16 December 2010
EMA/CHMP/773322/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Xiapex

collagenase clostridium histolyticum

On 16 December 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xiapex, 0.9 mg, powder and solvent for solution for injection intended for the treatment of Dupuytren's contracture in adult patients with a palpable cord. The applicant for this medicinal product is Pfizer Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xiapex is collagenase clostridium histolyticum. Collagenases are proteinases that hydrolyze collagen under physiological conditions. Injection of Xiapex into a Dupuytren's cord, which is comprised mostly of interstitial collagen types I and III, results in enzymatic disruption of the cord.

The benefits with Xiapex are its ability to demonstrate a reduction in the contracture of all joints treated (metacarpophalangeal and/or proximal interphalangeal) to 5° or less, approximately 4 weeks after the last injection. Xiapex also demonstrated a decrease in the degree of contracture and increasing both the range of motion from baseline for all joints treated and the subject global assessment of treatment satisfaction.

The most common side effects are oedema peripheral, contusion, injection site pain, pain in extremity and injection site haemorrhage. Serious adverse reactions of tendon rupture, tendonitis, other ligament injury and complex regional pain syndrome related to the medicinal product were reported.

A pharmacovigilance plan for Xiapex will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of Dupuytren's contracture in adult patients with a palpable cord". Xiapex must be administered by a physician appropriately trained in the correct administration of the product and experienced in the diagnosis and management of Dupuytren's disease.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Xiapex and therefore recommends the granting of the marketing authorisation.