



QSM/MC/IEA.104

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Information Exchange System

Alert No. 104

Rapid Alert Notification of a Quality Defect in Prednisolone-Gentamicin (Pred-G) Eye Drops

The information exchange officers in Germany, Chile, Botswana, Namibia and Zimbabwe are advised of the following regulatory information:

The Irish Medicines Board has issued a Rapid Alert Notification of a Quality Defect with subsequent product recall for Pred-G eye drops, an ophthalmic suspension containing prednisolone and gentamicin. Some batches of the product failed to comply with the Preservative Efficacy Test criteria of the European Pharmacopoeia, although the content of the preservative was within specification at the end of the shelf-life for each batch of Pred-G tested. The product is manufactured by Allergan Pharmaceuticals (Ireland) Limited, Castlebar Road, Westport, Co. Mayo and is currently not available in Ireland. The marketing authorization for Pred-G in Ireland has been withheld pending further investigation.

This information is being issued to the above member states in view of distribution of Pred-G in these countries.

Reference:

Fax message (EU/EEA Rapid Alert for Defective Product Recall) received on 5 October 2001 from the Irish Medicines Board.