European Medicines Agency

London, 03 August 2009
Doc Ref. EMEA/464490/2009

Public Statement on the expiry and withdrawal of the marketing authorisation in the European Union for

Posaconazole SP
(posaconazole)

On 25 October 2005, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Posaconazole SP (posaconazole), indicated for use in the treatment of fungal infections in adults (invasive aspergillosis, fusariosis, chromoblastomycosis and mycetoma, coccidioidomycosis and oropharyngeal candidiasis), and for prophylaxis of invasive fungal infections in patients receiving remission-induction chemotherapy for acute myelogenous leukemia or myelodysplastic syndromes, and in hematopoietic stem cell transplant.

Posaconazole SP (posaconazole) had not been marketed in Europe since this initial marketing authorisation. In accordance with article 14(4) of Regulation (EC) No 726/2004 ('sunset clause'), the marketing authorisation of a medicinal product lapses if the product has never been marketed in one of the Member States within three years of its initial authorisation, calculated from the entry into force of the Regulation (20 November 2005) for products authorised before this date.

Because of this, from 20 November 2008, the marketing authorisation for Posaconazole SP is no longer valid.

Noxafil (posaconazole) is an identical product authorised in the EU.

Pursuant to the expiry of the marketing authorisation, the European Assessment Report (EPAR) for Posaconazole SP will be updated to reflect that the marketing authorisation is no longer valid.

Noël Wathion
Head of Unit for the Post-Authorisation Evaluation
of Medicinal Products for Human use

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu