EUROPEAN
COMMISSION

Brussels, 3.11.2021
C(2021) 7992 final

COMMISSION IMPLEMENTING DECISION

of 3.11.2021

on the annual renewal of the conditional marketing authorisation for the medicinal product for human use "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", granted by Decision C(2020) 9598(final), and amending that Decision

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 Agency[1], and in particular Article 10(2) and 14-a thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[2],

Having regard to the application submitted by BioNTech Manufacturing GmbH, on 18 June 2021, under Article 6(2) of Regulation (EC) No 507/2006 with a view to the annual renewal of the conditional marketing authorisation for the medicinal product "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)",

Having regard to the grouping of variations in accordance with Article 7(2) of 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 products[3], including an extension within the meaning of Annex I thereto, submitted by BioNTech Manufacturing GmbH,

Having regard to the opinions of the European Medicines Agency, formulated on 14 October 2021 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", entered in the Union Register of Medicinal Products under the number EU/1/20/1528 and authorised by Commission Decision C(2020) 9598(final) of 21 December 2020, remains in compliance with the requirements of Article 14-a of

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 92, 30.3.2006, p. 6.
[3] OJ L 334, 12.12.2008, p. 7.

Regulation (EC) No 726/2004 of the European Parliament and of the Council, and Regulation (EC) No 507/2006,

(2) The conditional marketing authorisation should therefore be renewed.

(3) 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.

(4) Decision C(2020) 9598(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(5) 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.

(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 conditional marketing authorisation granted by Decision C(2020) 9598(final) of 21 December 2020 is renewed.

Article 2

Decision C(2020) 9598(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 3

The period of validity of the renewed authorisation shall be one year from 21 December 2021.

Article 4

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

Done at Brussels, 3.11.2021

For the Commission

Sandra GALLINA
Director-General

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For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION