

本署檔號 Our Ref. : (2) in DH SEB CD/8/101/1

September 18, 2019

Dear Medical Superintendent / Hospital Chief Executive,

**Alert on the brand of antiseptic solution “Pro-Medi Prosept” contaminated
with *Burkholderia cepacia* complex**

We would like to draw your attention to the incident of detection of *Burkholderia cepacia* complex in a brand of antiseptic solution called “Pro-Medi Prosept” (**Annex I**), which contains 0.05% chlorhexidine. The Department of Health (DH) urges healthcare workers and members of the public not to use Pro-Medi Prosept solution for wound and catheter site management. We would like to solicit your support to advise patients (especially renal patients on dialysis) to be cautious with the use of antiseptics for wound care at home.

B. cepacia is a group of bacteria that are commonly found in water, soil, and moist environments. It is generally not pathogenic to healthy people but those who have weakened immune system or chronic lung diseases may be more susceptible to infection with the bacteria. Transmission of *B. cepacia* from contaminated medicines and devices has been reported. *B. cepacia* can also be spread to susceptible persons by person-to-person contact, contact with contaminated surfaces and exposure to *B. cepacia* in the environment. The infection can be treated with appropriate antibiotics.

The incident was reported to DH by Queen Mary Hospital (QMH) upon environmental investigation for renal dialysis patients with *B. cepacia* infection. In early September 2019, *B. cepacia* was identified from the catheter exit site of four renal patients in QMH. Environmental investigation was carried out to ascertain whether there was a common source of infection.

The environmental investigation revealed that samples of Pro-Medi Prosept collected from a healthcare product shop in QMH and community pharmacies were cultured positive for *B. cepacia* with a bacterial count ranging from about 1,000 to 10,000 colony-forming units per milliliter. The product was distributed by Sources



(U.S.A.) Medicines Limited (“Sources”). The product is not classified as a pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap 138). Samples of the product have been collected by DH for laboratory tests. Based on the findings of QMH, Sources has voluntarily recalled the product from the market. Sources has also set up a hotline (2411 3463) to answer related enquiries.

Retrospective review by QMH found that there was an increase in cases of *B. cepacia* isolated from renal patients since 2018. From January 2018 – September 2019 (as of September 16), 53 renal patients with *B. cepacia* infection were detected in QMH (25 in 2018 and 28 in 2019 so far). Among them, five cases had invasive infections (1 bacteremia and 4 peritonitis). There is currently no evidence that any of the patients died of the infection. So far, there is no information on the source(s) of infection of these patients. DH has liaised with the Hospital Authority to carry out epidemiological investigation on cases of *B. cepacia* infection since 2018 to see if their infection was related to any possible use of the concerned product. DH has also contacted local private hospitals and registered renal dialysis centres to understand if they observed the emergence of *B. cepacia* complex infection among their patients. DH’s investigation is still ongoing.

Prepacked aqueous chlorhexidine is commonly used by renal dialysis patients for skin disinfection and catheter exit site care at home. Please advise your patients to stop using the above brand of chlorhexidine solution for wound care and catheter exit site cleaning. A list of registered pharmaceutical products containing chlorhexidine solution for antiseptic use or disinfection that are available in Hong Kong is shown in **Annex II**. Alternatively, sterile normal saline (0.9% saline) is also advised to be used for catheter exit site care at home. Of note, antiseptic products not indicated for wound care should not be used for that purpose or on broken skin.

Please draw the attention of the healthcare professionals and supporting staff in your institution/ working with you to the above. May I take this opportunity to thank you for your continuous support in combating infectious diseases in Hong Kong.

Yours faithfully,



(Dr. S K CHUANG)

For Controller, Centre for Health Protection
Department of Health

Annex I

Picture of the product “Pro-Medi Prosept”



Annex II

List of registered pharmaceutical products containing chlorhexidine solution for antiseptic use or disinfection that are available in Hong Kong

Item	Product Name Full Description	All Active Ingredients	HK Reg. No.	Certificate Holder
1	CHLORHEXIDINE ANTISEPTIC SOLN 0.05%	Chlorhexidine acetate 0.05%w/v	HK-42687	BAXTER HEALTHCARE LTD
2	0.05% CHLORHEXIDINE & 0.5% CETRIMIDE SOL	1. Chlorhexidine acetate 0.05%w/v, 2. Cetrimide 0.5%w/v	HK-42684	BAXTER HEALTHCARE LTD
3	0.015% CHLORHEXIDINE & 0.15% CETRIMIDE SOL	1. Chlorhexidine acetate 0.015%w/v, 2. Cetrimide 0.15%w/v	HK-42682	BAXTER HEALTHCARE LTD
4*	HIBICET HOSPITAL CONCENTRATE	1. Chlorhexidine gluconate 1.5%w/v, 2. Cetrimide 15%w/v	HK-06769	DCH AURIGA (HONG KONG) LIMITED - HEALTHCARE DIVISION
5*	MICROSHIELD 5 5% CHLORHEXIDINE CONC SOLN	Chlorhexidine gluconate 5%w/v	HK-37070	DCH AURIGA (HONG KONG) LIMITED - HEALTHCARE DIVISION
6	BAXEDIN 2%-70% SOLUTION	1. Chlorhexidine gluconate 2%w/v 2. Isopropyl alcohol 70%v/v	HK-58765	SINO-ASIA PHARMACEUTICAL SUPPLIES LTD

*** Please note that for items 4 and 5, they should be diluted in accordance with the manufacturer's instruction before use.**