24 July 2025
EMEA/H/C/004594

Update as of 11 August 2025:

The company for Jelrix has requested a re-examination of EMA's July 2025 opinion. Upon receipt of the grounds of this request, the Agency will re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Jelrix (cartilage-forming cells, autologous)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Jelrix, a medicine intended for the treatment of cartilage defects in the knee.

The Agency issued its opinion on 24 July 2025. The company that applied for authorisation, Tissue Engineering Technologies AG, TETEC, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Jelrix and what was it intended to be used for?

Jelrix was developed as a medicine used to repair defects to the cartilage in the knee in patients who are experiencing symptoms (such as pain and problems moving the knee). It was to be used in patients whose bones have finished growing and with defects of a surface area between 2 and 12 cm^2.

Jelrix is a dispersion and solution for implantation containing cartilage-forming cells, that have been prepared from the patient's own tissue.

How does Jelrix work?

Cartilage in the knee can be damaged because of an accident, such as a fall or a sports injury. Jelrix contains cells made from the patient's own healthy cartilage cells and was only to be used to treat the patient it was prepared for. When the cells are implanted into the patient's knee cartilage, they were expected to attach to the area of the defect and produce new tissue, thereby repairing the defects in the knee.

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

What did the company present to support its application?

The company presented results from one main study involving 100 adults and adolescents from 14 years of age with cartilage defects in the knee and whose bones finished growing. All patients received Jelrix. The main measure of effectiveness was the knee injury and osteoarthritis outcome score (KOOS), which assesses the pain, symptoms, impact on daily living, sport and recreational activities, and quality of life. It is graded on a scale from 0 to 100 (where 0 means severest symptoms and 100 means no symptoms). The KOOS was self-measured by patients 24 months and 60 months after treatment. In addition, the results from the Jelrix study were compared with those from another study where patients were treated with microfracture (a type of surgery used to treat defects in cartilage).

What were the main reasons for refusing the marketing authorisation?

The agency had concerns about the lack of data to support the suitability of the manufacturing process and its control strategy to ensure that the quality of the medicine meets the required standards. In addition, the positive effects seen on KOOS could not be attributed to the effects of Jelrix as the study did not include a comparison group; people in the study might have improved from the surgery and rehabilitation they received, rather than treatment with Jelrix.

Therefore, the Agency's opinion was that the benefits of Jelrix did not outweigh its risks and it recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no ongoing clinical trials or compassionate use programmes with Jelrix.