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Public statement

Vistide

Withdrawal of the marketing authorisation in the European Union

On 22 August 2014, the European Commission withdrew the marketing authorisation for Vistide (cidofovir) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Gilead Sciences International Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product.

Vistide was granted marketing authorisation in the EU on 23 April 1997 for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2007. Due to manufacturing problems the product had been in short supply in the EU since February 2013.

During the shortage, healthcare professionals used alternative medicinal products and generic medicine containing cidofovir. Due to ongoing manufacturing challenges as well as a decreasing incidence of CMV retinitis in adults with AIDS, Gilead Sciences International Ltd decided to request the withdrawal of the marketing authorisation for Vistide.

The European Public Assessment Report (EPAR) for Vistide will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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