European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 11 August 2005
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PUBLIC STATEMENT ON
VALDYN (valdecoxib)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 24 June 2005 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use Valdyn. This followed the notification by the Marketing Authorisation Holder (Pharmacia Europe EEIG) on 21 June 2005 to voluntarily withdraw the Marketing Authorisation for Valdyn as there are no plans to market this product in the future.

Valdyn (valdecoxib) was indicated in the treatment of symptomatic relief in the treatment of osteoarthritis or rheumatoid arthritis and the treatment of primary dysmenorrhoea.

It should be noted that there is still one Community Marketing Authorisation valid but suspended throughout the European Union for medicinal products containing valdecoxib, i.e. Bextra.

As a consequence to this decision the European Public Assessment Report for Valdyn has been removed from the EMEA website.

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NOTES:
1. The EMEA Scientific Committee (CHMP) recommended the suspension of the Marketing Authorisation for Bextra (valdecoxib) in June 2005 further to the Cox-2 inhibitors class review. The Press Release on the concluded actions on Cox-2 inhibitors can be found here

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