EUROPEAN
COMMISSION

Brussels, 10.10.2022
C(2022) 7342 final

COMMISSION IMPLEMENTING DECISION

of 10.10.2022

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", a medicinal product for human use and repealing Decision C(2020) 9598(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 Agency[1], and in particular Articles 10(2) and 14-a(8) thereof,

Having regard to the data submitted by BioNTech Manufacturing GmbH, on 17 June 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 21 December 2020, authorisation for the placing on the market of "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" was granted by Decision C(2020) 9598(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 17 June 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(2020) 9598(final) should therefore be replaced.

(4) The medicinal product "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" 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 use[2].

(5) It is therefore appropriate to replace the conditional marketing authorisation with a marketing authorisation not subject to specific obligations.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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 "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", the characteristics of which are summarised in Annex I to this Decision. "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" is registered in the Union Register of Medicinal Products under number EU/1/20/1528.

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 "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" 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(2020) 9598(final) of 21 December 2020.

Article 6

This Decision is addressed to BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Deutschland.

Done at Brussels, 10.10.2022

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION