Rapid Alert Notification of a Quality Defect

			Ref. No. MT//I/01/01
1	**To: (see list of countries attached, if more than one)**		
2	**Product Recall Class of Defect**	**I**	**Counterfeit/Fraud (please specify) N/A**
3	**Product: Cefuroxime**		**Maltese Marketing Authorisation number:** **MA 032/00201** **For use in humans Yes**
4	**Brand name: Axetine**		**INN: cefuroxime**
5	**Dosage form: powder for solution for injection**		**Strength: 750mg**
6	**Batch number: C605R**		**Expiry date: 06/2008**
7	**Pack size:**		**Date manufactured: 06/2006**
8	**MA holder: Medochemie Ltd.**		
9	**Manufacturer*: Medochemie Ltd.** **Limasol -Cyprus**		**Contact person (Maltese Rep of MA holder)** **Mr Oliver Scicluna** **Telephone: 00356 23859239**
10	**Details of defect:** **Presence of sizeable piece of glass found in a vial after reconstitution**		
11	**Information on distribution including exports (type of customer, e.g. hospitals):** **Distributed to the following countries: Malta, Estonia, Bulgaria, Ukraine**		
12	**Action taken by issuing Authority: Recall of defected batch. All other batches were quarantined.**		
13	**Proposed action: Recall of defected batch and all other batches to be quarantined awaiting investigation results.**		
14	**From (issuing Authority): Medicines Authority** **198, Rue d'Argens** **Gzira GZR03** **Malta**		**Contact person:** **Telephone:** **00356 2343 9142**
15	**Signed:**	**Date:** **25th January 2007**	**Time:**

* The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC and the holder of the authorisation on behalf of whom the Qualified Person has released the batch in accordance with Article 51 of Directive 2001/83/EC.