



Brussels, 12.10.2023
C(2023) 6997 final

COMMISSION IMPLEMENTING DECISION

of 12.10.2023

withdrawing, at the holder's request, the marketing authorisation granted by Decision C(2022)4522(final) for "COVID-19 Vaccine (inactivated, adjuvanted) Valneva - COVID-19 vaccine (inactivated, adjuvanted, adsorbed)", 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency¹,

Having regard to the application submitted by Valneva Austria GmbH on 28 September 2023 with a view to the withdrawal of the marketing authorisation for the medicinal product "COVID-19 Vaccine (inactivated, adjuvanted) Valneva - COVID-19 vaccine (inactivated, adjuvanted, adsorbed)",

Whereas:

- (1) The placing on the market of the medicinal product "COVID-19 Vaccine (inactivated, adjuvanted) Valneva - COVID-19 vaccine (inactivated, adjuvanted, adsorbed)", which is entered in the Union Register of Medicinal Products under the number EU/1/21/1624 was authorised by Commission Decision C(2022)4522(final) of 24 June 2022.
- (2) Following the holder's request, that authorisation should be withdrawn,

HAS ADOPTED THIS DECISION:

Article 1

At the holder's request, the marketing authorisation granted by Decision C(2022)4522(final) of 24 June 2022 for the medicinal product "COVID-19 Vaccine (inactivated, adjuvanted) Valneva - COVID-19 vaccine (inactivated, adjuvanted, adsorbed)" is withdrawn.

Article 2

The withdrawal referred to in Article 1 shall be applicable with effect from 1 December 2023.

¹ OJ L 136, 30.4.2004, p. 1.

Article 3

This Decision is addressed to Valneva Austria GmbH, Campus Vienna Biocenter 3, 1030 Wien, Österreich.

Done at Brussels, 12.10.2023

For the Commission

Sandra GALLINA

Director-General

