



Department of  
**Health, Social Services  
and Public Safety**

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

From The Chief Pharmaceutical Officer  
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Our Ref: **PHC/27/2011**

Date: 26 October 2011

**For Action:** Assistant Director Pharmacy and Medicines Management,  
HSC Board & BSO  
Heads of Pharmacy and Medicines Management of  
HSC Trusts  
Regulation Quality Improvement Authority

**DRUG ALERT**  
**MEDICINES RECALL**  
**FOR IMMEDIATE ACTION**  
**Recall to Hospital and Wholesaler level**

Dear Healthcare Professional

**ELI LILLY AND CO LTD**

**Xigris 5mg and 20mg**  
Powder for solution for infusion  
Drotrecogin alfa (activated)

**EU/1/02/225/001-002**

**Immediate withdrawal of all distributed stock**

Eli Lilly has informed us that all distributed stock of Xigris is being recalled following discussions with the European Medicines Agency. This action is being taken following new clinical trial findings which show a lack of efficacy and call into question the risk-benefit profile of the product. Specifically, this relates to the results from the PROWESS-SHOCK study, where overall 28-day mortality in Xigris-treated patients (N=846) was 26.4% compared to 24.2% in the placebo control group (N=834); (p=0.31, RR=1.09 [0.92-1.28]).

Patients currently being treated with Xigris should have treatment discontinued. No new patient treatment should be initiated. For further medical information please call Eli Lilly Medical Information on 01256 315000.

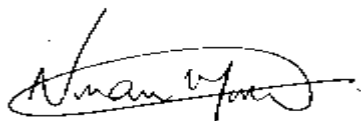
Suspected adverse reactions should be reported to the MHRA by use of a Yellow Card, which is available from MHRA, Freepost Yellow Card or electronically via <http://www.yellowcard.gov.uk>.

Any unused stock should be returned to the original supplier for credit. For enquiries related to product returns please call 0800 012 1178.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly

Yours sincerely



**DR NORMAN MORROW**  
Chief Pharmaceutical Officer

For information:

CMO  
CNO  
CDO  
CSSO  
SMO  
Director, Health Estates  
Public Health Branch  
DHSSPS, Library  
Extended nurse prescribers

Regional Medicines and Poisons Information Service  
Regional Director of Supplies  
RPQAS  
Pharmaceutical Society of NI  
Senior Prison Pharmacist  
Prison Service, Dundonald House  
Nursing Officer, Health Estates  
Medical Officer, Castle Buildings  
Regional Procurement Pharmacist  
NICPLD