20 May 2021
EMA/CHMP/273246/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Spherox

spheroids of human autologous matrix-associated chondrocytes

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Spherox.

As Spherox is advanced therapy medicinal product (tissue engineered product), the CHMP's positive opinion is based on an assessment by the Committee for Advanced Therapies.

The marketing authorisation holder for this medicinal product is CO.DON AG.

The CHMP adopted an extension to the existing indication as follows:

> Repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee (International Cartilage Regeneration & Joint Preservation Society [ICRS] grade III or IV) with defect sizes up to 10 cm^2 in adults **and adolescents with closed epiphyseal growth plate in the affected joint.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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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