



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Closure of EU manufacturing site for MACI

Arrangements in place for existing patients to complete their treatment

On 5 September 2014, the marketing authorisation holder for the advanced therapy medicine MACI (matrix applied characterised autologous cultured chondrocytes) closed the EU manufacturing site for the medicine, which is located in Denmark. Consequently, the licence of the manufacturing site was withdrawn. MACI is unavailable for new patients in the EU until a new manufacturing site has been registered in the EU. The closure was due to commercial reasons and the safety and effectiveness of MACI has not changed.

The European Medicines Agency has been working with the marketing authorisation holder since June 2014 to ensure that patients who had already started the treatment procedure were able to complete their treatment. A letter was sent to healthcare professionals informing them of the site closure and requesting that they notify the marketing authorisation holder of those patients who wish to complete their treatment. In addition, surgeons were asked not to start new patients on MACI.

Following the closure of the site, the marketing authorisation holder has been requested to store any remaining biopsies that have not yet been used to allow for potential later treatment with MACI, unless patients and their treating surgeons have explicitly indicated that they do not wish to complete treatment with MACI.

Information to patients

- The EU manufacturing site for MACI has been closed for commercial reasons and the product will remain unavailable for new patients in the EU until a new manufacturing site has been registered. The safety and effectiveness of the product has not changed.
- Patients who have already started treatment (i.e. those who have had their biopsies taken) should have been informed about the closure and should have discussed arrangements for completion of treatment with their treating surgeon.
- The company has made arrangements to store any existing biopsies so that treatment can be completed unless patients and their treating surgeons explicitly indicated that they no longer wish to complete treatment with MACI.



Information to healthcare professionals

- Surgeons and hospitals that have been using MACI were informed in June 2014 of the planned closure of the EU manufacturing site for MACI. The site has now been closed and MACI remains unavailable for new patients in the EU until a new manufacturing site has been registered in the EU.
- The closure was due to commercial reasons and is not related to any change in the safety and effectiveness of MACI.
- New patients should be treated with a suitable alternative and surgeons should not order new biopsy kits for MACI.
- For patients who have already started treatment (i.e. those who have had their biopsies taken) company has made arrangements to store any existing biopsies so that treatment can be completed unless patients and their treating surgeons have explicitly indicated that they no longer wish to complete treatment with MACI.

More about the medicine

MACI is an implant used to repair cartilage defects at the ends of the bones of the knee joint. MACI is an advanced therapy medicinal product called a 'tissue engineered product'. This is a type of medicine containing cells or tissues that have been manipulated so that they can be used to repair, regenerate or replace tissue.

MACI was on the market since 1998 in individual EU countries according to national procedures. It was subsequently evaluated through the European Medicines Agency to comply with the EU regulation on advanced therapies, which requires all advanced therapies in EU Member States to undergo an evaluation by the Agency in order to obtain an EU-wide marketing authorisation; this was obtained in 2013. Since 2013 MACI has been marketed in Denmark, Greece and the UK.

More about the closure of the manufacturing site

Following the closure of the manufacturing site and because EU legislation¹ requires authorised medicines to have a registered manufacturing site, a review was initiated at the request of the European Commission on 10 September 2014 (under Article 20 of Regulation (EC) No 726/2004) to determine whether the marketing authorisation for MACI should be suspended or revoked.

Because MACI is an advanced therapy medicine, the review was carried out by the Committee on Advanced Therapies (CAT), and was subsequently endorsed by the Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. Based on the draft opinion adopted by the CAT, the CHMP adopted a final opinion on 25 September 2014, recommending the suspension of the marketing authorisation for MACI until a new manufacturing site is registered in the EU. The final opinion will now be sent to the European Commission, which will issue a legally binding decision in due course.

¹ Article 118 of Directive 2001/83/EC, which specifies that a marketing authorisation must be suspended in case any one of the requirements laid down in Article 41 (such as the need for a manufacturing site) is no longer met.

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