

Press release

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Subject: Medicines Alert and Recall of Casodex

Contact: Press Office 020 7084 3535 / 3564 press.office@mhra.gsi.gov.uk
Out of hours 07770 446 189

Recall of Counterfeit Casodex batch

The MHRA has been alerted to a counterfeit batch of Casodex (Bicalutamide) 50mg tablets (batch number 65520). This drug is used in the treatment of patients with prostate cancer. The MHRA has issued a drug alert to recall this product from the market, to minimise the risk to patients.

The MHRA was contacted by a wholesaler, who was offered a suspicious batch of Casodex by another wholesaler. This is now subject of a Class 1 medicines recall, today, 01 June 2007. 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 this medication, with the batch number of 65520. They should take their medication with them, so their pharmacist can check it and return it to the licensed manufacturer, AstraZeneca, for further examination. At present there is no evidence of patients having any adverse reactions specifically related to the counterfeits. Patients should consult their GP if they have any treatment or health concerns.

Note to Editors

1. Casodex contains the active ingredient called Bicalutamide. This drug is used in the treatment of patients with prostate cancer. The MHRA is working in conjunction with AstraZeneca the licence holder.

2. The MHRA investigation is continuing into this case. At present we are investigating the possibility of links with the counterfeit drug recalls of Zyprexa (24 May 2007) and Plavix (25 May 2007)
3. The initial laboratory tests on the seized counterfeits (batch 65520) show that the samples contain approximately 75% 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 meantime we have issued a recall to minimise the risks to patients.
4. 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.
5. What are parallel imports? Parallel imported products are often sold at lower prices in the EU and are allowed to be imported and relabelled for sale in the UK. Parallel imported products have a marketing authorisation issued by the MHRA. The repacking and relabelling of parallel imports are inspected by the MHRA but the importation and re-distribution takes place outside the original manufacturer's supply chain.

Ends