Medicines Authority

Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL

ACTION WITHIN 48 HOURS

Date: 10th April, 2007 Our Ref: MDR 3-4/07

Dear Wholesale Dealer/Managing Pharmacist

Serolf Trading Agency Ltd., Malta

Phlebodia (diosmin) 600mg film-coated tablets MA 617/00101

Batch Number	Expiry date	Pack size	First distributed
6005	01/03/2008	30 tablets	19/05/06
6015	17/07/2008	30 tablets	21/11/06

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed of a Medicinal Product Defect dated 6th April 2007 by the French Authority(AFSSAPS). The reason for the recall concerned the manufacturing step to comply with the microbiological requirements which was not in accordance with the Marketing Authorisation.

The recall is being carried out under the supervision of the Medicines Authority and has been classified as a Class 2 recall up to pharmacy level.

Thanks and regards

Muriel Giglio
Medicines Inspector