Worldwide withdrawal of Xigris (drotrecogin alfa)

Your attention is drawn to that the Department of Health (DH) has been informed by Eli Lilly Asia, Inc. that the company decided to withdraw Xigris worldwide due to new clinical trial findings of lack of efficacy and the subsequent impact on the benefit-risk profile of the product.

The company's decision is based on the 28-day mortality results from the PROWESS-SHOCK trial, which was conducted as part of an EU regulatory commitment to confirm the benefit-risk profile of the drug. While there was no new safety finding, the study showed no 28-day survival benefit of Xigris in septic shock patients.

In Hong Kong, Xigris for Inj. 5mg (HK-51126) and Xigris for Inj. 20mg (HK-51125) have been registered by Eli Lilly Asia Inc. since year 2003. They are prescription medications and are indicated for treatment of adult patient with sepsis with multiple organ failure. The company has written to DH to cancel the registration of the product on 25 October 2011 and DH has posted the news on the website of Drug Office on the same day.

During our daily surveillance today, it was found that the European Medicines Agency, the U.S. Food and Drug Administration and Health Canada also issued announcements regarding the withdrawal of Xigris. For details, please refer to the following links:

1. Hong Kong Department of Health
   http://www.drugoffice.gov.hk/eps/webpage.jsp
2. European Medicines Agency
3. U.S. Food and Drug Administration
4. Health Canada

We are committed to providing quality client-oriented service
Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.drugoffice.gov.hk at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Ms. Pamela LI)
for AD(D)