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Public Statement

Fablyn (lasofoxifene)

Cessation of validity of the marketing authorisation in the European Union

On 24 February 2009, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Fablyn (lasofoxifene), indicated for the treatment of osteoporosis in postmenopausal women. The marketing authorisation holder was notified on the 26 February 2009.

Fablyn (lasofoxifene) 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.

Because of this, from 27 February 2012, the marketing authorisation for Fablyn is no longer valid.

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the European Assessment Report (EPAR) for Fablyn will be updated to reflect that the marketing authorisation is no longer valid.

Francesco Pignatti
Acting Head of Sector of Safety and Efficacy
Human Medicines Development and Evaluation