



Brussels, 3.10.2022
C(2022) 7163 final

COMMISSION IMPLEMENTING DECISION

of 3.10.2022

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Spikevax - elasomeran", a medicinal product for human use and repealing Decision C(2021) 94(final)

(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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency¹, and in particular Articles 10(2) and 14-a(8) thereof,

Having regard to the data submitted by MODERNA BIOTECH SPAIN, S.L., on 4 July 2022,

Having regard to the opinion of the European Medicines Agency, formulated on 15 September 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) On 6 January 2021, authorisation for the placing on the market of "Spikevax - elasomeran" was granted by Decision C(2021) 94(final) subject to certain requirements, in accordance with Article 14-a of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006.
- (2) The specific obligations of the conditional marketing authorisation are fulfilled, in view of the data submitted on 4 July 2022.
- (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(2021) 94(final) should therefore be replaced.
- (4) The medicinal product "Spikevax - elasomeran" complies with the requirements set 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 use².
- (5) It is therefore appropriate to replace the conditional marketing authorisation with a marketing authorisation not subject to specific obligations.
- (6) 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 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Spikevax - elasomera", the characteristics of which are summarised in Annex I to this Decision. "Spikevax - elasomera" is registered in the Union Register of Medicinal Products under number EU/1/20/1507.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The placing on the market of "Spikevax - elasomera" shall be subject to this Decision from the date of its notification.

The period of validity of the marketing authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision repeals and replaces Decision C(2021) 94(final) of 6 January 2021.

Article 6

This Decision is addressed to MODERNA BIOTECH SPAIN, S.L., Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España.

Done at Brussels, 3.10.2022

For the Commission

Sandra GALLINA

Director-General

