13 September 2016

Public statement

ChondroCelect

Withdrawal of the marketing authorisation in the European Union

On 29 July 2016, the European Commission withdrew the marketing authorisation for ChondroCelect (characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins) in the European Union (EU), which will become effective as of 30 November 2016. The withdrawal was at the request of the marketing authorisation holder, TiGenix NV, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

ChondroCelect was granted marketing authorisation in the EU on 5 October 2009 for repair of single symptomatic cartilaginous defects. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2014.

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Report (EPAR) for ChondroCelect will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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