The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PUBLIC STATEMENT ON
VITRASERT IMPLANT (Ganciclovir)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 18 March 1997 The European Commission granted a marketing authorisation for the whole European Union to Chiron B.V. for VITRASERT IMPLANT (Ganciclovir), indicated for the local treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). This marketing authorisation was transferred on 24 February 2000 to Dr. Gerhard Mann Chem. Pharm. Fabrik GmbH.

On 21 November 2001 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Vitrasert implant.

On 2 April 2002 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Vitrasert implant". Pursuant to this decision the European Public Assessment Report for Vitrasert implant has been removed from the EMEA website.

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