COVID-19 Vaccine (inactivated, adjuvanted) Valneva

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0004	Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include a booster dose for adults 18 to 50 years of age based on the interim results from study VLA2001-301 (Booster part); this is a randomised, observer-blind, controlled, superiority study to compare the immunogenicity of COVID-19 Vaccine	23/02/2023	24/03/2023	SmPC and PL	The homologous and heterologous booster recommendation was supported by data from study VLA2001-301 (Booster Part). After the main part of the study VLA2001-301 (assessed in the initial marketing authorisation application), all participants vaccinated with a primary series of either 2 doses of COVID-19 Vaccine (inactivated, adjuvanted)

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	(inactivated, adjuvanted) Valneva to COVID-19 Vaccine (ChAdOx1-S [recombinant]), where participants received a booster dose of COVID-19 vaccine Valneva; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to section 4.4 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Valneva (also referred to as VLA2001) or 2 doses of COVID-19 Vaccine (ChAdOx1-S [recombinant]) were offered a booster dose with COVID-19 Vaccine (inactivated, adjuvanted) Valneva. The GMFR fourteen days post-booster/pre-boost was higher in the VLA2001 primed group (27.7 [95% CI: 20.0, 38.5]) compared with the COVID-19 Vaccine (ChAdOx1-S [recombinant]) primed group (3.0 [95% CI: 2.2, 4.0]). The GMFR fourteen days post-booster/fourteen days after primary vaccination was higher in the VLA2001 primed group (3.6 [95% CI: 2.8, 4.7]) compared with the COVID-19 Vaccine (ChAdOx1-S [recombinant]) primed group (1.6 [95% CI: 1.1, 2.2]). This was suggestive of an adequate boosting response. Overall, the safety profile of the VLA2001 booster vaccination was similar to the safety profile after the VLA2001 primary immunisation scheme. In addition, the safety profile after the VLA2001 booster vaccination was comparable between the VLA2001 and COVID-19 Vaccine (ChAdOx1-S [recombinant]) primed groups.
PSUSA/11001 /202208	Periodic Safety Update EU Single assessment - SARS-CoV-2 virus, strain wuhan hCoV-19/Italy/INMI1-isl/2020, inactivated (Valneva)	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0007/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological	17/02/2023	24/03/2023	SmPC and PL	The SmPC (Annex I) and the Package Leaflet (Annex IIIB) have been updated to reflect the change in shelf life to 21 months when stored at 5°C ± 3°C.

	medicinal product in accordance with an approved stability protocol B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
IB/0006	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	22/11/2022	25/11/2022	SmPC and PL	The SmPC (Annex I) and the Package Leaflet (Annex IIIB) have been updated to reflect the change in shelf life to 18 months when stored at 5°C ± 3°C.
IB/0003	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	21/09/2022	27/09/2022	SmPC, Labelling and PL	Sections 6.3 and 6.6 of the SmPC (Annex I), section 9 of Labelling (Annex IIIA), and the Package Leaflet (Annex IIIB) have been updated to reflect the change in the in-use shelf life after first opening to "either up to 6 hours when stored below 25°C or up to 48 hours when stored at 2-8°C with a maximum time of 2.5 hours at room temperature (15–25°C)".
IB/0002/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a	12/09/2022	27/09/2022	Annex II	Update in Section A of Annex II, adding a manufacturer of the biological active substance.

	biological/immunological medicinal product B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
IB/0001/G	This was an application for a group of variations. B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	25/07/2022	28/07/2022	SmPC and PL	Section 6.3 of the SmPC and section 6 of the PL have been updated to reflect the extension of the shelf-life of the finished product from 12 months to 15 months when stored at 5°C ± 3°C. Furthermore, the PI has been updated to implement the official abbreviation "AgU" for Antigen Units.