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Public statement

Somatropin Biopartners

Cessation of validity of the marketing authorisation in the European Union

On 9 November 2017, the marketing authorisation of Somatropin Biopartners (somatropin) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, BioPartners GmbH, had not marketed Somatropin Biopartners in the EU since its initial marketing authorisation. In accordance with the provisions of Article 14(4) of Regulation (EC) No 726/2004 ("sunset clause"), 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. The European Commission had granted an exemption from the 'sunset clause' for Somatropin Biopartners; however the exemption expired on 8 November 2017.

BioPartners GmbH confirmed that the product had not been marketed as they were unable to supply it.

Somatropin Biopartners was granted marketing authorisation in the EU on 5 August 2013 for the replacement therapy of endogenous growth hormone in adults with growth hormone deficiency.

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(EPAR) for Somatropin Biopartners will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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