Annex I

Scientific conclusions and grounds for the suspension of the marketing authorisation presented by the European Medicines Agency

Marketing Authorisation Suspended

Scientific conclusions

On 8 September 2014, Aastrom Biosciences notified the European Medicines Agency of the withdrawal by the Danish authorities of the manufacturing licence for the manufacturing site for the active substance, finished product and batch release of MACI (matrix-applied characterised autologous cultured chondrocytes): Genzyme Biosurgery ApS, Oliefabriksvej 45, DK - 2770 Kastrup, Denmark.

In view of the above, the European Commission initiated a procedure under Article 20 of Regulation (EC) No 726/2004 on 10 September 2014, requesting the Agency to give its opinion on whether the marketing authorisation for MACI should be suspended or revoked in accordance with Article 118 of Directive 2001/83/EC.

The CHMP considered that this information does not impact the safety and efficacy profile of MACI but that in the absence of an authorised manufacturing site, the requirements laid down in Article 41 of Directive 2001/83/EC are no longer met.

The CHMP therefore recommends the suspension of the marketing authorisation for MACI in accordance with Article 118 of Directive 2001/83/EC.

For the suspension of the marketing authorisation to be lifted, the MAH shall register a site for manufacture of the active substance, finished product and batch release.

In addition, the MAH should continue to ensure that all remaining biopsies are stored under appropriate conditions to allow later treatment of the relevant patients with MACI, unless the patient concerned has explicitly indicated that he/she does no longer wish treatment with MACI.

Grounds for the suspension of the marketing authorisation

Whereas

- The Committee considered the notification under Article 20 of Regulation (EC) No 726/2004 for MACI and the draft CHMP opinion prepared by the CAT
- The Committee concluded that in view of the absence of an authorised manufacturing site for the active substance, finished product and batch release, the requirements laid down in Article 41 of Directive 2001/83/EC are no longer met

The CHMP therefore recommends the suspension of the marketing authorisation for MACI in accordance with Article 118 of Directive 2001/83/EC.

For the suspension to be lifted, the MAH shall register a manufacturing site for the active substance, finished product and batch release (see Annex II).

In addition, the MAH should continue to ensure that all remaining biopsies are stored under appropriate conditions to allow later treatment of the relevant patients with MACI, unless the patient concerned has explicitly indicated that he/she does no longer wish treatment with MACI.

Marketing Authorisation Suspended