COMMISSION IMPLEMENTING DECISION

of 17.2.2016

relating to the designation of "Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)
COMMISSION IMPLEMENTING DECISION

of 17.2.2016

relating to the designation of "Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(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 GW Research Ltd on 24 November 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 21 January 2016 by the Committee for Orphan Medicinal Products and received by the Commission on 27 January 2016,

Whereas:

(1) The application submitted by GW Research Ltd concerning the medicinal product “Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant” was validated on 2 January 2016 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant" 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 “Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant” is designated as an orphan medicinal product for the indication: Treatment of glioma. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/16/1621.

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 GW Research Ltd, Sovereign House, Vision Park, Chivers
Way, Histon, Cambridge CB24 9BZ, United Kingdom.
Done at Brussels, 17.2.2016

For the Commission
Xavier PRATS MONNÉ
Director-General