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Public statement

Tasermity

Cessation of validity of the marketing authorisation in the European Union

On 26 February 2015, the marketing authorisation of Tasermity (sevelamer) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Genzyme Europe BV, had not marketed Tasermity 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.

Tasermity was granted marketing authorisation in the EU on 26 February 2015 for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.

Tasermity is an identical product to Renagel, which remains authorised in the EU.

The European Public Assessment Report (EPAR) for Tasermity will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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

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