Medicines Authority
Inspectorate and Enforcement Division
198, Rue d'Argens,
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Malta

Telephone: +356 2343 9116 **Facsimile: +356 2343 9161**

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 3rd November 2004 Our Ref: MDR 1-11/04

Dear Healthcare Professional,

Associated Drug Co Ltd c/o Astra Zeneca

Pulmicort 200 microgram/dose pressurised metered dose inhaler (pMDI) **MA number: N/A**

(budesonide)

Batch Number	Expiry Date	Pack Size	First Distributed
576-04	04/2006	100 dose pMDI	October 2004

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed, following a Rapid Alert notification dated 2nd November 2004 by the Dutch Health Authority (IGZ – Inspectorate of Health Care), that there is the possibility that the dose delivered by the inhalers is variable: the dose could be too low or nothing at all. The reason of the defect is a wrongly manufactured spray can holder (actuator). Astra Zeneca decided to recall all batches produced with the defective batch of actuators.

The local distributors for Astra Zeneca in Malta, namely Associated Drug Co Ltd together with the local representatives for Astra Zeneca have decided to voluntarily recall the only affected batch distributed on the local market ie batch 576-04.

The recall is being carried out under the supervision of the Medicines Authority and is up to pharmacy level.

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A recall letter is also being sent out by the company, after being reviewed by the Medicines Authority, to pharmacists and doctors.

Thanks and Regards

Karl De Marco
Medicines Inspector