The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PUBLIC STATEMENT ON
TIKOSYN (dofetilide**)**

VOLUNTARY WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 29 November 1999, the European Commission granted a marketing authorisation for TIKOSYN (dofetilide) for the whole European Union to Pfizer Ltd, UK. TIKOSYN is a Class III antiarrhythmic agent indicated for the conversion of persistent atrial fibrillation or atrial flutter to normal sinus rhythm and Maintenance of sinus rhythm

TIKOSYN is not marketed anywhere in the EU. On 12 January 2004, Pfizer Ltd notified the European Commission of its decision to voluntarily withdraw the Community Marketing Authorisation for TIKOSYN for commercial reasons. Alternative treatments are available in Europe for this indication.

On 2 March 2004, the European Commission issued a decision to withdraw the Marketing Authorisation for TIKOSYN. Consequently, the European Public Assessment Report for TIKOSYN has been removed from the EMEA website.

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