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Public statement

Zevalin (ibritumomab tiuxetan)

Cessation of validity of the marketing authorisation in the European Union

On 4 January 2024 the marketing authorisation of Zevalin (Ibritumomab tiuxetan) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Ceft Biopharma s.r.o., discontinued marketing of Zevalin in the European Union (EU) in May 2020. 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. The European Commission rejected a request for an exemption from the 'sunset clause' for Zevalin.

Ceft Biopharma s.r.o. confirmed that it discontinued the marketing of the product due to manufacturing reasons.

Zevalin was granted marketing authorisation in the EU on 16 January 2004 for the treatment of non-Hodgkin's lymphoma (NHL) and follicular lymphoma.

The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2009.

The European Public Assessment Report (EPAR) for Zevalin has been updated to indicate that the marketing authorisation is no longer valid.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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