



Bristol-Myers Squibb Pharmaceuticals Limited

Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH
Tel 01895 523000 Fax 01895 523010

Direct Healthcare Professional Communication on ViaSpan Solution regarding Potential for Product Contamination

29th March 2012

Dear Healthcare Professional,

Bristol-Myers Squibb (BMS) would like to inform you of important new safety information regarding ViaSpan solution indicated for the preservation of isolated liver, kidney, or pancreas prior to implantation in a recipient.

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/lots of potentially affected ViaSpan in those countries where alternatives to ViaSpan exist.
- Please find list below of affected batches

Batch Number	Expiry Date
16EM0070	14 December 2012
16EG0217	25 July 2012
16EG0074	31 July 2012
16EI0001	01 September 2012
16EK0008	05 October 2012
16FA0001	08 January 2013

- If you have any affected batches/lots, please follow the instructions in the Urgent Field Safety Notice that was issued on 29th March 2012

Based on this information, for those patients where an organ transplant has taken place or cannot be delayed and where, for the time being, no alternatives to ViaSpan is available, the following guidance is provided to healthcare professionals

- As a precautionary measure, close medical monitoring is recommended for any patients who recently underwent or will undergo an organ transplantation in which ViaSpan had been used or will be used as an organ preservation solution.
- Health care 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 characterize and treat infections as well as to preserve newly transplanted organs should be undertaken in



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conformity with the standard of care in place in any given institution (transplant center, 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 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 event reporting

Suspected adverse events should be reported to the Devices Division at the Medicines and Healthcare products Regulatory Agency, or electronically via the website at <http://www.mhra.gov.uk>.

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 0800 731 1736 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 0800 731 1736 or via email at medical.information@bms.com.

Yours sincerely,

Dr Rick Lones
UK Executive Medical Director
BM MFPM MRCGP DipIMC DRCOG