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

TETEC Tissue Engineering Technologies AG withdrew its application for a marketing authorisation of Jelrix for the treatment of cartilage defects in the knee.

The company withdrew the application on 11 November 2025.

The European Medicines Agency had recommended refusing marketing authorisation in July 2025. The company had then requested a re-examination of the Agency's opinion, but it withdrew the application before the re-examination had finished.

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 who have 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 collected from the patient's own healthy cartilage and was therefore only to be used to treat the patient it was prepared for. Once implanted into the patient's knee cartilage, these cells were expected to attach to the area of the defect and produce new tissue, thereby repairing the defects in the knee joint.

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 in the joint had finished growing. All patients received Jelrix; the main measure of effectiveness was the knee injury and osteoarthritis outcome score (KOOS), which assesses the severity of symptoms such as pain, impact on daily living, sport and other physically demanding activities, and quality of life. It is graded on a scale from 0 to

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100 (where 0 means the most severe symptoms and 100 means no symptoms). In addition to receiving Jelrix, patients in the study underwent surgery and received rehabilitation. There was no comparison group in this main study.

The KOOS was self-measured by patients 24 months after treatment and compared with results from another study where patients were treated with microfracture (a type of surgery used to treat defects in the cartilage).

How far into the evaluation was the application when it was withdrawn?

The initial evaluation finished on 24 July 2025, and the European Medicines Agency recommended refusing marketing authorisation. The company then requested a re-examination of the Agency's recommendation, but it withdrew the application before this re-examination had finished.

What did the Agency recommend at that time?

At the time of the initial evaluation, 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, it was not possible to conclude that the positive effects seen on KOOS could be attributed to Jelrix as 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 for Jelrix for the repair of defects to the cartilage in the knee in patients who are experiencing symptoms.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that their decision was based on the input received from the agency.

Does this withdrawal 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.