



SINGAPORE, 27 OCTOBER 2011

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.

HSA UPDATES NO 6/2011

HSA UPDATES ON THE VOLUNTARY WORLDWIDE RECALL OF XIGRIS®

Eli Lilly and Company has voluntarily recalled Xigris® [drotrecogin alfa (activated)] worldwide due to new clinical trial findings of lack of efficacy of the product.

2 Xigris® has been licensed locally since August 2002 for use in the reduction of mortality (number of deaths) in adult patients with severe sepsis* who have a high risk of death.

Background

3 The decision by Eli Lilly to withdraw Xigris® from the market was based on the recent 28-day mortality results from a clinical trial called the PROWESS-SHOCK**. In this clinical trial, Xigris® failed to show a survival benefit in patients with severe sepsis and septic shock. The study revealed an overall 28-day mortality of 26.4% in Xigris®-treated patients compared to 24.3% in the placebo control group. One possible reason for these findings could be that the standard of care for patients with sepsis and septic shock have advanced over the years.

HSA's Actions

4 Xigris® is available in both public and private healthcare institutions. The local recall of Xigris® is with immediate effect from today. Healthcare professionals have been informed of the recall and are advised to discontinue patients who are currently on Xigris® and not to initiate treatment in new patients.

**Severe sepsis is characterised by whole-body inflammation, presence of infection and organ dysfunction.*

***The PROWESS-SHOCK is a placebo-controlled study and was conducted to determine if Xigris® treatment provides significant mortality reduction improvement in patients with septic shock compared with placebo treatment. This study also assessed the effectiveness of Xigris® in reducing 28-day mortality in patients with septic shock.*

HEALTH SCIENCES AUTHORITY 27 OCTOBER 2011

- **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.

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