COMMISSION IMPLEMENTING DECISION

of 19.6.2013

relating to the designation of "Sodium chlorite" 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 products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Shore Limited on 26 February 2013 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 15 May 2013 by the Committee for Orphan Medicinal Products and received by the Commission on 21 May 2013,

Whereas:

(1) The application submitted by Shore Limited concerning the medicinal product "Sodium chlorite" was validated on 15 March 2013 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Sodium chlorite" 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 "Sodium chlorite" is designated as an orphan medicinal product for the indication: Treatment of amyotrophic lateral sclerosis. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/13/1139.

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.

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[1] OJ L 18, 22.1.2000, p.1.