18 May 2017
EMA/CHMP/304021/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Spherox

spheroids of human autologous matrix-associated chondrocytes

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Spherox, intended for the repair of certain cartilage defects of the knee. As Spherox is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies. The applicant for this medicinal product is CO.DON AG.

Spherox will be available as an implant suspension containing as active substance 10–70 three-dimensional spheroids/cm², each composed of a cartilage matrix with the patient's own chondrocytes, isolated from healthy cartilage and cultured *in vitro* (ATC code: M09AX02).

The benefits with Spherox are its ability to repair symptomatic cartilage defects of the femoral condyle and the patella of the knee with defect sizes up to 10 cm^2. The most common side effects are graft delamination, hypertrophy, joint effusion, arthralgia, and joint swelling.

The full indication is:

"Repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee (International Cartilage Repair Society [ICRS] grade III or IV) with defect sizes up to 10 cm^2 in adults."

It is proposed that Spherox is administered by an appropriately qualified physician and in a specialised hospital setting.

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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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

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