

Press release

Date: 24 May 2007
Time: 2.00pm
Subject: Medicines Alert and Recall of Zyprexa

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Recall of Counterfeit Zyprexa batches

The MHRA has been alerted to three counterfeit batches of Zyprexa (Olanzapine) 10 mg tablets. This drug is used in the treatment for patients with schizophrenia, bipolar disorder and similar conditions.

The MHRA has issued a drug alert to recall this product from the market, to minimise the risk to patients. To date, it is believed that two of the batches have reached patient level. We take this very seriously and a criminal investigation is being carried out.

Patients should contact their pharmacist as soon as possible, if they are taking medication from the following; Zyprexa (Olanzapine) 10mg tablets with the batch numbers A229505, A200127, A216454 (or one of these numbers with a prefix or suffix). They should take their medication with them so their pharmacist can return it to Eli Lilly (the manufacturer) for examination. At present there is no evidence of patients having any adverse reactions specifically related to the counterfeit batches. Patients should consult their GP if they have any treatment or health concerns.

Patients with concerns can contact Eli Lilly on 0800 032 0741.

Note to Editors

1. Zyprexa contains the active ingredient called Olanzapine. Zyprexa belongs to a group of medicines called antipsychotics. It is indicated in the treatment for schizophrenia and bipolar disorder. Zyprexa is centrally licensed by the European Medicines Agency (EMA) and we are working

in conjunction with them. Eli Lilly is the licence holder. Zyprexa (Olanzapine) is licensed by the EMEA and was licensed on 27 September 1996.

2. The MHRA was informed by Eli Lilly. Eli Lilly was informed by a company who prints labelling for their products, after a repackager had contacted them after becoming suspicious.
3. One person has been arrested and is on bail. They have not yet been charged. MHRA investigatory enquiries are continuing.
4. The initial laboratory tests on the seized counterfeits show that the samples contain approximately 60% of the labelled active ingredient. A counterfeit may also contain harmful ingredients. Work is ongoing to obtain more information about any additional ingredients in these counterfeit tablets, but in the interim we have issued a recall to minimise patient risk.
5. Counterfeits are notoriously difficult to detect with the untrained eye and even experts sometimes require full forensic laboratory tests to determine whether a suspect product is indeed a counterfeit. Although there are some visual differences between genuine and counterfeit stock in this case, they are not all clear. We do not feel that patients should be responsible for physically examining their packs if they bear the suspect batch numbers, therefore we strongly recommend taking the product back to their GP or pharmacist who can contact Eli Lilly and arrange for the product to be returned for analysis. Lilly are the best people to carry out these tests to differentiate the genuine article from the fake.

Ends