EUROPEAN
COMMISSION

Brussels, 22.10.2020
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COMMISSION IMPLEMENTING DECISION

of 22.10.2020

amending the marketing authorisation granted by Decision C(2005)457 for "Orfadin - Nitisinone", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE SWEDISH 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 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],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Swedish Orphan Biovitrum International AB in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 17 September 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(2) The review of the data submitted by Swedish Orphan Biovitrum International AB, on 29 February 2020 has shown that the new therapeutic indication of the medicinal product "Orfadin - Nitisinone" is based on significant pre-clinical tests or clinical studies. Therefore, the one-year period of data exclusivity in accordance with Article 10(5) of Directive 2001/83/EC should be granted.

(3) Decision C(2005)457 should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

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1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 334, 12.12.2008, p. 7.

(4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2005)457 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2005)457 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

Based on the conclusions set out in Annex IV to this Decision, the one-year period of data exclusivity is granted in accordance with Article 10(5) of Directive 2001/83/EC.

Article 3

This Decision is addressed to Swedish Orphan Biovitrum International AB, 112 76 Stockholm, Sverige.

Done at Brussels, 22.10.2020

For the Commission

Sandra GALLINA
Director-General