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Human Medicines Development and Evaluation

Public statement on Bondenza

Withdrawal of the marketing authorisation in the European Union

On 23 February 2004, the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Bondenza, (ibandronic acid), which had been approved for treatment of osteoporosis in postmenopausal women at increased risk of fracture.

The marketing authorisation holder (MAH) responsible for Bondenza was Roche Registration Ltd.

On 27 March 2013, the European Commission issued a decision to withdraw the marketing authorisation for Bondenza, following its receipt of a letter dated 14 February 2013 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Bondenza 150 mg film-coated tablets (Bondenza tablets) were marketed in the following European countries: Spain

Bondenza 3 mg solution for injection (Bondenza IV) was not marketed in any European country.

Pursuant to this decision, the European public assessment report for Bondenza will be updated to reflect that the marketing authorisation is no longer valid.

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