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Public statement

KOGENATE Bayer (octocog alfa)

Cessation of validity of the marketing authorisation in the European Union

On 31 December 2022, the marketing authorisation of KOGENATE Bayer (octocog alfa) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Bayer AG, permanently discontinued marketing of KOGENATE Bayer in the European Union (EU) in December 2019. In accordance with provisions of the sunset clause[1], the marketing authorisation of a medicinal product lapses if the product had not been marketed in any EU Member States for three consecutive years.

Bayer AG confirmed that it discontinued the marketing of the product because it no longer intends to market or retain the marketing authorisation for this medicinal product.

KOGENATE Bayer was granted marketing authorisation in the EU on 4 August 2000 for the treatment of haemophilia A.

The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2005. It was then granted unlimited validity in 2010.

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Public Assessment Report (EPAR) for KOGENATE Bayer will be updated to indicate that the marketing authorisation is no longer valid.

[1] Article 14(5) of Regulation (EC) No 726/2004 ("sunset clause")

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