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 II /	Outcome:	23/07/2026	28/07/2026	SmPC,	Addition of a new strain (XFG) resulting in ten

[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/0000356879	Q.I.a.6 Changes to the active substance of a vaccine against human coronavirus or other vaccine that has the potential to address a public health emergency in the Union - Q.I.a.6.a) Replacement or, upon agreement of the relevant authorities, addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human coronavirus vaccine or other vaccine that has the potential to address a public health emergency in the Union - Accepted			Labelling and PL	monovalent presentations (EU/1/20/1507/041-50).
Variation type IB / EMA/VR/0000333464	Outcome: Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.a) Minor change in the manufacturing process - Accepted	08/05/2026			
Variation type IB / EMA/VR/0000322894	Outcome: This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted B.I.c.3 Change in test procedure for the	01/04/2026			

	immediate packaging of the active substance - B.I.c.3.z Other variation - Accepted				
Variation type IA_IN / EMA/VR/0000334813	Outcome: Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted	20/03/2026			
Variation type IB / EMA/VR/0000326167	Outcome: Q.II.e.1 Change in immediate packaging of the finished product - Q.II.e.1.z Other variation - Accepted	03/03/2026			
Variation type IB / EMA/VR/0000323203	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - 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	19/02/2026			

Variation type IB / EMA/VR/0000316350	Outcome: C.I.7 Deletion of: - C.I.7.z Other variation - Accepted Type IB C.I.7.z - To delete from the Spikevax marketing authorisation: - all Spikevax original dispersion for injection presentations (EU/1/20/1507/001-003), - all Spikevax bivalent Original/Omicron BA.1 dispersion for injection presentations (EU/1/20/1507/004-005 and 007-008), - all Spikevax bivalent Original/Omicron BA.4-5 dispersion for injection presentations (EU/1/20/1507/006 and 009-010), and - all Spikevax XBB.1.5 dispersion for injection presentations (EU/1/20/1507/011-018 and 027-030). Furthermore, the MAH has taken the opportunity to update the SmPC, to reflect the conclusion or change in the status of studies.	20/01/2026	28/07/2026	SmPC, Annex II, Labelling and PL	To delete from the Spikevax marketing authorisation: - all Spikevax original dispersion for injection presentations (EU/1/20/1507/001-003), - all Spikevax bivalent Original/Omicron BA.1 dispersion for injection presentations (EU/1/20/1507/004-005 and 007-008), - all Spikevax bivalent Original/Omicron BA.4-5 dispersion for injection presentations (EU/1/20/1507/006 and 009-010), and - all Spikevax XBB.1.5 dispersion for injection presentations (EU/1/20/1507/011-018 and 027-030).
Variation type IB / EMA/VR/0000308399	Outcome: B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	19/01/2026			
Variation type II / EMA/VR/0000264109	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL	15/01/2026	28/07/2026	SmPC and PL	Please refer to Scientific Discussion 'Spikevax-VR-000264109'.

	PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted 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 A grouped application consisting of: C.I.13: Update of section 4.6 of the SmPC in order to update the information on pregnancy, based on the final results from clinical study mRNA-1273-P905 listed as a category 3 study in the RMP. This is an observational study using routinely collected health data in five European countries monitoring safety of Spikevax in pregnancy. The package leaflet is updated accordingly. C.I.4: Update of section 4.8 of the SmPC in order to update the frequency of the adverse reactions ''Anaphylaxis'' and "Erythema multiforme" from ''Not known'' to ''Rare'', based on final results from clinical study mRNA-1273-P904 listed as a category 3 study in the RMP. This is a non-interventional, post-authorisation active surveillance safety study using secondary data to monitor real-world safety of the Spikevax in the EU. The package leaflet is updated accordingly. An updated				

	RMP (version 13.0) is approved.				
Variation type IB / EMA/VR/0000319486	Outcome: This was an application for a group of variations. B.I.b) Control of active substance - B.I.b.z Other variation - Accepted 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 Other variation - Accepted	12/01/2026			
Variation type IB / EMA/VR/0000313403	Outcome: B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	16/12/2025			
Variation type IA / EMA/VR/0000314549	Outcome: This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities	16/12/2025			

	for which the manufacturer/importer is responsible do not include batch release - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted 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/0000303827	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted	24/11/2025	28/07/2026	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000304729	Outcome: 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			
Variation type IB / EMA/VR/0000303014	Outcome: 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			

Variation type II / EMA/VR/0000282182	Outcome: 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	Outcome: 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	Outcome: This was an application for a group of	18/09/2025			

	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 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	Outcome: 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	24/07/2025	25/07/2025	SmPC	

	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.				
Variation type II / EMA/VR/0000278795	Outcome: 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	24/07/2025	25/07/2025	SmPC, Labelling and PL	
Variation type II / EMA/VR/0000266225	Outcome: 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	03/07/2025			

	study in the RMP. This is an observational, real-world study of the effectiveness of Spikevax.				
Variation type IB / EMA/VR/0000264400	Outcome: 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			
Variation type IA / EMA/VR/0000264865	Outcome: 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 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	

Variation type IB / EMA/VR/0000256116	Outcome: B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	09/04/2025			
Variation type II / EMA/VR/0000245103	Outcome: 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			
Variation type IB / EMA/VR/0000253535	Outcome: 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	18/03/2025			
Variation type IB / EMA/VR/0000244889	Outcome: This was an application for a group of variations.	25/02/2025			

	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				
PSUR / EMA/PSUR/0000257883	EURD: PSUSA/00010897/202412 Active substance: elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5), SARS CoV 2 JN.1 mRNA	10/07/2025			Maintenance

	Outcome: Maintenance				