European Medicines Agency

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PUBLIC STATEMENT ON

Trudexa
(adalimumab)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 1 September 2003 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Trudexa, 40 mg solution for injection, intended for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

The marketing authorisation holder (MAH) responsible for Trudexa is Abbott Laboratories. On 20 June 2007, the European Commission was notified by the MAH of its decision to voluntarily withdraw the marketing authorisation for Trudexa for commercial reasons. Trudexa was never placed onto the market in any member state of the European Economic Area.

Therapeutic alternatives are available throughout the European Union, including an identical product, Humira, and other tumour necrosis factor (TNF) blockers.

On 9 July 2007 the European Commission issued a decision to withdraw the marketing authorisation for Trudexa. Pursuant to this decision the European Public Assessment Report for Trudexa will be updated to reflect that the marketing authorisation is no longer valid.

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