COMMISSION IMPLEMENTING DECISION

of 17.7.2017


(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)
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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, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by SFL Regulatory Affairs Consulting Ltd on 22 March 2017 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 June 2017 by the Committee for Orphan Medicinal Products and received by the Commission on 21 June 2017,

Whereas:

(1) The application submitted by SFL Regulatory Affairs Consulting Ltd concerning the medicinal product “Polyphenyl(disodium 3-O-sulfo-beta-D-glucopyranuronate)-(1→3)-beta-D-galactopyranoside” was validated on 18 April 2017 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Polyphenyl(disodium 3-O-sulfo-beta-D-glucopyranuronate)-(1→3)-beta-D-galactopyranoside" 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 “Polyphenyl(disodium 3-O-sulfo-beta-D-glucopyranuronate)-(1→3)-beta-D-galactopyranoside” is designated as an orphan medicinal product for the indication: Treatment of anti-MAG neuropathy. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/17/1893.

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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 SFL Regulatory Affairs Consulting Ltd, Davenport House, 16 Pepper Street, Canary Wharf, London E14 9RP, United Kingdom.
Done at Brussels, 17.7.2017

For the Commission
Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION