



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

Date: 28th May 2007

Our Ref: MDR 6-05/07

Dear Healthcare Professional,

Plavix 75mg coated tablets
(clopidogrel)

MA Number:
EU/1/98/069/001a-007b

Batch Number	Expiry Date	Pack Size	First Distributed
3098	n/a	28 tablets	n/a
6Y098	n/a	28 tablets	n/a

Following a Rapid Alert Notification of counterfeit batches issued by the UK Regulatory Authority (MHRA) and in consultation with Charles de Giorgio Ltd, the local representative of the Marketing Authorisation Holder Sanofi-Aventis, the Medicines Authority is issuing a drug alert notification for the above mentioned batches of Plavix 75mg coated tablets.

The MHRA in conjunction with the EMEA, and assistance from Sanofi-Aventis, are recalling any parallel distributed stock of Batches 3098 and 6Y098 (and batch variants) of clopidogrel tablets branded as Plavix following the discovery of counterfeit tablets in the legitimate supply chain.

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

Managing Pharmacists and Responsible Persons are instructed to immediately notify the Medicines Authority, and withhold from sale by placing in quarantine, any packs of Plavix 75mg bearing the above mentioned batch numbers and any variants eg 6Y098/1 as parallel distribution companies may have added a prefix or suffix to the batch number if repackaging was needed to differentiate between packaging runs.

Thanks and regards

Karl De Marco
Medicines Inspector