European Medicines Agency

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PUBLIC STATEMENT ON

Parareg
(cinacalcet)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 22 October 2004 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Parareg, cinacalcet. Parareg is approved for the treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy, and for the reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

The marketing authorisation holder (MAH) responsible for Parareg was Dompé Biotec S.p.A. The European Commission was notified by letter dated 10 November 2008 of the MAH's decision to voluntarily withdraw the marketing authorisation for Parareg for commercial reasons.

Parareg was only marketed in Italy. Mimpara is an identical product available in the European Union. Patients have therefore been switched to Mimpara.

On 5 December 2008 the European Commission issued a decision to withdraw the marketing authorisation for Parareg. Pursuant to this decision the European Public Assessment Report for Parareg will be updated to reflect that the marketing authorisation is no longer valid.

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