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28 February 2013
VIS-13-002

Vistide (Cidofovir) 75 mg/ml concentrate for solution for infusion (EU/1/97/037/001)

Direct Healthcare Professional Communication regarding a product recall leading to a shortage in commercial supply in the EU

Dear Healthcare Professional,

Gilead Sciences International Limited would like to inform you of the following:

Summary

- Gilead has encountered a manufacturing problem affecting Vistide
- Although batches in Ireland have not been affected and there are no quality or safety concerns, the manufacturing problem will lead to a shortage.
- At the present time, there are no available lots of Vistide in the supply chain to replace the affected lot.
- Gilead recommends that healthcare professionals consider alternative treatment options until this is resolved.
- Gilead takes the opportunity to remind healthcare professionals that Vistide is only approved for the treatment of CMV retinitis in adults with acquired immunodeficiency syndrome (AIDS) without renal dysfunction

This information is being sent in agreement with the national competent authority and the European Medicines Agency.

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Further information

Vistide is indicated for the treatment of cytomegalovirus (CMV) retinitis in adults with acquired immunodeficiency syndrome (AIDS) and without renal dysfunction.

Call for reporting

Any suspected adverse reactions to Vistide should be notified to the company directly at Gilead via e-mail to csafety@gilead.com or by telephone +44 1223 897500 and/or to the Irish Medicines Board using the online form at www.imb.ie or by using the freepost yellow card system. The IMB can also be contacted on +353-(0)1-6764971.

Company contact point

For further information, please contact:

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Sincerely,

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Gilead Sciences