



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  
Heads of Pharmacy and Medicines Management of HSC Trusts  
Regional Quality Improvement Authority

Our Ref: PHC/16/11

Date: 11 May 2011

## **DRUG ALERT MEDICINES RECALL**

Dear Healthcare Professional

**Janssen-Cilag Ltd**

<b>Prezista Tablets 400mg</b>	<b>EU/1/06/380/003</b>
<b>Darunavir (as ethanolate)</b>	

Batch Number	Expiry Date	Pack Size	First Distributed
AFZOCOO	May 2012	60	21 September 2010

Janssen-Cilag Ltd has advised us that the above batch is being recalled to hospital and pharmacy level following complaints of musty and mouldy odours. The problem is caused by trace amounts of 2, 4, 6-tribromoanisole (TBA) in some bottles which is derived from a preservative used on wooden pallets during distribution.

Patients should not discontinue their antiretroviral treatment without first consulting with their healthcare professional. If patients return their Prezista tablets because of an uncharacteristic odour, it should be replaced and the occurrence reported to Janssen Recall Helpline on free phone number 0800 0323013.

We understand that no serious adverse events have been associated with this contamination issue which includes additional batches distributed elsewhere in Europe. The marketing authorisation holder is aware of two complaints linked to non-serious gastrointestinal symptoms such as vomiting and nausea which may be caused

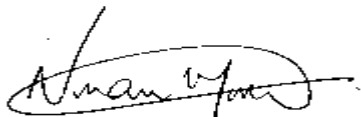
by the contaminant. For medical information enquiries please call Janssen Recall Helpline on free phone number 0800 0323013.

All unused stock of this batch of Prezista tablets should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please call Janssen-Cilag Ltd on 0800 333001.

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