

Dear All,

The MHRA and NHSBT would like to update you with regard to the potential contamination of Viaspan organ perfusion solution with *Bacillus cereus*.

You will already be aware that the manufacture has placed this product on hold (ceased distribution) because of the contaminant which was identified in fluid used to test the integrity of the production line and not in the perfusion fluid itself. Bristol-Myers Squibb Pharmaceuticals Limited has now informed us that they are conducting a precautionary recall of this product in those countries where alternatives to Viaspan exist. A copy of the recall letter is attached. The advice regarding this recall from MHRA and NHSBT is as follows:

- For renal transplantation continue to use Soltran (Marshall Solution) as previously advised.
- For liver, pancreatic and bowel transplants where possible use alternatives to Viaspan such as Celsior (Genzyme) or HTK (Custidol).
- In liver, pancreatic and bowel transplant where no alternatives to Viaspan are available then the manufacturer has suggested that Viaspan can still be used with caution.

The MHRA and NHSBT will support this view but would recommend the following:

- During the retrieval process the samples of Viaspan Solution from each batch used should be sent for culture by the relevant retrieval team.
- The recipient should be informed about the potential contaminant and be consented accordingly.
- Continue to remain highly vigilant for signs of infection or rejection.
- Clinicians may wish to consider prophylactic use of antimicrobials following discussion with their local micro-biologist.

It is important to note that neither NHSBT or MHRA have been made aware of any adverse reactions associated with this potential contaminant which may have been ongoing since July 2011. We would request that any suspected associated infections be reported to both NHSBT and MHRA. We will issue further advice as soon as we receive any further information regarding this product. In the meantime we would recommend that all Transplant Units act urgently to locate a source of alternative perfusion solutions as mentioned above. For further clinical advice please contact either:

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Please share this information with your **pharmacist and transplant microbiologists.**