



Brussels, 11.2.2020
C(2020) 856 final

COMMISSION IMPLEMENTING DECISION

of 11.2.2020

withdrawing, at the holder's request, the marketing authorisation granted by Decision C(2012)8481(final) for "Picato - ingenol mebutate", a medicinal product for human use

(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 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 Agency¹,

Having regard to the application submitted by LEO Laboratories Ltd on 8 January 2020 with a view to the withdrawal of the marketing authorisation for the medicinal product "Picato - ingenol mebutate",

Whereas:

- (1) The placing on the market of the medicinal product "Picato - ingenol mebutate", which is entered in the Union Register of Medicinal Products under the number EU/1/12/796 was authorised by Commission Decision C(2012)8481(final) of 15 November 2012.
- (2) The Commission initiated a procedure in accordance with Article 20(2) of Regulation (EC) No 726/2004 and requested the opinion of the European Medicines Agency as to whether the marketing authorisation should be maintained, varied, suspended or withdrawn.
- (3) Following the opinion of the European Medicines Agency, formulated on 16 January 2020 by the Pharmacovigilance Risk Assessment Committee, the Commission adopted on 17 January 2020 as provisional measures the decision C(2020)383(final) for " Picato - ingenol mebutate ".
- (4) Decision C(2020)383(final) suspended the marketing authorisation. The final decision on this procedure in accordance with Article 20(3) of Regulation (EC) No 726/2004 is pending.
- (5) In parallel, the marketing authorisation holder submitted a request to withdraw the marketing authorisation.
- (6) Following the holder's request, that authorisation should be withdrawn.

¹ OJ L 136, 30.4.2004, p. 1.

(7) This withdrawal is without prejudice to the outcome of the pending procedure under Article 20 of Regulation (EC) No 726/2004,

HAS ADOPTED THIS DECISION:

Article 1

At the holder's request, the marketing authorisation granted by Decision C(2012)8481(final) of 15 November 2012 for the medicinal product "Picato - ingenol mebutate" is withdrawn.

Article 2

This Decision is addressed to LEO Laboratories Ltd, 285 Cashel Road, Crumlin, Dublin 12, Ireland.

Done at Brussels, 11.2.2020

For the Commission

Anne BUCHER

Director-General

