



From The Chief Pharmaceutical Officer  
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**For Action:** Directors of Pharmaceutical Services of the Boards & CSA  
Directors of Pharmaceutical Services of HSC Trusts  
Regional Quality Improvement Authority

Our reference: PHC/4/09

Date: 3 February 2009

## **DRUG ALERT MEDICINES RECALL**

Dear Healthcare Professional

### **Genzyme Europe BV**

**Fabrazyme 5mg powder for reconstitution**

**Agalsidase Beta 5mg per ml when reconstituted**

**EU/1/01/188/004-006**

**Please replace the Drug Alert issued yesterday (2 February 2009) with this revised document. There are two changes present in this update:-**

- 1. Only single 5mg vials are involved and the title has been revised to Fabrazyme 5mg powder for reconstitution.**
- 2. Genzyme have informed us that an additional batch is involved which has been added to the list below.**

<b>Batch Number</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>First Distributed</b>
A8049H01	Aug 2011	1 vial per carton	12/11/2008
A8049H06	Aug 2011	1 vial per carton	05/12/2008
A8049H09	Aug 2011	1 vial per carton	09/01/2009
A8060H02	Oct 2011	1 vial per carton	14/01/2009

Genzyme Europe BV are recalling all remaining stock of the above batches due to incorrect fill volumes in a low proportion of the vials supplied. The problem only affects the above quoted batch numbers of the 5mg/ml (when reconstituted) formulation.

All unused stock of the above batches should be quarantined and returned for credit via the original supplier. For returns and credit enquiries, please contact Genzyme Therapeutics on 01865 405200.

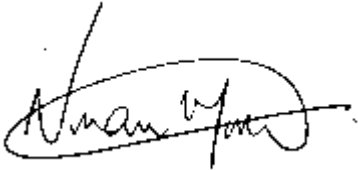
For medical information enquiries, please contact Genzyme Therapeutics on 01865 405200.

This product is normally used in hospital pharmacies and clinics and not by General Practitioners.

Recipients of this Drug Alert should bring this to the attention of relevant contacts by copy of this letter. Primary Care Trusts are being copied for information purposes and we do not believe it is necessary to forward this to Community Pharmacists and General Practitioners.

Area Boards/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  
NICPPET