COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.10.2009
C(2009)7726

COMMISSION DECISION

of 5.10.2009

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "ChondroCelect - Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins", a medicinal product for human use

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by TiGenix NV, on 20 June 2007, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 25 June 2009,

Whereas:

(1) The medicinal product "ChondroCelect - Characterised viable autologous cartilage-forming cells expanded in vivo expressing specific marker proteins" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2] and in Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004[3].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The marketing authorisation should be subject to compliance with conditions, set out in Annex II to this decision. The implementation of certain of these conditions

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 324, 10.12.2007, p. 121.

with regard to the safe and effective use of the medicinal product is to be ensured by the Member States, in accordance with Article 127a of Directive 2001/83/EC. To this effect, Commission Decision C(2009)7727 of 5.10.2009 is simultaneously being addressed to the Member States.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "ChondroCelect - Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins", the characteristics of which are summarised in Annex I to this Decision. "ChondroCelect - Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins" shall be registered in the Community register of medicinal products under number(s)

EU/1/09/563/001	ChondroCelect - 10000 cells/µl - Implantation suspension - Implantation - Vial (glass/alu) - 1 ml - 1 falcon tube with 1, 2 or 3 vials + 1 syringe + 18G intravenous catheter + 2 Vicryl 6.0

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to TiGenix NV, Romeinse straat 12/2, B-3001 LEUVEN, België.

Done at Brussels, 5.10.2009

For the Commission
Heinz ZOUREK
Director-General