

Medicines Authority Inspectorate and Enforcement Division 198, Rue d'Argens, Gzira Malta Telephone: +356 2343 9142

Facsimile: +356 2343 9161

Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 23rd January 2007

Our Ref: MDR 1-1/07

Dear Healthcare Professional,

Europharma Ltd.

| Axetine (cefuroxime) 750mg powder for solution for injection | MA 032/00201 |
|--|--------------|
|--|--------------|

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| C605R | June 08 | | July 2006 |
| | | | |

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed by the Responsible Person of the Government Pharmaceutical Services that a sizeable piece of glass was found in a vial of cefuroxime 750mg powder for solution for injection after reconstitution was carried out. Consequently the local distributor Europharma Ltd. was notified and a class 1 recall was initiated voluntarily.

The 1 batch which had been distributed locally has been recalled by Government Pharmaceutical Services. The recall was carried out under the supervision of the Medicines Authority.

Thanks and Regards

Muriel Giglio Medicines Inspector