



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/30/09

Date: 7 October 2009

**DRUG ALERT**  
**MEDICINES DEFECT INFORMATION**  
Caution in Use  
**For distribution to hospital pharmacists**

Dear Healthcare Professional

**Focus Pharmaceuticals Limited**  
**Fluconazole 2mg/ml Solution for Infusion**  
**(Fluconazole)**  
**PL 20046/0055**

Batch number	Expiry date	Pack size	First distributed
0802849	08/2013	25ml	01/12/2008
0802740	08/2013	100ml	01/12/2008
0802760	08/2013	100ml	24/09/2009
0802773	08/2013	100ml	24/09/2009
0802818	08/2013	100ml	02/10/2009
0802834	08/2013	100ml	02/10/2009

Focus Pharmaceuticals Limited has informed the MHRA that there is an error in the patient information leaflet (PIL) supplied in the above batches of Fluconazole 2mg/ml Solution for Infusion, concerning the dose to be administered **to children** for the indication mucosal candidiasis.

The leaflet text reads:

Treatment of mucosal candidiasis - the usual dose is 3-12mg/kg per day. 6mg/kg may be given on day 1.

The text should read:

Treatment of mucosal candidiasis – the usual dose is 3mg/kg per day. 6mg/kg may be given on day 1.

The remaining text of the leaflet is correct, as is the labelling of the product and the SPC.

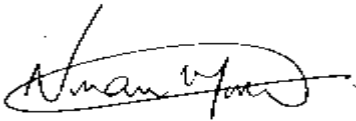
Due to current product shortages, these batches are not being recalled. Focus Pharmaceuticals Limited has confirmed that no further batches containing the incorrect PIL will enter the market.

### **Further information**

For further enquiries, please telephone Focus Pharmaceuticals Limited on 01283 495280.

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

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