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Drug Alert

CLASS 1 MEDICINES RAPID ALERT NOTIFICATION

Action Now - including out of hours

Date:8th February 2007

Our Ref: MDR 1-02/07

Dear Healthcare Professional.

Plavix 75mg coated tablets

AMM 347 945 - 7

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|------------|-------------------|
| 3051 | 02/09 | 28 tablets | NA |
| 3091 | 05/09 | 28 tablets | NA |

Following a Rapid Alert Notification of counterfeit batches issued by the French Regulatory Authority AFSSAPS and in consultation with the local representative of Sanofi-aventis, Charles de Giorgio Ltd., the Medicines Authority is issuing a rapid alert notification for the above mentioned batches of Plavix 75mg coated tablets.

The French Agency has been alerted by EMEA of Plavix 75mg counterfeiting in the UK. These counterfeits have usurped original Plavix 75mg numbers (3051-3091). As a precautionary measure and in agreement with French Agency, Sanofi-aventis France has decided to recall the 28 tabs boxes of Plavix 75mg bearing batch numbers 3051 & 3091.

As a result a batch recall of the above mentioned batches has been initiated in France.

The Medicines Authority has confirmed with Charles de Giorgio Ltd. that the named batches were not distributed in Malta through the legal distribution channels.

Pharmacists, Responsible Persons and Qualified Persons are instructed to immediately notify the Medicines Authority, and withhold from sale, any unusual packs of Plavix 75mg bearing the above mentioned batch numbers.

Thanks and regards

Eloise Buontempo Medicines Inspector