



EUROPEAN
COMMISSION

Brussels, 23.11.2023
C(2023) 8197 (final)

COMMISSION IMPLEMENTING DECISION

of 23.11.2023

**amending the marketing authorisation granted by Decision C(2013)5155(final) for
“PHEBURANE - Sodium Phenylbutyrate”, a medicinal product for human use**

(Text with EEA relevance)

(ONLY THE DUTCH 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency¹, and in particular Article 10(2) thereof,

Having regard to the application for an extension within the meaning of Annex I 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 products², submitted by Eurocept International BV on 26 January 2023 under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 14 September 2023 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) Decision C(2013)5155(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.
- (3) 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(2013)5155(final) should therefore be replaced.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2013)5155(final) 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

This Decision is addressed to Eurocept International BV, Trapgans 5, 1244 RL Ankeveen, Nederland.

Done at Brussels, 23.11.2023

For the Commission

Sandra GALLINA

Director-General