



Direct Healthcare Professional Communication on ViaSpan Solution for Organ Preservation, PA2/75/1, regarding Potential for Product Contamination

1st May 2012

Dear Healthcare Professional,

In agreement with the Irish Medicines Board, Bristol-Myers Squibb (BMS) would like to inform you of important **follow-up information** regarding the initial DHCP communication issued on 30th March 2012 (see initial communication below) **for ViaSpan solution** indicated for the preservation of isolated liver, kidney, or pancreas prior to implantation in a recipient.

Follow-up to the initial communication:

The following information may be helpful in selecting an empirical antimicrobial agent if *Bacillus Cereus* infection is suspected.

- Based on the results of antibiograms performed on strains of *Bacillus Cereus* detected during the testing procedures in two different laboratories, the recommendation for empirical treatment, while awaiting local antimicrobial susceptibility results for the isolate, would be:
Moxifloxacin, Ciprofloxacin (not for paediatric use), Gentamycin (not as monotherapy), Imipenem, Tigecyclin.
- Vancomycin demonstrated intermediate resistance and should be avoided.
- The strain was resistant to the following antibiotics; Cefepim, Cefuroxim, Cefotaxime, Daptomycin, Penicillin, Ampicillin, Augmentin, Rifampicin, Erythromycin and Clindamycin.
- Antimicrobial treatment of *Bacillus cereus* infections should take into account local infectious disease knowledge and practices as well as individual patient's characteristics.

Initial communication:

The initial communication is provided below for completeness. All content remains current and valid except the paragraph strikethrough which is replaced by the above follow up information.



Summary

- A potential for ViaSpan contamination by *Bacillus cereus* during the manufacturing process was discovered following routine testing procedures and investigations by the production site.
- At the present time, there is no evidence of contamination in the ViaSpan that has been released to the marketplace.
- Bristol-Myers Squibb has decided, as a precautionary measure to recall all batches of potentially affected ViaSpan in those countries where alternatives to ViaSpan exist.
- Please find a list below of affected batches:

Batch Number	Expiry Date
16EG0217	25 July 2012
16EI0001	01 September 2012
16EK0008	05 October 2012
16FA0001	08 January 2013

- If you have any affected batches, please follow the instructions in the Recall letter that was issued on 29th March 2012.

Based on this information, for those patients who have undergone an organ transplant, the following guidance is provided to healthcare professionals.

- As a precautionary measure, close medical monitoring is recommended for any patients who recently underwent an organ transplantation in which a unit from a potentially affected batch of ViaSpan was used as an organ preservation solution.
- Healthcare personnel working in transplant units should be alert and vigilant to detect any signs and symptoms of systemic as well as local infections (central nervous system, heart, respiratory or cutaneous) occurring in those post-transplant patients.
- All necessary usual medical measures to characterise and treat infections as well as to preserve newly transplanted organs should be undertaken in conformity with the standard of care in place in any given institution (transplant centre, hospital).

Further information on recommendations to healthcare professionals

- *Bacillus cereus* is a Gram-positive aerobic or facultatively anaerobic, motile, spore-forming, rod-shaped bacterium that is widely distributed environmentally. *Bacillus cereus* is associated mainly with food poisoning. In addition to food poisoning, it



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causes a number of systemic and local, non-gastrointestinal-tract infections in susceptible patients, such as individuals who are immunologically compromised transplant recipient that may lead to organ rejection and/or other severe medical conditions.

- ~~Antimicrobials noted to be effective in the empirical management of a *Bacillus cereus* infection while awaiting antimicrobial susceptibility results for the isolate include ciprofloxacin and vancomycin. Antimicrobial treatment of *Bacillus cereus* infections should take into account local infectious disease knowledge and practices.~~

Adverse reaction reporting

Suspected adverse reactions should be reported to the Irish Medicines Board, or electronically via the website at www.imb.ie.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions for ViaSpan may also be reported to Bristol-Myers Squibb via telephone at 1 800 749 749 or via email at medical.information@bms.com.

For further information

Should you have any questions regarding the use of ViaSpan, please contact Bristol-Myers Squibb Medical Information at 1 800 749 749 or via email at medical.information@bms.com.

Yours sincerely,

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