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Public statement

Macugen

Withdrawal of the marketing authorisation in the European Union

On 17 December 2018, the European Commission withdrew the marketing authorisation for Macugen (pegaptanib sodium) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, PharmaSwiss Ceska Republika s.r.o, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Macugen was granted marketing authorisation in the EU on 31 January 2006 for the treatment of neovascular (wet) macular degeneration (AMD). The marketing authorisation was initially valid for a 5-year period. It was renewed for an additional 5-year period in 2010 and granted unlimited validity in 2015. The product had not been marketed in the EU since 1 January 2019.

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European Public Assessment Report (EPAR) for Macugen will be updated to indicate that the marketing authorisation is no longer valid.

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