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Public statement

Fexeric

Cessation of validity of the marketing authorisation in the European Union

On 13 January 2020, the marketing authorisation of Fexeric (ferric citrate coordination complex) ceases to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Keryx Biopharma UK Ltd., had not marketed Fexeric in the EU since its initial marketing authorisation. In accordance with the provisions of the sunset clause[1], the marketing authorisation of the medicinal product lapsed as the product had not been placed on the market in any of the EU Member States within three years of its initial authorisation and during the two extensions which were granted by the European Commission at the end of the three-year period.

Akebia Europe Limited confirmed that the product had not been marketed due to delays in identifying a commercial partner for the EU market.

Fexeric was granted marketing authorisation in the EU on 23 September 2015 for the treatment of hyperphosphataemia in patients with chronic kidney disease. The marketing authorisation was initially valid for a 5-year period.

The European Public Assessment Report (EPAR) for Fexeric will be updated to indicate that the marketing authorisation is no longer valid.

[1] Article 14(4-6) of Regulation (EC) No 726/2004 ("sunset clause")

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