

**Safeguarding public health**  
**Defective Medicines Report Centre**  
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## **DRUG ALERT**

### **CLASS 1 MEDICINES RECALL**

**Action Now - including out of hours**  
**PATIENT LEVEL RECALL**

Date: 24 May 2007

EL(07)A/06

Our Ref: MDR 15-05/07

Dear Healthcare Professional,

### **Counterfeit Parallel Distributed Product**

**Zyprexa Tablets 10mg**  
**(Olanzapine)**

**EU/1/96/022/009**

**The MHRA in conjunction with the EMEA, with assistance from Eli Lilly and Company Ltd are recalling any parallel distributed stock of Lots A200127, A216454 and A229505 (and lot variants) of Olanzapine tablets 10mg branded as Zyprexa following the discovery of counterfeit tablets in the legitimate supply chain. Please read the comments below about lot number variants used in the parallel distribution trade.**

This counterfeit material was supplied in French livery via parallel distributors into the UK supply chain. Both genuine Lilly manufactured product and counterfeit product may be present in the UK supply chain. Stock presenting a patient risk may be present as French livery cartons with an overlabel applied by a parallel distributor or has been recartoned into an English carton by the parallel distribution repacking process.

All the above lots are genuine Lilly lot numbers for which the original lots were all supplied to France in French livery.

**Please note that Lilly routinely supply stock to the UK market which is not parallel distributed and is in UK Lilly livery. This stock is not affected. None of this stock has the above lot numbers or variants.**

We have limited information about this problem and understand the EMEA has allowed nearly 40 UK parallel distributors to supply this product.

#### **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)

**Medicines and Healthcare products Regulatory Agency**

Market Towers 1 Nine Elms Lane London SW8 5NQ

T 020 7084 2000 F 020 7084 2353 [www.mhra.gov.uk](http://www.mhra.gov.uk)

An executive agency of the Department of Health

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Please be aware of the following issues concerning lot numbers:-

1. Parallel distribution companies may have added a prefix or suffix to the lot number, such as A200127/1 to differentiate different packing runs. These lot number variants are included in the scope of the recall.
2. Parallel distribution companies may occasionally use a completely different lot number on the carton. **If the lot number on the carton is not in the format 'XXXXXXX or XXXXXXX/X' recipients are advised to contact the parallel distributor listed on the carton for clarification.** We intend to provide updated data on this area if we receive additional information.

#### Actions Required

**Recipients are asked to attempt to recover tablets from patients,** quarantine all remaining stock and return as listed below.

We request that all stock of the attached lot number and variants be returned to Eli Lilly for examination and suggest you keep full details of any returns. **Please telephone the Customer Services Team at Eli Lilly on 0800 032 0741 to make arrangements for return.**

The issue of reimbursement should be discussed with your original supplier and we suggest you keep full records.

**Please do not return stock to your original supplier but contact Eli Lilly as mentioned above. Your cooperation is requested in this matter as it will provide useful information about the origins and scope of the problem.**

Additional information is available in the FAQs sheet attached.

Primary Care Trusts are asked to bring this information to the attention of Community Pharmacists and professionals with an interest in mental health by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager

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### FAQs

#### **Why has a Class 1 Drug Alert been issued in this case?**

Initial tests show that samples only contain about 60% of the labelled active ingredient. In addition, a counterfeit is likely to show a different bioavailability profile and may contain harmful degradants. Work is ongoing to obtain more information but in the interim we consider a recall is needed to minimise patient risk.

#### **Why are both French cartons and some in English livery used?**

In some cases the parallel distributor buys the product in small cartons and applies their own label. In other cases the distributor buys the product in large cartons and packs down into smaller amounts in their own carton.

#### **Why cannot you be more specific about the lot numbers used?**

It is the decision of the parallel distribution company whether they use a prefix, suffix or completely different lot number. We expect that most will use a prefix or suffix but cannot rule out the use of a completely different number on the carton. We believe that waiting for a full answer from nearly 40 companies would provide an unacceptable delay to the Drug Alert.

#### **Why have you requested that all stock goes to Lilly for examination?**

Although there are visual differences between genuine and counterfeit stock some are subtle and we do not feel that recipients should be asked to do this work. In addition, we need to obtain as much information as possible about this problem.

#### **What is the difference between parallel distribution and parallel imports?**

Parallel traded products are often sold at lower prices in the EU and are allowed to be imported and relabelled for sale in the UK. Parallel distributed products have a marketing authorisation issued by the EMEA and parallel imported products have a marketing authorisation issued by the MHRA.

In both cases the repacking and relabelling are inspected by the MHRA but the importation and/or distribution takes place outside the original manufacturer's supply chain.

#### **Are there any differences between the supply of these lots?**

We have no evidence that lot A229505 reached the patient but with lots A200127 and A216454 there is some evidence that product has reached the patient. We request your cooperation in checking to the same extent for all three lots due to the serious nature of the problem.