



**SINGAPORE, 8 March 2012**

## **HSA UPDATES**

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**HSA UPDATES NO 2/2012**

### **HSA SUSPENDS USE OF ALBUMIN PRODUCT FROM CSL BIOTHERAPIES AS A PRECAUTIONARY MEASURE**

The Blood Services Group (BSG) of the Health Sciences Authority (HSA) was notified today by CSL Biotherapies (CSL) of a quality issue involving the manufacture of its 20% albumin product in their facility in Australia.

2 CSL notified BSG that some batches of its albumin products manufactured before 25 January 2012 were found to have been contaminated with trace amounts of ethylene glycol, due to equipment failure. None of the affected batches involved albumin products supplied to Singapore. As a precaution, CSL is continuing to conduct further testing to determine if other batches are affected and to determine their quality and safety. Only albumin products are affected and all other products manufactured by CSL are not affected.

3 BSG has been advised by CSL that the levels of ethylene glycol detected in the affected batches of albumin products are very low, and are unlikely to pose a risk to patient safety. To date, there have been no reports to BSG or CSL of any adverse events from patients who have used the albumin products manufactured by CSL. The 20% albumin product supplied by BSG is used primarily in treating patients with very low levels of albumin, such as those with advanced liver disease, nephrotic syndromes and advanced malignancies. It may also be used for severe burns involving lung damage.

4 As a precautionary measure and until further information is available, BSG has immediately quarantined all its existing stocks of albumin products from CSL Biotherapies and has instructed hospitals holding these products to suspend their use until further notice. To ensure that patients continue to have access to albumin products, BSG has made arrangements for alternative products to be made available.

5 HSA has been in close contact with its blood service and regulatory counterparts in Australia, and it has been ascertained that any toxicity due to ethylene glycol would occur acutely and delayed effects beyond 72 hours would not be expected. HSA is also conducting tests on the current batches of albumin products from CSL at its Applied Sciences Group laboratories.

6 HSA will update the public as soon as new information is made available.

**HEALTH SCIENCES AUTHORITY**  
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