

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: 1 June 2007

EL(07)A/08

Our Ref: MDR 40-05/07

Dear Healthcare Professional,

Counterfeit Parallel Imported Product

Casodex Tablets 50 mg
(Bicalutamide)

Multiple PLPI Licences

The MHRA with assistance from AstraZeneca UK Ltd, are recalling any parallel imported stock of Lot 65520 (and lot variants) irrespective of livery of Bicalutamide tablets 50 mg branded as Casodex following the discovery of counterfeit tablets in the legitimate supply chain. Please read the comments below about lot number variants used in the parallel import trade.

This counterfeit material was supplied in French livery via parallel importers into the UK supply chain. Counterfeit product may be present in the UK supply chain alongside genuine manufactured product. Stock presenting a patient risk may be present as French livery cartons with an overlabel applied by a parallel importer or may have been recartoned into an English carton by the parallel import repacking process.

The above lots are genuine AstraZeneca lot numbers for which the original unchanged lots were supplied to France in French livery.

Please note that AstraZeneca routinely supply stock to the UK market which is not parallel imported and is in UK branded livery. This stock is not affected and bears the Product Licence number PL 17901/0005. None of this stock has the above lot numbers or variants.

A large number of parallel importers are licensed to handle this product and we are grateful for your cooperation in checking all parallel imported stock.

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

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An executive agency of the Department of Health

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

1. Parallel import companies may have added a prefix or suffix to the lot number, such as 65520/1 to differentiate different packing runs. These lot number variants are included in the scope of the recall.
2. Parallel import companies may occasionally use a completely different lot number on the carton. **If the lot number on the carton is not in the format of one of the quoted batch numbers with or without a suffix or prefix, recipients are advised to contact the parallel importer listed on the carton for clarification.** We intend to provide updated data if we receive additional information.

Actions Required

Recipients are asked to attempt to recover tablets from patients bearing lot number 65520 (and variants of this number).

Quarantine all remaining stock bearing lot number 65520 (and variants of this number) and return as detailed below for examination. We suggest you keep full details of any returns.

During normal working hours, please telephone the AstraZeneca Customer Services Team on 01582 837837 and for out of hours please telephone Medical Information on 01582 836836 to discuss the return of the affected stock.

The issue of reimbursement should be discussed with your original supplier (not AstraZeneca) and we suggest you keep full records.

Please do not return stock to your original supplier but contact AstraZeneca Customer Services, to discuss the return of the affected stock. 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 Q&As sheet attached.

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

Yours faithfully
Ian Holloway
MHRA DMRC Manager

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Q&As

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

Initial tests show that samples only contain about 75 percent 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 importer buys the product in small cartons and applies their own label. In other cases the importer repacks into their own carton.

Why can you not be more specific about the lot numbers used?

It is the decision of the parallel import 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 many companies would provide an unacceptable delay to the Drug Alert.

Why have you requested that all stock goes to AstraZeneca for examination?

We have requested the assistance of AstraZeneca to effect an efficient recall. Although there are visual differences between genuine and counterfeit parallel distributed stock, some differences are subtle. In addition, we need to obtain as much information as possible about this problem.

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.