Spikevax

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	B.II.f.1 Change in the shelf-life or storage	24/11/2025		SmPC,	

[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).

EMA/VR/0000303827	conditions of the finished product - B.II.f.1.z Other variation - Accepted			Labelling and PL	
Variation type IB / EMA/VR/0000304729	B.II.c.3 Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Other variation - Accepted	10/11/2025	N/A		
Variation type IB / EMA/VR/0000303014	B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.z Other changes - Accepted	10/11/2025	N/A		
Variation type II / EMA/VR/0000282182	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of final report from study mRNA-1273-P910 listed as category 3 study in the RMP. This is a multi-database observational study that utilized routinely collected secondary data in the European region to investigate the natural course of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2 in terms of morbidity and identified relevant prognostic factors.	02/10/2025			

Variation type II / EMA/VR/0000291533	B.I.a.6 Changes to the active substance of a vaccine against human coronavirus - B.I.a.6.a Replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human coronavirus vaccine - Accepted	18/09/2025	24/09/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000292694	This was an application for a group of variations. B.II.c.4 Change in synthesis or recovery of a nonpharmacopoeial excipient (when described in the dossier) or a novel excipient - B.II.c.4.z Other changes - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.c) Control of excipients - B.II.c.z Other variation - Accepted B.II.c) Control of excipients - B.II.c.z Other variation - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for	18/09/2025	N/A		

	batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted				
Variation type II / EMA/VR/0000272245	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2 and 5.1 of the SmPC in order to update information regarding the data in the paediatric population, based on results from the final report for study mRNA-1273-P206. This is a Phase 2, two-part study (open-label [part 1] followed by observer-blind/randomised [part 2]) to evaluate the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273.214 SARS-CoV-2 Vaccine (Spikevax bivalent Original/Omicron BA.1) in Participants Aged 12 Weeks to <6 Months.	24/07/2025	25/07/2025	SmPC	
Variation type II / EMA/VR/0000278795	B.I.a.6 Changes to the active substance of a vaccine against human coronavirus - B.I.a.6.a Replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human	24/07/2025	25/07/2025	SmPC, Labelling and PL	

	coronavirus vaccine - Accepted				
Variation type II / EMA/VR/0000266225	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study mRNA-1273-P901 listed as a category 3 study in the RMP. This is an observational, real-world study of the effectiveness of Spikevax.	03/07/2025	N/A		
Variation type IB / EMA/VR/0000264400	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	30/04/2025	N/A		
Variation type IA / EMA/VR/0000264865	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	16/04/2025	25/07/2025	Annex II and PL	

	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted				
Variation type IB / EMA/VR/0000256116	B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	09/04/2025	N/A		
Variation type II / EMA/VR/0000245103	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study mRNA-1273-P203 listed as a category 3 study in the RMP. This is a phase 2/3, randomized, observer-blind, placebo-controlled study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 SARS-CoV-2 vaccine in healthy adolescents 12 to <18 Years of Age.	27/03/2025	N/A		
Variation type IB / EMA/VR/0000253535	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process	18/03/2025	N/A		

	of the active substance - Accepted				
Variation type IB / EMA/VR/0000244889	This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.z Other changes - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.z Other changes - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.z Other changes - Accepted	25/02/2025	N/A		

PSUR / EMA/PSUR/0000257883	- -				Maintenance