COMMISSION IMPLEMENTING DECISION

of 28.4.2016


(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)
COMMISSION IMPLEMENTING DECISION

of 28.4.2016


(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products¹, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Richardson Associates Regulatory Affairs Ltd on 10 December 2015 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 23 March 2016 by the Committee for Orphan Medicinal Products and received by the Commission on 4 April 2016,

Whereas:

(1) The application submitted by Richardson Associates Regulatory Affairs Ltd concerning the medicinal product “Cannabidiol” was validated on 25 January 2016 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Cannabidiol" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.

(3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product “Cannabidiol” is designated as an orphan medicinal product for the indication: Prevention of graft-versus-host disease. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/16/1645.

Article 2

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to Richardson Associates Regulatory Affairs Ltd, Tripps Farmhouse Lower End, Great Milton, Oxfordshire OX44 7NJ, United Kingdom.

Done at Brussels, 28.4.2016

For the Commission
Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION