24 February 2020
EMA/95504/2020
EMEA/H/C/002048

Public statement

Xiapex

Withdrawal of the marketing authorisation in the European Union

On 5 December 2019, the European Commission withdrew the marketing authorisation for Xiapex (collagenase *Clostridium histolyticum*) in the European Union (EU). The withdrawal is effective as of 1 March 2020. The withdrawal was at the request of the marketing authorisation holder, Swedish Orphan Biovitrum AB (publ), which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Xiapex was granted marketing authorisation in the EU on 28 February 2011 for treatment of Dupuytren's contracture/ Peyronie's disease in adult patients.

The European Public Assessment Report (EPAR) for Xiapex will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union