European Medicines Agency

London, 16 January 2009
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Public statement on
Zenapax
(daclizumab)

Withdrawal of the marketing authorisation in the European Union

On 26 February 1999, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Zenapax (daclizumab), indicated for the prophylaxis of acute organ rejection in de novo allogeneic renal transplantation and used concomitantly with an immunosuppressive regimen, including cyclosporine and corticosteroids in patients who are not highly immunised.

On 22 April 2008*, the marketing authorisation holder (MAH) responsible for Zenapax, Roche Registration Limited, notified the European Commission of its decision to voluntarily withdraw the marketing authorisation for Zenapax for commercial reasons. The MAH confirmed that this decision is not related to any safety concerns with Zenapax.

On 10 June 2008, the European Commission issued a decision to withdraw the marketing authorisation for Zenapax, with effect from 1 January 2009. Pursuant to this decision, the European public assessment report (EPAR) for Zenapax will be updated to reflect that the marketing authorisation is no longer valid.

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