



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/11/11

Date: 29th March 2011

DRUG ALERT
MEDICINES RECALL
CLASS 4 MEDICINES DEFECT INFORMATION

Dear Healthcare Professional

Pharmacia Limited
Various Products

Pfizer has informed us that it has identified some issues in patient information leaflets (PILs) for three products for which the Marketing Authorisation holder is Pharmacia Limited. All three products are distributed in Pharmacia Limited livery. The details are as follows:

Cyclophosphamide 50mg Tablets - PL 0032/0335

Pfizer has informed us that it has identified some issues in patient information leaflets (PILs) for three products for which the Marketing Authorisation holder is Pharmacia Limited. All three products are distributed in Pharmacia Limited livery. The details are as follows:

Batch number	Expiry date	Pack size	First distributed
1382571	Dec 2013	1 x 100	1 Mar 2011

There is an error in section 6 of the current PIL (dated April 2010) entitled 'Further Information'. The tablet is described as 'a white sugar coated capsule'. The description should read 'a brown sugar coated tablet'. The correct information is provided in the Summary of Product Characteristics (SmPC).

To avoid stock disruption, distribution of affected stock will continue until corrected stock is available. This is expected by the end of June 2011.

Kemicetine Succinate 1g Injection PL 0032/0341

Chloramphenicol sodium succinate

All unexpired stock

There is an error in section 3 of the patient information part of the current and previous PILs entitled 'How Kemicetine Succinate Injection is given'. Under dosage for children, the wording 'daily in divided doses' is missing. The wording should read 'Children: The equivalent of 50mg/kg chloramphenicol according to body weight, daily in divided doses every six hours.' The correct information is provided in the professional information part of the leaflet and in the SmPC. To avoid stock disruption, distribution of affected stock will continue until corrected stock is available. This is expected by the end of June 2011.

Solu-Medrone 2 gram for injection PL 0032/0073

Methylprednisolone sodium succinate

Batch number	Expiry	Pack size	First distributed
S02306	Use by Dec 2012	1 vial active + 1 vial diluent	4 Aug 2009
S10776	Use by Dec 2012	1 vial active + 1 vial diluent	8 Jun 2010
Y00957	Use by Feb 2015	1 vial active + 1 vial diluent	Not yet distributed

There are two errors in the 'Information for Doctors and Pharmacists' section of the current PIL (dated November 2009).

1. Under 'Posology and method of administration', '**In cerebral oedema**', the following wording is included: 'Methylprednisolone should not be used routinely in the treatment of severe head injuries.....' This is incorrect. The wording in the PIL should reflect the information given in the SmPC under 'warnings and precautions' which is 'Corticosteroids should not be used for the management of head injury'
2. Under 'Posology and method of administration', '**For treatment of acute spinal cord injury**', dosage information in the PIL is provided under two headings, 'For patients initiated on treatment within 3 hours of injury' and 'For patients initiated on treatment within 3 to 8 hours of injury. This is incorrect, as is the instruction under the first heading which states '..... then a continuous infusion of 5.4mg/kg per hour for 47 hours'. The wording in the PIL should reflect the wording given in the SmPC, which is as follows: 'administer intravenously 30mg methylprednisolone per kilogram of body weight in a bolus dose over a 15 minute period, followed by a 45 minute pause, and then a continuous infusion of 5.4mg/kg per hour for 23 hours. There should be a separate intravenous site for the infusion pump. The treatment should begin within eight hours of injury.'

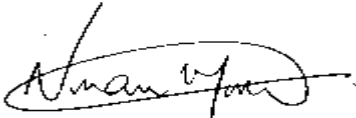
To avoid stock disruption, distribution of affected stock will continue until corrected stock is available. This is expected by the end of June 2011.

For medical information enquiries concerning these issues, please contact Pfizer Medical Information on 01304 616161.

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