



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE**

9 MARCH 2012

HSA RECALLS ALBUMEX 20® (20% ALBUMIN) FROM CSL BIOTHERAPIES AS A PRECAUTIONARY MEASURE

The Health Sciences Authority (HSA) is recalling all supplies of Albumex 20® (20% albumin) manufactured by the Australian bio-pharmaceutical company CSL Biotherapies (CSL) from public hospitals as a precautionary measure following detection by HSA's laboratories of trace amounts of ethylene glycol in samples of the product.

2 The Blood Services Group (BSG) of HSA was notified yesterday by CSL that some batches of 20% albumin solution that were manufactured in Australia before 25 January 2012 were contaminated with trace amounts of ethylene glycol due to equipment failure. The company has similarly notified authorities in Australia, New Zealand and Hong Kong where the products are used. HSA immediately suspended the supply and use of all batches of CSL albumin products from the public hospitals yesterday evening while the company and HSA conducts further investigations and testing. HSA remains in close contact with its counterparts in Australia and CSL for close monitoring of the situation.

3 Tests conducted at HSA's laboratories today confirmed the presence of trace amounts of ethylene glycol (an alcohol generally used as a coolant), in one batch of Albumex 20®. HSA and CSL have assessed that the levels of ethylene glycol detected in the albumin products are very low and are unlikely to pose a risk to patient safety. Toxicities would arise only at levels much higher than those detected in the products and if they occur, they would appear acutely and delayed effects beyond 72 hours would not be expected. To date, there have been no reports to HSA or CSL of any adverse events from patients who have used the albumin products manufactured by CSL.

4 Albumex 20® is only one of several albumin products available and used in Singapore. HSA has worked with suppliers of other brands of albumin products to ensure that our hospitals have continued supplies of albumin products for use. Albumin is primarily used in treating certain patients with very low levels of albumin such as those with advanced liver and kidney diseases or severe burns.

HSA's advisory

5 Patients are advised not to be unduly alarmed by this finding as the health risk is assessed to be low. HSA has alerted doctors in the hospitals who may have used the affected albumin products within the last three days to contact their patients to monitor for any adverse events, although the occurrence of these events is unlikely. Patients who have received albumin products and are still concerned may wish to consult their doctors.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
9 MARCH 2012**

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

About HSA's Blood Services Group

The Blood Services Group (BSG) of HSA, as the national blood service, secures the nation's blood supply by ensuring a safe and adequate blood supply. It operates the Bloodbank@HSA and Bloodbank@Woodlands. It is responsible for collecting, processing, testing and distributing blood and blood products to all hospitals in Singapore. It also provides specialist transfusion medicine services in immunohaematology and tissue typing and is actively engaged in the cutting edge therapeutic research area of cell processing.