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Public statement

Glybera

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Glybera (alipogene tiparvovec) expired on 28 October 2017 following the decision of the marketing authorisation holder, uniQure biopharma B.V., not to apply for a renewal of the marketing authorisation.

uniQure biopharma B.V. confirmed that it did not apply for renewal of the authorisation due to the lack of demand for this product.

Glybera was granted marketing authorisation in the European Union (EU) on 25 October 2012 as a one time, single-administration gene therapy for adult patients with familial lipoprotein lipase deficiency.

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

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Report (EPAR) for Glybera will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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