30 April 2012
EMA/284281/2012
Human Medicines Development and Evaluation

Public statement on

PhotoBarr (porfimer sodium)

Withdrawal of the marketing authorisation in the European Union

On 25 March 2004 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product PhotoBarr (porfimer sodium) for Photodynamic therapy (PDT) for ablation of high-grade dysplasia (HGD) in patients with Barrett's Oesophagus (BO).

The marketing authorisation holder (MAH) responsible for PhotoBarr was Pinnacle. The European Commission was notified by a letter dated 29 November 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for PhotoBarr for commercial reasons. PhotoBarr was only marketed in France.

On 20 April 2012 the European Commission issued a decision to withdraw the marketing authorisation for PhotoBarr.

Pursuant to this decision the European Public Assessment Report for PhotoBarr will be updated to reflect that the marketing authorisation is no longer valid.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union