Executive Officer, Health Sciences Authority