EUROPEAN
COMMISSION

Brussels, 28.6.2024
C(2024) 4669 final

COMMISSION IMPLEMENTING DECISION

of 28.6.2024

revoking Decision C(2018) 4831 (final) refusing marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Aplidin - plitidepsin", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE SPANISH 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 Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Pharma Mar S.A., on 27 October 2016, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to Commission Implementing Decision C(2018) 4831 (final) of 17 July 2018 by which the Commission refused a marketing authorisation to Pharma Mar S.A. for the medicinal product "Aplidin - plitidepsin",

Whereas:

(1) In order to obtain a marketing authorisation in the Union for a medicinal product, an applicant must submit a dossier meeting the requirements laid out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2,] and in particular Article 8(3) thereof.

(2) If, after verification of the particulars and documents, it appears that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product, the marketing authorisation shall be refused.

(3) For the medicinal product "Aplidin - plitidepsin" the marketing authorisation was refused by Commission Decision C(2018)4831(final) of 17 July 2018. The refusal was based on opinions of the European Medicines Agency, formulated on 14 December 2017 and on 22 March 2018 by the Committee for Medicinal Products for Human, concluding that the safety and efficacy of the medicinal product was not properly or sufficiently demonstrated. The scientific conclusions of the Agency were informed by a scientific advisory group, which had been convened at the request of the applicant.

1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 311 28.11.2001, p. 67.

(4) By application lodged on 1 October 2018, the applicant brought an action under Article 263(4) TFEU for the annulment of the Commission Implementing Decision C(2018)4831 final of 17 July 2018, refusing marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Aplidin – plitidepsin", a medicinal product for human use. This case is pending before the Court of Justice of the European Union (T-594/18RENV). Amongst other things, the applicant alleged a breach of the principle of objective impartiality by the Agency during the application for Aplidin.

(5) Following the delivery of the Judgment of the Court of Justice of 14 March 2024, in case D & A Pharma v Commission and EMA, C-291/22 P, EU:C:2024:228[3] the Commission has reassessed the criteria applied for the participation of experts in the administrative procedure in the case of Aplidin and whether the relevant EMA's rules governing conflict of interests are able to guarantee the objective impartiality of those experts.

(6) In particular, in the D & A Pharma judgment, the Court has clarified that, even though the Agency rules for the handling of competing interests of scientific committees' members and experts involved in its activities provided for a set of restrictions and limitations, the application of those rules in specific circumstances could be incompatible with the principle of objective impartiality, as set out in Article 41(1) of the Charter and that "*it would be inappropriate in order to ensure that the re-examination procedure in question is conducted impartially. It is sufficient to observe, in that regard, that a refusal to grant an MA for the rival product under re-examination is likely to be of considerable commercial interest to the company at the instigation and/or under the sponsorship of which such an expert carries out his or her activity as principal investigator. His or her participation in the expert group consulted by the CHMP in the context of that re-examination would give rise to a legitimate doubt as to the existence of possible bias"*[4].

(7) In light of the clarification provided by the D&A judgment, the Commission notes that one of the consulted scientific advisory group experts who was involved in the development of a "rival" product was allowed to take part to the marketing authorisation procedure of the medicinal product "Aplidin - plitidepsin", in accordance with the Agency rules applicable at the time.

(8) To avoid any doubt as regards the objective impartiality of the assessment of the application, it seems therefore appropriate to revoke Commission Implementing Decision C(2018) 4831 (final) and to subsequently send back to EMA the opinions of the CHMP, asking the reassessment of the application starting at the point of time of the identified procedural irregularity.

(9) The revocation of this Decision is in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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3 Judgment of 14 March 2024, Debregeas et associés Pharma (D & A Pharma) v European Commission and European Medicines Agency, C-291/22P, EU:C:2024:228 paragraphs 71-118.

4 Ibidem. at paragraph 114.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2018) 4831 (final) shall be revoked.

Article 2

This Decision is addressed to Pharma Mar S.A., Avenida de los Reyes 1, Polígono Industrial La Mina, 28770 Colmenar Viejo, Madrid, España.

Done at Brussels, 28.6.2024

For the Commission

Sandra GALLINA
Director General