



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

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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For Action: Assistant Director Pharmacy and Medicines Management
HSC Board & BSO
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our Ref: PHC/31/09

Date: 5 November 2009

DRUG ALERT
MEDICINES RECALL
CLASS 2 MEDICINES RECALL
Action Within 48 Hours
PHARMACY OR EQUIVALENT LEVEL RECALL

Abraxis BioScience Ltd
Abraxane 5mg/ml powder for suspension for infusion
Paclitaxel Albumin
EU/1/07/428/001

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---------------------|--------------------|--------------------|--------------------------|
| 405692A | 12/2009 | Single 50 ml vials | 12/2008 |

Abraxis BioScience Ltd are recalling all remaining stock of the above batch as a precautionary measure. Particulate matter has been found in other batches of Abraxane made in the same time period.

Medical Information enquiries should be telephoned to 0207 081 0850.

Please quarantine any remaining stocks of this batch. Recipients will be contacted by Aexxdis (the appointed distributor) and given instructions for stock returns. For any related enquiries, please telephone Aexxdis on 05603 141 956.

Supplies of the licensed UK presentation of Abraxane are not expected to return to normal until the end of Q1 2010.

A Dear Healthcare Professional (DHCP) letter is being distributed by Abraxis to physicians which will recommend that patients are switched to alternate therapies if judged clinically acceptable.

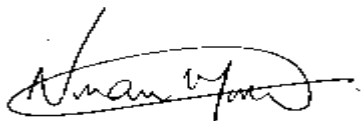
For any patients who cannot be switched to other products, imports of unlicensed Abraxane are being permitted. Unlicensed packs will not be labelled in accordance with the normal UK format and the prescriber accepts responsibility for their use in the best clinical interests of the patient.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

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
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

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