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Public statement

Thorinane

Cessation of validity of the marketing authorisation in the European Union

On 15 September 2019, the marketing authorisation of Thorinane (enoxaparin sodium) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Techdow Pharma Netherlands B.V., had not marketed Thorinane in the EU since its initial marketing authorisation. In accordance with provisions of the sunset clause[1], the marketing authorisation of the medicinal product lapsed as the product had not been marketed in any of the EU Member States within three years of its initial authorisation.

Techdow Pharma Netherlands B.V. confirmed that the product had not been marketed due to business reasons.

Thorinane was granted marketing authorisation in the EU on 15 September 2016 for prophylaxis of thromboembolic disorders of venous origin.

The marketing authorisation was initially valid for a 5-year period.

Thorinane was a duplicate application to Inhixa, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Inhixa.

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European Public Assessment Report (EPAR) for Thorinane will be updated to indicate that the marketing authorisation is no longer valid.

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

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