Health and Healthcare Improvement Directorate
Pharmacy and Medicines Division

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11 May 2011

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG ALERT NOs 14 and 15 – CLASS 2

Please see the attached drug alerts for onward transmission as below.

Please could all Directors of Pharmacy forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

1. Please could Medical Directors forward this alert to:-

- General Practitioners
- Relevant Clinics
- Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

Leslie Smith
pp

IRENE FAZAKERLEY
Pharmacy Division

Safeguarding public health
Defective Medicines Report Centre
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Telephone +44 (0)20 3080 6574

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 hours

For distribution to GPs, Pharmacies, wholesalers and relevant clinics

Date: 11 May 2011 EL (11)A/14 Our Ref: MDR 15-05/11

Dear Healthcare Professional,

Janssen-Cilag Ltd

Prezista Tablets 400mg	**EU/1/06/380/003**
Darunavir (as ethanolate)	

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.

MHRA Distribution:
Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Date: 11 May 2011 EL (11)A/14 Our Ref: MDR 15-05/11

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.

Recipients of this Drug Alert are requested to bring it to the attention of relevant professionals by copy of this letter. Primary Care Trusts are asked to forward this information to General Practitioners, Community Pharmacists and relevant clinics by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager

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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 hours

For distribution to GPs, Pharmacies, wholesalers and relevant clinics

Date: 11 May 2011 EL (11)A/15 Our Ref: MDR 17-05/11

Dear Healthcare Professional,

AstraZeneca UK Ltd

Zoladex 3.6mg Single-dose syringe applicator	**PL 17901/0064**
Goserelin (as acetate)	

Batch Number	Expiry Date	Pack Size	First Distributed
HK081	10/2013	Single pouch	20 April 2011

AstraZeneca UK Ltd has advised us that the above batch is being recalled to hospital and pharmacy level following concerns about the integrity of the pouch in a small number of cases. The issue is limited to one batch and has arisen during packing at the factory. We understand that the pouch is not the primary sterility barrier but performance of desiccant material in the pouch could be adversely affected during storage.

Recipients are requested to quarantine any remaining stock and return it to their original supplier for credit. For enquiries related to stock returns, please call AstraZeneca UK Supply Chain on 0800 032 0501.

For medical information enquiries please contact AstraZeneca UK medical information on 0800 783 0033.

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Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Date: 11 May 2011 EL (11)A/15 Our Ref: MDR 17-05/11

AstraZeneca does not anticipate any supply issues associated with this limited recall.

Recipients of this Drug Alert are requested to bring it to the attention of relevant professionals by copy of this letter. Primary Care Trusts are asked to forward this information to General Practitioners, Community Pharmacists and relevant clinics by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager